California Environmental Protection Agency

Air Resources Board

Final Statement of Reasons for Rulemaking

Including Summary of Comments and Agency Responses

PUBLIC HEARING TO CONSIDER ADOPTION OF A PROPOSED REGULATION TO LIMIT OZONE EMISSIONS FROM INDOOR AIR CLEANING DEVICES

Public Hearing Date: September 27, 2007
Agenda Item No.: 07-9-3

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State of California
AIR RESOURCES BOARD

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I. GENERAL

A. Overview

Assembly Bill 2276 (Pavley, Chapter 770, Statutes of 2006) requires the Air Resources Board (ARB or Board), on or before December 31, 2008, to develop and adopt regulations, consistent with federal law, to protect public health from ozone emitted by indoor air cleaning devices used in occupied spaces. AB 2276 establishes Health and Safety Code sections 41985-41986, which require that the regulations adopted by the Board include: 1. An emission concentration standard for ozone emissions from air cleaning devices which is equivalent to the applicable federal limit; 2. Testing procedures to determine ozone emissions from the devices; 3. Certification procedures the ARB will use to verify that the devices meet the emission concentration standard; and, 4. Package labeling requirements. AB 2276 also authorizes the regulations to contain a ban on devices that do not meet the ozone emission standard, procedures for authorizing independent laboratories or other certified organizations to verify that devices meet the emission standard, an exemption for devices that emit *de minimis* levels of ozone, and any other element the Board deems necessary to protect public health from emissions of ozone from indoor air cleaning devices that exceed the emission standard and are used in occupied spaces.

On September 27, 2007, the Board conducted a public hearing to consider adoption of a regulation to accomplish the goals set forth in AB 2276. The proposed regulation the Board adopted is described herein. It would establish an ozone emission concentration standard, and requirements for certification, labeling and recordkeeping for indoor air cleaning devices that are introduced into commerce in California and used in occupied spaces. The proposed regulation would establish an emission concentration standard of 0.050 part per million (ppm) for ozone released by indoor air cleaning devices for use in occupied spaces. This is the same emission concentration standard that is established by federal law for air cleaners that are medical devices (see: 21 CFR section 801.415). In addition, under the proposed regulation, manufacturers of indoor air cleaning devices would also have to follow certain test procedures established in the proposed regulations to obtain ARB's certification that devices comply with the concentration standard, and then also follow the regulation's

labeling and recordkeeping requirements. The proposed regulation also contains exemptions for devices that are used in certain industrial applications in unoccupied spaces and devices that are designed, marketed and used solely as an "in-duct" unit that is physically integrated with a central heating and air conditioning system. Devices that use only mechanical filtration technologies emit *de minimis* levels of ozone and are exempt from the ozone testing requirement but still must meet labeling and other requirements of the regulation.

The "Staff Report: Initial Statement of Reasons for Proposed Rulemaking (ISOR, Staff Report), Proposed Regulation to Limit Ozone Emissions from Indoor Air Cleaning Devices" was made available to the public beginning August 9, 2007. This ISOR, which is incorporated by reference herein, contains an extensive description of the rationale for the proposed regulation. At the September 27, 2007 hearing, the Board approved the proposed regulation with various modifications to the original proposal. These modifications were made available for public comment beginning June 30, 2008, for a period of 15 days (15-day comment period). The 15-day notice of proposed modifications to the proposed regulation and the appendices to the notice are incorporated by reference here. A second 15-day notice was issued on July 16, 2008 for the purpose of adding three references to the rulemaking record and to make two corrections to the reference list in the ISOR; this second 15-day notice also is incorporated by reference here.

In accordance with Government Code section 11346.9(a)(1), this Final Statement of Reasons for Rulemaking (FSOR) updates the ISOR by identifying and explaining the modifications that were made to the original proposal. In accordance with Government Code section 11346.9(a)(3), the FSOR also summarizes the written and oral comments received during the 45-day comment period preceding the September 27, 2007 hearing; comments received at the public hearing on September 27, 2007; and comments received during two, separate 15-day comment periods. Agency responses are also included.

B. Public Outreach and Participation

Extensive effort was made to obtain input from manufacturers, the general public, and interested stakeholders throughout the development of this regulation. In order to facilitate public involvement, an email listserve and Internet webpage (http://www.arb.ca.gov/research/indoor/aircleaners/aircleaners.htm) were made available in November 2006. The ARB invited any individuals with interest in this regulation to join the listserve at (http://www.arb.ca.gov/listserv/listserv.php) in order to receive email notification of all notices given and actions taken related to the development of the proposed regulation order. The initial list was formed from ARB's existing indoor air quality lists, email and address information for all companies identified as producing air cleaners that intentionally emit ozone, or ozone generators (OGs), and known associations and manufacturers of non-OG air cleaners. There are approximately 2,000 individuals or companies registered for the listserve. For companies that use private distributors, attempts were made to obtain lists of their distributors, but were unsuccessful.

Three public workshops were conducted between December 2006 and June 2007. At the first workshop on December 13, 2006, ARB staff discussed the requirements of AB 2276, presented a draft regulation concept, outlined the proposed regulation schedule, and responded to questions. During the second workshop on March 29, 2007, ARB staff presented a draft regulation order and preliminary economic impact analysis. Additional time was taken to discuss the proposed ozone emission test method, which at that time followed the March 2007 Certification Bulletin for Section 37 of Standard 867 of the American National Standards Institute and Underwriters Laboratories, Inc. (ANSI/UL). At the third and final public workshop on June 11, 2007, staff discussed the revised proposed regulation order, the staff report, and further analysis of the economic impacts of the regulation. The public was able to attend each workshop in person or participate via teleconference and/or Webcast. A three week written public comment period was provided following each workshop. Comments were received from a variety of stakeholders, including manufacturers, professional organizations, testing/certification entities, public health organizations, and private citizens. When preparing the Staff Report, ARB staff considered the comments received at the public workshops; those comments helped to shape the proposed regulation.

To solicit additional information and comments, staff held numerous individual meetings and teleconferences with testing laboratory representatives, manufacturers and other industry representatives, the American Lung Association, and scientific research experts. These meetings helped provide ARB staff with information needed for the development of the test method, certification procedures, labeling requirements, economic impacts, and regulation effective dates.

In addition to the actions listed above, ARB staff also conducted a general outreach program on intentional ozone generators both prior to and during the development of the regulation. The general outreach program included: (1) production of a fact sheet describing intentional ozone generators and their potential harmful effects; (2) contacting relevant organizations to convey information to their constituents; (3) submission of articles for publication in newsletters and other print media; and (4) where possible, speaking to interested groups. The fact sheet was distributed to: county and regional air quality management districts, local health and environmental health officers; twelve professional medical organizations; seven physician groups; numerous local asthma and allergy organizations throughout the state; senior citizen organizations; health-related non-profit organizations; and over a dozen business associations. Each organization was then personally contacted to describe the problems with ozone generators, answer questions, and provide additional information and printed materials for publication in newsletters. Organizations throughout California were extremely helpful in conveying factual information on ozone generators to their constituencies.

As noted above, the Staff Report/ISOR and associated materials were released for public review 45 days prior to the planned Board public hearing date of September 27, 2007.

Should the proposed regulations be approved and take effect, staff plans to conduct additional outreach to retail associations, large retail chains, and other distributors and sellers to assure that all affected parties are aware of the regulatory requirements. Under the proposed regulation, manufacturers are required to notify their distributors and retailers about this regulation, and to provide contact information for those businesses to ARB. Staff plans to follow up to assure that all on such lists have been notified, and to respond to any questions they may have. Staff also will continue to check for manufacturers who may not be aware of this regulation.

C. The September 27, 2007 Board Hearing

At the Board's September 27, 2007 hearing the staff proposed a number of specific changes to its original August 9, 2007 proposal. These changes addressed some of the stakeholders' concerns; unfortunately, however, these modifications did not gain all stakeholders' full support for the staff's proposal. At the September 27, 2007 hearing, the Board heard opposing testimony from the manufacturers and dealers of ozone-generating air cleaning devices. After considering all of the testimony and staff's modified proposal, the Board voted to adopt the staff's proposal as modified, with some additional changes.

At the conclusion of the September 27, 2007 hearing, the Board voted unanimously to adopt Resolution 07-40 (Resolution), in which it approved the originally proposed regulation with the modifications described below. The Resolution directed the Executive Officer to incorporate the modifications (set forth in Attachment B to the Resolution) into the proposed regulatory text, with the exception of the proposed nine-month sell-through period, and with such other conforming modifications as may be appropriate. In accordance with section 11346.8 of the Government Code, the Board directed the Executive Officer to adopt modified sections after making the modified text available to the public for comment for a period of at least 15 days. The Board further directed the Executive Officer to consider written comments regarding the modified text that may be submitted during this period, make modifications as may be appropriate in light of the comments received, and present the regulations to the Board for further consideration if warranted.

On June 30, 2008, the text of the proposed modifications to the originally proposed regulation was made available for a supplemental 15-day comment period by issuance of a "Notice of Public Availability of Modified Text and Availability of Additional Documents" (15-day Notice). The Notice described each modification and several additions and corrections to the rulemaking record, and the modified regulation order language with the modifications clearly indicated was attached to the Notice. The 15-day Notice and its appendices were mailed on June 30, 2008, to all parties identified in section 44(a), title 1, CCR, along with other interested parties. The 15-day Notice and its appendices were also posted on the ARB's Internet site for the rulemaking on June 30, 2008. The documents are incorporated herein by reference. Eight comments were received during this first supplemental 15-day comment period. Three additional references were added to the rulemaking record and made available for an additional 15-day comment period in a second 15-day notice (Second 15-day Notice) that was

issued on July 16, 2008. Two comments were received during the second 15-day comment period.

After considering the comments submitted during the two 15-day comment periods, the Executive Officer subsequently issued Executive Order R-08-010, which adopted new sections 94800-94810 of title 17 of the California Code of Regulations (CCR) with the modifications made available for comment.

This FSOR updates the Staff Report by identifying and providing the rationale for the modifications made to the originally proposed regulatory text. It also contains a summary of the comments the Board received on the regulatory action during the formal rulemaking process and ARB's responses to those comments.

D. Economic and Fiscal Impacts

The Board makes determinations concerning the costs or savings necessarily incurred by public agencies and private persons and businesses in reasonable compliance with the proposed regulatory action. Those determinations are presented below and in specific detail in the ISOR.

Pursuant to Government Code sections 11346.5(a)(5) and 11346.5(a)(6), the Board has determined that the proposed regulatory action would create costs to the ARB as defined in Government Code section 11346.5(a)(5) and (6). The ARB is expected to incur ongoing costs of approximately $175,000 per year for one additional staff and contract funds to implement the regulation and enforce compliance. Costs would not be created for any other state agency, or in federal funding to the state. The regulation would not create costs or mandate to any local agency or school district whether or not reimbursable by the state pursuant to part 7 (commencing with section 17500), division 4, title 2 of the Government Code, or other nondiscretionary cost or savings to state or local agencies.

In developing this regulatory proposal, the ARB staff evaluated the potential economic impacts on representative private persons or businesses. The proposed regulation would affect the manufacturers, distributors, sellers, and consumers of portable indoor air cleaners if the products are marketed for sale in California. The potential economic impact of the regulations would primarily include the cost to test air cleaning devices to certify that they meet the 0.050 ppm emission concentration standard for ozone, and the cost to label the products as certified. Additionally, all manufacturers of ozone generators and a few manufacturers of electrostatic precipitators and ionizers that do not meet the emission limit would also need to redesign their products. Annualized costs for a typical small-share business (producing an average of three models of air cleaners) during the first five years were estimated to be between $50,000 and $179,000, and for a typical larger share company (producing an average of 6-8 models of air cleaners) were estimated to be between $132,000 and $357,000. These estimates included all aspects of certification, i.e., testing, labeling, redesign for those requiring it, and certification paperwork. The added cost to consumers was estimated to range from $11 to $16 per air cleaner, if all costs are passed on, for air cleaners that currently cost from about $100-$700. The total statewide cost to businesses and representative

private persons or consumers to comply with the proposed regulation during the first five years was estimated to be $8,000,000, the cost to businesses, or $12,100,000, the cost to consumers if compliance costs and a profit margin were passed on to consumers. Some small manufacturers may be impacted over the short-term due to costs for testing as well as the possible need for some to redesign certain models. The potential long-term impacts, however, were estimated to be insignificant. Costs are also expected to decline rapidly after five years because it is estimated that there would only be turnover costs for the introduction of new models. ARB believes that all of the potential economic impacts on manufacturers are either absorbable or would be passed on to consumers. Because manufacturers are fully expected, and required, to comply with the regulations, enforcement costs to manufacturers should also be negligible.

The Board has made a determination that the proposed regulatory action would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states or on representative private persons. Of an estimated 61 manufacturers of indoor air cleaning devices, three large manufacturers and at least three smaller manufacturers are based in California. All manufacturers of indoor air cleaning devices marketed for sale in California would be subject to the proposed regulations, so there should be no effect on the business competitiveness of the California-based manufacturers.

In accordance with Government Code section 11346.3, the Board has determined that the proposed regulatory action would not affect the creation or elimination of jobs within the State of California, the creation of new businesses or elimination of existing businesses within the State of California, or the expansion of businesses currently doing business within the State of California. Overall, the impacts should be absorbable. A detailed assessment of the economic impacts of the proposed regulatory action can be found at pages 32-45 of the ISOR which are incorporated here by reference.

The Board has also determined, pursuant to title 1, CCR, section 4, that the proposed regulatory action would affect small businesses. Some distributors and retailers of ozone generators are one- and two- person businesses where there may be significant impacts if their manufacturers decide to not seek certification for the California market. The Board knows of no alternatives to the proposed regulation that would lessen the impact on small businesses and comport with the requirements of AB 2276.

In accordance with Government Code sections 11346.3(c) and 11346.5(a)(11), the Board has found that the proposal would establish no reporting requirements, but it would establish certain recordkeeping requirements. Under the proposal, businesses would have to maintain certain specified records relating to production, quality control, sales and testing for three years and make them available to the Air Resources Board upon request. The Board has found that these recordkeeping requirements are necessary for the health, safety, and welfare of the people of the State of California**.**

E. Alternatives

Alternatives to this regulatory action were considered in the Staff Report, in accordance with Government Code section 11346.2. For the reasons set forth in the Notice, in the

Staff Report, in staff's comments and responses at the hearing, and in this FSOR, ARB has determined that no reasonable alternative considered by the agency, or that has otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the regulatory action was proposed or would be as effective or less burdensome to affected private persons than the regulation adopted by the Board.

II. MODIFICATIONS TO THE ORIGINAL PROPOSAL

Various modifications to the original proposal were made to address comments received during the 45-day public comment period preceding the September 27, 2007 public hearing; comments received at the September 27, 2007 hearing; and to clarify the regulatory language. At the September 27, 2007 hearing, the Board modified the proposed regulation to extend the compliance date from 12 to 24 months after the effective date of the regulation, and to delete the subsequent nine month sell-through period. These modifications were approved by the Board as part of Resolution 07-40, and were proposed in response to comments received after the publication of the Staff Report but before the September 27, 2007 hearing. Attachment B of Resolution 07-40 contains the modifications staff suggested at the hearing.

Subsequent to the Board hearing, revisions to Section 37 of American National Standards Institute/Underwriters Laboratories, Inc. (ANSI/UL) Standard 867 were published by UL on December 21, 2007. Section 37 is the ozone emission concentration test method referenced in the proposed regulation. The final, approved Section 37 contained additional minor revisions compared to the version of Section 37 provided in the ISOR for this regulation as Appendix E.

The Resolution directed the Executive Officer to incorporate the modifications into the proposed regulatory text, with such other conforming modifications as may be appropriate, and to make the modified regulatory language available for a supplemental comment period of 15 days. The Resolution also directed staff to report back to the Board regarding progress of the certification program.

These modifications are described below. As directed by the Board, a "Notice of Public Availability of Modified Text and Availability of Additional Documents" (15-day Notice), together with a copy of the modified sections of the proposed regulation, was made available to the public for a supplemental comment period from June 30, 2008 to July 16, 2008. The Notice and the appendices thereto are incorporated herein by reference. A "Second Notice of Availability of Additional Documents" (Second 15-day Notice) was issued on July 16, 2008, initiating a second 15-day comment period from July 16 to July 31, 2008 to add three references to the rulemaking record and make two corrections to the references list in the ISOR. The Second 15-Day Notice also is incorporated herein by reference. After the close of the two 15-day comment periods, the Board's Executive Officer determined that no additional substantive modifications should be made to the proposed air cleaner regulation. However, several non-substantive edits were made to improve the clarity and formatting of the regulation. The Executive Officer subsequently issued Executive Order R-08-010, which adopted the regulation.

Following is a summary of the modifications made to the originally proposed regulation.

A. Summary of Proposed Modifications

The following explains and identifies the modifications by section number.

1. In Section 94801, a definition for the ANSI/UL Standard 867 has been added to specify that all references to ANSI/UL Standard 867 are to the December 21, 2007 version of the standard plus the three associated Certification Requirement Decisions issued by UL for Section 37 of that standard through April 2008.

2. In Section 94801, subsection (a)(15)(I) was added. This adds odor control in the motor vehicle reconditioning and detailing industry (provided no people are physically present) to the definition of industrial use.

3. The definition of "Label" in Section 94801(a)(16) has been modified to allow adhesive stickers to be used to satisfy package labeling requirements until April 1, 2011 instead of until January 1, 2010.

4. The compliance date in Section 94802 was changed from 12 months to 24 months after the effective date of the regulation, as approved by the Board. Extending the compliance date was recommended by staff at the September 27, 2007 public hearing in response to public comments and staff's analysis indicating that additional time would be necessary to be able to test all of the air cleaners covered by the regulation.

5. The nine-month sell-through provision in Section 94802 was deleted, as directed by the Board.

6. In Section 94804(b), language indicating that "mechanical filtration only" devices must meet ANSI/UL Standard 507 or any electrical safety standard that succeeds that standard has been revised to remove the reference to future standards. UL has indicated that Standard 507 may be combined with Standard 867 in the future, so that all air cleaner testing is covered under a single standard; if such an action is taken, ARB will consider the need to update this regulation at that time. Section 94804(b) also now specifically requires documentation that "mechanical filtration only" air cleaners have met ANSI/UL Standard 507.

7. In Section 94804, Certification Requirements, subsection (c)(1), the name and telephone number for the primary contact were added as additional items of information.

8. In Section 94804, Certification Requirements, subsection (c)(3), manufacture date and serial number were added as two additional items of information required about the indoor air cleaning devices being tested.

9. Section 94805(b) of the proposed regulation was revised to specify the versions of ANSI/UL Standards 867 and 507 that are to be used for meeting the test requirements in the regulation. Testing must be performed following the ANSI/UL Standard 867 for electronic air cleaners or 507 for mechanical filtration air cleaners, whichever is applicable, and ozone emissions will be determined using the testing protocol provided in Section 37 of ANSI/UL Standard 867. Both standards (867 and 507) were included in Section 94805 by reference. An earlier version of Section 37 was made available on August 9, 2007 for review under this regulation because, at the time of the September 2007 public hearing, Section 37 was undergoing revision. The revisions were completed and approved by ANSI/UL in late December 2007. The current approved version of the applicable standard is ANSI/UL Standard 867, Fourth Edition, published December 21, 2007. The September 27, 2007 version of ANSI/UL Standard 507, Ninth Edition, was specified as the version of that standard that will be used to test mechanical filtration air cleaners.

10. Section 94805(c) was revised to additionally include three Certification Requirement Decisions (CRDs) that have been issued by UL to clarify certain provisions of the Section 37 (ANSI/UL Standard 867) ozone test. These were released by UL on March 4, 2008; April 17, 2008; and April 18, 2008.

11. In Section 94805(d), language was added to specify that annual submittal of internal audit reports and associated follow-up audit reports may be required of test laboratories.

12. In Section 94806, a six-month extension for meeting the labeling requirement was added for models that have been submitted for testing, but have not yet received ARB certification by the end of the 18th month from the effective date of the regulation. This extension applies only to the labeling requirements; devices must still be tested and must complete the ARB certification process by the end of the 24th month after the effective date of the regulation, and must meet all labeling requirements within six months of the postmark date of notification of ARB certification.

Other nonsubstantial modifications were also made throughout the regulation to correct grammatical and typographical errors, correct references and citations, and improve the overall clarity of the document.

B. Additions to the Rulemaking Record and Corrections

1. The Initial Statement of Reasons released for public review on August 9, 2007 erroneously referenced the 1980 ANSI/UL Standard 867. The correct citation was changed to read: ANSI/UL, 2004. UL Standard for Safety for Electrostatic Air Cleaners, UL 867, Fourth Edition, February 27, 2004.

2. A more recent version of ANSI/UL Standard 867 was released on December 21, 2007 and is the version incorporated by reference into the revised

regulation; it has been added to the rulemaking record and will be cited as: ANSI/UL 2007a. UL Standard for Safety for Electrostatic Air Cleaners, UL 867, Fourth Edition, December 21, 2007. The complete ANSI/UL Standard 867 may be obtained at http://www.comm-2000.com.

3. The proposed regulation (Section 94805) includes ANSI/UL Standard 507 as the test method to be used for verification of compliance for devices that are mechanical-filtration devices only. A copy of Standard 507 was added to the rulemaking record and is cited as follows: ANSI/UL, 2007b. UL Standard for Safety for Electric Fans, UL 507, Ninth Edition, September 27, 2007. A copy of ANSI/UL Standard 507 may be obtained at http://www.comm-2000.com.

4. In the ISOR, two references were included to the U.S. Food and Drug Administration regulations governing labeling of medical devices (21 CFR 801) and the maximum acceptable level of ozone for specific devices (21 CFR 801.415). A revised title 21 of the Code of Federal Regulations is issued on approximately April 1 each year. Staff relied on the 2007 versions during the development of this regulation, but the 2005 versions were cited in the ISOR. The correct citation should have been to the year 2007. The corrected citations are as follows:

   FDA (U.S. Food and Drug Administration), 2007a. 21 CFR 801.415, Maximum acceptable level of ozone. April 1, 2007.

   FDA, 2007b. 21 CFR 801. Medical Devices. Labeling. April 1, 2007.

   Both of these are available at:
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=801.

5. In the ISOR, the reference for Boeniger, 1995 was omitted from the reference list. The omitted citation was added:

   Boeniger MF, 1995. Use of ozone generating devices to improve indoor air quality. *J American Industrial Hygiene Association* 56: 590-598.

6. The following references were added into the hearing record which the Board compiled for this rulemaking action, including all the information upon which the proposal was based.

   California Department of Health Services (CDHS), 2006. "Pandemic Influenza Preparedness and Response Plan," September 26, 2006. Excerpts from document: Table of contents (pgs i – vi); Chapter 1 (pgs 1-16); Chapter 4 (pgs 74-75) and Chapter 5 (pgs 78-92), including Appendix C "Recommendations for Infection Control in the Healthcare Setting."
   http://www.cdph.ca.gov/HealthInfo/discond/Documents/pandemic_influenza_preparedness_response_plan 06.pdf

Gauderman WJ, McConnell R, Gilliland F, London S, Thomas D, Avol E, Vora H, Berhane K, Rappaport EB, Lurmann F, Margolis HG, and Peters J, 2000. Association between Air Pollution and Lung Function Growth in Southern California Children. *American Journal of Respiratory and Critical Care Medicine*, 162:1383-1390.

Gauderman WJ, Gilliland GF, Vora H, Avol E, Stram D, McConnell R, Thomas D, Lurmann F, Margolis HG, Rappaport EB, Berhane K, and Peters JM, 2002. Association between Air Pollution and Lung Function Growth in Southern California Children – Results from a Second Cohort. *American Journal of Respiratory and Critical Care Medicine*, 166:76-84.

Gilliland FD, Berhane K, Rappaport EB, Thomas DC, Avol E, Gauderman WJ, London SJ, Margolis HG, McConnell R, Islam KT, and Peters JM, 2001. The Effects of Ambient Air Pollution on School Absenteeism Due to Respiratory Illness. *Epidemiology*; 12(1): 43-54. January 2001.

Hodgson, A., K. Ming and B. Singer, 2004. *Quantifying Object and Material Surface Area in Residences*. LBNL Report #56786, Lawrence Berkeley National Laboratory, Berkeley, CA.

Lee, K., J. Vallarino, T. Dumyahn, H. Özkaynak, and J. Spengler, 1999. Ozone Decay Rates in Residences. *J. Air & Waste Management Assoc*., 49:1238-1244.

Offermann, F. J., 2008. Ventilation and Indoor Air Quality in New Homes, presentation of study results as Chairman's Seminar, Air Resources Board, May 6. See http://www.arb.ca.gov/research/seminars/offermann/offermann.pdf

U.S. EPA, 2007. "Ozone Generators that are Sold as Air Cleaners," last updated on August 9, 2007. Only available via the web site: http://www.epa.gov/iaq/pubs/ozonegen.html

Wilson, A. L., Bell, J., Hosler, D., and Weker, RA, 2003. Infiltration, Blower Door and Air Exchange Measurements in New California Homes, in *Proceedings of IAQ Problems and Engineering Solutions Specialty Conference*, Air and Waste Management Association and U. S. EPA, Research Triangle Park, NC, July.

C. Supplemental Additions to the Rulemaking Record and Corrections Noticed on July 16, 2008

A "Second Notice of Availability of Additional Documents" (Second 15-day Notice) was issued on July 16, 2008, initiating a second 15-day comment period from July 16 to July 31, 2008 to add three references to the rulemaking record and make two corrections to references in the ISOR.

The following additional references were added into the rulemaking record which the Board compiled for this rulemaking action, including all the information upon which the proposal was based.

1. UL, 2007a. EOKL.GuideInfo: Deodorizers, Ozone Generator Type. June 25. http://database.ul.com/cgi-bin/XYV/template/LISEXT/1FRAME/showpage.html?name=EOKL.GuideInfo&ccnshorttitle=Deodorizers,+Ozone+Generator+Type&objid=1074006830&cfgid=1073741824&version=versionless&parent_id=1073986290&sequence=1.

2. UL, 2007b. OETX.GuideInfo: Ion Generators. June 25. http://database.ul.com/cgi-bin/XYV/template/LISEXT/1FRAME/showpage.html?name=OETX.GuideInfo&ccnshorttitle=Ion+Generators&objid=1074024628&cfgid=1073741824&version=versionless&parent_id=1073990618&sequence=1.

3. UL, 2008. AGGZ.GuideInfo: Electrostatic Air Cleaners. April 25. http://database.ul.com/cgi-bin/XYV/template/LISEXT/1FRAME/showpage.html?name=AGGZ.GuideInfo&ccnshorttitle=Electrostatic+Air+Cleaners&objid=1073997187&cfgid=1073741824&version=versionless&parent_id=1073984036&sequence=1

The following two citations in the reference list to the ISOR were corrected as follows:

1. In the ISOR released for public review on August 9, 2007 the reference for Phillips *et al*. (1999) cited on pages 1 and 7 was omitted from the reference list on page 49. This reference is being added to the rulemaking record and is cited as follows:

   Phillips, TJ, Bloudoff DP, Jenkins PL, and Stroud KR, 1999. Ozone emissions from a "personal air purifier". *J. Exposure Analysis and Environmental Epidemiology* 9: 594-601.

2. The Initial Statement of Reasons erroneously referenced the Freedonia Group Report #1829 as being published in 2003. The correct date is 2004. The correct citation should be as follows: Freedonia Group, 2004. Consumer water purification and air cleaning systems to 2008. Report #1829. Cleveland, OH. Note that this reference is variously cited as "The Freedonia Group (2004)" and "Freedonia (2004)" in several locations in the Staff Report.

III. SUMMARY OF COMMENTS AND AGENCY RESPONSES

The Board received written comments during the 45-day public comment period for the proposed regulation; written and oral comments at the September 27, 2007 public hearing; and written comments during the two 15-day comment periods. A combined list of commenters is provided in subsection A below. Subsection B contains comments, grouped by subject area, and agency responses.

Set forth below in subsection B is a summary of each objection or recommendation specifically directed to the proposed regulation or to the procedures followed by ARB in

proposing or adopting the regulation. Each comment is followed by the agency response explaining how the proposed action was changed to accommodate each objection or recommendation, or the reasons for making no change. The comments have been grouped by topic wherever possible. Comments that do not involve objections or recommendations specifically directed towards the rulemaking, or to the procedures followed by ARB in this rulemaking are generally not summarized below. Additionally, any other referenced documents are not summarized below.

Each comment and agency response is marked with identification information in parentheses to denote the commenter as listed in subsection A and the person(s) responsible for submitting/presenting the comment(s). For example, comments submitted from the comment letter number 1 in subsection A are marked as: (1-Smith).

A. Combined List of Commenters

Written Comments Submitted During the 45-day Comment Period Before the September 27, 2007 Public Hearing

1. Smith, Carl – Greenguard
2. Hutchinson, Nicole – and 350 similar American Lung Association form letters
3. Wallace, Lance – U.S. EPA
4. Shaughnessy, Richard – University of Tulsa
5. Nazaroff, William – University of California, Berkeley
6. Marsden, James – Kansas State University
7. Marsden, James – Kansas State University
8. Corsi, Richard – University of Texas, Austin
9. Gold, Sharon
10. Hatesohl, Pamela – Food Safety Systems, LLC
11. Franken, Laurence
12. Kowalczyk, Brandi
13. Brickman, Robert and Greg Montoya – California Consumers for Freedom of Choice
14. Johnston, Allen – EcoQuest International
15. Weschler, Charles – Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey
16. McClary, Howard – ClearWater Tech
17. Morrison, Glenn – University of Missouri – Rolla
18. Sorrells, Kent M.
19. Montoya, Greg – submitted by Brickman, 626 form letters for California Consumers for Freedom of Choice
20. Woodford, Amy – submitted by Brickman
21. Kavin, Karen – submitted by Brickman
22. Barnes, Rebecca – submitted by Brickman
23. Elder, Angela – submitted by Brickman
24. Arthur, Joseph – submitted by Brickman
25. Rano, Mike – submitted by Brickman
26. Maple, Frank – submitted by Brickman

27. Norlien, Kathleen – Minnesota Department of Health
28. Giddens, Michelle – submitted by Brickman
29. Lori Recatto – submitted by Grijalva
30. Johnston, Allen – EcoQuest International
31. Baskin, Robert
32. Kammer, Claire – Underwriters Laboratory
33. Johnston, Allen – EcoQuest International
34. Naylor, Robert – representing EcoQuest International
76. Barnes, Ronald – Prozone

Written Comments and Oral Testimony, or Written Comments Only, Received at the September 27, 2007 Public Hearing

35. King, Brian (written comments only)
36. Jakpor, Otana – (oral hearing testimony at transcript page 64; written comments)
37. White, Levi – (transcript page 92; written comments)
38. Webb, Lee (transcript page 91; written comments)
39. Pruitt, Greg (transcript page 96; written comments)
40. Andreatta, Sally (transcript page 102; written comments)
41. Quintana, Colleen (transcript page 104; written comments)
42. Marsden, James (written comments only)
43. Kleinman, Michael – University of California, Irvine (transcript page 60; written comments)
44. Morris, Wayne – Association of Home Appliance Manufacturers (AHAM) (transcript page 136; written comments)
45. Chaves, Ronald (transcript page 150; written comments)
46. Holmes-Gen, Bonnie – American Lung Association of California (transcript page 118; written comments)

Oral Testimony Only at the September 27, 2007 Public Hearing

47. Ospital, Jean – South Coast Air Quality Management District (transcript page 62)
48. Johnston, Allen – EcoQuest International (transcript page 67)
49. Wilson, Richard (page 72)
50. Naylor, Robert – EcoQuest International (transcript page 74)
51. Sorrells, Kent – EcoQuest International (transcript page 77)
52. Perkins, Debra (transcript page 86)
53. Lozano, Carmel (transcript page 88)
54. Lozano, Tom (transcript page 90)
55. Perkins, Robert (transcript page 94)
56. Feder, Gary – Hunter Fan (transcript page 98)
57. Perez, Laarni (transcript page 106)
58. Sy, Leonardo (transcript page 107)
59. Perez, Sherwin (transcript page 108)
60. Amendola, Joe (transcript page 109)
61. Barnes, David (transcript page 111)

62. Grijalva, Mark (transcript page 112)
63. Cherabi, Johnny (transcript page 114)
64. Olsen, Martin (transcript page 116)
65. Fuehrer, Chris (transcript page 122)
66. Montoya, Greg – California Consumers for Freedom of Choice (transcript page124)
67. Brickman, Bob – California Consumers for Freedom of Choice (transcript page 127)
68. Gold, Sharon (transcript page 130)
69. Hawkins, Jeff (transcript page 133)
70. Hudgins, Chris – Association of Home Appliance Manufacturers (transcript page 135)
71. Sullivan, Kirk – International Association of Air Cleaner Manufacturers (transcript page 141)
72. Dolphin, Glory – International Association of Air Cleaner Manufacturers (transcript page 142)
73. Korthof, Douglas (transcript page 145)
74. Rothman, Gary (transcript page 147)
75. Carmichael, Tim – Coalition for Clean Air (transcript page 152)
76. See above under #34

Written Comments Submitted During the 15-day Comment Period

1. Wallace, Lance
2. Morris, Wayne – AHAM
3. Jacobson, Catherine – 3M Company
4. Barnes, Ronald – Prozone
5. Feder, Gary – Hunter Fan Company
6. Montoya, Greg – California Consumers for Freedom of Choice, submitted by Robert Brickman
7. Naylor, Robert – representing EcoQuest International
8. Wright, Cheri – Kaz, Inc.

Written Comments Submitted During the Second 15-day Comment Period

1. Scott, Camille
2. Barnes, Ronald – Prozone Water Products

B. Summary of Comments Received During the 45-day Public Comment Period and Board Hearing and Agency Responses

Various studies are cited throughout the Responses to the following Comments. These studies are part of the record for this rulemaking and appear in the list of References on pages 49-54 of the Staff Report, or were added to the record by the June 30, 2008 15-day Notice or the July 16, 2008 Second 15-day Notice and are listed above in Section II where the two 15-day notices are discussed.

SUPPORT

1. Comment: In general, we support the regulation to limit ozone emissions from indoor air cleaning devices. **(1-Smith; 2-Hutchinson; 3-Wallace; 4-Shaughnessy; 5-Nazaroff; 8-Corsi; 15-Weschler; 16-McClary; 17-Morrison; 36-Jakpor; 43-Kleinman; 44-Morris; 46-Holmes-Gen; 47-Ospital; 56-Feder; 70-Hudgins; 71-Sullivan; 72-Dolphin)**

Agency Response: We appreciate the supportive comments.

2. Comment: I fully support the proposed regulation, and believe California has taken a sensible approach. There is anecdotal evidence of hazardous ozone levels produced by ozone generators. For example, the University of Minnesota evaluated the use of ozone generators to control odors in hog barns, but concluded that the ozone levels would be hazardous to the hogs' health. The Minnesota Department of Health staff have received calls from many individuals who are experiencing worsening of their breathing problems (decreasing lung function), and tell staff that they have an ozone-generating air cleaner, or multiple ozone air cleaners in their living quarters. The Department has also evaluated the use of an ozone generator for treating odors in hockey equipment in a sports arena, and found that indoor ozone levels reached 0.56 ppm. **(27-Norlien)**

Agency Response: We appreciate the supportive comments and the anecdotal information.

3. Comment: We support the proposed regulation but note that the 0.050 ppm ozone limit may result in unsafe levels of byproducts of indoor ozone chemistry (oxidation products). Even 50 ppb of ozone is sufficient to have meaningful undesirable consequences in terms of indoor chemistry. **(15-Weschler)**. Fifty ppb of ozone (0.050 ppm) would result in about 30 ppb of volatile byproducts, including several ppb of formaldehyde, which would be at or above guideline levels for preventing cancer and chronic respiratory effects in humans. **(5-Nazaroff)**

Agency Response: We agree that indoor ozone reactions can produce significant levels of toxic and irritant byproducts such as formaldehyde, as discussed in the ISOR (pages 2, 4, 8, and 14). However, AB 2276 [Health and Safety Code sections 41985.5 and 41986(a)(1)] requires that the regulation shall include the "emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for air cleaning devices." That is the 0.050 ppm standard applied to medical devices by the federal Food and Drug Administration (see: 21 CFR section 801.415).

The comment by Nazaroff does not provide supporting documentation for his estimate of resultant indoor formaldehyde levels, but his estimates are consistent with those in recent studies. In a study of indoor ozone with reactive cleaning product compounds, researchers found that 60 ppb of ozone in the room produced 11-20 ppb of formaldehyde over 12 hours (Nazaroff *et al.*, 2006 and

Singer *et al.*, 2006; both cited in ISOR on pages 14 and 46). The peer-reviewed article submitted by Weschler estimates conservatively that indoor inhalation of ozone's oxidation products are roughly one-half to twice indoor inhalation intakes of ozone and much greater than outdoor intakes of oxidation products (Weschler CJ, 2006. *Environmental Health Perspectives* 114:1489–1496, submitted by **15-Weschler).** The Response to Comment 6 is incorporated by reference here.

4. Comment: We support the proposed regulation, but note that more recent studies suggest that the health effects of indoor ozone and its chemical reaction byproducts can have a significant public health impact, even at very low levels of ozone. One commenter cites articles on epidemiological studies that provide insights into ozone's effects on respiratory stress and mortality at outdoor ozone levels below those for current air quality standards, and suggests that health effects may be occurring at even lower levels of indoor ozone. **(8-Corsi)** One commenter states that epidemiology studies show that ozone has a significant association with increased mortality at levels well below 0.050 ppm, and a clinical study of a small number of sensitive individuals showed clinically significant loss of lung function at ozone levels as low as 0.04 ppm, but the commenter did not give specific references. **(43-Kleinman)** A commenter referred to two peer-reviewed articles from a study of indoor ozone and ozone by-products in an aircraft cabin, at levels slightly above the proposed limit of 0.050 ppm. One article (submitted with the comment) indicates that the ozone and its byproducts produced significant worsening of 12 Sick Building Syndrome symptoms in the human subjects, such as eye and nasal irritation, headache, dizziness, mental tension, and claustrophobia. The other article indicates that the resultant concentrations of several byproduct compounds were above odor threshold levels. **(5-Nazaroff**) Another commenter provided a peer-reviewed article that reviews the scientific literature on the impacts of ozone oxidation products, and shows the growing evidence that some resulting products from indoor ozone reactions are even more harmful than ozone itself. **(15-Weschler)** The article includes estimates of the impact of indoor ozone on indoor particulate matter and aldehyde exposures and provides indirect evidence to connect morbidity/mortality to indoor ozone and its oxidation products.

Agency Response: We agree that recent literature has pointed to possible health impacts at lower levels of exposure to ozone. However, such studies are few in number and do not provide an adequate basis for a reduced emission concentration of ozone at this time. We also agree that indoor ozone's reaction byproducts can be significant, as discussed in the Response to Comment 3, which is incorporated here. The study of aircraft cabin passengers is not directly applicable to exposures in homes, classrooms, and offices, but it confirms the importance of exposures to indoor ozone byproducts. We will consider all of these and other such studies in future actions related to this air cleaner regulation. However, AB 2276 [Health and Safety Code section 41985.5 and 41986(a)(1)] requires that the regulation shall include the "emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for air cleaning devices." That is the 0.050 ppm standard applied to medical

devices by the federal Food and Drug Administration (21 CFR section 801.415). The Response to Comment 6 is incorporated by reference here.

5. Comment: I support the proposed regulation, but suggest that the ARB consider two standards – one for room purifiers and a more stringent one for personal purifiers as a greater effect was observed after exposure to a personal air purifier. **(36-Jakpor)**

Agency Response: We disagree with this comment. The suggestion to adopt two standards is contrary to the enabling legislation. AB 2276 [Health and Safety Code sections 41985.5 and 41986(a)(1)] requires that the regulation shall include the "emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for air cleaning devices." That is the 0.050 ppm standard applied to medical devices by the federal Food and Drug Administration (21 CFR section 801.415). AB 2276 includes all indoor air cleaning devices, such as personal air purifiers as well as room air purifiers, and precludes setting different standards for the two different devices. The statute requires consistency with federal regulations, so personal air purifier devices and room devices alike will have to be certified to the same ozone emission standard. Most people carry personal air cleaning devices approximately six inches from their mouths and noses, but the test protocol in the regulation requires testing at two inches from the device. Because ozone concentrations can decrease rapidly with distance from the air cleaner, the standard should be protective.

6. Comment: The 0.050 ppm ozone standard should be reviewed periodically to account for future research into the effects resulting from exposure to ozone and ozone reaction by-products. ARB should consider a lower standard in the near future because ozone introduced into an indoor environment can increase the total mass of inhalable compounds. A commenter presented a paper describing a rationale for an indoor ozone concentration limit of 0.005 ppm. **(4-Shaughnessy; 8-Corsi; 17-Morrison)**

Agency Response: We agree with the comment that the 0.050 ppm ozone standard should be reviewed periodically to assess the need to adjust it based on new research, but disagree with the comments that the proposed regulation should include an emission standard lower than 0.050 ppm of ozone in the near future. While we concur that there are some recent studies showing a likelihood of adverse effects below 0.050 ppm for some sensitive groups, those studies are few in number and provide an inadequate basis for a lower standard at this time. AB 2276 (Health and Safety Code sections 41985.5 and 41986), the statute authorizing the ARB to adopt the air cleaner regulation, requires that the regulation include an emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for medical devices established in federal regulation (21 CFR section 801.415). The concentration limit of 0.050 ppm specified in the statute is below the state's outdoor 8-hour health-based ambient air quality standard of 0.070 ppm. The lower level is appropriate because exposure to ozone from air cleaners may occur over periods of time longer than 8 hours, and a lower ozone concentration is thus

needed to assure the same level of protection as the outdoor standard. The ARB staff periodically review research findings relating to the state ambient air quality standard for ozone, and will pursue authorization to set a lower standard in the future if warranted.

BASIS & SCOPE OF REGULATION

7. Comment: The proposed 0.050 ppm level is selected based on current health data, or lack thereof, on the effects of ozone at less than 0.050 ppm concentration in the space, and coincides with the FDA limit of 0.050 ppm concentration in the space. **(4-Shaughnessy)**

Agency Response: We agree with the part of the comment that concerns the federal law (FDA) 0.050 ppm ozone concentration standard and disagree with the rest of the comment. As discussed in the ISOR (page 5) and in our Responses to Comments 3 through 6, the 0.050 ppm emission concentration limit is based on the U.S. FDA limit of 0.050 ppm for both air accumulating in the space and for air passing through the device, as required by the AB 2276. We also compared this limit to current health-based standards for California and the U.S., and to the results of current health effects studies, which are less stringent than the U.S. FDA standard (ISOR, page 6). The UL 867 test method uses an 8- or 24-hour steady state measurement at two inches from the device, which is consistent with the FDA standard because it addresses both the level of accumulated ozone level and the level of ozone passing through the device.

8. Comment: To fully evaluate the indoor accumulation of ozone, one must consider not only contributions from indoor sources, but also that from the outdoor environment. The broader scenario of including outdoor air sources should also be considered in the final evaluation as to resultant indoor ozone accumulation and whether or not it is below the 50 ppb level related to the FDA Standard (note: it is recognized that the authors of the CA regulation are only citing the FDA limit as one of the Standards currently in place; thus the information provided here is for reference purposes only). (**4-Shaughnessy**)

Agency Response: We do not agree with the comment that we should consider outdoor ozone contributions to indoor ozone levels in assessing accumulation of ozone above 0.050 ppm. The enabling legislation (AB 2276) requires that the regulation be consistent with the U.S. FDA limit of 0.05 ppm for medical devices, which does not consider the contribution of outdoor ozone. The U.S. FDA limit applies to both air accumulating in the space and to air passing through the device (an emission concentration). The UL 867 test method uses an 8- or 24-hour steady state measurement at two inches from the device, which is consistent with the U.S. FDA standard because it addresses both the level of accumulated ozone and the level of ozone passing through the device.

We agree with the comment regarding the importance of outdoor ozone in contributing to indoor and personal ozone exposure. The ARB staff periodically

review research findings relating to the state ambient air quality standard for ozone, and will pursue authority to set a lower standard in the future if warranted. Responses to Comments 3, 4 and 6 are incorporated by reference here.

9. Comment: There has been no medical or scientific evidence to support actual user harm, i.e. there is no data in the staff report to show that persons were harmed by ozone from indoor air cleaning devices. Staff relied on questionable exposure studies rather than actual medical or epidemiological-based evidence. Staff has admitted there are no indoor based medical or epidemiological studies showing actual consumer or public health harm from low indoor emissions of ozone. The fact that staff recognizes that there have been no epidemiological studies on the effects of indoor ozone exposure would suggest that any regulation is premature. There are no peer-reviewed studies that show people are hurt or injured (by these devices). **(9-Gold; 13-Brickman; 30-Johnston; 34-Naylor; 74-Rothman)**

Agency Response: We disagree with this comment and incorporate Responses to Comments 3-8, 36-37 and ISOR pages 6-8, 12-25 by reference here. The ISOR describes at pages 15 –25 the adverse effects on health that have been demonstrated in both outdoor epidemiological studies and in controlled exposure studies of human subjects. While there have been no epidemiological studies of indoor ozone exposures, the evidence of harm demonstrated in controlled exposure studies is overwhelming. Ozone is ozone whether it is present in an indoor or outdoor setting. Studies described in the Staff Report found decrements in lung function in response to ozone exposure, pulmonary inflammation where ozone damages the tissues lining the respiratory airways, airway hyperresponsiveness where muscle cells in the large airways contract in response to irritants, and demonstrate how asthma can be exacerbated by exposure to ozone. These effects occurred at levels as low as 0.08 ppm after just a few hours of exposure. It is reasonable to conclude that longer exposures such as those caused by an ozone generator operating for prolonged periods of time in a home would produce similar effects at lower levels.

A study of the effects of indoor exposures alone would be difficult to conduct, because many people are also exposed to harmful levels of ozone in outdoor air. Such a study also is unnecessary given the extensive, solid evidence of the harmful effects of ozone already in the scientific literature.

The weight of evidence demonstrating the harm of breathing ozone is further detailed in the ARB staff report on the California ambient health standard for ozone (ARB, 2005b) as discussed on page 6 and pages 15-59 of the ISOR and incorporated here by reference. Moreover, AB 2276 requires the ARB to adopt regulations to protect the public from exposures to levels of ozone greater than 0.05 ppm caused by indoor air cleaning devices in occupied spaces.

10. Comment: Personal air purifiers would be banned under the proposed regulation. **(19-Montoya)**

Agency Response: We disagree with this comment. Personal air purifiers that meet the ozone emission concentration limit, based on testing by a laboratory approved by ARB for the updated UL 867 test method, would comply with the proposed regulation, as discussed in the ISOR (page 2, "Types of Air Cleaners Covered by This Regulation").

11. Comment: Appliances and office equipment can produce ozone indoors and should be regulated too. **(19-Montoya)**

Agency Response: We disagree with this comment. The commenter did not cite any supporting studies, and we are not aware of any studies showing significant emissions of ozone from appliances or office equipment resulting in indoor ozone concentrations of concern in homes or offices. In any case, AB 2276 [Health and Safety Code sections 41985.5 and 41986(a)(1)], the enabling legislation for the proposed regulation does not authorize ARB to address indoor ozone sources other than air cleaners.

12. Comment: Staff should remove compliance with the entire ANSI/UL Standard 867 requirements from the regulation. **(13-Brickman)**

Agency Response: Staff previously addressed the issue of compliance with ANSI/UL Standard 867 in its entirety within Section V.F. of the ISOR (pages 28-30), which is incorporated by reference here. Briefly, the inclusion of the electrical safety testing requirement compliance ensures that any indoor air cleaning devices that have to undergo redesign in order to comply with the ozone emission standard or that are based on new future designs to meet this regulation, do not present a fire safety hazard due to the redesign or design of the device. This requirement complies with the provision in the authorizing statute that the regulation may include "(A)ny other element the state board determines necessary to protect the public health from emissions of ozone from indoor air cleaning devices that exceed the emission concentration standard for ozone emissions from air cleaning devices and are used in occupied spaces." [Health and Safety Code section 41986 (c)(4)].

EFFECTIVENESS OF OZONE

13. Comment; ARB should balance the benefits and risks of air cleaners that use ozone and allow consumers to choose the air cleaner that works best for them, rather than criminalizing our exercise of Freedom of Choice. We urge the Board to slow down and stop the rush to judgment, and take time to further consider other options presented by the California Consumers for Freedom of Choice. **(13-Brickman)**

Agency Response: We disagree with this comment. The use of indoor ozone for air cleaning in occupied spaces has significant health risks but no significant benefits, as discussed in the ISOR (pages 7-8, 13-25 and in our responses to Comments 14-26, all of which are incorporated by reference here). Moreover,

such an approach would be contrary to AB 2276, which requires that the regulation shall include the "emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for air cleaning devices." Health and Safety Code sections 41985.5 and 41986(a)(1), 21 CFR section 801.415.

We have fully considered the options suggested by the commenter and others during the development of the regulation and in both the ISOR (pages 12-13) and Responses to Comments 39-42, all of which are incorporated here by reference. In short, those options were found to be insufficiently protective and/or inconsistent with the directives of AB 2276. We are not rushing to judgment, as evidenced by the fact that three workshops were held to obtain stakeholder and public input as the regulation was developed, as described on pages 10-12 of the ISOR, and pages 4-7 above, which are incorporated here by reference. The scientific evidence of the harmful effects of ozone exposure is mature and overwhelming.

Finally only air cleaners that that produce unhealthful levels of ozone will be eliminated from consumers' choice. No specific models or types of air cleaners are banned. In fact, there are many models of air cleaners available that will remain available, as discussed in Responses to Comments 10, 36, and 61, which are incorporated here by reference.

14. Comment: ARB should recognize the important public health benefits associated with low levels of indoor ozone and submits a paper entitled "White Paper: The Application of Ozone Technology for Public Health and Industry" (2005). **(11-Franken)**

Agency Response: We disagree with this comment. This paper (sponsored by EcoQuest International, a manufacturer of indoor air cleaning devices that generate ozone) summarizes ozone applications in various manufacturing industries, and its potential for reducing the risk of infection in the home and in health care facilities. In discussing disinfection, the author cites ozone levels ranging from 0.1 ppm to 9 ppm being used to kill microorganisms, levels that would be significantly above the level of our proposed standard. The paper fails to support any claims of the benefits of using low levels of ozone and instead supports our position that much higher levels of ozone are required to kill microorganisms or to disinfect.

The author includes mention of health concerns; in discussing the possible disadvantages of ozone technology, he states that "(B)ecause ozone cannot differentiate between good organic molecules and bad, it can, in excessive amounts, oxidize us." The author goes on to explain that there is concern that ozone generators can produce unsafe levels in the rooms in which they are used, that there are some devices on the market that are capable of producing ozone concentrations well above accepted health guidelines, and that because ozone dulls the sense of smell, perceived odor is not a reliable indicator of ozone's

presence. These concerns mirror our concerns and those of the Legislature in passing AB 2276.

It appears that the author also subscribes to the theory that there are good and bad forms of ozone, the former generated from oxygen and the latter formed from room air. We are unaware of any differences in the potential harm to human health from ozone regardless of how it is generated. Ozone is ozone and its effects are described in the ISOR at pages 15-19 and were reviewed by the ARB in the most recent revision of the State ambient air quality standard for ozone (ARB, 2005b). Similarly, the author appears to take the position that ozone is not the major constituent of smog, but rather that ozone is actually cleaning up the air pollution. We disagree and cite the atmospheric chemistry of ozone which is discussed in the ISOR at pp 19-20. The cited portions of the ISOR and the ARB, 2005b study are incorporated by reference here.

15. Comment: Regarding the significant public health benefits of the proposed regulation from reductions in indoor ozone and its chemical reaction products such as formaldehyde, this assumes that there is a problem in the first place. This has not been established – only assumed. **(30-Johnston)**

Agency Response: We disagree with this comment. The use of indoor ozone for air cleaning in occupied spaces has significant health risks but no significant benefits, as discussed in the ISOR (pages 7- 8, 13-25) and in our responses to Comments 14 and 16-26, which are incorporated here. The production of hazardous levels of indoor ozone well above health-based standard levels by some air cleaners, especially ozone generators, has been established in scientific studies using a test home, test room, or test chamber under well characterized conditions (ISOR, pages 20-25). These portions of the Staff Report are incorporated by reference here.

16. Comment: Several commenters submitted personal testimonials that they had observed reduced health symptoms and/or odors in their homes or other settings after using an air cleaner that produces ozone. Some of the commenters requested that the Board not adopt the proposed regulations because the regulation would ban their devices, while the testimonials submitted by 14-Johnston were more general in nature. **(14-Johnston [includes 49 testimonial letters dating back to the year 2000 from across the country]; 12-Kowalczyk**, **20-Woodford; 21-Kavin; 22-Barnes; 23-Elder; 24-Arthur; 25-Rano; 26-Maple; 29-Recatto; 31-Baskin, 37-White; 38-Webb; 39-Pruitt; 40-Andreatta; 41-Quintana; 45-Chavez, 49-Wilson, 52-Perkins; 53-Lozano; 54-Lozano; 55-Perkins; 57-Perez; 58-Sy; 59-Perez; 60-Amendola; 61-Barnes; 62-Grijalva; 63-Cherabie; 64-Olsen; 65-Fuehrer; 69-Hawkins; 73-Kortoff; 74-Rothman)**

Agency Response: We disagree with this comment and incorporate Responses to Comments 14, 15, and 17-26 by reference here. Assuming for the sake of argument that the testimonials are true, they do not outweigh the overwhelming scientific evidence of the harmful effects of exposure to elevated levels of ozone

such as lung inflammation and decrements in lung function, the association of ozone with increased mortality rates, and increased hospitalizations and school absences as discussed in the ISOR at pages 15-25 and incorporated by reference here. Nor do those comments relieve ARB of the duty to adopt regulations pursuant to the requirements of AB 2276. While we accept these as personal experiences using ozone-generating air cleaners, we are not aware of any reliable scientific studies that show any health benefits resulting from exposure to ozone. The testimonials do not negate the need for the proposed regulation nor do they indicate that the proposed regulation should be modified. We are also aware that many ozone generators contain multiple technologies (e.g. ionizers and electrostatic precipitators) that do effectively remove particles and could be, at least in part, responsible for the claimed improvements. Our concern resides with the ozone that is emitted from certain types of air cleaners and is the underlying reason for the proposed regulation.

17. Comment: One commenter stated that ozone, including that from lightning, has a natural cleansing effect on air quality. **(30-Johnston)**

Agency Response: We disagree with this comment. While ozone can remove a few pollutants (primarily aromatic hydrocarbons like benzene) because of its high reactivity, it does not effectively remove most other pollutants in the outdoor or indoor air. Please see Responses to Comments 14-16, 18-26, and 37 and the Staff Report at pages 7-8 and 15-25, which are incorporated by reference here. In addition, the byproducts of the ozone reactions can be toxic or irritant compounds (Staff Report, pages 2 and 8; Weschler, 2006) and ultrafine and fine particles, which can affect human health and impair regional visibility.

18. Comment: Safe levels of ozone have now been scientifically proven to kill dangerous indoor air and surface contaminants such as staph, mold, mildew, odors, etc. **(13-Brickman)** Low levels of ozone – 0.02 ppm – have proved effective in controlling microbiological hazards on inoculated surfaces. Two of the commenters refer to a paper by Ortega *et al.* which was submitted by Johnston. **(6-Marsden; 9-Gold; 10-Hatesohl; 13-Brickman; 30-Johnston; 34-Naylor; 39-Pruitt; 42-Marsden; 65-Fuehrer; 66-Montoya; 74-Rothman)**

Agency Response: We disagree with this comment. The views expressed by the commenters and in the Ortega paper are out of step with the weight of scientific evidence. The Ortega *et al.* paper is unreliable. The paper, titled "Efficacy of EcoQuest Radiant Catalytic Ionization (ActivePure) Cell and Breeze AT Ozone Generators at Reducing Microbial Populations on Stainless Steel Surfaces", is undated, and does not indicate either where or if it has been published, and for these reasons it cannot be determined whether it was peer-reviewed. There are other indications of the paper's unreliability. The paper concludes that an EcoQuest Radiant Catalytic Ionization (RCI) Cell and an EcoQuest Breeze AT ozone generator were able to reduce microbial populations on stainless steel surfaces. The paper, however, is poorly referenced (containing only two references) and does not include sufficient information to support the stated conclusions. It fails to describe the size, construction or any

other characteristic of the mini-environmental chamber, how the ozone was generated, and how it was introduced into the chamber. It states in the results section at page 3 that the ozone concentration was 0.02 ppm, but does not explain how that level was maintained. The paper states that the subject microbial populations were coated on highly polished stainless steel surfaces; this creates the most ideal conditions for exposure to the ozone, conditions that are unlikely to be encountered in real world settings where mold is hidden behind baseboards and in soft wall materials. The paper also fails to state what the relative humidity was in the chamber, despite the fact that it is known that higher humidities can result in more significant microbial inactivation. Finally, the paper concludes that the RCI Cell was more effective than the ozone generator, yet there is no discussion of how much ozone was produced by the RCI Cell or what other mechanisms may have contributed to produce the results shown.

The conclusions of the Ortega *et al.* paper, which applies only to microbes on a smooth surface, differ from the conclusions of Foarde *et al.* (1997) cited in the ISOR on page 8. Foarde *et al.* found much higher concentrations of ozone (6 to 10 ppm) were required for significant kill on smooth surfaces. The study described the exposure chamber and monitoring in detail, and showed higher kill rates with higher relative humidity. In the Foarde *et al*. study, when organisms were placed on actual building materials that would reflect real world environments, no microbial kill was observed even at levels as high as 9 ppm. The Foarde study is peer-reviewed and adequately supported by references, indicating that it is more reliable than the Ortega paper.

Moreover, the U.S. Environmental Protection Agency (2007; see 15-day Public Notice, as shown above in Section II) has concluded that ozone used at concentrations that do not exceed health standards does not effectively remove viruses, bacteria, mold or other biological pollutants. Referring to airborne microbes, the U. S. EPA stated that ozone concentrations would have to be 5-10 times higher than health standards before ozone could decontaminate the air sufficiently to prevent survival and regeneration of the organisms. Even at high concentrations, ozone may have no effect on biological contaminants embedded in porous materials. The Responses to Comments 14, 19, 21 and 26 are incorporated by reference here.

19. Comment: The regulation will eliminate product and technology options to treat and protect against known natural and health and safety-related disasters (for example, SARS, staph infection or contamination, other infections, mold and smoke from wildfires and flooding, bacterial contamination, etc.). **(9-Gold; 10-Hatesohl; 11-Franken; 13-Brickman)** The regulation will eliminate safe options (ozone-generating air cleaners) that would protect against healthcare associated infections and pandemic influenza. The regulation will unduly limit consumers' choices and not in the best interest of consumers. **(13-Brickman)**

Agency Response: We disagree with this comment and incorporate pages 2, 4, 6-8, 10, 15-25 of the Staff Report by reference here. As noted on page 4 of the Staff Report, manufacturers of ozone generators (OGs) often claim that "safe"

levels of ozone can remove indoor air pollutants such as particles, gases, allergens, viruses, odorous compounds, mold, and bacteria. However, while ozone is somewhat effective in killing mold and bacteria on building material surfaces, it is effective only at extremely high levels – over 5.0 ppm – and even those levels do not denature or remove microbial residues and spores in building materials where their presence can trigger asthma and allergy symptoms (Foarde *et al*., 1997; see ISOR page 8).

Ozone treatment is recognized by scientists as an effective means of killing microorganisms for purifying water, but not as a means of cleaning indoor air. Extensive expert testimony in the successful lawsuit by the federal government against Alpine Air and Living Air, two OG manufacturers, confirmed the almost complete lack of effectiveness of ozone for indoor air treatment (FTC, 2002). In fact, ozone reacts only with some gases of concern (aromatic hydrocarbons such as benzene) and with terpenes, such as limonene and pinene, which produces significant increases in other pollutants such as formaldehyde and ultrafine particles, which can be harmful to health (Boeniger, 1995; Nazaroff and Weschler, 2004; Hubbard *et al*., 2005).

Based on a review of studies [e.g. Foarde *et al.* (1997) from the ARB's ISOR and Grinshpun *et al.* (2007) provided by commenters], it is clear that ozone used at concentrations below health standards would be ineffective to treat or prevent such disasters. Remediation of contaminated environments is exempt under the regulation [see sections 94801(a)(14), and 94803] and would be subject to other regulatory restrictions such as occupational standards to protect workers engaged in the remediation. We also note that ozone-generating air cleaners are ineffective at removing particulate pollution and smoke (Grinshpun *et al.* 2007; U.S. EPA, 2007 cited in the 15-day Public Notice and Section II above), except when they include physical filters, ionizers or electrostatic precipitation technologies in the device.

The regulation is in consumers' best interests because it protects them from unhealthful exposures to ozone from air cleaning devices. Consumers have many other air cleaners to select from, as discussed in Response to Comment 36, which is incorporated here. The regulation does not ban any technology, but rather sets out the criteria that all must meet, as discussed in Response to Comment 57, which also is incorporated here by reference.

20. Comment: Peer review studies demonstrate the effectiveness of the Wein personal air purifier. **(13-Brickman; 30-Johnston)**

Agency Response: We disagree with this comment. The commenters did not cite or provide the peer-reviewed studies to support this claim, and staff is not aware of any such studies in the extant literature. In any case, the proposed regulation does not address the effectiveness of air cleaners, only their ozone emissions and their electrical and fire safety. The ISOR (pages 7, par. 4) cited the peer-reviewed article by Phillips *et. al*. (1999), which reported that ozone emissions from an earlier model of the Wein personal air purifier exceeded

0.200 ppm at a 3-inch distance, a concentration much greater that the proposed 0.050 ppm limit at two inches in UL 867 Section 37. Please see the Staff Report at pages 7-25 and the previous Response to Comments 14-19 and 21-16, which are incorporated by reference here.

21. Comment: Staff ignores the latest science including peer-reviewed and published science that substantiates ozone's safe and beneficial use in indoor air cleaning process. Commenters cite Grinshpun *et al.* (2007) and Ortega *et al.* (undated) as evidence that ozone-generating air treatment systems remove particles and odors from the air, and the substantial inactivation of pathogens including bacteria, viruses and mold spores in the air and on surfaces in indoor environments. **(9-Gold; 13-Brickman; 66-Montoya; 30-Johnston; 33-Johnston; 34-Naylor)**

Agency Response: We disagree with this comment and incorporate our Response to Comments 3-6, 14-19 and 22-26 by reference here as well as pages 7-8 of the ISOR. The Kansas State study (Ortega *et al.* paper) is analyzed and responded to in the Response to Comment 18 above. In summary, the Ortega paper is unpublished (and may not be peer-reviewed) and undated, and it inadequately describes the testing protocol that investigators followed. For example, the paper doesn't provide a description of the testing chamber, the conditions under which the testing was done, and how ozone was generated, monitored and maintained at 20 ppb.

The paper by Grinshpun *et al.* (2007) studied the removal of particles with a prototype air purifier from EcoQuest that used an ion emitter and photocatalytic oxidation by a "radiant catalytic ionization (RCI) technique." Particle removal was studied in a large room-sized test chamber and the inactivation of microorganisms in a small test chamber (a cube approximately one and a half meters on a side). The authors themselves however, attribute the particle removal to the ionizing feature of the air cleaner, and conclude that the biocidal effect is a result of the photocatalytic oxidation that formed "reactive species such as hydroxyl radicals, valence-band holes, superoxide ions, and hydrogen peroxides." The authors also state that while ozone generators can inactivate viable microorganisms, the inactivation occurs at concentrations significantly exceeding health standards in the ppm range (page 606); that "the ozone produced by the RCI cell is not believed to cause significant microbial inactivation because its level was not sufficient" (page 611); and finally, the authors themselves caution against using devices that generate ozone. The authors noted that the ozone concentration in the small test chamber reached 50 ppb in about 5 minutes, and on page 610, they state that "the use of such devices (that generate ozone) in confined occupied air spaces may not be appropriate as their continuous operation may eventually lead to excessive ozone levels, and, in the presence of certain chemical compounds, produce nanoparticles."

Staff periodically reviews the basis of the state's ambient air quality standard for ozone which is a serious outdoor air pollution problem in California. Therefore, staff are familiar with the most recent published and ongoing health research and

are unaware of any current science that substantiates the safe and beneficial uses of ozone in occupied spaces. The ARB's most recent review of the standard was in early 2005 (ARB, 2005b).

22. Comment: "I request that you agree to a group demonstration by a local certified expert on the use of this equipment. This demonstration could be performed in less than 20 minutes. Given the unquestionable success of the demonstration I hope you will accept the opportunity to evaluate these technologies personally before you make your decision based on written word. This may be the most basic opportunity needed to validate your decision. As an elected official, how could you reject an opportunity to make a decision that you could justify from personal experience?" **(28-Giddens)**

Agency Response: We disagree with this comment. Given the wealth of scientific information available (described in pages 7-25 of the ISOR, which are incorporated here by reference), such a demonstration is unnecessary. Regarding the successful use of ozone to treat indoor air, we rely on peer-reviewed, scientific studies and controlled tests that provide sound information. As described in the ISOR (page 8), ozone generators are not effective in removing indoor air pollution or microbes except at unhealthful levels of ozone, but in any case, effectiveness is beyond the scope of the proposed regulation which addresses the emissions of ozone from such devices. The best way to make a determination about the device's ozone emissions would be for the manufacturer of the air cleaning equipment to have it tested for ozone emissions and compliance under the proposed regulations. To test the effectiveness of the air cleaner, the commenter might also have the device tested in a laboratory certified to measure Clean Air Delivery Rates for particle removal, using the AHAM standard test method (see http://www.cadr.org).

23. Comment: The proposed regulation violates the spirit and intent of California's Statewide Preparedness Pandemic Influenza law. The proposed regulation would ban safe, scientifically-proven devices capable of killing many if not all of these deadly pathogens. **(13-Brickman; 30-Johnston)**

Agency Response: We disagree with this comment and incorporate Responses to Comments 4, 6, 14, 16, 18, 19, and 21 by reference here. No peer-reviewed information on the effectiveness of ozone in effectively reducing influenza-type viruses was provided in the public comment process. Staff also reviewed the California Department of Health Services' report titled "Pandemic Influenza Preparedness and Response Plan" (September 8, 2006) including portions of the report that addressed infection control in healthcare settings and also non-pharmaceutical containment measures. Nowhere in the report is the use of ozone-generating air cleaners suggested or recommended. Neither AB 2276 nor the proposed regulations violate either the letter or spirit of the cited law.

We also reiterate the conclusions stated by the U.S. EPA (2007, as cited in the 15-day Public Notice and Section II above) regarding the use of ozone to control airborne microbes that ozone concentrations would have to be 5-10 times higher

than health standards before ozone could decontaminate the air sufficiently to prevent survival and regeneration of the organisms. Similarly, Foarde *et al.* (1997; see page 8 of ISOR) found that much higher ozone levels would be required to inactivate microbial hazards.

24. Comment: Ozone is proven to reduce formaldehyde. **(30-Johnston; 51-Sorrells**)

Agency Response: We disagree with this comment. The commenters did not cite any references to support this claim. In fact, indoor ozone rapidly produces significant concentrations of indoor formaldehyde and other toxic pollutants and irritants when common indoor organic compounds are present, as discussed in the ISOR (page 8, paragraph 2). A study by Chen *et al.* (2005, cited in the ISOR at page 8) includes an ionizing air cleaner that produces ozone. The authors reported that this air cleaner removed very little of the formaldehyde that had been added to the test chamber (Table 21, Unit P5, Clean Air Delivery Rate). In addition, in a recent review of the scientific literature submitted as a comment on the regulation, Dr. Glenn Morrison concluded the following regarding ozone: "The reaction rates with most odorous compounds are too small to effect any significant change in exposure." (see 17-Morrison, line 173 *et seq*. of submitted article).

25. Comment: The point about ozone reducing a few odorous compounds while also masking odors is unfounded. Ozone does not mask the odor, but rather changes or neutralizes it. **(30-Johnston)**

Agency Response: We disagree with this comment. As discussed in the ISOR and supported by numerous scientific studies (ISOR, page 2, paragraph 2; page 8, paragraph 2), ozone only reduces the concentrations of a few odorous compounds, but simultaneously masks odors by causing fatigue of the olfactory sense. Ozone reacts quickly with mono-alkene compounds such as pinene and limonene, pine and citrus odor compounds. However, it reacts too slowly for most odorous compounds to be an effective removal mechanism. Furthermore, as discussed above in Responses to Comments 3 and 4, incorporated herein, the products of ozone reactions with odorous compounds can be toxic and irritant compounds, so that indoor air quality may actually be worsened. The commenter does not provide references to refute the statements in the ISOR and the supporting scientific studies.

26. Comment: Recent university peer-reviewed and published studies completely debunk the biased assessment that indoor air cleaners are not efficacious. **(30-Johnston; 31- Baskin)**

Agency Response: We disagree with this comment and incorporate Responses to Comments 18 and 21 by reference here. As stated in the responses to those comments, commenters rely on two studies, one of which (Ortega *et al*.) is undated, unpublished, and fails to adequately document how testing was done to show that low levels of ozone can effectively inactivate pathogens. The other

study (Grinshpun *et al.*, 2007) attributes particle removal to the ionizing feature and the microbial inactivation to the photocatalytic oxidation. The authors of the Grinshpun study state that much higher levels of ozone would be necessary to inactivate microbes, and that the prototype device being tested did not emit high enough levels of ozone to do this. We incorporate the discussion at pages 6-8 and 13-25 of the Staff Report by reference here.

GENERAL

27. Comment: ARB should conduct an expanded public outreach and education effort, including information regarding ozone's ineffectiveness in cleaning air, its link to serious health effects, and information on approved air cleaners that are available to the public. **(46-Holmes-Gen)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed regulation or to the procedures followed in proposing or adopting the proposed regulation. Without waiving this objection, we respond as follows. We agree with this comment. We plan to increase our public outreach effort to various stakeholder groups, and list on our website those air cleaners that ARB has certified for sale in California.

28. Comment: ARB should include strong enforcement provisions backed by consistent enforcement by State officials, especially for enforcement of internet sales in California. **(46-Holmes-Gen**)

Agency Response: We agree with this comment. The proposed regulation establishes clear, enforceable requirements and Health and Safety Code sections 42400-42405 prescribe stringent civil and criminal penalties for violations of them. We plan to closely monitor California sales through all routes, including through the internet and mail order. As discussed in the ISOR (page 31), pursuant to proposed section 94806, internet web pages as well as other sales outlets must display an advisory warning for indoor air cleaners that lack ARB certification, stating, for example, "Device does not meet California requirements, cannot be shipped to California." in a prominent place. In addition, all affected manufacturers must submit to ARB documentation that they have provided a copy of the final regulation order to all of their known distributors, retailers, and sellers (ISOR, page 31).

29. Comment: Indoor air cleaning or air treatment systems that also provide for particulate removal through forms of ionization are not usually referred to as ozone generators. Many of these would not be defined as Electronic Precipitators because of the different ionization technologies employed. To define any indoor air cleaning or air treatment systems that by design produce ozone in addition to particulate removal is inappropriate and may be confusing from a public policy perspective. Certain Photocatalytic Oxidation (PCO)

systems produce very low levels of ozone and these are not of public health concern. **(30-Johnston)**

Agency Response: We disagree with these comments. Regarding the definition of "ozone generator," any air cleaner that produces ozone by design should be considered an ozone generator even if it incorporates other air cleaning technologies. From the public health perspective, it is essential (not misleading) to know that a device can produce harmful amounts of ozone indoors. In any event, however, AB 2276 does not differentiate between ozone generating devices that use ionization to remove particles and devices that merely generate ozone. AB 2276 requires that the regulation shall include the "emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for air cleaning devices." That is the 0.05 ppm standard applied to medical devices by the federal Food and Drug Administration (FDA). Health and Safety Code sections 41985.5 and 41986(a)(1), 21 CFR section 801.415. In obedience to AB 2276, the proposed regulations define "indoor air cleaning device" to include any product "whose stated function is to reduce the concentration of airborne pollutants . . ." Regarding the comment that certain photocatalytic oxidation devices produce very low levels of ozone that are not of public concern, the commenter does not provide supporting evidence or references. We cannot say yet whether or not they would meet the requirements of the proposed regulation, but if the regulation were to take effect these devices would undergo the testing required to make this determination. Regarding the public health concern about such devices, we disagree. Only a few such devices have been tested for ozone emissions (Chen *et al.*, 2005; Chen *et al.*, 2006), so we cannot draw any broad conclusions. In addition, PCO devices can produce significant amounts of indoor formaldehyde and other harmful oxidation products. In any case, if the regulation were to take effect, such devices will be required to undergo testing to obtain ARB certification under the proposed regulation, which will assure that their ozone emissions are safe for public use.

30. Comment: The proposed regulation is being orchestrated by vested companies seeking to eliminate ozone generators. Vested older technology and product manufacturers tend to resist the introduction of newer and competitive technology and product manufacturers. Given the report, it is logical to assume that special interest groups have resorted to deceptive assertions only intended to influence your judgment. You are being lied to by people who represent organizations that are greedy and corrupt. Biased sponsors of this proposed rulemaking have not even had the decency to include one testimonial in their reports. Staff has in part erroneously relied on complaints and testimonials from school boards, teacher and parent organizations, physicians, hospitals, and their associations, that ozone generators are dangerous and that other air cleaners such as those meeting the American Lung Association's (ALA) guidelines should be used. Staff also have relied on misinformation from the California Lung Association and ALA who have participated in legislative and regulatory activities at the state, federal, and international levels promoting regulation of all ozone emitting devices. **(13-Brickman; 28-Giddens; 64-Olsen; 66-Montoya)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed regulatory action or to the procedures followed in proposing or adopting the action. Without waiving this objection, we respond as follows. We disagree with this comment. AB 2276 requires the ARB to develop and adopt regulations, consistent with federal law, to protect public health from ozone emitted by indoor air cleaning devices used in occupied spaces. (Health and Safety Code section 41986(a).) There is a wealth of scientific evidence that indicates high levels of ozone emitted by devices that claim to be air purifiers is harmful to human health. See, e.g. the legislative findings at Health and Safety Code section 41985(a)-(g), and the discussion in the Staff Report at pages 7-8 and 15-25, which is incorporated by reference here. AB 2276 and the scientific information discussed in the staff report are the reasons and basis for staff's actions and recommendations. We have considered all comments we received in the process of developing the proposed regulation, as discussed in Responses to Comments 9, 16, 22, and 45, which are incorporated here by reference.

31. Comment: Staff failed to present certain data from the UC Berkeley survey results. The survey report shows that consumers purchased air cleaners to remove particulate matter as well as microbial, bacteria, mold and chemical contaminants, and to protect children; a high percentage (73%) of the owners surveyed are aware that their devices emit ozone; and many respondents (81 percent of ozone generator owners) believe the air in their homes has improved. **(13-Brickman; 30-Johnston)**

Agency Response: We disagree with this comment. Even if accurate, the comment does not justify modifying or withdrawing the proposed regulations, which are required by AB 2276 and are justified by the great weight of scientific evidence of the harmful effects of exposure to ozone. The reasons why members of the public purchased ozone generators or their perceptions of the devices' emissions and efficacy do not outweigh this scientific evidence or justify failing to follow the dictates of AB 2276. We incorporate Responses to Comments 6 and 9 by reference here and Staff Report pages 6-8, 12-25 as well.

In the UC Berkeley survey discussed in the Staff Report on pages 10 and 21-25, the ARB funded a random telephone survey of a representative sample of California households to estimate how many households own indoor air cleaners that generate ozone, and gather information about how these devices are used. The survey is cited in the staff report for the purpose of documenting the estimated numbers of air cleaners and ozone generators in California households, and the manner in which they are used. The survey found that most users operated their units 24 hours a day throughout the year, which is cause for concern if the units being used are ozone generators.

The study did find that 73 percent of ozone generator owners were aware that their devices emitted ozone. However, as the report cautioned, the small sample size (33 for that particular question) makes it difficult to extrapolate with much confidence about the conclusions as compared to other results where there were

more responses. The survey report also notes that many ozone generators incorporate more than one air cleaning technology and may have a particle filter, ionizer or electrostatic precipitator; these, in fact, do reduce particle levels. Owners need to understand that it may be these technologies, not the ozone that may be cleaning the air.

The survey indeed found that the three most common reasons given for purchasing an air cleaner were concerns about allergies and asthma, particulate matter, and indoor air quality in general. Other reasons included removing pet dander and mold/bacteria, to control tobacco smoke, the presence of chemical contaminants and to protect children. As stated in the responses to Comments 14, 18, 19, and 21 above, ozone will not effectively remove viruses, bacteria, mold or other biological pollutants unless the ozone concentration is well above health standards, so these reasons for the purchase of ozone generators do not justify modifying or withdrawing the regulation.

In fact, the ozone emissions from air cleaners may be causing reported health symptoms in the users. The survey study found that about 22 percent of the ozone generator users reported currently using the device very little or not at all: 18 percent of these households reported that this was because the air cleaner did not seem to work, and 9 percent reported that this was because the device made household members feel sick (Piazza *et al.*, 2006, as cited in the ISOR at pages 23-25). These results suggest that the use of ozone generators in homes produces adverse health effects rather than improving the quality of the indoor environment. However, the small sample size for such households makes it difficult to extrapolate with much confidence about the conclusions as compared to other types of air cleaners or to other results where there were larger numbers of responses.

A copy of the full final report (Piazza *et al.,* 2006) is in the record and is available on the ARB web site at: http://www.arb.ca.gov/research/apr/past/05-301.pdf.

32. Comment: Regarding the air cleaner testing conducted by ARB, what type of room were the products tested in? Were they real world environments? The EPA has stated that indoor the air is up to 5 times more polluted than outdoor air? In this scenario that means there is plenty of organic matter for ozone to cancel itself out before it can reach high levels. **(30-Johnston)**

Agency Response: We disagree with the comment. The ARB's testing was conducted under conditions that were very realistic and representative of the real world. As discussed in the ISOR (page 20; Appendix C) and the report by ARB (2006a), the ARB study was conducted in a small room the size of a small bedroom or office in a home. It was furnished with a composite wood desk and a cloth material chair, and had linoleum flooring and wallboard ceilings and walls, all of which provide reaction surfaces for ozone which would decrease the ozone levels as they would in actual homes. The temperature, humidity, and air exchange conditions were the same as conditions commonly found in homes. The room conditions would be characterized as a realistic high exposure

scenario, rather than an extreme worst case such as a test chamber with very low air exchange and very little surface reactivity to ozone.

33. Comment: Many consumers, including the American Red Cross, have successfully used indoor air cleaning devices equipped with optional and scalable ozonation at higher levels to rid residential and business environments of odors, chemicals, bacteria and mold from wild fires, forest fires and other disasters without incident. EcoQuest donated Fresh Air devices for use in the Pentagon following the September 11, 2001 attacks. Other examples were cited of Breeze AT air cleaners being donated for use by the Red Cross in shelters set up in San Bernardino during the forest fires in Southern California to address odor problems. **(13-Brickman; 33-Johnston)**

Agency Response: We disagree with this comment. Even if accurate, the comment does not justify modifying or withdrawing the proposed regulations, which are required by AB 2276 and are justified by the great weight of scientific evidence of the harmful effects of exposure to ozone. Donations of ozone generators, whether the devices were dual use or scalable, and whether the recipients used the devices or not, do not outweigh this scientific evidence or justify failing to follow the dictates of AB 2276. We incorporate Responses to Comments 6, 9, 18-21, 23-24 by reference here and Staff Report pages 6-8 and 12-25 as well.

Assuming *arguendo* that EcoQuest did donate its air cleaners does not prove that the devices are safe to use, or were used at all. The only thing that is clear is that the Pentagon, Red Cross, etc. did not specially select the devices or purchase them themselves. The purpose of the air cleaner regulation is to prevent potentially harmful exposures of vulnerable persons (especially older persons and children) to ozone emitted by ozone-generating air cleaners. Ozone from intentional ozone generators will react with certain substances in the air to form other materials including other potentially harmful substances (e.g., formaldehyde). As noted in the one published paper by Grinshpun *et al.* (2007) cited by commenter Johnston, it is the ionizing feature of the air cleaners (not the ozone) that is responsible for removing particles in the air. Grinshpun also noted that much higher levels of ozone (significantly exceeding health standards) are necessary to inactivate viable microorganisms. This conclusion also contradicts this comment.

34. Comment: No solid evidence demonstrates that 500,000+ IACD owners are exposed to dangerous ozone levels. **(30-Johnston)**

Agency Response: We disagree with this comment. The 2006 study by Piazza *et al.*, showed that over 800,000 Californians live in households that used ozone generators within the last 5 years and high percentages of California households reported operating their air cleaners 24 hours a day, seven days a week. ARB data shows that ozone generators can elevate indoor ozone levels significantly. Under these circumstances, many Californians' exposure to high levels of ozone from indoor air cleaning devices is virtually assured. In AB 2276, the Legislature

declared that, "[o]zone emitted from indoor air cleaning devices poses an unnecessary risk to public health . . ." [Health and Safety Code section 41985(g)].

The results of the recent statewide telephone survey funded by the ARB to determine the percentage of California households who own and use air cleaners, combined with laboratory test data showing room concentrations produced by various types of ozone-emitting air cleaners, were used to develop estimates of the population's pre-regulation exposure to ozone as described on pages 21 – 25 of the ISOR. The survey found that 2.28 percent of California households, comprised of about 828,000 people, used intentional ozone generators in the past five years, and that 7.83 percent of California households, comprised of 2,200,000 people, used air cleaners that emit lower levels of ozone as a by-product of their design. About 64 − 72 percent of the households reported using air cleaners 24 hours a day, seven days a week year round, meaning there is a constantly-emitting source of ozone in those homes, which virtually assures that residents are exposed to elevated levels of ozone. The room concentration measurements used in the analysis were from ARB's tests conducted in a simulated small room (ARB, 2006a), and data from the scientific peer-reviewed literature (see references in ISOR at pages 7-8), both of which showed the very high levels of ozone reached when intentional ozone generators are used in a room. The commenter does not offer any specific criticisms of the methodology used by ARB staff to estimate the potential exposures to households that own and use ozone-generating air cleaners or by-product devices, but simply argues with the conclusion.

35. Comment: Regarding air cleaning technologies that use ozone, spaces with such air treatment systems in operation typically have lower measurable ozone levels than would be found outside. (**30-Johnston**)

Agency Response: We disagree with this comment. The commenter did not provide supporting evidence for this comment. As discussed in the ISOR, air cleaning technologies that intentionally use ozone (ozone generators) can produce indoor ozone levels exceeding the state 8-hour ambient air quality standard of 0.070 ppm, and levels may reach 0.650 ppm indoors (ISOR, pages 7-10.and 20-25, which are incorporated by reference here; ARB, 2006a, "Evaluation of Ozone Emissions from Portable Indoor 'Air Cleaners' That Intentionally Generate Ozone", as cited in the ISOR). In comparison, the average "natural background" ozone concentration outdoors in California is much lower: 0.015 to 0.040 ppm ozone in areas near sea level without major anthropogenic contributions to outdoor ozone (ARB, 2005b, Vol. 2, as cited in the ISOR). Even in areas with anthropogenic influences the outdoor ozone levels are in the lower range of those produced indoors by ozone generators: the one-hour indicator for maximum outdoor ozone concentrations for all areas of California in 2001-2003 ranged from 0.082 to 0.178 ppm. Furthermore, unlike the indoor ozone levels produced year-round by ozone generators, outdoor ozone levels only become elevated during hot weather and during part of the day, so that many locations in California never exceeded the previous federal one-hour standard of 0.120 ppm, while the maximum number of exceedances

was only 48 days per year at one location (ARB, 2005b, Vol. 2, Table 7-2, as cited in the ISOR).

36. Comment: If the Board takes away my purifier, what can I use in its place? (**9-Gold**)

Agency Response: We disagree with this comment. The proposed regulations would not authorize taking anyone's air purifier away. There are many air cleaner models on the market that emit little or no ozone (ISOR, pages 6-8 and pages 23-24). We estimated that there are 94 models of the "ozone by-product" type, and 79 models of the mechanical filtration type currently on the market (ISOR, pages 34-35). All of the mechanical filtration models and most of the by-product models should be able to meet the proposed regulation and be available to Californians. Some of these models are effective in removing airborne particles (AHAM, 2007; Consumers Union, 2005a,b,c; all as cited in the ISOR).

Available data indicate that indoor air cleaners that generate high levels of ozone are not effective in controlling indoor air pollution, mold, bacteria, animal allergens, and other biological pollutants (ISOR, page 8, which is incorporated by reference here). Actions to remove or control the sources of indoor air pollutants are generally more effective than treatment by an air cleaner (U.S. EPA, 2007; see 15-day Public Notice and Section II above).

37. Comment: The Staff Report's conclusions come from studies that correlate outdoor ozone concentrations with asthma onset and exacerbation, and other effects, and the studies fail to account for other constituents of outdoor air pollution. More recent studies show that particulate matter, specifically PM2.5 is the primary culprit, not ozone. An ARB-sponsored study reported in 2000 that children's lung function inhibition was NOT primarily due to ozone, but rather PM and NO_2, etc. **(30-Johnston)**

Agency Response: We disagree with this comment. The comment referring to particulate matter being the primary culprit relates the conclusions of a single study (Gauderman *et. al*., 2000) done as part of the Southern California Children's Health Study, a 10-year prospective research study of respiratory health in children in 12 southern California communities supported by the ARB. In this study the authors found that nitrogen dioxide, particulate matter and acid vapors were the most important air pollutants in relation to children's lung function. However, in a subsequent analysis of a second cohort of children, the investigators found there was a significant reduction in lung function growth (peak expiratory flow rate) related to ozone exposure (Gauderman *et al.*, 2002; see 15-day Public Notice and Section II above).

Other peer-reviewed, published scientific papers from the Children's Health Study have documented that: (1) short-term exposures to ozone were associated with a significant increase in school absences (up to 1.3 million per year) from both upper and lower respiratory illnesses, including asthma attacks (Gilliland *et al.*, 2001); and (2) children living in high ozone communities and who are

especially active were not only more likely to have their asthma exacerbated by exposure to ozone, but were up to three times more likely to *develop* asthma (McConnell, *et al.*, 2002). The ISOR also describes at page 15 the extensive scientific literature on the adverse effects of ozone on human health that was compiled by ARB in its most recent review of the State ambient air quality standard for ozone (ARB, 2005a).

38. Comment: The following is a list of questions and comments submitted by **76 – R. Barnes** from Prozone, and agency responses. These are presented together here for ease of review, due to the interrelatedness of some of the questions.

Question #1 Recently we have evaluated and seen several air purification and sanitation systems that emit toxic chemicals and that include:
Chlorine dioxide
NOX
NO
NO_2
N_2O
N_2O_2
Nitrous Compounds
Hydrochloric Acid
Carbon Monoxide
Formaldehyde
Chloroforms
Carbon Tetra Chloride
Sodium Chloride
Potassium Chloride
Sodium Hypochlorite
Aldehydes
Aromatic Chemicals such as Vicks
Other ketones

These are all byproducts of other than our air purification systems and have all shown to function at toxic levels. UV ozone generators do not produce these byproducts as corona units do. How do you separate or discriminate between them? **(76-Barnes)**

Q.1. Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed regulation or to the procedures followed in proposing or adopting the proposed regulation. Without waiving this objection, we respond as follows. We disagree with this comment. AB 2276 requires that the regulation shall include the "emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for air cleaning devices." That is the 0.050 ppm standard applied to medical devices by the federal Food and Drug Administration (FDA). Health and Safety Code sections 41985.5 and 41986(a)(1), 21 CFR section 801.415. In obedience to AB 2276, the proposed regulations contain a

definition of “indoor air cleaning device” that includes any product “whose stated function is to reduce the concentration of airborne pollutants . . .” Clearly, the statutes authorize regulations that address ozone emissions from indoor air cleaning devices no matter what technology they employ. The statutes do not authorize the regulation of other pollutants.

The proposed regulations do not distinguish between types of ozone generators because we have not seen data indicating that other chemicals are emitted at unhealthful levels by one type of device, and the commenter but did not provide any citations of published, peer-reviewed scientific articles that support that claim. Again, the authority granted by Assembly Bill 2276 is for setting emission limits for ozone only; not to regulate any other emissions from air cleaners.

Question #2 There is a new production of devices that use some of the above toxic chemical (sic) as air purifiers and these devices are a direct response to getting around your limitations on ozone air purification and sanitation systems and do not fall under the current guidelines of your present standards.
With each of these units emitting such by products at toxic levels how and why were these units authorized to be sold in California? **(76-Barnes)**

Q.2. Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed regulation or to the procedures followed in proposing or adopting the proposed regulation. Without waiving this objection, we respond as follows. We disagree with this comment and incorporate Response to Comment Q.1 by reference here. We are not aware of the devices described in this question, but would hope that manufacturers of indoor air cleaning devices will act responsibly and not replace ozone with another toxic chemical. If the commenter has data showing these harmful emissions, we would appreciate receiving it. However, AB 2276 does not authorize ARB to regulate toxic emissions from indoor air cleaners other than ozone.

Question #3 Why is the production of air ducting ozone systems allowed and why do they not fall under the current guidelines of your present standard? **(76-Barnes)**

Q. 3. Agency Response: We disagree with this comment. As discussed on page 27 of the ISOR, which is incorporated by reference here, the proposed regulations have exempted in-duct systems because there is no data showing that they produce ozone at levels that pose a risk to health, and they would require a different test method. While these systems release some ozone, it typically is at low levels which decrease rapidly with distance from the vent, so that little or no ozone gets into the rooms served by the system. As we indicate in the ISOR on page 27, we will reconsider this exemption in the future if we become aware of data showing a potential risk.

Question #4 If there is to be a limitation on the air quality devices, then control must be an “across the board evaluation” which should include consideration of

all of the above listed byproducts. If you are going to limit air quality devices why have you not established an across the board evaluation process which should include a list of all of the above mentioned by-products? **(76-Barnes)**

Q. 4. Agency Response: We disagree with this comment and incorporate our Responses to Q. 1 and Q. 2 by reference here. As indicated above in the response to Q. 1, AB 2276 provides authority to us only for the regulation of ozone emissions from indoor air cleaning devices.

Question #5 Pure UV Ozone emitting devices are non-toxic and the irritants that can possibly be produced by such a machine have reversible biological symptoms that can be reverse (sic) within 24 hours of exposure unlike the above toxic components. Why would you choose not to allow ozone emitting devices that are non-toxic and the irritants that can be produced by these machines have reversible biological symptoms that usually are reversed with in 24 hours of exposure unlike the above toxic components? **(76-Barnes)**

Q. 5. Agency Response: We disagree with this comment and incorporate our Responses to Q. 1 and Q. 2 by reference here. Again, we have seen no data or peer-reviewed, published scientific papers that show that the ozone from such devices is non-toxic, and that the symptoms caused by them are completely reversible. As discussed in the ISOR on pages 15-19 (see http://www.arb.ca.gov/regact/2007/iacd07/isor.pdf), ozone has been shown to produce adverse health effects when humans were exposed in chambers with only clean air and ozone for short durations. Exposures in homes would typically be for longer periods, and thus would have even greater potential for harming occupants' lungs.

Question #6 The byproducts of a corona ozone generator system are NOX and are accumulative and have a toxic biological effect. Why would you allow a machine that gives off NOX which is accumulative and can have a toxic biological effect? (**76-Barnes**)

Q. 6. Agency Response: We disagree with this comment and incorporate our Responses to Q. 1 and Q. 2 by reference here. We have not seen scientific data that shows that NOx levels from air cleaners pose a health problem. We would appreciate receiving such data if it is available. Additionally, as stated above, we do not have authority to regulate anything emitted from air cleaners other than ozone.

Question #7 Who is authorized to test independently within California for noncompliance and what is the formal controlled procedures and who pays for these services? (**76-Barnes**)

Q. 7. Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed regulation or to the procedures followed in proposing or adopting the proposed regulation. Without waiving this objection, we respond as follows. Currently two

labs – Underwriters Laboratories, Inc. and Intertek (ETL) – plan to provide testing services to manufacturers who need their air cleaners tested to meet our regulatory requirements. They can begin testing once their test chambers are ready and we have audited them. Once they are able to conduct the new UL 867 Section 37 test, we will post information about how to contact them on our website at http://www.arb.ca.gov/research/indoor/aircleaners/aircleaners.htm and send an email to those on our listserve for the regulation. We will also post the final certification application form. A general description of the process and a sample certification application were provided in the ISOR at pages 27-28 and Appendix D. Device manufacturers will pay for the testing. ARB will enforce the regulations.

Question #8 Who was authorized to publish non-controlled testing of tested and ETL approved Prozone Products which were done in a non-controlled environment with detrimental negative comments and marketing impact having been portrayed on your web site as a violating product? **(76-Barnes)**

Q. 8. Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed regulation or to the procedures followed in proposing or adopting the proposed regulation. Without waiving this objection, we respond as follows. We disagree with this comment. We have not seen the ETL results mentioned in this comment, but based on available information discussed below, doubt that the two devices we tested would pass the ETL test. As any private party or university, we can purchase and test devices to obtain needed emissions information. Our purpose was to determine in general the ozone levels produced by ozone-generating air cleaners that are currently marketed in California. As described in the report the commenter refers to (see: http://www.arb.ca.gov/research/indoor/o3g-rpt.pdf), each air cleaner was tested in three different ways: a face test, a room air concentration test, and an emissions test. The methods used were based on methods used by scientists that have conducted similar studies of emissions from air cleaners, and included advice from university and federal government scientists. Because it was an internal room, our test room was relatively controlled in terms of temperature and air exchange rate, and likely resulted in LOWER ozone levels than would have been measured in a stainless steel test chamber, because we placed a chair and a pressed wood desk in the room, which had painted walls. The chair, desk, and walls are made of materials that act as a “sink” for ozone, meaning that they provide a surface and substances with which ozone will react, thus reducing the concentration of ozone in the air in the room. This was done to better simulate real world conditions compared to an empty test chamber. Our test method otherwise generally followed the old Section 37 method in UL Standard 867 in that we tested at 2 inches from the face of the device and used 0.05 ppm as the acceptable limit. However, we did not use the immediate post-test “background” measurement in the calculation of the room concentration because it is not a true background measurement, but rather is a measure of the emissions from the device measured soon after the device was shut off. The revised Section 37 test method approved through the ANSI/UL process remedies this situation, and

subtracts the true background level (pre-test level in room that has been aired out) from the highest measured value.

The outdoor levels of ozone were very low on the days the Prozone models were tested. Yet, the Prozone air cleaners produced ozone levels in the chamber several times the 0.050 ppm level, and it was very clear that they could produce harmful levels of ozone in a home. Prozone is included with other intentional ozone generators on our website because we want people to be aware that these devices can pose a health risk.

Question #9 In order to comply to your standards, all units must be marked "must be only used in an indoor environment" or unit must be able to be reduce Ambient California ozone from .09 ppm to .05 ppm? Label stating "for Indoor Use Only in California"? **(76-Barnes)**

Q. 9. Agency Response: We disagree with this comment. None of the phrases included in the comment would be required. The labeling required for certified devices is specified in section 94806 of the regulation, which was included as Appendix B in the ISOR and is incorporated by reference here. The labeling required for exempt industrial use devices is specified in section 95803 of that same appendix. It is unclear what is meant by the phrase "…or unit must be able to reduce ambient California ozone from .09 ppm to .05 ppm"…there is no requirement for ozone reduction.

Question #10 Why must California labeling with associated compliance costs be used on all products sold elsewhere? **(76-Barnes)**

Q. 10. Agency Response: We disagree with this comment. The proposed regulations (see section 94800) would apply only to products that are sold, supplied, offered for sale or introduced into commerce in California. Products sold elsewhere do not need to meet the requirements of the proposed regulation. However, products sold via the Internet, mail order catalogs, etc. available to Californians would have to meet the proposed requirements because such devices are available for sale to anyone and can be purchased by California citizens.

Question #11 If price of conformity is required on all products sold elsewhere, all products should have an estimated cost of California conformity ($15.00 plus markup=$30.00) printed on all packaging? This is hardly "negligible for a product that costs $99.00. **(76-Barnes)**

Q. 11. Agency Response: We disagree with this comment. There is no such requirement. On pages 41-42 of ARB's staff report (ISOR), in the Cost to Consumer section, we calculated that the median cost increase to consumers for ozone generators would be $16, not $30 as the comment suggests (see Column E of Table VI-6, Potential Cost to Consumer). Note that this estimate includes all costs associated with the regulation as well as a 50 percent markup

(Column D). This $16 price increase translates to a 5 percent median price increase (Column F); of course, some products would have a smaller or larger percent increase than the median increase in the sales price, depending on the model's current price. The overall impact on manufacturers who typically have products in a wide price range is not expected to be significant.

In addition, we believe our estimate of the cost increase to consumers is likely a substantial overestimate, because we used conservative assumptions. For example, we assumed that the cost increase would be spread over 5 years (ISOR, page 36, par. 2), but for some models of air cleaners their model life may be much longer than five years, especially if the internal components do not change. In addition, the actual certification cost per model may be much lower because some models already have UL certification for electrical safety.

The labeling required for certified devices is specified in section 94806 of the proposed regulation, which was included as Appendix B in the ISOR and is attached to the 15-day Notice as Appendix II. The labeling required for exempt industrial use devices is specified in section 95803 of that same appendix.

Question # 12 How are you going to enforce noncompliant Chinese duplicators of product from copying certification numbers and prevent bogus sales against U.S. manufactures and what is the U.S. manufacturers' recourse provided by California? **(76-Barnes)**

Q. 12. Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed regulation or to the procedures followed in proposing or adopting the proposed regulation. Without waiving this objection, we respond as follows. We disagree with this comment. The proposed regulations would apply to the violations described in the comment and the ARB plans to investigate and take enforcement action against all violations. The proposed regulations do not provide legal recourse for manufacturers as the comment alludes to—AB 2276 does not authorize it. Other laws, may, however, but they are beyond the scope of this rulemaking.

Question #13 How do you dictate non legislative values to nongovernmental agencies, over which you have no jurisdiction, with non verifiable data on pure ozone (atmospheric ozone) extracted from "ground level" ozone studies? **(76-Barnes)**

Q. 13. Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed regulation or to the procedures followed in proposing or adopting the proposed regulation. Without waiving this objection, we respond as follows. We disagree with this comment. AB 2276 requires that the regulation shall include the "emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for air cleaning devices." That is the 0.05 ppm standard applied to medical devices by the federal Food and Drug Administration

(FDA). Health and Safety Code sections 41985.5 and 41986(a)(1), 21 CFR section 801.415. In obedience to AB 2276, the proposed regulations contain a definition of "indoor air cleaning device" that includes any product "whose stated function is to reduce the concentration of airborne pollutants . . ." Clearly, the statute only authorizes regulations that address ozone emissions from indoor air cleaning devices and does not differentiate between atmospheric and ground level ozone. Indeed, ozone is the same chemical with the same characteristics wherever it is found.

The health studies discussed in the staff report are not from "ground level" ozone studies but are human chamber studies in which people were exposed to various levels of ozone in clean (filtered) air for short periods.

Question #14 In further consideration it should be noted that California some years ago had proposed legislation to ban the use of chlorine sanitation in all swimming pools because of the emissions of chloroform gas. This is a toxic gas that remains in the smog, has been highly documented. Just another example of this disproportionate considered legislation (sic). Shouldn't toxic gases be eliminated before irritating gases? **(76-Barnes)**

Q. 14. Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed regulation or to the procedures followed in proposing or adopting the proposed regulation. Without waiving this objection, we respond as follows. We disagree with this comment. AB 2276 requires that the regulation shall include the "emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for air cleaning devices." That is the 0.05 ppm standard applied to medical devices by the federal Food and Drug Administration (FDA). Health and Safety Code sections 41985.5 and 41986(a)(1), 21 CFR section 801.415. In obedience to AB 2276, the proposed regulations contain a definition of "indoor air cleaning device" that includes any product "whose stated function is to reduce the concentration of airborne pollutants . . ." Clearly, the statute only authorizes regulations that address ozone emissions from indoor air cleaning devices.

Chloroform and other chlorinated compounds may be regulated under other legal authorities. However, ozone is more than just an irritating gas. As indicated in the ISOR on pages 15-19, and in many other government reports and journal articles as referenced in the ISOR, exposure to ozone over time can result in permanent lung damage and serious respiratory disease. Estimates indicate that ozone has widespread effects on the population. For more information on the health effects of ozone, please see our ARB staff report, Review of the California Ambient Air Quality Standard for Ozone, 2005, http://www.arb.ca.gov/research/aaqs/ozone-rs/rev-staff/rev-staff.htm#Summary.

Question #15 Why do you not allow Ozone producing devices to be used when there are no humans to be in occupied spaces until the unit has reduced the

ozone below acceptable levels? Why not allow devices that generate and annihilate ozone in a cyclic manor when there are no occupants? **(76-Barnes)**

Q. 15. Agency Response: We disagree with this comment. AB 2276 requires that the regulations shall include the "emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for air cleaning devices." That is the 0.05 ppm standard applied to medical devices by the federal Food and Drug Administration (FDA). Health and Safety Code sections 41985.5 and 41986(a)(1), 21 CFR section 801.415. In obedience to AB 2276, the proposed regulations contain a definition of "indoor air cleaning device" that includes any product "whose stated function is to reduce the concentration of airborne pollutants . . ." The federal standard that AB 2276 requires harmony covers indoor air cleaning devices used in occupied spaces, which means spaces that are intended to be occupied by people for extended periods of time, not continuously. This comment is inconsistent with AB 2276 and applicable federal law. We also incorporate the Responses to Comments 40 and 42 by reference here.

We have not seen any data showing an ozone-producing device that "reduces the ozone" to acceptable levels in a cyclical fashion. The Prozone Whole House air cleaner that we tested had an operational cycle that cycled on and off, producing ozone levels well above acceptable health benchmarks and then allowing ozone to decay, but such a cycle would be very harmful to anyone who might enter an unoccupied home without realizing the device was operating. As defined in the regulation, "occupied space" means an enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices. This is the same definition that is used by the federal Food and Drug Administration for air cleaners that are medical devices. By prohibiting use in occupied space even when that space may be unoccupied for short periods of time, the regulation assures protection of individuals who may not have knowledge of such a device operating in such a space that they may enter.

Question #16 This Legislation is based on irrational political hysteria. Shouldn't it be based sound impartial scientific studies not linked to EPA smog air quality standards? **(76-Barnes)**

Q. 16. Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed regulation or to the procedures followed in proposing or adopting the proposed regulation. Without waiving this objection, we respond as follows. We disagree with this statement. AB 2276 is based on the overwhelming weight of scientific evidence that ozone is unhealthful. Please see the Staff Report at pages 1-2, 6-8, and 13-25, which are incorporated by reference here. Additionally, the legislation was supported by nearly all of the air cleaner industry except for some manufacturers of intentional ozone generators, because they recognized that ozone levels produced by some air cleaners are harmful to human health. Additionally, many health professionals also supported the bill. Indeed, it was

based on impartial scientific studies of health impacts of ozone–the human chamber exposure studies discussed above and on pages 15-59 of the ISOR, which are incorporated herein.

ALTERNATIVES

39. Comment: Staff should allow the use of additional warning labels on high-emitting devices rather than regulating the emissions from these devices**. (9-Gold; 13-Brickman; 34-Naylor; 48-Johnston; 50-Naylor)** A possible solution that would allow the use of ozone functioning higher that 0.05 ppm in non-occupied spaces would be to modify the original label or create a new label. **(13-Brickman)**

Agency Response: We disagree with this comment. Assembly Bill 2276 requires ARB to develop a regulation to limit the ozone emissions from indoor air cleaning devices used in occupied spaces, consistent with the federal limit of 0.05 ppm. Allowing devices capable of exceeding this level to be available to the public would not meet the legislative intent of AB 2276. The use of additional warning labels is essentially a continuation of the status quo, and does not assure prevention of indoor exposures to ozone levels above 0.050 ppm. This comment was initially addressed in Section II.C.2 (on page 13) of the ISOR, which is incorporated by reference here along with Responses to Comments 3-8 and 40-42. Moreover, this approach would be inconsistent with federal law and AB 2276. Clearly, AB 2276 and the federal law it references require the regulations to set an emission concentration standard for ozone.

40. Comment: Staff should allow the sale of dual-use devices which have high-emitting modes for unoccupied use. **(9-Gold; 13-Brickman; 55-Perkins)** Allow consumers the option to use some higher than the Federal 0.05 ppm in "non-occupied" areas of premises and any area not then being occupied during the use of an air cleaning device to more quickly clean up and sanitize dangerous indoor pollutants such as mold, mildew, bacteria, viruses, odors, etc. **(13-Brickman)**

Agency Response: We disagree with this comment and incorporate Responses to Comments 3-8, 39, 41-42 and 56 by reference here. Staff previously considered this option when it was initially suggested in comments at the regulation development workshops and this is discussed in the ISOR at page 13, alternative number 2. Staff were concerned about the likelihood of improper or unknowing operation of these dual-use devices in occupied spaces, because they can often produce ozone levels several times higher than the California Ambient Air Quality Standard levels. Situations can easily develop where a device is left on high-emitting mode by a responsible adult when the house is not occupied, but a child or other member of the family can return home, not know the unit was operating in the high mode, and be exposed to very unhealthful ozone levels. Staff have provided an industrial exemption for devices that exceed the 0.050 ppm emission standard and are intended for specific remedial uses in

unoccupied spaces, so that such devices can be used where necessary. However, this would assure that they are only used by trained professionals subject to occupational regulations who can ensure the indoor space remains unoccupied during air cleaner use. This comment is addressed in Section II.C.2 (on page 13) of the ISOR, which is incorporated by reference here. Moreover, this approach would be inconsistent with federal law and AB 2276.

41. Comment: Staff should allow the warranty service of malfunctioning non-compliant devices purchased prior to the regulation effective date, and allow their shipment into California without penalty should such devices require repair or replacement. **(9-Gold; 13-Brickman)**

Agency Response: We disagree with this comment and incorporate Responses to Comments 3-8, 39-40 and 42 here. The regulation strikes a proper balance between protecting public health and whatever interests individuals might have in using a high emitting device that was purchased before the proposed regulation takes full effect. Manufacturers, instead of repairing or replacing a high emitting device under warranty, should replace it with a compliant device. The availability of this option, the public health interests involved in protecting users from high levels of ozone, and the enforcement issues that would be raised by this comment all argue against following it. In order to adequately protect public health from indoor exposures to elevated ozone levels, only certified devices may be shipped into California after 24 months following the effective date of the regulation. Any non-certified device, even if purchased before the effective date of the regulation, would still be subject to the regulation if it leaves the state for repair/replacement because the device that would then be re-entering the state would be in violation of the ozone emission standard. It would be difficult to determine whether devices entering the state were replacements or renovated devices, and this would create a large loophole to the regulation. Moreover, this approach would be inconsistent with federal law and AB 2276.

42. Comment: The ARB rejects consumer intelligence and English language literacy by California consumers as factors to reject product labeling and operational warning alternatives. California Consumers for Freedom of Choice (CCFC) urged the Board to consider warning labels and instructions on the use of ozone emitting purifiers in English or alternative languages as an alternative to the staff's proposal. **(9-Gold; 13-Brickman; 60-Amendola)**

Agency Response: We disagree with this comment and incorporate Responses to Comments 39-41 and the discussion of Alternative 2 on page 13 of the ISOR by reference here. Product labeling and other written warnings are not adequately protective to assure that ozone-generating air cleaners will not result in persons being exposed to harmful concentrations of ozone. The intent of the authorizing statute is to assure that all air cleaners sold for use in California will comply with a 0.050 ppm emission concentration limit to assure adequate protection from exposures to ozone. Moreover, this approach would be inconsistent with AB 2276 and federal law.

TEST METHODS

43. Comment: The proposed testing method is conducted in a sterile chamber that does not represent a typical indoor environment. (**6, 42-Marsden; 9, 68-Gold; 10-Hatesohl; 13, 67-Brickman; 16-McClary; 18, 51-Sorrells; 24-Arthur; 28-Giddens; 30, 48-Johnston; 34, 50-Naylor; 35-King; 52-Perkins; 61-D. Barnes; 62-Grijalva; 64-Olsen; 66-Montoya; 69-Hawkins**) We are unable to understand the rationale for testing in a sealed chamber. Why not devise a more realistic test in a real world environment, i.e. in a typical residential environment furnished with commonly accepted items such as furniture, carpet, curtains, fans, etc. **(13-Brickman)**

Agency Response: We disagree with this comment. The reasons for using the updated chamber test method in Section 37 of ANSI/UL Standard 867 are: 1) it assures consistency of results across testing laboratories; 2) the details of the test method are actually based on real world measured values; 3) AB 2276 [Health and Safety Code section 41986(b)(2)] directs ARB to consider using existing test protocols such as the ANSI/UL test method; and 4) the ANSI/UL Section 37 test has been the standard accepted and used by the industry for many years.

The precise control of surface loss is necessary because surface loss of ozone is the major source of variability in chamber measurements, and must be controlled in order to have consistency of results across laboratories. The requirement in UL 867 Section 37 that testing be done in a stainless steel chamber (or some other non-porous and non-reactive material) is described in the ISOR (at pages 29-30 and Appendix E, which are incorporated here by reference) and is necessary to assure that the results are the same for a given device regardless of which laboratory conducts the test. Using a chamber with relatively non-reactive surfaces and with air mixing, temperature, humidity and other factors well controlled assures accurate ozone measurements and air cleaner certifications that that can be verified by other test laboratories (ANSI/UL, 2007a). Adding furniture or other reactive surfaces to a test chamber would make it very difficult to obtain accurate, repeatable test results, because the pieces of furniture would not be identical, and would have different levels of reactivity with ozone.

Nonetheless, the UL 867 Section 37 test method specifies test chamber conditions that in fact simulate the removal of ozone in typical indoor environments (ANSI/UL 2007a). To simulate realistic conditions, the revised UL 867 test method that will be used for meeting this regulation is based on the following real-world values from actual field measurements:

- An indoor-outdoor Air Exchange Rate of 0.2 air changes per hour. This is typical of new single-family homes with relatively tight construction in California (Wilson *et al.*, 2003; Offermann, 2008; see 15-day Public Notice and Section II above for both).

- A surface loss rate for ozone (V_d) of 0.98 m/h, based on the 10th percentile value from a residential study by Lee *et al*. (1990; see 15-day Public Notice and Section II above).

- A chamber volume (V) of 30 m^3, the smallest anticipated room within which an indoor air cleaning device may potentially be used.

- A Surface to Volume Ratio (A/V) of 2.5 m^2/m^3, Surface:volume ratios for 12 bedrooms ranged from 2.3 to 4.7 m^2/m^3, as observed by Hodgson *et al*. (2004; see 15-day Public Notice and Section II above). The value chosen is near the lower end of this range.

Using these real-world values, the UL 867 Section 37 method requires that the chamber's air exchange rate be adjusted to reach the equivalent conditions in a typical home, i.e., an overall ozone removal rate from surface loss and air exchange ($N_{apparent}$) of 1.33 air changes per hour and an ozone half life of 31 ± 2 minutes. This half-life is then verified before each air cleaner model is tested. Responses to Comments 44-46 and 48-50 are incorporated here by reference.

44. Comment: The proposed emission test protocol is outdated and designed for different devices. **(9-Gold; 10-Hatesohl; 11-Franken; 13-Brickman; 30-Johnston; 61-Barnes; 66-Montoya; 67-Brickman; 68-Gold; 69-Hawkins**). Test method UL 867 was originally developed for the purely incidental emission of ozone from electrostatic precipitators and other electrical appliances, i.e., for devices where the emission of ozone had absolutely nothing to do with the appliance's functioning or purpose. It is unclear how this old test clearly intended for incidental and unnecessary ozone could be transformed into the "defining test protocol" for different products and different technologies that intentionally produce otherwise safe low levels of ozone for cleaning purposes. **(13-Brickman**) It was never intended for air purifiers that intentionally produce ozone. **(48-Johnston)**

Agency Response: We disagree with this comment. The test method cited in the regulation, Section 37 of ANSI/UL Standard 867, underwent formal ANSI/UL revision and updating in 2007 (ANSI/UL 2007a), so it is very current. This revision process, which was open to the public, met with the approval of numerous scientific research experts, manufacturers, trade associations, government agencies and testing laboratories. These revisions, some of which were discussed in the Response to Comment 43, incorporated here by reference, along with Responses to Comments 45, 46 and 48-50, create a more robust test method that provides reproducible and accurate ozone emissions results within a controlled testing environment. Thus, the test method referenced in the regulation has been modernized to address previous inadequacies.

We also disagree with comment about the test method not being designed for products that intentionally produce ozone. In the recently updated test method, UL 867 Section 37.1.2 refers to ozone limits for "A portable air cleaning product for household use", and Section 28.A.1 states that "Ozone monitoring circuitry

shall not be user-defeatable or user-adjustable." (ANSI/UL, 2007a). This clearly indicates that portable indoor air cleaners of any type, including those that produce such substantial amounts of ozone that an ozone monitor may be needed, are addressed by this test method. Regarding the health and safety impacts of ozone, it does not matter if the ozone is emitted intentionally or as a by-product – ozone is ozone and it can potentially harm someone regardless of how or where it is emitted.

AB 2276 [Health and Safety Code section 41986(b)(2)] encourages the use the UL 867 test method for this regulation. We considered this method along with other test methods currently being used to measure ozone emissions from portable indoor air cleaning devices (ISOR, pages 12-13).

Finally, UL documents indicate that ANSI/UL Standard 867 is a requirement for testing portable electronic air cleaners, including ozone generators, electrostatic precipitators, and ionizers (UL, 2007a,b; UL, 2008).

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45. Comment: Private standard setting organizations developing standards are capable of excluding certain products or manufacturers; oftentimes, these organizations operate in private with participating members who have potential or actual conflicts of interest with those directly impacted by the standards. There is little in the way of explanation as to how the testing revisions came about. **(9-Gold; 13-Brickman; 30-Johnston)**

Agency Response: We disagree with this comment. The ANSI/UL Standard 867 Section 37 recently underwent revision via the formal ANSI revision process. This is an open, consensus approval process that provided the public the opportunity to comment on proposed revisions that were agreed upon by a

collection of scientific research experts, manufacturers, trade organizations, government agencies and testing laboratories. Prior to ANSI approval, any comments received were issued a response which was evaluated prior to either approval or a request for additional revisions. In this process there was ample opportunity for anyone to provide input on the Standard or Section under review. Additionally, we provided the revisions in our workshop materials and in the ISOR (Appendix E, incorporated here) for public comment, and explained them during the workshops and the Board hearing. Responses to Comments 43-44, 46 and 48-50 are incorporated here by reference.

46. Comment: The test method using an ozone measurement at two inches from the air cleaner is not appropriate. Two commenters questioned appropriateness of a test method using an ozone measurement at two inches and a stainless steel chamber **(35-King; 28-Giddens)**. Some commenters stated that a person holding their face 2 inches from the air cleaner for 24 hours was not imaginable **(16-McClary)**. One commenter stated that she would have an asthma attack if she were only two inches away from a heater, or a burn injury if she were only two inches from a stove burner. We all use these appliances and it would be equally ludicrous to ban these as it would to ban air purifiers **(23-Elder).** One person commented that the 2-inch protocol was equivalent to limiting the surface temperature of a radiant wall heater to only 80 degrees at two inches **(35-King).** Another commenter stated that the 2-inch measurement was not scientifically relevant to non-ESP products and technologies designed to emit low levels of ozone **(30-Johnston)**. Another commenter claimed that this test method would fail an air cleaner that produced less than 0.050 ppm ozone in other parts of the room **(13-Brickman).**

Agency Response: We disagree with these comments and incorporate Responses to Comments 43-45 and 48-50 by reference here. Response to Comment 43 addresses the suitability of a stainless steel chamber. Regarding the appropriateness of the ozone measurement at two inches, it is appropriate because it is part of an overall test chamber method that is designed to obtain accurate, reliable results and to prevent harmful exposures under high but realistic exposure conditions. By measuring close to the face of the air cleaner, the test method assures that individuals close to the device will be protected.

In regard to whether the 2-inch distance is imaginable, staff believes the 2-inch distance is not unrealistic. A child or adult could unknowingly be that close to an air cleaner while sleeping (some people keep the air cleaner on their nightstands next to the bed). Personal air purifiers are meant to be used close to one's mouth and nose; some manufacturers actually direct customers to hold a personal air purifier within an inch or two of their faces for extended periods of time when their allergies are particularly bad. At least one manufacturer in the past has actually recommended in their instruction manual that users of the personal air purifier place the air cleaner directly under their nose.

In regard to heaters and stove burners which produce instant harm at two inches versus an air purifier, people without asthma would not be likely to move away

from an ozone-emitting air cleaner to avoid an asthma attack because they would not necessarily experience immediate effects. Ozone exposure causes people to quickly lose their sense of smell and the respiratory and eye irritation might not be severe enough to trigger an avoidance response.

Regarding the comparison to designing a radiant heater base on a 2-inch measurement, the analogy does not apply to an air cleaner that emits ozone, which provides a very limited benefit, if any, but can cause serious harm to health, as discussed in Responses to Comments 19-21 and 24-25 which are incorporated here.

Regarding relevance to non-ESP devices, the scope of the UL 867 Section 37 test method for ozone emissions includes both ESPs and any type of portable air cleaner other than those using only a mechanical filtration method. As discussed in Response to Comment 44, which is incorporated here, the method definitely is suitable for all types of portable air cleaners. In addition, the 2-inch measurement in the original standard was retained in the revised standard after the standard underwent formal public review through the ANSI process and received approval from numerous scientific experts, government agencies, and other stakeholders.

Regarding measurements at 2-inches versus those in other parts of the room, the ozone measurement at 2 inches is designed to be health-protective in that ozone concentrations at greater distances would be lower due to dispersion, dilution, and reaction of the ozone emitted by the device. In addition, ozone concentrations at 2 inches should initially be higher than the distant measurement, but both measurements should be similar once a steady-state condition is reached. This is due to the rapid air mixing rates and rapid build up of the ozone in the test chamber.

47. Comment: Test lab signatures on the certification application should not be from the lab technician, but rather from a person whose job title includes responsibility for determination of regulatory compliance. **(32-Kammer)**

Agency Response: We agree with this comment and have modified ARB's Certification Application as suggested by the commenter.

48. Comment: Commenters proposed an alternate test method that includes a "furnished" room sized according to the air cleaner's rated output. The air cleaner would be placed at one end of the room at a height of six feet. Ozone would be measured at six locations along the other walls. The air cleaner would be tested at the highest and lowest settings for ozone output. Ozone limits would be required as follows: < 0.050 ppm average of all six locations over 24 hours; < 0.080 ppm 8-hour average; and < 0.100 ppm maximum instantaneous concentration during the test. **(30-Johnston; 34-Naylor)**

Agency Response: We disagree with this comment. AB 2276 [Health and Safety Code sections 41985.5 and 41986(a)(1)] requires that the regulation shall include

the "emission concentration standard for ozone emissions that is equivalent to the federal ozone emissions limit for air cleaning devices." That is the 0.05 ppm standard applied to medical devices by the federal Food and Drug Administration (21 CFR section 801.415). AB 2276 also encourages the use of the UL test method. This is discussed further in Responses to Comments 3-8 and 43-44 and 46 which are incorporated here by reference. The proposed regulation complies with both parts of AB 2276, but the alternate method proposed by commenters does not. The proposed alternate ozone limits are consistent with the 0.050 ppm ozone limit at 24 hours, but not with the 0.050 ppm limit at 8 hours.

This proposed alternate test method is unlike any method currently used to test a wide variety of air cleaners. It would not be suitable for regulatory compliance testing because the furnishings would produce uncontrolled losses of ozone, making the test results very difficult to repeat or to compare among testing laboratories. This would create great uncertainty among consumers and manufacturers. In addition, a test method that requires various room sizes would be unduly time-consuming for testing laboratories to conduct and expensive for manufacturers. Finally, the proposed method does not address the control of the air exchange rate, air filtration, and air mixing. These important factors are addressed by the UL 867 Section 37 test method as discussed in Response to Comment 43 incorporated here by reference.

49. Comment: The test method creates a zero ozone standard, which is inconsistent with federal law. **(50-Naylor)**

Agency Response: We disagree with this comment. The U.S. FDA standard of 0.05 ppm ozone for medical devices does not specify in detail the test conditions or room characteristics. However, it does specify the concentration as being that in the volume of air circulating through the device or in the volume of air accumulated in the enclosed space. The UL 867 Section 37 test method is consistent with this specification. It also reflects realistic values for factors that affect ozone concentrations in homes, as discussed in the Responses to Comments 3-8 and 43-46, 48, and 50 incorporated here by reference. Therefore, the 0.050 ppm ozone limit in the test method would be roughly equivalent to 0.050 ppm in the real world where ozone deposition losses are often greater than those in typical test chamber conditions, but air exchange rates are often lower.

50. Comment: Recommend the use of 0.2 – 0.35 air changes per hour rather than the specified 0 – 0.35 ach because a room with no air changes would be unbearable for a person. **(16-McClary)**

Agency Response: We agree with this comment. The test method has been revised to require the air exchange to be based on the reactivity of the chamber, such that the overall removal rate for ozone during the test will be the same regardless of which chamber a test is conducted in, however not necessarily at the precise rate the commenter suggests. This is achieved by using a variable air exchange rate that is based on the reactivity of each chamber in order to

achieve the same total ozone loss rate in each test chamber. This is described in more detail in Response to Comment 43, which is incorporated here by reference.

EXEMPTIONS

51. Comment: Are in-duct air cleaners exempt from the proposed regulation? **(3-Wallace)**

Agency Response: Yes, Section 94803(b) of the proposed regulation exempts in-duct air cleaners that are designed, marketed, and used solely as a physically integrated part of a central heating, air conditioning, or ventilating system. The ARB will evaluate new information about possible ozone emissions from such systems as it becomes available to see if in-duct devices need to be regulated.

52. Comment: Exemptions – The regulation as proposed restricts the use of high-emitting (greater than 0.05 ppm ozone) devices, creating a *de facto* business and usage monopoly for commercial and industrial providers. **(9-Gold; 13-Brickman; 40-Andreatta; 66-Montoya; 67-Brickman).** "I have installed many ozone-generating purifiers over the last three years …and have had NO health issues or complaints….If you limit my access to this equipment what will I use to help my clients in these areas?" **(40-Andreatta)**

Agency Response: We disagree with this comment and incorporate Responses to Comments 3-8 and 40 by reference here. As discussed on page 13 of the ISOR, staff considered options for dual-purpose (low and high ozone-emitting settings for occupied and unoccupied use, respectively) air cleaners and enhanced labeling as options to the proposed regulation. Staff believes that the risk is high for misuse of such air cleaners, which would result in the air cleaners being operated on the high ozone ("away" or "unoccupied") setting when household members are present. Even if the air cleaner is set correctly initially by a responsible adult, a child or visitor could easily turn the dial or switch to the high ozone setting, thus posing a serious risk to their health. We do not believe that the regulation establishes a monopoly, because the industrial exemptions specified in section 94803 and as defined in section 94801(a)(15) allow a variety of industrial and commercial businesses to continue to purchase many brands of high ozone-emitting air cleaners for use in unoccupied spaces when needed for their businesses. Commercial operators may continue to purchase high ozone-emitting air cleaners for use in their clients' homes when those homes are not occupied.

Although some users of high-ozone air cleaners may not have experienced health symptoms or received any complaints from their clients, this is not evidence that there is no risk of health impacts. A wealth of scientific studies such as those discussed on pages 15-25 of the ISOR (which are incorporated by reference here) have shown that individuals sensitive to ozone may experience symptoms at such levels, and others may experience damage to their lung

tissues and other long term effects that do not necessarily produce immediate symptoms.

EFFECTIVE DATE OF REGULATION

53. Comment: The proposed effective date is too soon; more time is needed. Certification bodies do not currently have a program or infrastructure in place to certify products to these new regulatory requirements…a January 2009 effective date may pose a market barrier for products being sold in the state of California. **(32-Kammer)**

Members of the Association of Home Appliance Manufacturers (AHAM) were concerned that the effective date proposed in the ISOR, which allowed only 12 months for companies to test and certify their air cleaners, was unrealistic due to the large number of models that would need to be certified, the fact that the test procedure had not been finalized, and the fact that no testing laboratories were yet available to perform the ozone test. AHAM estimated that 25-27 months could be required for all air cleaner models to be tested, and thus they supported the revised certification period that staff proposed to the Board at the Board hearing to allow 24 months for manufacturers to test and certify their air cleaners. **(70-Hudgins, 44-Morris)**

Agency Response: We agree with this comment. The staff proposed and the Board approved modifications to the staff's initial proposal to accommodate these comments' concerns. The Board concurred with the staff's revised proposal and industry's request to allow 24 months for manufacturers to test and certify their air cleaners. Section 94802 of the regulation has been revised accordingly.

54. Comment: Commenters requested a longer (12-month) sell-through period rather than the proposed 9-month sell-through period. AHAM and the Hunter Fan Company stated that the longer period is needed because appliances have a seasonal sales pattern (fall and spring) and a longer shelf-life (12-18 months) than most consumer products. A sell-through period of less than one year could result in disruption in the availability of air cleaning products and in manufacturers missing an important sales season, particularly those whose devices are last in the queue for testing at the test facilities. **(44-Morris; 56-Feder)**

Agency Response: We disagree with this comment. The Board carefully weighed the requests of the industry representatives and others who commented on the sell-through period at the Board meeting (see Comment 55, below, opposing the sell-through period) before making their decision. However, we believe that eliminating the sell-through period contained in staff's original proposal was in the best interest of the public, based on the potential harm to health that ozone-generating air cleaners can cause, and the fact that the certification period was extended to 24 months after the effective date of the regulation, per staff's suggestion in response to public comment, thus giving

substantial advance notice to manufacturers and retailers. The Board considered options such as a rolling sell-through period tied to the certification date of each model, a 60-day sell-through period instead of the 9-month period proposed or the 12-month period requested by industry, and other approaches, but we believe that these options are too complex to administer and enforce, unnecessary given the 24-month certification period and not adequately protective of public health. As suggested by the Chair, potential inequities for manufacturers whose devices are not able to be tested until late in the certification period could be addressed through an enforcement policy approach.

55. Comment: Commenters suggested not allowing a sell-through period. **(46-Holmes-Gen; 75-Carmichael)**

Agency Response: We agree with this comment. As discussed above in Response to Comment 54, incorporated herein, After much deliberation, the Board agreed with this comment and directed staff to modify the proposed regulation to remove the sell-through period in light of the additional time allowed for testing and certification (for a total of 24 months after the effective date of the regulation), because they felt strongly that high ozone-emitting air cleaners should not be sold in California any longer than necessary, and they did not want to further delay full implementation of the regulation.

LEGAL ISSUES

56. Comment: The definition of "occupied space" in the proposed regulation expands the scope of AB 2276 and is inconsistent with accepted dictionary definitions. It does not properly differentiate between spaces that are actually occupied versus those that are intended to be occupied. It is also inconsistent with court interpretations which typically interpret "occupied" to mean something closer to "actual presence". **(13-Brickman; 34-Naylor; 50-Naylor)**

Agency Response: We disagree with this comment. The proposed regulation's use of the term "occupied space" is entirely reasonable and is identical to the way the term is defined in federal law—all in obedience to federal preemption in this area and the specific dictates of AB 2276. The discussions appearing at pages 1, 5-6, 8, 9, and 31 of the Staff Report are incorporated by reference here.

Federal law considers ozone generating air cleaners to be "medical devices" when they are marketed with claims of positive health impacts. Federal law sets emissions levels for the devices and preempts state regulation in this area. (See *U.S. v. Bowen* (9th Cir. 1999) 172 F.3d 682). State regulation of ozone generating air cleaners is preempted to the extent it is inconsistent with or imposes requirements in addition to federal law, but states may apply for a waiver of federal preemption which may be granted by the Commissioner of Food and Drugs in a noticed rulemaking. (21 CFR section 808.1) Federal law sets a 0.05 ppm emission standard for these devices, but the federal Food and Drug Administration has exercised its enforcement authority in this area

sparingly, if at all, and devices that emit harmful levels of ozone are reaching customers' hands.

AB 2276 enacted Health and Safety Code sections 41985-41986. In Health and Safety Code section 41985(g) the Legislature declared that:

"Ozone emitted from indoor air cleaning devices poses an unnecessary risk to public health, and, therefore, it is the intent of the Legislature that the state board establish regulations to promote improved public health by restricting ozone emissions generated by these devices."

Section 41985.5 provides, in pertinent part, that the federal emission limitation for ozone concentration means, for the purposes of AB 2276, "ozone at a level in excess of 0.05 part per million by volume of air" measured, "in the atmosphere of enclosed space intended to be occupied by people for extended periods of time."

Section 41986(a) provides:

"On or before December 31, 2008, the state board shall develop and adopt regulations, consistent with federal law, to protect public health from ozone emitted by indoor air cleaning devices, including both medical and nonmedical devices, used in occupied spaces."

Section 41986(c)(4) provides that the implementing regulations may include:

"Any other element the state board determines to be necessary to protect the public health from emissions of ozone from indoor air cleaning devices that exceed the emission concentration standard for ozone emissions from air cleaning devices and are used in occupied spaces."

Section 41986(e) provides:

"It is the intent of the Legislature that this section be interpreted and applied in a manner that is consistent with federal law. The regulations adopted by the state board pursuant to this section shall be consistent with federal law. The state board may, to the extent a waiver is required, seek a preemption waiver from the federal government to authorize the state board to adopt regulations that are more stringent than federal law."

The applicable federal law is 21 CFR section 801.415. Section 801.415 establishes a maximum acceptable level of ozone emitted by medical devices. Section 801.415(c)(1) defines the standard as "an accumulation of ozone in excess of 0.05 part per million by volume of air . . . in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g. houses, apartments, hospitals, and offices."

In obedience to AB 2276 and federal law the proposed regulation provides at section 94801(a)(25) that occupied space "means an enclosed space intended to

be occupied by people for extended periods of time, e.g. houses, apartments, hospitals, and offices."

Again, Health and Safety Code section 41986(a) enacted by AB 2276 requires that the regulation be consistent with federal law: "On or before December 31, 2008, the state board shall develop and adopt regulations, consistent with federal law, to protect public health from ozone emitted by indoor air cleaning devices, including both medical and nonmedical devices, used in occupied spaces." The FDA's regulation for ozone-generating medical devices, 21 CFR 801.415, defines occupied space as "an enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices." ARB believes that this definition is appropriate for this regulation as well, and so is using the same definition as the FDA. [Section 94801(a)(25)] This does not at all expand the scope of AB 2276, but instead strictly conforms to it. Additionally, the Legislature clearly recognized this definition as appropriate because it is included in section 41985.5(a) in the Legislature's findings and declarations as part of the definition of "federal ozone emissions limit for air cleaning devices." In the face of the overwhelming amount of direct authority on this issue, the authorities cited by the commenters are unpersuasive.

57. Comment: California Consumers for Freedom of Choice submits that no one really wants to create a regulation that raises immediate antitrust and deceptive practice concerns (State and Federal) and the ARB should analyze the Staff's proposal to make sure this does not happen. To assist ARB in this process, the commenter offers discussion of the following points: 1) that vested older technology and product manufacturers tend to resist the introduction of newer and competitive technology and its manufacturers; 2) private standard setting organizations oftentimes by design or inadvertently through voting members develop standards capable of excluding certain products or manufacturers…and the end result is that the standard setting organization ends up substituting the panel's private policy for what should be public policy set by an actual government entity; and 3) it is important to assess who really gains and who loses most from the staff proposed regulation. **(13-Brickman)**

Agency Response: We disagree with this comment. The proposed regulation does not raise antitrust and deceptive practice concerns. The proposed regulation sets an emission standard and establishes certification, testing and labeling requirements for indoor air cleaning devices used in occupied spaces that emit ozone. The proposed regulation does this consistent with federal law and in response to the requirements of AB 2276. The proposed regulation would apply equally to anyone who seeks to introduce indoor air cleaning devices into commerce in California, regardless of the specific technology or manufacturer involved. In fact, the proposed regulation specifically avoids banning any particular technology, but rather sets out the ozone emission performance criteria and labeling requirements that must be met. The economic impacts of the proposed regulation were discussed in the Staff Report at pages 32-45 which are incorporated by reference here. The commenter provides no

credible authority to support this comment and we could not find any. Responses to comments 30, 45 and 52 are also incorporated by reference here. Finally, the proposed regulation benefits all consumers because it protects them from unacceptable levels of exposure to ozone from air cleaning devices.

58. Comment: The proposed regulation is an unconstitutional restriction on the ability of persons to choose the type of air cleaner they need. **(39-Pruitt)**

Agency Response: We disagree with this comment. The proposed regulation sets an emission standard and establishes certification, testing and labeling requirements for indoor air cleaning devices used in occupied spaces that emit ozone. The proposed regulation does this consistent with federal law and in response to the requirements of AB 2276. The proposed regulation would apply equally to anyone who seeks to introduce indoor air cleaning devices in commerce in California. The wealth of scientific evidence of the harmful effects caused by exposure to ozone provides a rational basis for the proposed regulations. The commenter provides no credible authority to support this comment and we could not find any.

59. Comment: The proposed regulation is inconsistent with workplace standards. Through the back door it bans devices that could result in concentrations over 0.05 ppm, imposes a stricter requirement than contemplated in the federal regulation and trumps the Cal/OSHA standard. 8 CCR Section 5155 shows that California's workplace standards do not regulate air contaminants except when employees are present and subject to exposure. **(34-Naylor)**

Agency Response: We disagree with this comment. Assuming for the sake of argument that it is true, it does not provide a reason to modify the proposed regulation. In any event, the proposed regulation is not inconsistent with workplace standards, and there is no "trumping" of the Cal/OSHA standard. Rather, it is a different type of standard that complements the Cal/OSHA standard. The proposed regulation limits the air concentration of ozone that can be produced by air cleaners that are used in occupied spaces. Workplace standards limit the average concentration that workers can be exposed to for given lengths of time. This makes sense because a worker may be near many different sources of ozone during his or her work day, and the total amount of exposure is what determines their risk. Exposure depends on two factors: the air concentration to which the person is exposed, and the duration of time over which the exposure occurs. Workers generally work 8-hour shifts, so the Personal Exposure Limit, or PEL, indicates the average concentration to which a worker may be exposed over an 8-hour period, whether they work indoors or outdoors. Short-term exposure limits, or STELs, are higher concentrations to which workers can be exposed for just 15-minute averages. However, as discussed above in Response to Comments 6 and 31 and in the ISOR on pages 1 and 10, people use air cleaners in their homes for 24 hours a day, seven days a week, across the year. Thus, to protect the health of people who use air cleaners in their homes, the level of ozone allowed to be produced by an air cleaner must be much less than the levels allowed in the workplace.

The proposed regulation does not ban air cleaners that can result in concentrations over 0.050 ppm; such devices are allowed to be sold and used for the industrial purposes specified in section 94801 of the proposed regulation, as long as they meet labeling requirements. The proposed regulation would not impose a stricter requirement than the federal regulation, and as discussed in the Response to Comment 56, is fully consistent with the federal requirements. In fact, air cleaners that are medical devices are not only required to meet the federal ozone limit, but also are required to meet the federal labeling requirements.

60. Comment: The regulation does not comply with the Administrative Procedures Act in that the ARB lacks authority to adopt the regulation as defined in Government Code section 11349.1. The regulation also doesn't meet the standard for consistency (in the same code section) because the proposed regulation is in conflict with, and contradictory to, the statute and the federal regulation. **(34-Naylor)**

Agency Response: We disagree with this comment and incorporate Response to Comment 56 by reference here. Also, the discussion in the ISOR on pages 5-6 and 8 is incorporated by reference here. AB 2276 provides ARB ample authority to adopt the proposed regulation. The proposed regulation is consistent with AB 2276 and federal law. The proposed regulation complies fully with the Administrative Procedures Act, including Government Code section 11349.1.

61. Comment: The proposed regulation is inconsistent with federal law. It goes beyond it by defining "used in occupied space" more broadly, and because in the context of federal law the federal labeling requirements recognize labeling or warnings for devices that are capable of exceeding the standard if not properly used. The proposed regulation goes beyond federal law in banning devices regardless of what labeling and warnings are used. **(34-Naylor)**

Agency Response: We disagree with this comment. The responses to comments 39, 40, 42, 56 and 57 are incorporated here and address the issue of the definition of "used in occupied space", among others. The proposed regulation is consistent with the federal regulation labeling requirements because Section 94806 will require air cleaners that are medical devices to be labeled in compliance with federal law, and because, regardless of federal labeling requirements, federal law nonetheless sets the 0.050 ppm standard and does not allow air cleaners to exceed that level (21 CFR 801.415). Thus the proposed regulation is consistent with federal law in that it bans devices that exceed 0.050 ppm and requires that medical devices have labeling that complies with federal labeling requirements.

62. Comment: The proposed regulation lacks a rational basis. The rationale behind the regulation's ban on devices that achieve the acknowledged benefits of ozone at higher levels in unoccupied spaces is that some consumer may not follow instructions or heed warnings to use the devices only when the space is

occupied. This ban would treat indoor air cleaners in a way that is virtually unique among consumer products. Consumers of every other potentially injurious but beneficial product (pesticides, lawn fertilizer, barbeque lighter, pharmaceuticals) are allowed to use that product so long as adequate warnings are given. The ban is not justified. First, as is the case with many consumer products, ozone at excessive levels naturally produces its own warning when used to excess. In this case, the warning is in the form of a pungent odor and immediate discomfort that would cause the consumer to turn off the device or exit the premises. **(34-Naylor)**

Agency Response: We disagree with this comment. Regarding the lack of a rational basis, the legislative findings for AB 2276 (Health and Safety Code sections 41985) lay out the rationale for ozone limits for indoor air cleaners, and Health and Safety Code section 41986 specifies certain requirements and guidelines for the regulation. The ISOR (pages 14-25) discusses the technical basis for the need to limit ozone emissions from consumer use of indoor air cleaners. The rationale for the regulation of ozone in occupied spaces as defined in the regulation is discussed in the response to Comment 56, which is incorporated here by reference. The inadequacy of warning labels or user instructions for consumers is discussed in our responses to Comments 39, 40, 42, and 52, which are incorporated here by reference.

We also disagree with the comment regarding the uniqueness of the proposed regulation. Regarding the examples given, some pesticides and pharmaceuticals have extensive warning labels but are not available to the public: commercial grade pesticides may only be purchased and applied by licensed pesticide applicators, and many drugs are available only by prescription from a doctor. These examples, in fact, illustrate precedent in regulation of beneficial products that can be hazardous at higher concentrations or doses.

We also disagree with the comment that people will be immediately affected by ozone's negative impacts at high levels and respond accordingly. The human sense of smell (olfactory sense) quickly dulls when exposed to ozone, so that perceived odor is not a reliable indicator of ozone's presence or concentration, as discussed in the ISOR (pages 8, 26) and our responses to Comments 14 and 46, incorporated here by reference. As discussed in Boeniger (1995) (see 15-day Notice and Section II above), at least three investigators have measured fairly rapid loss of the ability to detect ozone, ranging from an average of 5 minutes to 22 minutes. Additionally, regarding the immediate discomfort caused by ozone exposure, we disagree that this would be sufficient to cause consumers to leave the room because discomfort typically is not immediate…the onset of noticeable symptoms takes time, and varies depending on dose, an individual's specific sensitivity, and other factors. While relatively low amounts can cause chest pain, coughing, and shortness of breath (ARB, 2005b, ISOR), these effects are not necessarily immediate and can also be attributed by the device user to other indoor air pollutants or allergens. In addition, ozone damage to the lung can occur without any noticeable signs. Therefore, discomfort symptoms are not reliable indicators of ozone's presence, and would not be expected to trigger an

immediate avoidance response by the occupant of a space with elevated ozone levels.

C. Summary of Comments Received During the (First) 15-day Public Comment Period and Agency Responses

1. Comment: UL Standard 867, Section 37.4 allows for monitoring for 8 hours instead of 24 hours, and defines a steady-state as one in which the slope between hours 7 and 8 is not positive. Let us assume that a true steady-state has been achieved. Then half of the measured slopes will show a small positive value and half will show a small negative value. According to the definition, half of all cases that indeed achieved a steady state after 7 hours would be wastefully required to complete 24 hours of testing. The definition of the steady state should allow *de minimis* positive slopes to be proof of a steady state. The value of this positive cutoff can be determined as a function of the allowed precision of the measurement method (I believe it is 2%) coupled with observations of the slopes obtained by Monte Carlo runs of 60 1-minute averages on a constant concentration subject to random 2% errors. **(01-Wallace)**

Agency Response: We disagree with the comment regarding the need to revise the test method to allow *de minimis* positive slopes for steady state concentrations of ozone. Although UL 867 is silent on this issue, *de minimis* positive slopes can be justified because the consideration of measurement precision in determining whether a positive slope exists is in accord with good scientific practices. Therefore, we would allow testing laboratories to incorporate measurement precision in interpreting the measurement data to determine whether this steady state criterion is met.

2. Comment: Definition #20, Mechanical Filtration, should include with appropriate filter materials, "those treated with an electrically charged filter medium." **(02-Morris; 05-Feder)**

Agency Response: We disagree with the comment. Mechanical filtration devices are contrasted with other air cleaning devices that contain an electrical current running through them in order to charge collection plates or create ionized particles. Filters that have been electrostatically treated prior to installation would be included as mechanical filters under the current definition. Filters that have an electrical voltage connection within the air cleaner itself would disqualify the air cleaner as mechanical only.

3. Comment: Suggest one change in Section 94804(c)(D) "Serial number of devices submitted for testing (where applicable)." as many small appliances such as air cleaners do not have serial numbers. **(02-Morris; 05-Feder; 08-Wright)**

Agency Response: We agree with the comment and will add the phrase as a non-substantive clarification.

4. Comment: AHAM members appreciate the additional time allowed to meet labeling requirements, but remain concerned about the numbers of units that require testing and the time needed to move product through the supply chain. We (AHAM) will report to the ARB next year on our progress. **(02-Morris; 05-Feder)** The time that the product takes to get through the supply chain and physically sold is not within the manufacturer's control. We are concerned about the number of units that require laboratory examination, the amount of time to test and the time needed to process the product through the retail supply chain. Product could remain in retailers' inventory for quite some time before it is actually sold. We respectfully ask that ARB consider basing the timing on a manufacture date vs. the date of sale. **(08-Wright)**

Agency Response: We disagree with this comment. We appreciate the concerns expressed regarding timing issues and will work with manufacturers and their representatives to monitor testing progress. However, we disagree with the request to base any requirement on manufacture date. This topic was discussed at the Board hearing on September 27, 2007, and the revised regulation already addresses this in part by extending the time for testing (in 94802), and allowing additional time to meet the labeling requirements [in section 94806 (a)]. Additionally, manufacture date was considered by ARB staff in early workshops for other aspects of the regulation; however, manufacture date code format varies across manufacturers, and the code is not readily visible to enforcement officials without completely opening the box and unwrapping the air cleaner, so the request was rejected. Responses to Comments 53-55 in the comments received during the 45-day public comment period are incorporated by reference here. These Responses to Comments address the effective date of the regulation and the amount of time needed for testing.

5. Comment: AHAM will work with the ARB to develop a notification letter to be used to comply with Section 94807, so that there is uniformity of information received by all retailers for members' products, and consistency in the timing of its receipt. **(02-Morris)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We agree with the comment. ARB will be glad to review AHAM's letter to its members and assure that the information provided is correct.

6. Comment: Section 94804(a) indicates the certification application must be completed and signed by both the manufacturer and the test facility. 3M requests that a stand-alone document containing the required information from the test facility may alternatively be attached to the manufacturer's section of the application in order to save time and reduce the burden on all parties. **(03-Jacobson)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree. The commenter misstates the sentence, which is that applications may be submitted by certain organizations that represent manufacturers, "as long as all required information and signatures from the manufacturer and test laboratory representatives are included." The signatures for the manufacturer and the test labs are on different pages of the application, with each confirming the veracity only of the information that they are providing. The test laboratory representative, for example, signs a page confirming only the ozone and electrical safety test results. ARB believes that all portions of the application must remain together in order to assure that testing is conducted on the model specified as submitted by the manufacturer. Additionally, ARB prefers that complete applications be submitted as a single document, for ease of review and processing.

7. Comment: Section 94804(c)(4)(D) requires a chain of custody form. 3M requests clarification on what kind of form is acceptable. **(03-Jacobson)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. Any form that documents the handling, transport and testing of the model unit tested is appropriate, as long as it contains the sequential signatures of those who received it at each step. Most test laboratories have such forms that are suitable.

8. Comment: 3M requests that national data be acceptable for the recordkeeping requirement contained in Section 94808 due to the difficulty of separating out data specific to California. **(03-Jacobson)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. Our regulation applies only to manufacturers, distributors, retailers and others who introduce air cleaners into commerce in California. Anyone covered by the proposed regulation would need to keep appropriate records in order to comply with its requirements. Records must be kept that would permit air cleaners that come under scrutiny in an enforcement action (i.e., sold in California) to be tracked and their history identified. Thus, California-specific data are required, not national data only.

9. Comment: Commenter assumes this comment will be acknowledged by mail because his August 10, 2007 comments were never responded to or acted on in the September 27, 2007 Board meeting. **(04-R. Barnes)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed

modifications, or the procedures followed in proposing or adopting them. Without waiving this objection we respond as follows. Comments received within the 45-day public comment period prior to the September 27, 2007 regulatory hearing were fully considered by the Board in its deliberations. Responses to comments received during the 45-day public comment period, along with responses to comments received during either of the 15-day notices issued on June 30, 2008 and July 16, 2008, will be provided in the Final Statement of Reasons (FSOR) which will be submitted to the Office of Administrative Law (OAL) as part of this rulemaking. The submission to the OAL will take place no later than August 8, 2008. Upon approval of the regulation by OAL, the FSOR (including written responses to all comments) will be posted on the ARB's air cleaner regulation web page at http://www.arb.ca.gov/regact/2007/iacd07/iacd07.htm. Comments are not acknowledged by mail. The commenter's other comments are responded to in Response to Comment 38 submitted during the 45-day public comment period; that response is incorporated by reference here.

10. Comment: Commenter suggests adding to the exclusion of "in-duct" systems (in section 94803) as follows: "Air cleaning system to be used in ducting system are (sic) to meet the requirements of Definition 94801(a)(14) and does not exempt 'in duct' electrostatic air cleaners. Systems may not have to be completely contained within (sic) air duct. Further the 948001(a)(14) device for ducting systems does not require integration by the OEM manufacturer only and can be attached at a later installation date. Current 'in ventilation systems requirements' to limit use of these devises (sic) constitutes a 'restriction of trade' and is not practical." **(04-R. Barnes)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. The current regulation does not restrict aftermarket systems from being installed, and does not limit installations to the original equipment manufacturer. In-duct systems are exempt as long as the air cleaner is "designed, marketed, and used solely as a physically integrated part" of a central heating, air conditioning, or ventilation system.

11. Comment: "94803 or 94801 (33). Definition of 'industrial supply outlet' is a distributor, or retailer of (sic) service organization that sells to industrial customers as part of normal business. Not (sic) definition at all." **(04-R. Barnes)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree. "Industrial supply outlet" is not defined in the regulation. In section 95803(a), the regulation provides an exemption for air cleaning devices used for various industrial uses, provided the devices are marketed through industrial supply outlets or businesses and that the devices be labeled as being solely for industrial use and

also contain a specified health warning. We believe "industrial supply outlets and businesses" is sufficiently clear.

12. Comment: The definition of "Listing Mark" should be changed to include listing marks of other certified labs (i.e. ETL, other); it does not just apply to UL. **(04-R. Barnes; 05-Feder)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment. "Listing mark" is a term specifically used by UL. Other laboratories use other terms such as "certification mark" which is included in the definitions in section 94801(a)(5).

13. Comment: The commenter appears to suggest that germicidal lamp systems, including titanium dioxide or any other photocatalytic or advanced oxidation devices, be exempted from the regulation in section 94803. **(04-R. Barnes)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with this comment. The commenter did not provide any data showing that such devices emit little or no ozone, and we are aware of only very limited measurements of ozone from such devices. Some germicidal lamp systems and advanced oxidation devices may produce ozone, and thus should be tested.

In this case providing an exemption would be counter to the intent of AB 2276 that all air cleaners be tested and certified as complying with an ozone emission concentration standard of 0.05 ppm prior to being sold for use in California. The regulation does provide a limited exemption from the ozone testing for devices using mechanical filtration only [section 94804(b)] based on their known *de minimis* ozone emissions.

14. Comment: Commenter suggests that an exemption be granted for "any contact communicator fans, blowers and mechanical filters (filtration only) that generate ozone by brush bounce, or dirty contactors." **(04-R. Barnes)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment. If these "fans, blowers and mechanical filters" fit the definition of an "indoor air cleaning device" in section 94801(a)(14), they would be required to be tested and certified under the regulation unless they are exempted under Section 94803 as industrial use or in-duct systems, or qualify as "mechanical filtration only" devices as defined in Section 94801(a)(20).

15. Comment: Commenter suggests that an exemption be added to section 94803 for "any cooling/air cleaning fans that cool high voltage or inductive electronic equipment capable of producing or distributing corona discharge." **(04-R. Barnes)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. Cooling fans do not appear to fit the definition of an "indoor air cleaning device" in section 94801(a)(14) and therefore would not be required to be tested. If the "high voltage or inductive electronic equipment capable of producing or distributing corona discharge" is an air cleaner as defined in Section 94801(a)(14), it would have to be tested.

16. Comment: Commenter wants to add a provision in Section 94809 that the "Executing Officer must provide manufacturer with a 'right of due process,' proper testing verification, description of violation and a proper time to cure a violation. Financial losses incurred by manufacture or distributor by improper or inappropriate recall shall be the financial responsibility of ARB or the State of California (as appropriate). Tests of all units conducted by ARB will be supplied along with any analysis done by ARB." (**04-R. Barnes)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment. The proposed regulations provide ample due process. Neither the ARB nor the State of California is responsible for any financial losses incurred by a manufacturer for complying with, or failing to comply with, the regulation adopted by the ARB in fulfillment of the legislative mandate in AB 2276. A recall could be imposed if a violation has occurred, and costs of correction are the responsibility of the entity that is in violation of the regulation. Test results that trigger enforcement actions would be provided to the violator. Violators and others have access to the courts.

17. Comment: Include in Section 94804 that once data is submitted it will be acted on in a timely manner and approval would not be unduly held or prioritized. There is no requirement on the manufacturer to conform to undue ARB imposed manufacturing standards. **(04-R. Barnes)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. The timeframe for review is provided in section 94804(d) of the regulation. A written notification will be provided within 30 days of receipt indicating whether the certification application has been accepted for review or, if incomplete, what additional information is

required. Within 30 days after application acceptance, written notification of certification approval or disapproval will be provided.

18. Comment: Commenter suggests adding to the definition of industrial applications in 94800 (a)(15) as item (j) "Any industrial application, with people not physically present, that completely contains the ozone process, or any ozone process that completely contains the ozone in a container incapable of having people occupy the container" so that these would be exempt from the regulation but must still comply with safety standards. **(04-R. Barnes)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. We disagree with the comment. The suggested exemption is far too broad to assure that no individuals would be exposed to excessive levels of ozone. Instead, we have defined only very specific industrial exemptions in the existing regulation.

19. Comment: California Consumers for Freedom of Choice (CCFC) repeats the objections raised in its September 24, 2007 comments and incorporates them by reference here. ARB staff has not adequately responded to objections raised, and on that basis the ARB regulations may violate the Administrative Procedures Act criteria for review. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment. We incorporate by reference here Response to Comment 9 above from the first 15-day comment period. Our written responses to comments received during the 45-day comment period, prior to or at the September 27, 2007 public hearing, will be submitted to the Office of Administrative Law (OAL) as part of the Final Statement of Reasons for this rulemaking, and will be posted on the ARB web site upon OAL approval. CCFC comments appear at Responses to Comments 9-13, 18-21, 23, 30-31, 33, 39-46, 52, and 56-57 in comments submitted during the 45-day public review period and are incorporated by reference here. These responses are fully responsive to all comments raised and comply with the Administrative Procedures Act.

20. Comment: Page 1 − The entire role of UL in these proceedings has been confusing and suspect. Staff's role also raises concerns. CCFC was under the impression that all UL proceedings, including testimonial and documentation records related to those proceedings, would be part of these (ARB) rulemaking proceedings. In this way, CCFC believed that all stakeholders could provide ongoing comments, raise objections, and participate in facilitating the development of an appropriate testing procedure in line with the mandate of AB 2276. Page 2 – CCFC is alarmed by the relative secrecy and confidentiality of the UL proceedings. This alarm is based on the latest submission of UL-related documents for comments here [in the 15-day notice] by staff, the lack of any UL

record of reviewing prior stakeholder comments and objections over testing procedures, no posting of complete UL 867 Standard references and revision deliberation documents for stakeholder access and review, and the results of CCFC's Internet searches for such documents. Further they are alarmed that apparently only staff has been involved in the UL proceedings to the exclusion of other participants. It thus appears that ARB staff may have acted as the sole "gate keeper" for the AB 2276 proceedings in determining what if any stakeholder comments and objections on proposed testing were formally submitted to the UL process. CCFC submits this is a "private rulemaking" on the "most critical component" with a single stakeholder in what may be a violation of the APA. The parallel UL proceeding did not afford all stakeholders an adequate opportunity to participate in developing the test procedure. CCFC also notes that UL conducted proceedings in 1999 on a UL indoor air quality standard that ARB participated in, but that CCFC could not find any publicly available documents on that proceeding. Page 3 – It remains unclear why staff (a) did not fully disclose the workings of this totally separate and parallel proceeding; (b) did not fully disclose how stakeholder comments and objections were being processed through this proceeding if at all; and (c) did not create an opportunity for all stakeholders to have a fully informed participation through the AB 2276 proceedings.
(06-Brickman)

Agency Response: We disagree with this comment. Both the ARB rulemaking and the UL proceedings were open to full public participation. There was nothing secretive or confidential about either the ARB or UL proceedings. The ARB rulemaking process is separate from the ANSI/UL standard revision process for UL's standards; however, both have public comment periods, and in this case, the two processes occurred somewhat concurrently. ARB's process included making the UL proposed changes available during each public review period on our website at http://www.arb.ca.gov/research/indoor/aircleaners/aircleaners.htm prior to each of the 2007 public workshops, and at http://www.arb.ca.gov/regact/2007/iacd07/iacd07.htm for the 45-day public comment period beginning August 9, 2007 and the two 15- day public review periods in 2008, so that interested stakeholders did not need to access the UL website if they wanted to comment to ARB regarding the revisions to the Section 37 test method. UL's separate process was indicated throughout the rulemaking process, including on prior entries of ARB's air cleaner webpage during the two 2007 workshops held by ARB, and in our written documents such as the ISOR on pages 28-30, where the many changes to the Section 37 test method are fully described.

The UL proceeding to revise Section 37 of Standard 867 followed UL's ANSI-approved regulations (see http://ulstandardsinfonet.ul.com/stp/regulations.html). Their public comment periods on various versions of the revisions and comments received ran from June 22, 2007 to July 26, 2007; September 21, 2007 to November 5, 2007; and November 15, 2007 to November 29, 2007. As always, the UL proposal was announced to the public via the ANSI Standards Action

newsletter (http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Action/2007%20PDFs/SAV3825.pdf). UL's standard-setting and revision process is completely open to the public. Previous documents are available via UL's distribution website at http://www.comm-2000.com/.

ARB staff participated on UL's *ad hoc* committee to develop revisions to Section 37 of Standard 867, as did 19 other individuals. Following UL's and ANSI's rules for such activities, members of the committee represented four stakeholder categories including producers, consumers, government, and general members. This group included Linda Brickman, an apparent relative of the commenter, who not only participated on UL's ad hoc committee for the Section 37 revision, but also submitted comments to UL on November 1, 2007. Her comments to UL mirrored many of the comments received by ARB on the proposed test method from Robert Brickman and Greg Montoya during the 45-day comment period. Brickman and Montoya's comments on the test method are summarized as Comments 43-46 in the FSOR section on comments received during the 45-day public review period. Those comments (43-46) and our responses to them are incorporated here by reference.

Brickman and Montoya's comments and all others on the Section 37 test protocol were fully considered by ARB during the development of the regulation and at the September 27, 2007 hearing. They were considered by ARB relative to ARB's rulemaking, not UL's actions. If ARB believed that changes were warranted by the comments received, we could have chosen to use only part of UL's Section 37 protocol, or something different entirely. As directed in AB 2276 [Section 41986(b)(2)], ARB considered the ANSI/UL standard as well as other possible test protocols in developing its regulation, as described in the ISOR pages 12-13. However, as discussed in Response to Comments 43 and 44 (incorporated here by reference) for the 45-day comment period, above, we agreed with the changes to Section 37 made by UL, and believe Section 37 of UL Standard 867 is the best ozone test method for this regulation.

Regarding UL's 1990s attempt to produce a broad indoor air quality standard, ARB staff participated as one of many interested stakeholders. The effort failed to produce a standard as UL had hoped, which may be the reason the materials associated with that effort do not pop up with an Internet search. In any case, the stakeholders for that effort worked with an entirely different set of UL staff members for a different purpose.

21. Comment: Page 3 – Staff reliance on UL 867 including Section 37 testing is flawed as UL 867 was never designed to cover all representative indoor cleaning devices and functionalities. The Scope of the standard is narrower than has been represented by staff, and is not entirely suited as the single testing procedure for manufacturers to utilize to determine ozone emissions.
Page 4 – The coverage is limited to electrostatic air cleaners intended to remove dust and other particles from the air; does not cover electrostatic air cleaners

used in hazardous locations; and does not cover air cleaners intended to remove particles other than dust and other particles normally found in heating and ventilation systems. Page 5 – UL 867 was not expanded or changed to address any types of air cleaners other than electrostatic air cleaners designed to remove dust and other particles found in heating and ventilation systems, i.e., UL 867 does not cover many of the functions listed in paragraph 14 of section 94801 (Definitions) including allergens, microbes (e.g. bacteria, fungi, viruses, and other microorganisms), smoke, fumes, gases or vapors, and odorous chemicals (emphasis added by commenter). **(06-Brickman; 07-Naylor)**

Agency Response: We disagree with the comment. As indicated in the more recent UL guidance on this standard (UL 2007a, 2007b, and 2008) included in the second 15-day notice and listed below, ANSI/UL Standard 867 is a requirement for testing portable electronic air cleaners, including ozone generators, electrostatic precipitators, and ionizers. Comments in the outdated Scope statement for Standard 867 regarding the unsuitability of Standard 867 for air cleaners used in hazardous environments apply to the fact that those devices require additional safety testing under UL requirements. The application of the standard to air cleaners also was discussed in each of the public workshops on the regulation.

This issue was also addressed in Response to Comment 44 in the comments submitted during the 45-day comment period, which is incorporated by reference here. As stated in that earlier response, the test method cited in the regulation, Section 37 of ANSI/UL Standard 867, underwent formal ANSI/UL updating in 2007 (ANSI/UL 2007a). This process, which was open to the public, met with the approval of numerous scientific research experts, manufacturers, trade associations, government agencies and testing laboratories. These revisions, some of which were discussed in the Responses to Comments 43, 45, 46, and 48-50 for comments submitted during the 45-day public comment period and which are incorporated by reference here, create a more robust test method that provides reproducible and accurate ozone emissions results within a controlled testing environment. Thus, the test method referenced in the regulation has been modernized to address previous inadequacies and is suitable for all of the types of air cleaners specified by UL.

References

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22. Comment: Page 4 – The ozone testing in Section 37 of UL 867 was designed to ensure that non-functional inadvertent or by-product ozone emissions did not produce a safety issue involving excessive ozone build-up when these products were placed per their user manuals next to a child sleeping or playing. Using a 2-inch testing location for this specific type of air cleaner technology and using a sterile environment made sense here based on manufacturers' representations of no intent to generate or emit functional ozone as part of the air cleaning process. Page 5 – Section 37 testing is designed solely around measuring the inadvertent or by-product emission of ozone that was never intended to be part of the air cleaner functionality in addressing non-dust or non-particulate. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with this comment. There is no valid scientific reason for testing to be different whether the ozone is produced intentionally or as a by-product; the Section 37 test is required in order to prevent persons from being exposed to harmful levels of ozone, inadvertent or intentional, emitted by an air cleaner. This issue was raised in comments from this commenter for the 45-day public comment period, and has been addressed in Responses to Comments 44 and 46 from that comment period, which are both incorporated by reference here.

We also disagree with the comment about the test method not being designed for products that intentionally produce ozone, and incorporate here by reference Response to Comment 21 above for comments submitted during the first 15-day public comment period. Further, as noted in the Response to Comment 44, in the recently updated test method, UL 867 Section 37.1.2 refers to ozone limits for "A portable air cleaning product for household use", and Section 28.A.1 states that "(O)zone monitoring circuitry shall not be user-defeatable or user-adjustable" (ANSI/UL, 2007a). This clearly indicates that portable indoor air cleaners of any type, including those that produce such substantial amounts of ozone that an ozone monitor may be needed, are addressed by this test method.

23. Comment: Page 5 – The parallel UL revision process was restricted and not broadened to include functional ozone testing issues and modifications to testing procedures. "Neither the current or proposed UL 867 Standard or Revision Process was expanded or changed to address any types of air cleaner products other than electrostatic air cleaners intended to remove dust and other particles normally found in heating and ventilating systems." Other types of air cleaners, including those with many of the functions indicated in the definition of "indoor air cleaning device" would not be covered by the UL 867 Standard. It is no wonder why CCFC comments and objections to UL867 were not addressed by UL as part of their revision process, assuming they were even transmitted to UL, since neither the then current, nor the standard revision process for UL 867 was intended to cover anything beyond the original scope of UL 867. The revision process purpose was solely to clarify and improve the repeat-ability of the current testing requirements in Section 37. **(06-Brickman)**

Agency Response: We disagree with the comment. The commenter is incorrect regarding the current scope of UL 867 as the standard addresses all portable air cleaners as explained in the more recent UL documents cited in Response to Comment 21 above from comments submitted during the first 15-day public review period, which is incorporated here by reference. Additionally, ARB has assessed and selected the revised UL Section 37 protocol as suitable for all air cleaners that would fall under this regulation. Regarding the purpose of the UL 867 (section 37) revision process, it was to clarify and improve the repeatability of the current testing requirements as stated; however, the improvements included applications specific to intentional ozone generating technologies, as discussed in Response to Comment 22 above, from comments submitted during the first 15-day public comment period and which is incorporated by reference here.

Contrary to CCFC's statements, their comments were addressed verbally at workshops and in a separate meeting requested by CCFC, and in writing in the ISOR and in the responses to the 45-day comments included in this FSOR. Responses to Comments 43-46 specifically addressed comments raised by CCFC received during the 45-day public comment period, and those Responses to Comments also are incorporated by reference here. Their 45-day comments also were posted on the ARB regulation website for UL and others to review.

24. Comment: Page 5 − A proposal for a new testing standard that addresses the safe emission of "functional ozone" as part of the air cleaning device (as opposed to inadvertent or by-product emission of "non-functional" ozone) should be submitted for UL consideration. **(06-Brickman)**

Agency Response: We disagree with the comment. Responses to Comments 21 - 23 submitted during the first 15-day public comment period, are incorporated here by reference. Such a request to UL is unnecessary as the current standard already addresses intentional ozone generators as well as other air cleaning devices. This would also contravene the requirements of AB 2276 which requires ozone generators to meet the 0.05 ppm standard whether the ozone is

intentionally emitted or not. However, the commenters are free to suggest whatever they wish to UL.

25. Comment: Page 6 − To the extent that the Board remains confused over UL's position with respect to the inherent limitations of the UL 867 Standard in not addressing all air cleaner devices and all the functions described in paragraph (14) of the definitions, CCFC would be amenable to convening an appropriate legal process whereby we could compel the production of documentation and the taking of depositions from UL to further substantiate the CCFC position. Staff's reliance on the application of UL 867 testing procedures to "all air cleaner devices" including those with functions beyond just removing dust and other particles normally found in heating and ventilating systems, was flawed or misplaced, as stated in Comment 21. **(06-Brickman)**

Agency Response: We disagree with the comment. We have consulted with UL regarding the current scope of UL Standard 867, and we fully understand it. UL provided the three references discussed above in the Response to Comment 21 (comments submitted during the 15-day comment period), which counter CCFC's narrow understanding of the scope of UL 867. Responses to Comments 21 and 22 from the first 15-day public comment period are incorporated by reference here. Responses to Comments 44-46 from the 45-day public review period also are incorporated here by reference. This comment would also contravene the requirements of AB 2276 which requires ozone generators to meet the 0.05 ppm standard whether the ozone is intentionally emitted or not.

26. Comment: Page 6 − CCFC submits that staff's reliance in 2005 in developing their own test chamber and testing procedures on air cleaners based on an application of UL 867-type testing procedures and their subsequent reports, public statements and other communications was similarly flawed or misplaced. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modified regulatory text, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment. We incorporate here by reference the Response to Question 8 of Comment 38 from the 45-day comment period responses to comments.

27. Comment: Page 6 – Reliance on the UL 867 Standard for testing would not only violate the APA and be contrary to the intent of AB 2276, but it would effectively foreclose the manufacturing for resale in California of non-electrostatic air cleaners or similar types of air cleaners intended to remove more than just dust and other particles. This would leave consumers with product choices grounded in 1980's air cleaner technology, and would result in a forced revocation of outstanding consumer product manufacturer warranties covering repair, maintenance and replacement situations relating to existing air cleaners that will not meet the proposed UL 867 Standard once implemented and cannot be reshipped back into the State. Page 7 – This will also limit manufacturer's ability

to offer the broadest array of air cleaner options to meet customer needs, and would likely create an Internet "black market" for air cleaners that may not meet the UL 867 Standard. **(06-Brickman)**

Agency Response: We disagree with the comment. The regulation addresses ozone emissions from portable air cleaners used in occupied spaces, pursuant to AB 2276 which identifies the UL standard. The intent of the regulation is to prevent persons from being exposed to ozone at concentrations greater than 0.050 ppm. AB 2276 references UL. The regulation conforms fully with the intent of AB 2276, as discussed in Responses to Comments 7, 43, and 44 from the 45-day public comment period, which are incorporated by reference here. The use of UL 867 as the test method is not contrary to the APA; we incorporate Responses to Comments 56 – 60 from the 45-day comment period here by reference, and we also incorporate Responses to Comments 20-25 above from this set of responses to comments received during the first 15-day comment period. Incorporating the UL standards by reference is permitted by title 1, California Code of Regulations because: they are voluminous and it would be cumbersome, unduly expensive and otherwise impractical to publish them in the California Code of Regulations; they were available upon request directly from ARB and were available from UL; and the notice of rulemaking clearly identifies the standards, and the regulation text clearly identifies the standards to be incorporated by title and date of publication. The ARB expects most air cleaners to be certified as not emitting more than the allowed ozone concentrations, including air cleaners that represent current technologies being developed, as discussed in the ISOR pages 34-35. Thus, consumers' choices will not be limited in the manner described by the commenter. This is further discussed in Responses to Comments 57 and 58 from the 45-day comment period, which are incorporated here by reference. Additionally, ozone generators re-shipped to California after repair and warranty service will be required to meet the requirements of this regulation, but this does not unduly restrict trade as discussed in Response to Comments 41, 57 and 58 from the 45-day public comment period, which are incorporated here by reference.

28. Comment: Page 7 - CCFC urges the Board to: (a) limit staff's proposed UL 867 testing to those devices intended under the Standard's scope and other products at the option of manufacturers; (b) direct staff to develop a new proposal that covers air cleaners not intended to be covered by UL 867; (c) convene a workshop of all stakeholders to review alternative testing procedures that recognize the use of low levels of ozone for cleaning occupied situations, and higher levels (at some reasonable level) for non-occupied situations; (d) adopt warning and usage labels on a trial basis and monitor their use; (e) adopt definitions of occupied and non-occupied based on actual physical presence; (f) remove from the industrial use exemption definition paragraph 15(F)(G)(H) and (I) and permit residential use of ozone under the same conditions where "no people are physically present" in order to avoid a regulatory created monopoly of these services to for-profit businesses; and (g) exempt from transportation into California any product or parts covered under product warranties in existence until expiration of the warranty. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with this comment which repeats in summary form previous comments made and responded to in Responses to Comments 19 -27 submitted during the first 15-day comment period, which are incorporated here by reference. In addition, we incorporate here by reference our earlier Responses to Comments 39, 41, 52, 56 and 61 submitted during the 45-day comment period.

29. Comment: Page 8 – The rationale used to support adding an industrial use in section 94801 (a)(15)(I) for odor control in motor vehicle reconditioning should support the same uses for consumers provided no people are physically present during the odor control process in their personal motor vehicles. This industrial use, along with the uses specified in subsections (a)(15)(F), (G) and (H), creates a regulatory monopoly to for-profit businesses on a pay per visit/treatment basis and places a financial burden on consumers. This is contrary to the intent of AB 2276 and in violation of the APA. (**06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with this comment and incorporate here by reference our Responses to Comments 39, 40, 42, and 52 in the comments submitted during the 45-day public comment period. As explained, the risk is high for potential misuse of air cleaners if such exemptions were allowed for consumers. The exemptions specified in section 94803 and as defined in section 94801(a)(15) allow a variety of industrial and commercial businesses to continue to purchase many brands of high ozone-emitting air cleaners when needed in their businesses. In addition, such businesses are regulated according to occupational standards for the protection of their employees.

30. Comment: Page 8 – Regarding additions to the Rulemaking Record on pages 5-7 of the 15-day notice, no copy of the complete ANSI/UL Standard 867 was posted to the ARB website for immediate access by stakeholders. Instead copies were available from UL at a high price, and UL Standard 507 was available at an even higher cost. Not providing all stakeholders with timely access to applicable UL Standards or other materials that form a basis for the regulation does not comply with the APA. **(06-Brickman)**

Agency Response: We disagree with this comment. A copy of the full UL Standard 867 was (and is) available for public review in our offices as required and as stated in the original public notice. In addition, throughout the rulemaking process, we provided updated versions of revisions to the Section 37 ozone testing protocol on our website, explained those changes in public workshops and the ISOR (pages 28-30), and sought public review and comment at each

step of the process through listserve announcements and public notices. To our knowledge, ARB never received a request for a hard copy of either standard. The specific version of UL Standard 507 that is to be used for the regulation was added to the rulemaking file in the first 15-day public notice. As noted by the commenter, however, both standards were always available from UL for a fee.

31. Comment: Page 8 − The ARB website and notice list references to all materials comprising the record for OAL review. During his testimony, Mr. Greg Montoya "proffered to staff and the Board a large box containing approximately 30,000 customer testimonials and letters of support for the CCFC positions". However, at no time prior to the Board deliberations following the end of testimony, nor at the conclusion of the hearing or any time thereafter, did staff or the Board review or arrange to receive these materials as part of the record of these proceedings. These letters were not officially acknowledged as being part of the record, and that failure affects the completeness of the record. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. None of these alleged testimonials or letters of support were submitted to ARB at the September 27, 2007 hearing, in response to the 45-day notice or either of the 15-day notices. In his testimony, Mr. Montoya claimed to have approximately 30,000 testimonials similar to his and the ones actually submitted by other commenters and witnesses (transcript at page 125), but did not indicate he was offering them for the record or wished to submit them. Regardless, the Board fully considered Mr. Montoya's testimony along with the testimony of the other witnesses in its deliberations and decision on the proposed regulation. A number of personal testimonials were submitted and were considered by the Board during the 45-day public comment period and at the public hearing on September 27, 2007. These testimonials were discussed in Response to Comment 16 in the comments submitted during the 45-day public comment period, which is incorporated by reference here. Inasmuch as the unsubmitted testimonials contained the same comments as those that were actually submitted, this response responds to both.

32. Comment: Page 9 – CCFC submits there are numerous factual flaws in Resolution 07-40; for example, the statement on the first page of the resolution (paragraph 3) that "exposure to 'high levels of' ozone is a public health concern" is factually flawed. (**06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment and incorporate by reference here our earlier Responses to Comments 3-9 (submitted in the 45-day comment period). In addition, the overwhelming evidence of the potential harm from exposure to ozone is presented on pages 15-25 in the ISOR.

33. Comment: Page 9 – CCFC states that on page 1 (par 4) in Resolution 07-40 there are factual misstatements over characterization of any air cleaner that includes ozone as part of the air cleaning technology, and failure to reference the difference between high levels of ozone in occupied spaces as opposed to safe levels of lower levels of ozone. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment. The fourth paragraph in the resolution simply states factual information contained in the ISOR at pages 6-8 (incorporated here by reference) that there are a number of manufacturers that market appliances labeled as "air purifiers" or "air cleaners" that can intentionally generate large amounts of ozone. The ISOR also documents that operation of these devices can result in elevated room concentrations above the health-based state and federal ambient air quality standards.

34. Comment: Page 9 – CCFC states that Resolution 07-40, paragraph 5, misstates the effectiveness of low levels of ozone for odor control and control of microorganisms; the resolution says that ozone is not effective, except at very high levels. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with this comment. First, the paragraph cited in Resolution 07-40 does not mention odor control. The statement is that ozone is not effective at cleaning the air, except at very high levels of ozone when it can reduce some microbe levels. The ineffectiveness of ozone for cleaning the air and controlling microorganisms is discussed in the ISOR at page 8, and in Responses to Comments 17 – 21, 24, and 26 submitted during the 45-day comment period and incorporated here by reference. The ISOR discussed the conclusions of Foarde *et al.* (1997) that much higher concentrations (ppm levels) are necessary for significant kills, and that similar ppm levels were ineffective when microbes were growing on building materials which make the ozone less effective. This conclusion was also reached by the U.S. EPA (2007) in a reference added during the first 15-day comment period. Finally, as discussed in Response to Comment 21 submitted during the 45-day comment period, the authors of one of the two papers submitted by commenters during the rulemaking themselves noted that while ozone generators can inactivate viable microorganisms, the inactivation occurs at concentrations significantly exceeding health standards in the ppm range (Grinshpun *et al.*, 2007 at page 606). Further, ozone emitted into indoor spaces even at levels below 0.050 ppm may have potential health impacts, either directly or from secondary chemicals that are formed, as discussed in Comments 3 and 4

from the 45-day comment period and our responses to those comments, which are incorporated here.

35. Comment: Page 9 – CCFC states that paragraph 8 on page 3 of the Resolution 07-40 contains factual misstatements over the relevancy of UL 867 Standard testing to other than electrostatic precipitators intended to remove just dust and particles from the air. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with this comment and incorporate by reference our above Responses to Comments 21 and 22 submitted in the 15-day public comment period, and Responses to Comments 43-46 and 48-50 submitted during the 45-day public comment period.

36. Comment: Page 9 – CCFC states that paragraphs 4 and 5 on page 4 of Resolution 07-40 contain factual misstatements over the adverse impact as there is no reference to the impact on manufacturers of purifiers that might meet the intent of AB 2276 but cannot overcome the testing flaws in UL 867, resulting in significant economic impact (for example, Sharper Image bankruptcy) and manufacturers being forced to abandon their product line in favor of 1980s ESP technologies that produce no ozone. Consumers will be denied cleaning solution options including ozone based options for occupied space use at affordable prices. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment. The Board conducted an extensive review of the potential impact on businesses and consumers as discussed in the ISOR (pages 32-45). Resolution 07-40 summarized several of the conclusions from the ISOR. As noted in Responses to Comments 21 and 22, submitted during the first 15-day public comment period and incorporated here by reference, the UL Standard 867 is not flawed, but has actually been improved and is required for a variety of air cleaning devices as described by UL in the references specified in Response to Comment 21. We submit that manufacturers abandoning product lines that intentionally generate ozone is consistent with the intent of AB 2276 to reduce public exposure to ozone, and that there remain many air cleaning devices available that are both effective and affordable to consumers. The bankruptcy of Sharper Image is not linked at all to this proposed regulation, which is not yet in effect.

37. Comment: Page 9 – CCFC states that paragraphs 2, 3, 4 , 5 , 8 and 9 on page 5 of Resolution 07-40 contain factual misstatements over (1) the health risk to low level exposure to ozone; (2) failure to mention there are no epidemiological studies to support the health risk statements; (3) the elimination of responsible use of products using low level ozone in occupied spaces in contrast to higher

levels of ozone when unoccupied; (4) potential impacts; and (5) the lack of reasonable and more effective alternatives for regulating air cleaners that intentionally generate controllable and scalable levels of "optional ozone" as part of their cleaning solution. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with this comment. The health impacts of exposure to ozone are discussed in the ISOR at pages 15-19; potential economic and environmental impacts are discussed in the ISOR at pages 32-47; and alternatives considered are discussed in the ISOR at pages 12-13. We incorporate by reference here Responses to Comments 3-9, 13, 15, 17-21, 26, 37, and 39-42 submitted during the 45-day public comment period.

38. Comment: Page 10 – In Attachment B to Resolution 07-40, CCFC disagrees with staff's proposed modification to section 94802 striking the phrase "for use or intended use in occupied spaces" and states that excluding any reasonable definition of "non-occupied or unoccupied space" is contrary to the intent of AB 2276 and may violate the APA. On page 2 of Attachment B, CCFC submits that changes affecting section 94805 can only apply to electrostatic precipitators in line with their other comments regarding the applicability of UL Standard 867. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We agree with the comment regarding section 94802, but disagree with the remainder of this comment. Attachment B to Resolution 07-40 was presented to the Board at the public hearing on September 27, 2007 and inadvertently showed the phrase "for use or intended use in occupied spaces" as being struck out and deleted. This attachment is superseded by the Modified Text shown in Appendix II to the 15-day Notice issued on June 30, 2008 for public review; the phrase remains in the modified text.

Regarding the definition of "occupied space" we disagree with the comment. We incorporate by reference here Response to Comment 56 from the comments submitted during the 45-day public comment period in which this issue was discussed at length, as well as Response to Comment 42 below in the comments submitted during the first 15-day public comment period and which is also incorporated by reference here. Regarding the applicability of UL 867 to air cleaners other than electrostatic precipitators, this issue has been previously addressed and we incorporate by reference here Responses to Comments 21 and 22 submitted during the first 15-day public comment period and Response to Comment 44 from the 45-day public comment period.

39. Comment: Page 10 – Regarding Appendix II (Modified Text for 15-day Public Comment Period June 30, 2008 – July 15, 2008), CCFC refers the reader to its earlier comments relating to (1) Definitions Par (14); (2) Industrial use/application Par (15); (3) "Occupied space" definition (25); (4) Sec 94803 on the Industrial use exemption; and (5) Sec. 94805 on the flawed nature of the Test Method. **(06-Brickman)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with this comment. CCFC's comment regarding the definition (14) of an indoor air cleaning device is part of their comment that UL Standard 867 does not apply to air cleaners other than electrostatic precipitators that collect dust and other particles. For that comment and also their comment on Section 94805 and the flaws in the test method, we incorporate by reference here the Responses to Comments 21 and 22 submitted during the 15-day public comment period. CCFC's comments on the industrial use exemption (Definition 15 and Section 94803) and its application to consumers were responded to in Response to Comment 29 above, submitted in the first 15-day public comment period, and that Response is incorporated here by reference. CCFC's comment on the definition of "occupied space" was addressed in Response to Comment 56 in the comments submitted during the 45-day public comment period, and also Response to Comment 42 below, submitted during the 15-day public comment period; both of these Responses are incorporated here by reference.

40. Comment: Page 10 – Appendices III and IV to the 15-day Notice are the December 21, 2007 revised version of Section 37 of ANSI/UL Standard 867 and the three Certification Requirement Decisions (CRDs) issued by UL that are associated with Section 37. CCFC refers the reader to its earlier comments on the inherent limitation of UL Standard 867, Section 37 Ozone Test. **(06-Brickman)**

Agency Response: We disagree with this comment and incorporate by reference here our earlier Responses to Comments 21 and 22 in the comments submitted during the first 15-day public comment period regarding the applicability of ANSI/UL Standard 867 to a variety of types of air cleaners. We also incorporate Response to Comment 44 from the 45-day comment period.

41. Comment: Page 1 − Commenter incorporates by reference comments submitted on September 24, 2007 which offered amendments to the regulation requiring detailed labeling and warnings that would allow the use of air cleaning devices in unoccupied residential settings. Those comments were rejected. **(07-Naylor)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment.

The Board considered the alternative of using warning labels to allow "dual use" devices that emit higher amounts of ozone for use by consumers in unoccupied locations, but concluded this alternative would continue the status quo in which there continues to be the likelihood of persons being exposed to unhealthful levels of ozone. This is a particular concern for children or elderly individuals with pre-existing respiratory disease who might enter a location with elevated ozone and not be aware of their exposure. This alternative was discussed in the ISOR at page 13, and is addressed in Responses to Comments 39-42 in the comments submitted during the 45-day public comment period, all of which are incorporated by reference here.

42. Comment: Page 1 – EcoQuest's previous comments also challenged the authority of the ARB under AB 2276 "to effectively ban the use of air cleaning devices which are designed and intended for use in unoccupied spaces." The Legislature would not lightly have deprived consumers of the ability to purchase an air cleaning device for use in attacking smoke odors in their homes. Page 3 – The core flaw in the regulation is the definition of "occupied space" which is not authorized by AB 2276 and, in banning devices while used in unoccupied spaces, is not in harmony with the intent of the statute and in fact conflicts with it. Page 4 - The proposed regulation appears to twist the definition of "occupied space" into something closer to "inhabited space." Page 5 – Definitions in California Penal Code Section 246 for inhabited space clearly show that the state differentiates between places that are occupied and those that are intended to be occupied (inhabited space). There is no reason to think that, in AB 2276, the Legislature meant the term "occupied" to be interpreted differently than in Section 246. **(07-Naylor)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment. We incorporate here by reference our earlier Responses to Comments 25, 39, 40, 42, 56, 60 and 61 submitted during the 45-day public comment period, where these issues were addressed at length. The definition of "occupied space" contained in the regulation is the same definition used in the U.S. Food and Drug Administration's regulation of medical devices (21 CFR 801.415) which is specifically referred to in AB 2276. Thus, the regulation is consistent with federal law, as required by AB 2276. Additionally, the regulation does not in any way "ban the use of air cleaners designed and intended for use in unoccupied spaces." Such devices are allowed to be manufactured, sold or introduced into commerce through industrial supply outlets or businesses for the purposes specified in section 94801(a)(15). The Penal Code cited in the comment is inapplicable here.

43. Comment: Page 6 − The proposed regulation is inconsistent with federal law. AB 2276 requires the regulation to be consistent with federal law. Commenter states that 21 CFR 801.415(c)(3) is in essence a labeling or warning obligation for devices which are capable of exceeding the standard if not properly used, as

when the space is not occupied. The proposed regulation allows for no such exception for ordinary consumers and is therefore inconsistent with federal law. Additionally, the regulation is inconsistent with workplace standards, which recognize a higher exposure limit of 0.10 ppm ozone for an 8-hour period. Those standards apply to the workplace while occupied. **(07-Naylor)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. This commenter's view of 21 CFR 801.415 is a misinterpretation of the federal regulation. As stated in the previous Responses to Comments 56 and 59 – 61 from the 45-day public comment period, incorporated here by reference, the federal labeling requirements do not indicate that improper use should be allowed, but are an additional caution beyond the 0.05 ppm federal emission limit. Section 94806 of the proposed regulation requires that air cleaners that are medical devices be labeled in accordance with federal requirements, and thus this regulation is consistent with federal law. Additionally, as explained in the earlier Responses to Comments 59-61 submitted during the 45-day public comment period, incorporated here by reference, this regulation is not inconsistent with federal workplace rules, because federal rules limit an individual's total personal exposure across their workday, while this regulation limits the amount of ozone that can be emitted from an air cleaner used in an occupied space. Contrary to the commenter's statement, federal workplace standards do not apply to the workplace while occupied, but rather apply to individual workers wherever they go.

44. Comment: Page 1 – Another application of low level ozone technologies is to attack microbes, including *E.coli*, on cooking and other stainless steel surfaces. Commenter attached a published article, Ortega *et al.* (2007), published in December after the Board hearing on the regulation. **(07-Naylor)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. The Ortega *et al.* paper is still unreliable. If the paper was peer-reviewed, reviewers failed to require that deficiencies be addressed in the paper, including: (1) there is no description of the controlled airflow test cabinet in terms of its construction, size, the reactivity of the materials used (e.g. stainless steel?) and its appropriateness as an exposure chamber; (2) there is no description of how the chamber was operated, e.g., was the RCI cell or ozone generator inside the cabinet, how many air changes per hour were used, etc. (chamber conditions can greatly affect ozone levels and test outcomes); (3) what were the bounds or range of ozone concentrations measured, and how was the average concentration of 0.02 ppm maintained (e.g. Grinshpun *et al.,* 2007, found ozone increased inside their chamber); (4) how much ozone was produced by the RCI cell?; and (5) why was the Breeze AT ozone generator only tested with two of the eight microbial

populations rather than the full eight that were tested with the RCI cell? Because the RCI cell was most effective against the two microbial populations used to test the Breeze AT, it invites speculation that the Breeze ozone generator was either tested only against these two more susceptible microbes, or was ineffective in reducing the remaining six and was therefore unreported. Additionally, it appears there is an error in the labels for Figures 1 and 2, which do not indicate "log" for the microbial count units. It also appears that the authors contradict their own findings by citing another reference (Khurana, 2003, a Master's thesis, not a peer reviewed publication) that found "that ozone levels of less than 9 ppm are all that is needed to remediate sick buildings for professional disinfection." The authors leave the reader to reconcile this very high concentration [which is consistent with references such as Foarde *et al.* (1997) cited in the ISOR] with their own experimental result for "highly polished stainless steel", a surface not normally found in typical indoor environments.

The scientific evidence regarding the limited effectiveness of ozone as a biocide is discussed at pages 2 and 8 in the ISOR, and in Response to Comment 34 above, submitted during the 15-day public comment period and which is incorporated here by reference. As discussed in Response to Comment 34, Grinshpun *et al.* (2007), a reference submitted by commenters during the 45-day public comment period, discusses at page 606 that much higher concentrations of ozone are required to inactivate microorganisms. The ineffectiveness of ozone as a biocide was also discussed in earlier Responses to Comments 14, 18, 19, 21, and 26, submitted during the 45-day public comment period, which are incorporated by reference here. The flaws of the Ortega *et al*. paper discussed in comments 18 and others remain. We stand by our conclusion based on other scientific literature that much higher concentrations of ozone are necessary to effectively reduce microorganisms in a typical indoor environment.

45. Comment: Page 7 – The test protocol is flawed. The UL 867 requirement to measure ozone two inches from the air outlet of the product will preclude the development and deployment of innovative air and surface cleaning technologies that still protect consumers from actual exposures above 0.05 ppm. In a home environment, ozone at 0.05 ppm at two inches would be barely detectable. This is important from a legal standpoint because the statute adopts a 0.05 ppm standard defined as "the generation of ozone at a level in excess of 0.05 part per million by volume of air circulating through the device or causing an accumulation of ozone in excess of 0.05 part per million by volume of air when measured under standard conditions at 25 degrees Celsius (77 degrees Fahrenheit) and 760 millimeters of mercury in the atmosphere of enclosed space intended to be occupied by people for extended periods of time" (21 CFR 801.415). The two inch rule, adapted from a protocol that only applies to electrostatic devices, will effectively preclude devices that actually meet the statutory standard. The Board does not have authority to do that. **(07-Naylor)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, or the procedures followed in proposing or adopting them. Without

waiving this objection, we respond as follows. These comments have been previously addressed in Responses to Comments 43-46 and 48-49 from the 45-day public comment period, which are incorporated by reference here. They also have been addressed in Responses to Comments 21-25 from the first 15-day public comment period, which are incorporated by reference here. Responses to comments 21-25 include a discussion of the three references from UL added to the rulemaking record in the second 15-day public comment period. These documents from UL clarify the current scope and use of ANSI/UL Standard 867 for all types of electronic air cleaners, not just electrostatic air cleaners as specified in the original scope for that standard, and verify the suitability of the Standard 867 test protocol for a variety of air cleaner types, including those that intentionally generate ozone. Further, the two-inch measurement point is fully consistent with the federal language regarding measuring the air "circulating through the device or causing an accumulation of ozone in excess of 0.05 ppm" because it measures the air at the point where ozone levels in either the air circulating through the device or accumulating in the room would be greatest, thus affording protection to room occupants anywhere in the room. This is particularly important to protect users of personal air purifiers, which are intended to be worn within inches of the user's mouth and nose.

46. Comment: Page 1 – EcoQuest supports the proposition that consumers should not be exposed to ozone concentrations that exceed the 0.05 ppm standard. **(07-Naylor)**

Agency Response: We agree with this comment and appreciate this support.

D. Summary of Comments Received During the Second 15-day Public Comment Period and Agency Responses

1. Comment: When my son got asthma at age 5, a relative gave us an air purifier. The model we got did not emit ozone however my husband and I couldn't believe or understand why these products give off ozone. The reason people buy these is mainly for respiratory conditions, so please don't allow the models that release this harmful byproduct. **(01-Scott)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, if any, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We appreciate the comment supporting the regulation to limit ozone emissions from indoor air cleaners used in occupied spaces. The regulation requires that air cleaners be tested to prevent ozone emissions from exceeding the U.S. Food and Drug Administration limit of 0.05 ppm for medical devices. As explained in the Staff Report (at pages 6 - 8), some air cleaners such as electrostatic precipitators (ESPs) and ionizers emit a relatively small amount of ozone as a by-product of their operation. Most such devices are safe for use, but a few may produce potentially harmful levels of ozone. However, a number of manufacturers market devices that are designed to intentionally emit ozone; these devices are also

called “ozone generators” and typically produce ozone in large quantities known to be harmful to human health. All of these types of air cleaners (ESPs, ionizers and ozone generators) will be subject to the testing and certification requirements of the proposed regulation.

2. Comment: The commenter provided a copy of two chapters (I – Introduction and III – Toxicity to Humans) from an undated publication titled “Bibliography of Ozone Technology Volume 2 – Physical and Pharmacological Properties” by Clark E. Thorp of the Armour Research Foundation. While undated it appears to have been published in the 1950s as there are several references to the 1940s in the chapters.

In the introduction, Thorp describes the controversy that existed at the time between scientists on one side with the federal Department of Health and the American Medical Association, which advocated setting the toxicity limits for exposure to ozone at extremely low concentrations, and on the other side, another group of investigators that supported the use of ozone for medical purposes and that thought the limits should be set much higher since they believed ozone to be less toxic. Thorp presents an argument that ozone created using cylinder oxygen contains no nitrogen oxides, while ozone created using air does contain nitrogen oxides, which impart a different odor to the ozone. He found that investigators reporting low toxic limits for ozone generally used air in their ozonizers while investigators reporting no, or very high, toxic limits generally were using cylinder oxygen. He concluded that the oxides of nitrogen were the chief cause of the differences in odor. Thorp cautions against charlatans who promote the sale of ozone generators using unsubstantiated medical claims and supported work to determine the true toxicity of ozone and assisted the “public health authorities and the AMA in decreasing the exploitation of ozone equipment for unproven medical purposes” (at page 117).

Chapter III discusses ozone as an irritant gas and cites experiments by Hill and Auberly (1921) that set a toxic limit of 1 ppm. The experiment was repeated 21 years later in 1942 with a special provision to exclude nitrogen oxides. Based on that experiment, Hill concluded that pure ozone was not poisonous as it breaks down in contact with the mucous membranes and oxygen only remains. Thorp states that Hill’s claim that 50 ppm is nontoxic may be overly optimistic for anything other than extremely short periods of exposure. The chapter goes on to present a chart of tentative ozone tolerance for humans (ozone concentration versus exposure time) and delineates concentrations/time regimes when effects may occur. Thorp cautions though that the chart is still only an estimate and should be used with extreme caution. **(02-R. Barnes)**

Agency Response: We object to this comment pursuant to Government Code section 11346.9(a)(3) because it is not specifically directed at the proposed modifications, if any, or the procedures followed in proposing or adopting them. Without waiving this objection, we respond as follows. We disagree with the comment and incorporate here by reference Responses to Comments 3-9, 14-15, 21, 26 and 62 submitted during the 45-day public comment period, all

relating to the potential health impacts of exposure to ozone. The health effects of breathing ozone are also described in the Staff Report at pages 15 – 25. As discussed in the staff report and earlier responses to comments, the evidence of the adverse effects of breathing ozone at much lower levels than those discussed by Thorp is overwhelming in the research that has been conducted in the 50 or so years since the publication of the reference submitted by the commenter. The staff is not aware of any current, scientific, peer-reviewed, published references that support the premise that ozone generated by using cylinder oxygen is any less harmful than ozone generated using room air, which appears to be the basis for the argument that ozone could be less toxic. As the author (Thorp) himself points out, at the time of the publication of this reference submitted by the commenter, there was controversy between investigators over the analysis (measurement of the concentration) of ozone which could lead to erroneous results including in his own publications, and there was controversy between health experts at the time about how toxic ozone was. Much research on the properties and health effects of ozone has been published since the 1950s, and that information supersedes the much older studies cited in Thorp. For these reasons, and in light of the weight of the evidence of the potential harm that can result from breathing ozone at levels much lower than those discussed by Thorp, the chapters of this book are not a reliable basis to argue that ozone is less toxic.