California Environmental Protection Agency

Air Resources Board

STAFF REPORT: INITIAL STATEMENT OF REASONS FOR PROPOSED RULEMAKING

PROPOSED REGULATION TO LIMIT OZONE EMISSIONS FROM INDOOR AIR CLEANING DEVICES

Research Division
Health and Exposure Assessment Branch

August 10, 2007

Arnold Schwarzenegger
Governor

State of California
AIR RESOURCES BOARD

INITIAL STATEMENT OF REASONS FOR PROPOSED RULEMAKIING

Public Hearing to Consider

ADOPTION OF PROPOSED REGULATION TO LIMIT OZONE EMISSIONS FROM INDOOR AIR CLEANING DEVICES

To be considered by the California Air Resources Board
on September 27-28, 2007

at

South Coast Air Quality Management District
21865 Copley Drive
Diamond Bar, California 91765

Air Resources Board
P.O. Box 2815
Sacramento, CA 95812

State of California
AIR RESOURCES BOARD

PROPOSED REGULATION TO LIMIT OZONE EMISSIONS FROM INDOOR AIR CLEANING DEVICES

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ABBREVIATIONS AND ACRONYMS

AAQS	Ambient Air Quality Standard
AB	Assembly Bill
AER	air exchange rate
ANSI	American National Standards Institute
ARB	California Air Resources Board
CAAQS	California Ambient Air Quality Standard
CADR	clean air delivery rate
Cal/OSHA	California Department of Industrial Relations, Occupational Safety and Health
CEQA	California Environmental Quality Act
COPD	chronic obstructive pulmonary disorder
CPSC	U.S. Consumer Product Safety Commission
BP	by-product ozone air cleaning device
CSA	Canadian Standards Association
DHS	California Department of Health Services
EPA	U.S. Environmental Protection Agency
ESP	electrostatic precipitator
FDA	U.S. Food and Drug Administration
FSOR	final statement of reasons
HSC	California Health and Safety Code
IACD	indoor air cleaning device
ISOR	initial statement of reasons
NRTL	Nationally Recognized Testing Laboratory
OG	ozone generator
OSHA	U.S. Occupational Safety and Health Administration
PCO	photocatalytic oxidation
SOP	standard operating procedure
UL	Underwriters Laboratories, Inc.
U.S.	United States
UV	ultraviolet
VOC	volatile organic compound

UNITS

ACH	air changes per hour
ft^2	square feet
m^3	cubic meter
nm	nanometer (one-billionth of a meter)
ppb	parts per billion by volume (such as one grain of sand in a billion grains of sand)
ppm	parts per million by volume (such as one grain of sand in a million grains of sand)
%	percent
µg	microgram (one-millionth of a gram)

EXECUTIVE SUMMARY

Regulation is Required and Necessary

Assembly Bill (AB) 2276 (Pavley, 2006; Health and Safety Code [HSC] Section 41986) directs the Air Resources Board (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. Indoor air cleaning devices that produce ozone intentionally have been shown to produce unhealthful ozone concentrations well above the health-based state and federal ambient air quality standards. Extensive scientific research has shown that exposure to ozone above these standard levels can cause respiratory symptoms (such as cough, wheeze, and difficulty breathing), reduced lung function, increased airway hyperreactivity, and increased airway inflammation. Additionally, exposure to ozone above the California standards has been associated with asthma onset and exacerbation, increased school absences, hospitalizations due to respiratory diseases, and premature death. The only limit for air cleaning devices currently in place is the U.S. Food and Drug Administration's ozone emission concentration limit of 0.05 ppm for medical devices.

Ozone Exposures are Too High

Several different research groups have found that some ozone generating air cleaners produce ozone concentrations several times higher than the California Ambient Air Quality Standard (CAAQS) of 0.070 ppm, 8-hour average, and 0.09 ppm, 1-hour average (Phillips *et al.*, 1999; Mason *et al*., 2000; Tung *et al.*, 2005; Britigan *et al*., 2006; ARB, 2006a). Additionally, ARB staff measured ozone emissions at the face of current ozone generating air cleaners, and observed ozone concentrations above 1 ppm at a distance of two inches from the face and concentrations as high as 0.567 ppm at a distance of 24 inches from the face (ARB, 2006a). These studies indicate that ozone emissions from indoor air cleaning devices can elevate room concentrations of ozone above state health-based standards, and create indoor ozone levels equal to a Stage 1 smog alert or an "unhealthy" rating using the Air Quality Index.

The highest levels of ozone are produced by indoor air cleaning devices that intentionally produce ozone, which are often referred to as "ozone generators". Two other types of air cleaners – ionizers and electrostatic precipitators – may emit ozone as a by-product of their design and function. These usually emit much lower levels of ozone than intentional ozone generators, but some emit ozone at levels of health concern. Mechanical air cleaners that use a physical filter to remove pollutants from the air typically emit very little ozone. Other technologies that may be utilized in an indoor air cleaning device include ultraviolet light and photocatalytic oxidation, both of which can emit ozone, but usually at low levels.

Recent survey results from Piazza *et al*. (2006) found that 14% of California households own one or more air cleaning devices, and 2% own an ozone generator. Of particular concern is that 45% of the households using an ozone generator also had children in the home, and 50% of those households had purchased the air cleaners to help one or more members with allergies or asthma. Additionally, a majority of households indicated that they operate their air cleaner continuously, 24 hours a day throughout the year. Based on these survey results and studies of air concentrations produced by these devices, well over 500,000 Californians are estimated to be routinely exposed to ozone concentrations above the 8-hour CAAQS of 0.070 ppm due to the use of an ozone generator. Piazza *et al*. also found that another 8% of California

households use an air cleaner that may emit ozone as a by-product; thus, the number of persons potentially exposed to unhealthful levels of ozone from their air cleaner is even higher than the 500,000+ persons affected by intentional ozone generators.

Ozone is Not Effective at Cleaning the Air

Manufacturers of ozone generators often claim that "safe" levels of ozone can remove indoor air pollutants such as particles, gases, allergens, viruses, odorous compounds, mold, and bacteria. In fact, ozone reacts with some indoor air chemicals to produce 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). While ozone reduces a few odorous compounds, it simultaneously fatigues the olfactory sense and reduces one's ability to smell odors, essentially masking odors rather than removing them. Ozone is somewhat effective in killing mold and bacteria on building material surfaces, but 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 (Foarde *et al*., 1997), which can continue to trigger asthma and allergy symptoms. Extensive expert testimony in the successful lawsuit by the Federal Trade Commission against Alpine Air and Living Air, two ozone generator manufacturers, confirmed the almost complete lack of effectiveness of ozone for indoor air treatment (FTC, 2002). More recently, Chen *et al.* (2005**)** confirmed that two ozone generators did not effectively remove volatile organic compounds from a test room, except for limonene, which reacts quickly with ozone to produce formaldehyde, a known human carcinogen and respiratory irritant.

Extensive Public Outreach

Throughout the development of this regulation, ARB staff made extensive effort to obtain input from manufacturers of air cleaners, other interested stakeholders, and the general public. In order to facilitate involvement with the proposed regulation, an email listserve and Internet webpage were made available in November 2006. Three public workshops were conducted between December 2006 and June 2007 to develop the proposed regulation and obtain public input. Additionally, numerous individual meetings and teleconferences were held with testing laboratory representatives, manufacturers and other industry representatives, the American Lung Association, and scientific research experts to obtain information needed to develop the test method, certification procedures, labeling requirements, economic impacts, and regulation effective dates.

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 personal contacts with, and materials 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; over a dozen business associations; senior citizen organizations; and health-related non-profit organizations.

Types of Air Cleaners Covered by This Regulation

This regulation addresses portable air cleaning devices designed for room, whole house, whole floor, and in-vehicle use, and those designed to be carried on one's person. Devices not covered in this regulation include in-duct devices that are an integrated component of a heating, air conditioning and ventilation system, and industrial use air cleaners. Industrial use devices are exempted as long as specified labeling and point-of-purchase requirements are met.

Testing, Labeling and Certification are Required

The proposed regulation would limit the ozone emission concentration from indoor air cleaning devices for sale in California to 0.050 ppm, consistent with the federal limit for medical devices; require compliance with electrical safety standards and specified labeling requirements; and require certification by ARB. The American National Standards Institute (ANSI) / Underwriters Laboratories, Inc. (UL) Standards 867 and 507 are the test methods that would be used to determine compliance with the requirements of this regulation. Ozone emissions from indoor air cleaners would be determined following the test conditions outlined in the 2007 revision of Section 37 of the ANSI/UL Standard 867. This revision is currently undergoing review through the ANSI standard revision process, but is expected to be finalized and approved in September 2007. Indoor air cleaning devices using only mechanical filtration for pollutant removal would be exempt from the testing requirement for ozone emissions, based on their known *de minimis* ozone emissions, but would still be required to obtain ARB certification by submitting verification of electrical safety certification based on Standard 507 and by following the labeling requirements. Any mechanical air cleaners certified to Standard 507 prior to the enactment of the proposed regulation would be eligible for certification without additional testing.

Any indoor air cleaning device for use in an occupied space, not qualifying for exemption, also would be required to display the proper label on product packaging prior to sale in California. Medical devices would be labeled to comply with federal law, and state “ARB certified”. Non-medical devices certified by ARB would be required to display a label with text that reads “This air cleaner complies with the federal ozone emissions limit. ARB certified.” on the product packaging. Air cleaners that qualify for exemption from this regulation would likewise be required to display a specified exemption label on their packaging. Any non-certified air cleaner for non-industrial use in occupied spaces would be required to display an advisory warning stating “Device does not meet California requirements; cannot be shipped to California.” in a prominent place on all Internet webpages, catalog pages and related materials for marketing and sale of the device. All air cleaners sold in California for use in occupied spaces would be required to display the appropriate electrical safety certification or listing mark on the product.

The proposed regulation would apply to any person, manufacturer, distributor, or retailer that manufactures or offers for sale indoor air cleaning devices, for use in occupied spaces, within the state of California. Manufacturers would be responsible for the initial certification of their devices for ozone emissions and electrical safety, and full compliance by the effective manufacture date. The effective manufacture date is proposed for 12 months following the effective date of the regulation, anticipated to be the date of approval by the California Office of Administrative Law. An effective sale date is proposed for 21 months after the effective date of the regulation; then only certified devices could be sold in California. This provision essentially allows distributors and retailers a nine month sell-through period.

Regulation Costs Not Significant for Businesses and Consumers

Potential economic impacts of the regulation would primarily be cost increases to most manufacturers to certify air cleaners, i.e., to meet testing and labeling requirements. An estimated 61 manufacturers and their distributors may be affected. For most manufacturers of ozone generators and a few manufacturers of by-product devices, this certification also would require redesign of some products to meet ozone emission limits. The potential economic impact for most manufacturers is estimated to be insignificant. However, some smaller manufacturers of these devices may be impacted over the short-term. The potential economic impacts on distributors, retailers, and consumers are estimated to be minimal, except for

distributors whose suppliers choose not to provide a compliant product. The potential fiscal impact on ARB is about $175,000 per fiscal year after approval of the regulation. No fiscal impact is anticipated for other state agencies and local agencies. The potential impact in California on jobs, business competitiveness, and business creation, elimination, or expansion is expected to be insignificant. The expected impact on consumers is estimated to be minimal, depending on how much of the certification cost and profit margin are passed on to consumers; the increased cost of purchasing an air cleaner is estimated to be no more than $11-16 per unit, for devices that currently cost from about $100-700 each.

Regulation Will Reduce Exposure to Ozone

The proposed regulation would provide significant public health benefits by greatly reducing the exposure of Californians to indoor ozone, especially in households that use indoor air cleaning devices. The proposed regulation would prevent the routine exposure of well over 500,000 Californians to ozone concentrations above the 8-hour CAAQS of 0.070 ppm due to the use of an indoor air cleaning device that emits ozone. Most importantly, many of these Californians are exposed to ozone levels several times greater than the health-based standard; thus their exposure reduction would be substantial. Reduction in ozone exposure would greatly reduce the risk of respiratory symptoms, reduced lung function, and increased airway inflammation and hyperreactivity. The regulation may also reduce asthma exacerbation, school absences, hospitalizations for respiratory disease, and other health impacts associated with ozone exposure above health-based standards. In addition, the reduced levels of indoor ozone would reduce the potential for oxidative damage to indoor materials and furnishings. The reduction of indoor ozone would also reduce exposure to chemical reaction products from ozone with other indoor pollutants, such as formaldehyde, a known human carcinogen.

Regulation is Recommended to Reduce Risk from High Ozone Air Cleaners

During the development of the proposed regulation, several alternatives were considered. These included no action, allowing devices with “occupied” and “unoccupied” settings (“dual use” devices) or use of devices labeled for unoccupied use, and selection of an alternate test method. Taking no action is not an acceptable option because AB 2276 requires ARB to regulate ozone emissions from indoor air cleaning devices, and the health risk posed by some air cleaners is clearly unacceptable. Allowing “dual-use” devices or high-emitting devices labeled for unoccupied space use only is not acceptable as these devices have the potential for very high ozone exposure if not used exactly as instructed, and this approach (written warnings) is essentially the status quo. While other test methods were considered, ARB staff propose to follow the test methods of ANSI/UL 867 and 507, because this avoids the substantial additional time and resource requirements involved with developing a new test method and utilizes the industry standard that is currently used by most manufacturers. Because testing to the ANSI/UL Standard 867 is already performed by existing third party laboratories, there is no added cost to the state of California to develop the test method or test facility to implement this regulation. The 2007 revision of ANSI/UL Standard 867 is health protective and is consistent with the federal ozone emissions limit of 0.05 ppm, as mandated by AB 2276.

After evaluating public input and considering several regulatory alternatives, ARB staff believe that the proposed regulation is necessary and beneficial for the protection of public health. The proposed regulation is both technologically and commercially feasible. Approval of the proposed regulation would greatly reduce the exposure of more than half a million Californians to acceptable levels, especially children and sensitive groups such as those with asthma and other respiratory diseases who commonly purchase air cleaning devices.

STAFF REPORT

I. Introduction

A. Overview

This Staff Report presents the technical justification and analysis for the proposed regulation of ozone emissions from indoor air cleaning devices (IACD). The report is part of the Initial Statement of Reasons (ISOR) for the Proposed Regulation Order to adopt Title 17 Sections 94800 to 94810 to the California Code of Regulations. The proposed regulation order is intended to satisfy the requirements of Assembly Bill (AB) 2276 (Pavley, 2006; see Appendix A for complete bill). The proposed regulation order is provided in Appendix B of this document.

The following information is included in this technical support document:

- A discussion of the process used to develop the proposed regulation, and the associated public outreach efforts.
- A discussion of the technical basis for the proposed regulation.
- A review of the need for indoor ozone emission reductions.
- A description of the proposed regulation.
- An analysis of the potential economic and environmental impacts from the proposed regulation.

B. Regulatory Authority

In 2006, AB 2276 was approved by the California Legislature and signed by Governor Schwarzenegger to address the serious threat to public health posed by the emission of ozone, either intentionally or as a by-product, by IACD. AB 2276 added Article 8, Sections 41985 and 41986 to Chapter 3 of Part 4 of Division 26 of the California Health and Safety Code (HSC). Section 41986 instructs the Air Resources Board (ARB or Board) to develop and adopt regulations, consistent with federal law, to protect public health from ozone emitted by IACD, including both medical and non-medical devices, used in occupied spaces. Section 41986 further stipulates that the regulations must include the following elements:

- An emission concentration standard for ozone emissions that is equivalent to the federal ozone emission concentration limit for IACD.
- Test procedures for manufacturers to utilize to determine ozone emissions from IACD.
- Certification procedures that enable the Board to verify that an IACD meets the emission concentration standard for ozone emissions using the testing procedures adopted by the Board.

- Package labeling requirements that indicate that an IACD is certified as meeting the emission concentration standard for ozone emissions.

AB 2276 also allows a ban on the sale of IACD that exceed the allowable emission concentration standard; procedures for allowing independent laboratories or others to verify products as meeting the standard; an exemption for IACD that emit only *de minimis* levels of ozone due to their design; and any other element the Board deems necessary to protect the public health from emissions of ozone from IACD.

C. Background

1. Ozone Properties and Standards

Ozone is a highly reactive molecule composed of three oxygen atoms. Ozone is a primary component of photochemical smog, and has been recognized and regulated as a serious outdoor pollutant for many years. Human exposure to ozone can damage the respiratory system. Ozone inflames and irritates respiratory tissues, and can worsen asthmatic symptoms in individuals with asthma. Ozone exposure can produce symptoms such as coughing, chest tightness, and impaired breathing. Elevated exposures have the potential to induce permanent lung damage, and chronic exposure can even increase the risk of premature death (ARB 2005b). Ozone can also damage plants, fabrics, rubber products, and building materials, such as paint and flooring (ARB 2005b).

To prevent these health and environmental impacts, ozone in the ambient (outdoor) air is currently regulated at both the federal and California state level. State and federal ambient air quality standards (AAQS) have been established for ozone, as shown in Table I-1 below. The U.S. Environmental Protection Agency (U.S. EPA) is currently considering revisions to the federal standard.

Table I-1. State and Federal Ambient Air Quality Standards for Ozone

Averaging Time	California Standard [a]	Federal Standard [a]
1 hour	0.09 ppm [b] (180 µg/m^3) [c]	NA
8 hour	0.070 ppm (137 µg/m^3)	0.08 ppm (157 µg/m^3)

Notes:
a. Ozone concentration determined using ultraviolet photometry
b. ppm: parts per million
c. µg/m^3: micrograms per cubic meter

2. Types of Air Cleaning Devices

The indoor air cleaning devices on the market use a variety of technologies to remove unwanted contaminants from users' indoor environments. Some of these technologies emit ozone during their operation. A number of manufacturers market appliances labeled as "air purifiers" or "air cleaners" that intentionally generate ozone; these are often referred to as "ozone generators" (OGs). Current OGs most often use metal plate electrodes or needle

electrodes to create electrical discharges that produce ozone, typically in large quantities. Two other types of IACD that may emit ozone as a by-product of their operation, hereafter referred to as by-product (BP) devices, include ionizers and electrostatic precipitators. These devices emit ozone as a by-product of their design, and typically emit much lower levels of ozone than do OGs. Ionizers release electrons into the air, forming ions with molecules in the air which then attract particles to form larger particles that have a greater tendency for deposition. Electrostatic precipitators (ESPs) utilize an electric corona to charge airborne particles and collect them with charged metal plates of opposite polarity. In addition to the technologies mentioned, IACD may also incorporate an ultraviolet (UV) illumination into their operation. The UV irradiation purportedly reduces the microbial activity of the 'treated or cleaned' air, essentially acting as a biocide. A new emerging technology for IACD is photocatalytic oxidation (PCO). Photocatalytic oxidation attempts to remove pollutants using UV irradiation in conjunction with a catalytic surface to produce hydroxyl radicals and superoxide ions which react with organic pollutants. Finally, another group of air cleaners, those that use only pleated fibrous filters or a similar physical barrier type technology, emit little or no ozone, and are not a concern; these are hereafter referred to as mechanical-filtration devices.

The market for portable air cleaning devices advertised for residential use has expanded substantially as public concern over indoor air pollutants has increased. Recent figures indicate that annual national sales of these products have surpassed $400 million (Consumers Union, 2005a). Additionally, national market data indicate the sale of IACD grew by 34% over the five years from 1998 to 2003, and the trend was expected to continue through at least 2008 (The Freedonia Group, 2004). Survey results from Piazza *et al.* (2006) found that two out of every three IACD in California homes were purchased since 2003. Thus, the market for IACD within California is showing rapid growth consistent with this expectation.

3. Ozone Concentrations Produced by Air Cleaners

The operation of IACD that produce ozone in the confined spaces of homes and commercial buildings may cause unhealthful ozone exposures, that is, elevated room ozone concentrations above the health-based state and federal AAQS for ozone. To ensure adequate protection of public health, the ozone emissions from IACD need to be limited, especially considering the observed and expected growth of this industry.

Sources of ozone emissions data for currently available models of IACD include U.S. EPA test reports, a small number of scientific journal articles, manufacturers' product test data (generally not available), and tests of four models by ARB staff. A test home study by researchers at the U.S. EPA found that an OG could produce indoor ozone levels up to three times the California Ambient Air Quality Standards (CAAQS) of 0.09 ppm averaged over one hour and 0.070 ppm averaged over eight hours (Mason *et al*., 2000). In another study, a number of IACD, including ESPs, ionizers and OGs, were evaluated in representative indoor room environments and found to produce steady-state indoor ozone concentrations as high as 0.650 ppm, which is over seven times the 1-hour CAAQS and over nine times the 8-hour CAAQS (Britigan *et al*., 2006). Measurements within a stainless steel test chamber showed ozone concentrations as high as 1.8 ppm, twenty times the 1-hour CAAQS, from one IACD which has both ESP and ionizer functions (Tung *et al.*, 2005). Ozone emissions as high as 0.389 ppm have been measured from a "personal air purifier" worn by the user near their face (Phillips *et al.*, 1999). Additional measurements of ozone emissions from current model OGs performed by ARB staff, described in Section IV.D. of this report, found face emissions and room concentrations of ozone well above 1-hour and 8-hour CAAQS (ARB, 2006a). Thus, previous

research indicates that ozone emissions from IACD may elevate room concentrations of ozone above acceptable health values, and thus pose a substantial health risk.

4. Ineffectiveness of Ozone in Cleaning Air

Manufacturers of OGs often claim that "safe" levels of ozone can remove indoor air pollutants such as particles, gases, allergens, viruses, odorous compounds, mold, and bacteria. In fact, ozone reacts only with some gases of concern (aromatic hydrocarbons such as benzene) and with terpenes, such as limonene and pinene, and this 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). While ozone reduces a few odorous compounds, it simultaneously fatigues the olfactory sense and reduces one's ability to smell odors; essentially masking odors rather than removing them. Ozone is somewhat effective in killing mold and bacteria on building material surfaces, but 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 (Foarde *et al*., 1997). This leaves them available to trigger asthma and allergy symptoms.

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). More recently, Chen *et al.* (2005) confirmed that two OGs did not effectively remove volatile organic compounds from a test room, except for limonene, which reacts quickly with ozone to produce formaldehyde, a known human carcinogen and respiratory irritant.

5. Government Authority

Prior to AB 2276, no California state agency had clear regulatory authority to address the problem of ozone emissions from IACD, and relevant federal programs had not been effective. An ozone emission concentration standard for IACD has been in existence since the late 1970s, under the U.S. Food and Drug Administration (FDA), for air cleaners that are considered medical devices, i.e., marketed with health claims (FDA, 2005a). The FDA standard for medical devices is a maximum of 0.05 ppm ozone in the air circulating through the device or in an enclosed space that is designed for human occupancy, but the specific test protocols are not well defined. Non-compliant devices cannot be used in houses, hospitals, medical offices, or other occupied spaces. The FDA requires listing and labeling of these devices, including the smallest room area allowed when using the device (FDA, 2005a,b). However, the FDA has conducted very little enforcement of their regulation to date. The U.S. Consumer Product Safety Commission (CPSC) has the authority to regulate air cleaners that are marketed without health claims, i.e., non-medical devices; however, it has not developed any regulations for IACD to date, although it is considering possible action (CPSC, 2006).

6. Industry Standards

The Underwriters Laboratories Inc. (UL), an independent, not-for-profit product safety certification organization, has developed an American National Standards Institute (ANSI) approved standard, ANSI/UL Standard 867, for testing electrostatic air cleaners. This standard evaluates the electrical safety and ozone emissions of this class of IACD. Certification to this

standard is voluntary; however, many retail establishments require electrical products to meet the relevant electrical safety standard before they will carry them in their stores. Section 37 of Standard 867 provides a test for ozone that limits room ozone concentrations to 0.050 ppm at two inches from the face of the device after 24 hours of continuous operation. However, until recently, the test method provisions were somewhat general, allowing for variability in how the test was conducted in various laboratories, which consequently allowed some high-emitting air cleaners that produce unhealthy ozone levels to pass the test (Niu *et al*., 2001a,b; Chen *et al.*, 2005; Mullen *et al.*, 2005). Consequently, UL convened an *ad hoc* committee to clarify and refine the details of the standard test protocol. This resulted in the publication by UL of their March 20, 2007 "Clarification for Ozone Testing of Electrostatic Air Cleaners and Ionizers," which is now undergoing review within the ANSI standards approval process. A final, revised test protocol is expected to be approved in September, 2007.

7. Previous Actions to Address Ozone Generating Air Cleaners

Efforts have been taken to reduce the potential exposure of the public to ozone from IACD. During the 1990s, ARB staff contacted two manufacturers of OGs, asking that they discontinue their production, marketing, and sale of IACD within California due to concern about excessive human exposure and unsubstantiated health claims. The OG manufacturers did not comply with this request. Several agencies and organizations have issued warnings about ozone generators. In 1997, the California Department of Health Services (DHS) issued a press release warning citizens of the potential harm from ozone generators (DHS, 1997). ARB issued similar press releases in 2005 and 2006 (ARB 2005a, 2006b). In 2000, ARB published a fact sheet on how to select a safe and effective indoor air cleaner, and in 2005, ARB published a fact sheet describing the dangers of OG use and established a website to inform consumers about specific models of known OGs, to help minimize their sale to Californians (ARB, 2006c). *Consumer Reports* has published several articles detailing IACD testing for efficacy and ozone emissions, in which they informed the public about IACD which exceeded the ANSI/UL Standard 867 requirements for ozone emission (Consumers Union 2005a,b). In 1998 the Canadian Standards Association (CSA) announced they would no longer certify for household use air cleaning devices that intentionally generate ozone, and invoked additional requirements for IACD for commercial use (CSA TIL H-13). Based on a risk evaluation conducted in 1999 and the action taken by CSA in 1998, Health Canada released a warning in 2000 which instructed consumers to avoid OG use in occupied spaces (Health Canada, 2000).

To date, only limited legal actions have been taken to address the ozone emissions from IACD. In 1995, the Federal Trade Commission (FTC) entered a consent order with Alpine Air (Alpine Industries), Living Air, and Quantum Air to prevent them from making unsubstantiated claims in marketing their ozone generator products, including claims regarding their effectiveness in indoor pollutant removal and the prevention of, or relief from, allergies, asthma, and other specified conditions (FTC, 1995). Subsequently, the FTC successfully sued Alpine Air for violating the consent order (FTC, 2002). The court fined the defendants $1,490,000 plus interest and costs. It also barred the defendants from: making health claims without scientific substantiation; making claims that their "air purifier" would remove any indoor air pollutant, except for visible tobacco smoke and some odors; making claims that their products prevent, or provide relief from, medical conditions of any kind; or claiming that sensors in the machines control the ozone levels in indoor spaces. Additionally, the Minnesota Attorney General successfully sued Alpine Air for consumer fraud in misrepresenting the effects of ozone and their air purifiers, and for price fixing through independent distributors (State of Minnesota, 1992a,b; 1993). However, neither the federal or Minnesota court decisions were successfully enforced, nor did they significantly affect the design or sales of ozone generators. These

collective actions have had little impact on the sales of ozone-generating air cleaners in California, which has seen increased sales in recent years.

8. Californians' Use of Air Cleaners

Recent survey results from 2,019 California households showed that a total of 14% of California households currently own an air cleaner or have owned one within the past five years (Piazza *et al*., 2006). Intentional OGs were reported in 2% of California households, potentially exposing 282,000 households, or 828,000 persons, to unhealthful levels of ozone. About 8% of California households use an air cleaner that may emit ozone as a by-product; thus, the number of persons potentially exposed is much higher. Of particular concern is that 45% of the households containing an OG also had children in the home. Children are a particularly vulnerable group because of the proportionally higher dose of ozone that they inhale due to their breathing rates and activity patterns, their developing lungs, and other factors. Additionally, the survey showed that 50% of the households that own air cleaners purchased them to help relieve allergies or asthma in one or more household members, and about 30% of households that own air cleaners own two or more units. The survey data also showed that most air cleaner owners operate their IACD year-round, 24 hours a day; thus there is the potential for significant indoor ozone exposure within the California population, including children.

II. Development of Proposed Regulation

A. 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 list serve 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 purposeful OGs, and known associations and manufacturers of non-OG air cleaners. There are approximately 2,000 individuals or companies registered for the list serve. 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 to develop the proposed regulation order. 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 follows the March 2007 Certification Bulletin for Section 37 of ANSI/UL Standard 867. 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 this report, ARB staff considered the comments received at the public workshops; many of 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.

This report and associated materials have been released for public review 45 days prior to the planned Board public hearing date of September 27, 2007, as required for proposed regulations. Staff will fully consider all comments received during that period, and respond to those comments as part of the regulatory process. An oral report summarizing the staff recommendations for regulating ozone emissions from air cleaners will be presented to the Board at the September 27 hearing.

Once a regulation is adopted by the Board, 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 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.

B. Comment Period and Board Hearing

Release of this Staff Report opens the official 45-day public comment period required by the Administrative Procedure Act prior to the public meeting of the Air Resources Board to consider the staff's recommendations. The public may present comments relating to this matter orally or in writing at the hearing, and in writing or by e-mail before the hearing. To be considered by the Board, written submissions not physically submitted at the meeting must be received no later than 12:00 noon, September 26, 2007 and addressed to one of the following:

Postal mail: Clerk of the Board
Air Resources Board
1001 I Street, 23rd floor
Sacramento, California 95814

Electronic submittal: http://www.arb.ca.gov/lispub/comm/bclist.php

Facsimile submittal: to the Clerk of the Board at (916) 322-3928

Information on the three public workshops, as well as summaries of the presentations from past workshops and meetings are available by calling 1-916-445-0753 or at the following ARB website: http://www.arb.ca.gov/research/indoor/aircleaners/aircleaners.htm. Inquiries concerning the substance of the proposed regulation may be directed to the designated agency contact persons, Ms. Peggy Jenkins, Manager of the Indoor Exposure Assessment Section, at (916) 323-1504 or by email at mjenkins@arb.ca.gov, or Mr. Chris Jakober, Air Pollution Specialist, at (916) 327-8693 or by email at cjakober@arb.ca.gov.

The agency representative and designated back-up contact persons to whom nonsubstantive inquiries concerning the proposed administrative action may be directed, are Ms. Amy Whiting, Regulations Coordinator, Board Administration & Regulatory Coordination Unit, (916) 322-6533 or Ms. Alexa Malik, Regulations Coordinator, (916) 322-4011. Requests for copies of the proposed regulation also should be directed to these contacts. The Board has compiled a record for this rulemaking action, which includes all the information upon which the proposal is based. This material is available for inspection upon request to the contact persons.

C. Evaluation of Alternatives

1. Different Test Method

As specified in HSC Section 41986, ARB is required to include testing procedures for determining the ozone emissions from IACD in the regulation. Section 41986 specifically requires ARB to consider the available ANSI/UL standard, as well as other existing and proposed test methods. Accordingly, ARB staff evaluated several different test methods prior to selection of Section 37 of ANSI/UL Standard 867. Additionally, ARB also considered developing a new test protocol beyond what is currently being used. Existing test methods that were considered included Blue Angel test methods RAL-UZ 62, 114 and 85 and ECMA Standard 328. The RAL test protocols are designed for office equipment, not for IACD, and were thus eliminated. ARB staff felt that the ECMA Standard 328 method was unacceptable due to the high air exchange rate (AER) of 1 ACH and a test chamber ozone half-life that was only required to be longer than 10 minutes.

After evaluation of existing test methods and possible development of a new emission rate method, ARB staff opted to follow the existing test methods of ANSI/UL. Using the existing ANSI/UL Standard 867 avoids substantial additional time requirements involved with developing a new test method and utilizes the industry standard that is currently familiar to manufacturers. To aid in refinement of Section 37 (the ozone emissions test section) of ANSI/UL Standard 867, UL formed an *ad hoc* committee to refine the method for improvements in repeatability and clarification, leading to a reduction in inter-laboratory variability. Since testing to the ANSI/UL Standard 867 is already performed by existing third party laboratories, there is no added cost to the state of California to develop the test method or test facility to implement this regulation. The

revised Section 37 of ANSI/UL Standard 867 is health protective and is consistent with the federal ozone emissions limit of 0.05 ppm, as mandated by AB 2276. Furthermore, selection of a test method that is currently utilized within the IACD manufacturing industry minimizes the impact that this regulation will have on manufacturers. Thus the revised ANSI/UL Standard 867 was chosen to be incorporated into this regulation.

2. Allow Dual-purpose Devices or Devices Labeled for Unoccupied Use

While developing this regulation ARB staff considered requests from OG manufacturers to allow IACD that utilize dual operation modes for occupied and unoccupied spaces, and those that emit high levels of ozone but are labeled for use only in unoccupied spaces. IACD having an "away mode" operating setting in addition to other settings (dual purpose devices) and those labeled for use in unoccupied settings typically produce ozone levels much greater than 0.050 ppm, usually several times higher than the CAAQS. ARB staff are concerned that even with more prominent warnings about the danger of using such devices, not all consumers will follow the manufacturers' instructions. For example, owners of dual purpose devices may use the device at the unoccupied setting while the space is occupied. Additional risk of exposure exists if one person were to set the device to operate in the "away mode" without informing a second person who may unknowingly enter the space while the device is producing high concentrations of ozone. The dual-purpose devices and devices labeled for unoccupied use have the potential for very high ozone exposure if not used exactly as instructed and this approach (written warnings) is essentially the status quo. Thus, ARB staff propose not to certify dual-purpose IACD under the proposed regulation, and to allow devices labeled for use in unoccupied spaces only for industrial purposes as defined in section 94801(a)(14).

3. No Action

A third alternative is to take no action. However, this is not an acceptable option because AB 2276 requires the ARB to regulate the ozone emissions from IACD, and regulation is necessary to protect the public's health from the elevated ozone exposures caused by some air cleaning devices.

D. Potential Regulation Benefits

The proposed regulation would provide significant public health benefits by greatly reducing the exposure of Californians to indoor ozone. The proposed regulation is estimated to prevent the routine exposure of well over 500,000 Californians to ozone concentrations above the 8-hour CAAQS of 0.070 ppm due to the use of an indoor air cleaning device that emits ozone. Most importantly, many of these Californians are exposed to ozone levels several times greater than the health-based standard.

This reduction in ozone exposure would greatly reduce the risk of adverse health impacts in a substantial fraction of the persons exposed, including reduced pulmonary function and increased lung inflammation and airway hyperresponsiveness to allergens. Young children and people with asthma would especially benefit from the avoided exposure. Exposure to ozone above the CAAQS has also been associated with increased risk of premature death, hospitalization for respiratory disease, emergency room visits for asthma for children, asthma onset and exacerbation, school absences, and minor restricted activity days for adults (ARB, 2005b). This proposed regulation may also reduce such health impacts in people living and working in buildings where ozone generating air cleaning devices are used. In addition, the

reduced levels of indoor ozone would reduce the potential for oxidative damage to indoor materials and furnishings (ARB 2005b).

This reduction of indoor ozone exposures would also reduce exposure to chemical reaction by-products from ozone. Indoor chemical reactions of ozone with certain substances from cleaning products and building materials are known to produce pollutants of health concern. Specifically, using products that contained terpenes such as pinene and limonene – the fragrance components of pine and citrus oils – in rooms where ozone is present results in the production of formaldehyde and ultrafine particles, which can potentially harm human health (Nazaroff and Weschler, 2004; Destaillats *et al*., 2006; Singer *et al*., 2006).

III. Technical Basis for Proposed Regulation

A. Technological Feasibility

The proposed emission concentration limit is considered technologically feasible if it meets one of the following criteria: (1) the limit is already being met by several IACD, or (2) the limit can reasonably be expected to be met in the time frame provided through additional development efforts.

Given the language stipulating consistency between the proposed regulation and the federal ozone emission concentration limit, ARB staff are bound to the federal emission level. This concentration limit is already being met by all mechanical filtration devices and most by-product IACD as described previously (Consumers Union 2005a,b; Chen *et al.* 2005). For the by-product devices that would exceed the emission limit, only a slight modification to product design is expected to be necessary to lower the ozone emissions to attain compliance with the proposed regulation, and thus is not considered technology forcing. Such modification may include the following: adjustment of electrode geometry and spacing, increase in corona wire surface temperature, and decrease in corona wire diameter (Liu *et al*., 2000). Thus, the proposed regulation is currently technologically feasible.

B. Commercial Feasibility

The term “commercially feasible” is not defined in California State law. ARB staff took the approach that the regulation is commercially feasible as long as the basic market demand for IACD can be met. Staff interpretation of basic market demand is based primarily on the decision set forth by the United States Court of Appeals for the District of Columbia in the case of International Harvester Company vs. Ruckelshaus, (D.C. Cir. 1973) 478 F.2d 615. The court ruled that the U.S. EPA could promulgate technology-forcing motor vehicle emissions limits which might result in fewer available models and a more limited choice of engine types for consumers, as long as the basic market demand for new passenger automobiles could generally be met.

For the purposes of this regulation the basic market demand is defined as the consumer need for a product that removes indoor air pollutants. Basic market demand should not be confused with consumer preference, where a particular brand or attribute is desired. By considering the fulfillment of the basic market demand for IACD, and not necessarily the consumer preference, it is likely that certain models of IACD will no longer be available for sale in California. The models that are most likely to be eliminated from the California market are the

intentional OGs. Ozone generators are found in just 2% of California households, which represent less than 15% of the IACD market in California, (see Piazza *et al*., 2006), but they constitute the majority of air cleaning devices that produce excessive indoor ozone exposures. A considerable majority of the current models of IACD marketed in California will remain available to consumers, although most OGs would have to be redesigned to attain compliance with the specified ozone emission standard. The proposed regulation allows the basic market demand for IACD to be satisfied, even though it would no longer be possible to manufacture and sell in California IACD that emit high levels of ozone.

IV. Need for Emissions Reductions

A. Health Effects of Ozone

The health effects resulting from exposure to ozone have been examined in detail and are summarized in an ARB staff report entitled *Review of the California Ambient Air Quality Standard for Ozone* (ARB, 2005b). The following provides an overview of the staff report findings.

Scientific studies have shown that exposure to ozone can result in increased respiratory symptoms (such as cough, wheeze, difficulty breathing, and chest tightness) reduced lung function, increased airway hyperreactivity, and increased airway inflammation. Moreover, exposure to ozone is associated with premature death, hospitalization for respiratory causes, increased school absences, and increased minor restricted activity days for adults (ARB, 2005b). As required by HSC 39605, special consideration needs to be made for infants and children in assessing the effects of ozone exposure. By virtue of their higher breathing rates, children are likely to inhale larger total doses of ozone than the general population. Furthermore, two studies have shown evidence of lower lung function in young adults raised in high ozone areas (Galizia & Kinney, 1999; Kunzli *et al.*, 1997). There is also evidence that children who play three or more sports may be at higher risk of developing asthma if they also live in high ozone communities (McConnell *et al.*, 2002).

Ozone in the ambient outdoor environment is currently a regulated pollutant at both the federal and California State level. In 2006, a new state ozone standard of 0.070 ppm (8-hour average) became effective, and the 1-hour standard of 0.090 ppm was retained. Because current outdoor ambient levels of ozone are sometimes above the State standards, significant health benefits would result by attaining the standards throughout California. Specifically the number of adverse health effects avoided each year is estimated to be:

- 630 premature deaths (310 - 950, probable range)
- 4200 hospitalizations due to respiratory diseases (2400 - 5800, 95% confidence interval [CI])
- 4.7 million illness-related school absences for children 5 to 17 years of age (1,200,000 - 8,600,000, 95% CI)
- 3.1 million minor restricted activity days for adults over 18 years of age (1,300,000 – 5,000,000, 95% CI)

Some other health effects that would be avoided to some extent include exacerbation of asthma, asthma attacks, and the onset of asthma; however, the reduction in these effects cannot yet be quantified.

B. Controlled Exposure Studies

While no epidemiology study to date has focused on the health effects of indoor ozone exposures, there is a body of controlled exposures studies that can be used to estimate the proportion of the general population that might experience adverse health outcomes from indoor exposures. These studies are based on known ozone concentrations, breathing rates, and exposure durations. Because of this, and because estimates of indoor activity levels and exposure durations are available, we can use these studies to make rough estimates of the proportion of people exposed to ozone from operation of ozone-emitting air cleaners who might experience adverse health outcomes for several endpoints.

1. Lung Function

A number of studies have investigated lung function responses to ozone. The most frequently reported measure of lung function is functional expiratory volume in one second (FEV1: the volume of air one can exhale in one second). This test is the most reproducible of the various measures of lung function, and consequently is the most frequently reported. The ARB staff report on the ozone standard concluded that a reduction in FEV1 of greater than 10% was an unacceptable level of response, and should be protected against (ARB, 2005b), and this convention is applied to the present analysis.

Results of studies of two-hour duration during which the subjects alternated periods of light to moderate exercise (comparable to walking at three miles per hour or less) are shown in Table IV-1 (Gliner *et al.*, 1983; McDonnell *et al.*, 1983; Kulle *et al.*, 1985; Horvath *et al.*, 1981, 1986; Drechsler-Parks *et al.*, 1987, 1990; Bedi *et al.*, 1988; Hazucha *et al.*, 1996).

Table IV-1. Percentage of Subjects Having Decreases in FEV1 Greater Than 10% and 20% with 2-Hour Ozone Exposures (Healthy Subjects)

Ozone (ppm)	% >10%	% >20%
0.18-0.20	20	5
0.24	35	22
0.30	60	35
0.40-0.45	55	30
0.50	77	48

These results suggest that significant numbers of people are likely to experience a decrease in lung function with two-hour or greater exposure to indoor ozone concentrations as low as 0.18 ppm. This concentration is well below the concentrations measured in ARB's chamber study of ozone generators (ARB, 2006a) and the Mason *et al.* (2000) chamber and test home study, which each ranged up to 0.300 ppm or higher.

Results of lung function studies of four hours duration that included alternating periods of light to moderate exercise (comparable to walking at three miles per hour or less) are summarized in Table IV-2 (Balmes *et al.*, 1996; Gong *et al.*, 1997).

Table IV-2. Percentage of Subjects Having Decreases in FEV1 Greater Than 10% and 20% with 4-Hour Ozone Exposures

Ozone (ppm)	Subjects	% >10%	% >20%
0.22	healthy	41	23
0.24	COPD	78	55
0.24	healthy	0	0

The results at 0.24 ppm reported in Table IV-2 are based on one small study (N=9 chronic obstructive pulmonary disorder (COPD) patients; N=10 healthy), which may not be representative of the broader population. However, the findings at 0.22 ppm, based on a larger group of subjects (N=56), suggest that a significant proportion of the population is likely to experience FEV1 decreases of concern with a 4-hour exposure at this level.

Table IV-3 summarizes the reduction in FEV1 for ozone exposures of 6.6 to 8 hours duration. These studies included moderate exercise of 50 minutes per hour, with a 30 minute break at the mid-point of the exposure (Folinsbee *et al.*, 1988; Horvath *et al.*, 1991; Peden *et al.*, 1997; Kehrl *et al.*, 1999; Jenkins *et al.*, 1999). While relevant in terms of exposure duration, it is likely that few people exercise to this extent indoors, likely overstating risks to a more sedentary population.

Table IV-3. Percentage of Subjects Having Decreases in FEV1 with 6.6 to 8-Hour Exposures

Ozone (ppm)	Subjects	% >10%	% >30%
0.08	healthy	26	12
0.10	healthy	31	4
0.12	healthy	46	13
0.16	asthmatics	41	18

The results provided in Table IV-3 suggest that a significant fraction of the population is likely to experience large decreases in lung function if they undergo 6.6- to 8-hour exposures to ozone concentrations as low as 0.08 ppm.

2. Pulmonary Inflammation

Pulmonary (lung + airway) inflammation is another common effect of ozone exposure. Ozone is a strong oxidant that can damage the tissues lining the airways, causing tissue injury and inflammation. Inflammation is the initial sign of tissue damage. Repeated ozone-induced injury and repair cycles lead to permanent damage to, and remodeling of, lung structure. Table IV-4 presents the percentage of healthy and asthmatic subjects who showed evidence for pulmonary inflammation following exposures to ozone for the concentrations and durations indicated (Seltzer *et al.*, 1986; Koren *et al.*, 1989; Graham & Koren, 1990; Devlin *et al.*, 1996; Peden *et al.*, 1997; Krishna *et al.*, 1997; Nightingale *et al.*, 2000; Newson *et al.*, 2000; Vaggagini *et al.*, 2001). In each case, subjects alternated periods of light to moderate exercise and rest during exposure.

Table IV-4. Percentage of Subjects Having Evidence of Pulmonary Inflammation Following Ozone Exposure

Ozone (ppm)	Exposure Time (hr)	Subjects	%
0.16	7.6	asthmatics	88
0.20	4	healthy	65
0.20	2	asthmatics	78
0.20	2	healthy	62
0.27	2	healthy	85
0.40	2	healthy	100

The results in Table IV-4 suggest that the majority of people exposed for 2 to 7.6 hours to ozone at concentrations greater than 0.16 ppm will develop evidence of pulmonary inflammation.

3. Airway Hyperresponsiveness

Airway hyperresponsiveness refers to the tendency for the muscle cells in the larger airways to contract in response to irritants (i.e., methacholine) or allergens. Research has shown that increased airway hyperresponsiveness is a characteristic of asthma, and that aggravation of hyperresponsiveness is associated with asthma exacerbation. Some non-asthmatic individuals also have hyperreactive airways. In addition, several studies showed that allergic asthmatics tend to have increased responses to allergen challenge following exposure to ozone, compared to that following exposure to filtered air. Table IV-5 shows the percentage of subjects who experienced increased airway hyperreactivity from methacholine or allergen challenge after controlled exposure to ozone (Seltzer *et al.*, 1986; Folinsbee *et al.*, 1988; Hiltermann *et al.*, 1995; Ball *et al.*, 1996; Jorres *et al.*, 1996; Kehrl *et al.*, 1999; Foster *et al.*, 2000).

Table IV-5. Percentage of Subjects Having Increased Airway Hyperreactivity in Response to Methacholine or Allergen Challenge Following Ozone Exposure

Ozone (ppm)	Exposure Time (hr.)	Subjects	%
0.10	7.6	asthmatics	89
0.12	1 (resting)	asthmatics	33
0.18	2 (mean)	healthy	88
0.25	3	asthmatics	100
0.40	2	healthy	100
0.40	2	asthmatic	66

As can be seen from Table IV-5, a large proportion of healthy and asthmatic subjects are likely to experience increased responses to irritants or allergens after ozone exposure.

4. Uncertainties

Controlled human exposure studies are typically from one to eight hours in duration, and are typically designed to simulate some form of outdoor activity. Because of this, most study designs include periods of light to moderate exercise, which may not be fully analogous to the longer, semi-chronic exposures likely in homes that operate ozone generating air cleaners. The controlled human exposure studies used in this analysis employed exercise that was comparable to walking at two to three miles per hour for 15 or 20 minute periods, alternated with rest periods of the same length for two to four hours, or for 50 minutes per hour for 6.6 to 8 hours. People are not typically completely at rest while indoors, except while sleeping; adults commonly engage in various types of housework and indoor exercise programs, and children engage in moderately active play. However, the breathing rates employed in the controlled human exposure studies may overestimate those typical of indoor activities to the extent that indoor activity is more episodic, less intense, or of shorter duration. Lung function and symptoms responses to ozone exposure plateau at levels primarily related to ozone dose rate (concentration x breathing rate). Consequently, the effect prevalences described above for two to eight hour exposures would likely be overestimates for populations who have lower breathing rates during indoor exposures. Exposure duration plays a role in response magnitude, although it is of less importance than either concentration or ventilation rate in driving effects. It should also be noted that the information in Tables IV-1 to IV-5 above is based on sample sizes that vary from as few as 8 subjects, to as many as 93 individuals. It is unknown to what extent the subjects studied are representative of the population as a whole. Because of this, the proportions of affected people shown in Tables IV-1 to IV-5 should be regarded as approximations. Finally, it should also be noted that purchasers of ozone generating air cleaners who find that the units adversely affect their breathing may stop using them. Piazza *et al.* (2006) found 29% of air cleaner owners had stopped using their air cleaner, but for a variety of reasons.

C. Physical and Chemical Properties

Ozone at ambient temperature and pressure is a pale blue, reactive gas comprised of three oxygen atoms, and thus is also referred to as triatomic oxygen. The gas has a pungent odor, with an odor threshold of approximately 0.010 – 0.030 ppm (NLM, 2007). Ozone is both corrosive and a strong oxidant, and can damage vegetation and a variety of materials including fabrics and building materials, such as paint, walls and flooring (ARB 2005b). Occasionally ozone may also be referred to as “super oxygen” and “activated oxygen” by some IACD manufacturers; however these are incorrect, misleading terms.

Ozone is primarily found in the stratosphere of the earth’s atmosphere, commonly referred to as the ‘ozone layer’ (U.S. EPA, 2007). The stratosphere is located between approximately 6-30 miles above the earth’s surface, with the ozone layer found between 10-25 miles above the surface. The ozone layer absorbs selective bands of radiation from the sun preventing it from reaching the earth’s surface. UV radiation in band C (<280 nm) is completely removed by the ozone layer, and most of band B (280-320 nm) is also absorbed. The shielding from UV-B is beneficial as it has been shown to contribute to various types of skin cancer.

Additional atmospheric ozone (~10%) is found in the troposphere (U.S. EPA, 2007). This tropospheric ozone is commonly referred to as “ground-level ozone” and is in the air that people breathe. Tropospheric ozone in California is primarily produced via photochemical reactions of volatile organic compounds (VOCs) and nitrogen oxides (NOx). Ambient ground-level ozone

concentrations exhibit a diurnal pattern as its formation reactions require the energy input from sunlight. Thus, ozone levels typically increase during the mid-day and decrease at night. However, transport of polluted air masses can result in high ozone concentrations at night. Ozone concentrations also exhibit seasonal variation with the length of day and night. Outdoor ozone levels are typically the highest in the summer, on hot, stagnant, and cloud-free days. Ozone can also be produced via electrical discharge, electrochemical and UV radiation, of which electrical discharge is the most efficient. Ozone production via electrical discharge, and possibly UV radiation, are of concern to IACD where ozone production may be either intentional or result as a by-product of operation.

D. Measured Ozone Emissions

In 2005, ARB staff evaluated several models of OGs to identify current emissions levels and to assess potential ozone exposure resulting from their use (ARB, 2006a). Room ozone concentration tests were conducted in a small room furnished with a desk and chair, under temperature, humidity, and air exchange conditions common in homes. The IACD were operated according to manufacturers' instructions. Prior to the room concentration tests, measurements were made at 2, 6, 12, and 24 inches from the face of each device to locate the major output stream for each and identify the range of emissions in preparation for the room concentration tests. The test methods used are described further in Appendix C.

Room concentration results for OGs, shown in Table IV-6, show that all of the models tested produce room concentrations that exceed health-based standards and can pose a serious risk to health. The Biozone® 500, the Prozone® Whole House, and the Prozone® Compact produced room concentrations that substantially exceed both the CAAQS of 0.09 ppm, 1-hour average, and 0.070 ppm, 8-hour average, for ozone. They also would exceed the U.S. FDA standard of 0.05 ppm that applies to medical devices (devices for which the manufacturers make health-related claims). Additionally, the Alpine Air XL-15 / LA Lightning Air RA 2500 unit exceeded the 1-hour and 8-hour CAAQS, as well as the FDA standard when set at a medium setting (ozone output for a 1,000 square foot area). This unit was not tested at its highest setting, but has been shown in other studies (e.g., Mason *et al*., 2000) to produce room levels over 0.300 ppm at its highest settings.

The Prozone® Whole House unit produced the highest room concentrations measured when operated in the continuous mode – over 0.400 ppm, more than four times the 1-hour CAAQS, and over six times the 8-hour CAAQS. Although the continuous mode is designed for an unoccupied home with greater volume than the test room in this study, consumers could naively operate the unit in this mode when their home is occupied, which would result in extremely high ozone exposures. Additionally, when operated for 15 minutes per hour as recommended by the manufacturer for occupied spaces, the Prozone® still produced unhealthy ozone levels: concentrations reached 0.09 ppm within 7 minutes, and the maximum 60-minute average was 0.119 ppm, well above both CAAQS.

Table IV-6. Room Concentrations Measured from Intentional Ozone Generators

Manufacturer and Model	Operational Setting	Maximum 60-minute average room concentration (ppm)	Minutes to reach 0.070 ppm (8-hr std)	Minutes to reach 0.09 ppm (1-hr std)
Alpine Air XL-15 / LA Lightning Air RA 2500	Low [a]	0.001	NA [b]	NA
	Medium	0.088	28	NA
Biozone® 500	Low	0.096	42	135
	High	0.099	111	162
Prozone® Whole House	Intermittent	0.119	6	7
	Continuous	0.435	6	7
Prozone® Compact A	On	0.109	18	31
Prozone® Compact B [c]	On	0.149	15	20

Notes:
a. Unit was set at low fan, with Ozonator turned to lowest setting.
b. NA: unit never reached the level indicated.
c. A second Prozone® Compact unit was purchased to test for between-unit variability.

Results of the face emissions tests for the four OGs are presented in Table IV-7. Of particular concern are the high ozone emission concentrations measured, several of which exceeded 1 ppm at the 2 and 6 inch measurement distances. Three OG tests yielded ozone concentration in excess of 0.360 ppm at a distance of 24 inches, which is over 4 times the 1-hour CAAQS. The elevated ozone concentrations observed at the measurement distances warrant public health protection to limit near-source ozone exposures from IACD, such as use near a bed or baby crib.

E. Estimated Pre-regulation Exposure to Ozone

The estimated residential concentrations of ozone resulting from the current use of portable indoor air cleaners in California are shown in Table IV-8, along with the estimated number of persons that experience each level of exposure. In total, well over 500,000 Californians are estimated to be routinely exposed to ozone concentrations above the 8-hour CAAQS of 0.070 ppm due to the use of an indoor air cleaning device that emits ozone. The supporting bases for this estimate are discussed below.

Table IV-7. Face Test Results for Intentional Ozone Generator Air Cleaners

		Ozone Concentration at Varying Distances from Unit Face (ppm) [a,b]			
Model	**Operational Setting**	**2”**	**6”**	**12”**	**24”**
Alpine XL-15 / Living Air 2500 [c]	2,500 ft^2; Fan at Low speed	1.29	1.17	0.907	0.567
	2,500 ft^2; Fan at High speed	0.781	0.718	0.580	0.373
Biozone® 500	Fan at Low speed	0.438	0.095	0.011	0.011
	Fan at High speed	0.379	0.144	0.043	0.013
Prozone® Whole House	Continuous mode (System on; Timer inactive; UV on)	1.03	0.815	0.577	0.389
Prozone® Compact B	On mode (no user-defined controls)	1.13	0.695	0.304	0.061

Notes:

a. Concentrations are 10-minute averages after the unit has been operating for at least 10 minutes.

b. For the face tests, values have not been adjusted for differences in background ozone levels, which ranged from 0-0.025 ppm during the testing.

c. The 2,500 ft^2 Ozonator setting was also used in the emission rate tests, but not in the room tests.

1. Indoor Ozone Concentrations: Ozone Generators

Table IV-8, Column B shows three ranges of ozone exposure for households using ozone generators (0.201-0.400, 0.101-0.200, and 0-0.100 ppm). These estimates are based on the following;

1. In a study of ozone generators in a single-family test home, Mason *et al.* (2000) reported in-home concentrations of 0.038-0.310 ppm for a larger, whole-house OG unit, and 0.018-0.065 ppm for a smaller OG unit. Various device settings, room locations, and central air system settings were tested. The air exchange rate of the home was similar to that typically found in newer and weatherized homes, but was not as low as some new homes.

2. In a study of ozone generators in a test room, Phillips *et al*. (ARB, 2006a), reported indoor ozone concentrations of 0.088-0.435 ppm for larger OG units, and 0.096-0.149 ppm for smaller OG units. Note that maximum ozone settings were not tested in some cases, and that devices with even higher ozone emission rates are on the market.

The in-home concentration values for ozone are reasonable estimates of average 8-hour exposures in California for several reasons:

- Current OG models by Alpine Air / EcoQuest have maximum settings that can produce even higher ozone levels than the settings used in the study by Mason *et al.* (2000).

- California adults on average spend 62% of their 24-hour day in their home, and children spend 76% of their time in their home. About 64-72% of California households with ozone-emitting air cleaners in a survey of 2,019 households reported operating their air cleaners continuously, 24 hours a day, 7 days a week (Piazza *et al*., 2006). This indicates that an 8-hour exposure duration may be a conservative assumption for most air cleaner users.

- 28-40% of California households with OG or BP devices have two or more such devices in their home (Piazza *et al.*, 2006), indicating that there may be multiple ozone emission sources in many homes (thus producing higher ozone concentrations) and that the residents may often be in close proximity to one of those ozone emission sources.

Table IV-8. Estimated Population Exposure to Ozone from Indoor Air Cleaners

A Type of Air Cleaner [a]	B In-Home Ozone Concentration (ppm) [b]	C Percent of Homes in Category	D Number of Persons Exposed in California [c,d] (C x Subtotal)
Ozone Generators	0.201 - 0.400	25	160,000
	0.101 - 0.200	45	290,000
	0 - 0.100	30	190,000
	Subtotal [e]	**100**	**650,000**
By-Product Devices	0.081 - 0.120	5	110,000
	0.021 - 0.080	15	330,000
	0 - 0.020	80	1,770,000
	Subtotal [f]	**100**	**2,200,000**

Notes:

a. The By-Product Device category includes devices that use ionizer, electrostatic precipitator (ESP), or photocatalytic oxidation (PCO) technologies, but are not ozone generators (OGs). Ionizers, ESPs, and other By-Product devices are combined due to lack of data on market share by type of air cleaner technology. Results in Piazza *et al.* (2006, pp. 87-88) suggest at least 34% of all brands reported in the survey were ionizers.

b. Ozone Generator concentration estimates are based on Mason *et al.* (2000) test house data, and ARB (2006a) test room data. By-Product concentration estimates are based on test chamber data from Chen *et al.* (2005, 2006), Mullen *et al.* (2005), Britigan *et al.* (2005), and Consumers Union (2005a,b).

c. Based on 2006 data on the number of households in California with certain types of indoor air cleaners, the number of persons per household, and the fraction of households that were presently using the device (78%) from Piazza *et al.* (2006).

d. Number of persons value is rounded to the nearest 10,000.

e. Actual value for number of persons is 10,000 more than the apparent subtotal, due to rounding.

f. Number of persons value is rounded to nearest 100,000.

2. Indoor Ozone Concentrations: By-Product Devices

The same approach as above for OGs was used for By-Product air cleaners, as shown in the lower part of Table IV-8. The pre-regulation ozone exposure estimates are based on reported results from room and test chamber studies of a number of different models studied by Chen *et al.* (2005, 2006), Mullen *et al.* (2005), Britigan *et al.* (2005), and Consumers Union (2005a,b). The fractions of the households exposed at the three different levels of ozone are based on the statewide survey data of Piazza *et al*. (2006), and an estimated distribution of model types with higher emissions. The two highest categories of ozone emissions, 0.081-0.120 ppm and 0.021-0.080 ppm, are estimated to account for 5 and 15% of the BP category respectively, for a total of 20%. The remaining 80% of the BP devices are estimated to emit very low amounts of ozone.

3. Percent of Homes in Exposure Category

Table IV-8, Column C shows the estimated fractions of homes likely to experience the ozone exposure ranges discussed above. Data are not currently available on the distribution of air cleaners by ozone emission rate and type, or on the distribution of ozone output settings used across homes. Therefore, a reasonable assumption was made that the size of the ozone generator and emission rate would correlate well with the size of the room where it is used. The size of the room where the device was used was also considered in estimating the indoor ozone exposures.

The statewide survey of 2,019 households in California discussed earlier (see Background) also provides information on room sizes where air cleaners are used. Piazza *et al.* (2006) indicates that about 50% of the OGs are used in larger rooms such as the living room. Presumably these are the larger, whole-house units with the highest emission rates, or devices designed for large rooms, and would be operated at the higher settings. As a conservative estimate, it is assumed that some of these households operate the device at lower settings or have higher air exchange rates and larger home volumes than the 1,200 square foot test home in Mason *et al.* (2000), and that household members would not typically spend a full 8 hours near the device. These assumptions lead staff to estimate that only about 25% of these households experience the highest range of ozone exposures.

The survey results showed that about 30% of OGs are used in medium sized rooms such as the master bedroom and the family room, and about 20% are used in other types of rooms. Presumably these units would be either smaller units with low or medium emission rates, or the larger whole house units used at low or medium settings. This suggests that, out of the remaining 75% of the households, the medium- and low-ozone exposure categories comprise about 45% and 30% respectively. Note that, depending on the ozone output setting and the tightness of the room, the resultant ozone concentration in the room could still be in the high range. Also, 28% of the households with OGs reported having two or more air cleaners (Piazza *et al.*, 2006), which could increase indoor ozone levels even further. Thus, 45% and 30% are reasonable, or perhaps even conservative, estimates for the medium- and low-ozone exposure categories, respectively.

In addition, the distribution of sales prices for OGs in California (Piazza *et al.*, 2006) was examined as an indicator of the size of the ozone generators, and this yielded a similar distribution as above.

4. Number of Persons Exposed

The estimates of the number of persons exposed are shown in Table IV-8, Column D. These estimates are based largely on the results of the statewide survey by Piazza *et al*. (2006). That survey found that 282,000 households (2.28%) comprised of 828,000 persons, reported owning an ozone generator within the past five years. About 78% of the households reported current use of an OG, yielding an estimated 650,000 persons currently exposed to ozone from OGs, as shown in Column D of Table IV-8.

This value was then multiplied by the percent of homes in each category (Column C), to yield the exposed population for each category of exposure level and air cleaner, as shown in Column D. Of the 650,000 subtotal for owners of ozone generators, 160,000 persons are estimated to be exposed to indoor ozone concentrations of 0.201-0.400 ppm over 8 hours or more, and 290,000 persons are estimated to be exposed to indoor ozone concentrations of 0.101-0.200 ppm over 8 hours or more.

The same approach was used to estimate the number of persons exposed to ozone from BPs, except that the statewide survey reported that 7.83% of households, comprised of 2,800,000 persons, owned BPs within the past five years. Accounting for the 78% current use rate, this yields an estimated subtotal of 2,200,000 persons currently using BPs in their homes. Of these persons, 111,000 persons are estimated to be exposed to indoor ozone concentrations of 0.081-0.120 ppm over 8 hours or more, and 330,000 persons are estimated to be exposed to indoor ozone concentrations of 0.051-0.080 ppm over 8 hours or more.

In summary, well over 500,000 Californians are estimated to be routinely exposed to ozone concentrations above the 8-hour CAAQS of 0.070 ppm due to the use of an indoor air cleaning device that emits ozone. Most importantly, many of these Californians are exposed to ozone levels several times greater than the health-based standard.

V. Proposed Regulation

This chapter provides a discussion of the proposed regulation required by AB 2276, and the rationale behind each section. Where applicable the key terms or concepts involved in the development of the proposed regulation are described in detail. The discussion in this Chapter is intended to fulfill the requirement of Government Code Section 11343.2, which requires a "plain English" summary of the proposed regulation be available to the public. The proposed regulation order, in its entirety, can be found in Appendix B. In short this proposed regulation requires that IACD intended for use in occupied spaces meet a 0.050 ppm ozone emission concentration limit, be labeled and marked appropriately, and be certified by ARB.

A. Applicability (Section 94800)

Section 94800 of the proposed regulation order indicates the responsible parties and the devices covered under the regulation. The proposed regulation would apply to anyone who manufactures, sells, supplies, offers for sale, or introduces into commerce IACD used or intended for use in occupied spaces. This regulation would apply to portable IACD designed for room, whole house, whole floor, whole building, and in-vehicle use, as well as those designed to be carried on one's person (because people typically spend substantial time indoors). The use

of some of these devices in spaces intended for occupied use has the potential for very high ozone exposure to the public.

Under the proposed regulation, any device used or intended for use in an enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices, would be banned from being introduced into commerce in California unless it met the proposed emission standard and other proposed requirements. In the staff's experience such measures as "dual use" settings and labeling are not effective in preventing exposures to high levels of ozone, especially in the case of air cleaning devices that are marketed for residential use. Users, including residential users, are inclined to use high emitting devices and set devices at high emission levels, particularly in light of misleading marketing claims alleging health benefits from ozone exposure. Users of these devices are commonly unable to accurately gauge the actual levels of ozone either emitted directly by these devices or which accumulate as the devices are used for periods of time for a variety of reasons, including the deadening effect of ozone on people's sense of smell (olfactory sense). While exiting an enclosed area may offer some protection to the person who sets a dual use device on a high setting or uses an otherwise high emitting device, this offers no protection to other people who may enter the area. For these reasons the staff proposes defining the term "occupied space" in the regulation in the same wide sense it is used in federal law at 21 CFR section 801.415 and paraphrased in HSC 41985.5(a). Under this proposed definition it would be a violation to introduce air cleaners into commerce in California unless they comply with the regulation's proposed requirements regardless of whether they are "dual" use or are labeled not for use in the presence of people because the proposed regulation would apply to all devices that can be used in an enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices. In addition to being consistent with federal law, this also carries out the intent of HSC section 41985.5(c)(1) which directs ARB to ban high emitting devices. Notably, the Health and Safety Code does not limit the regulation only to devices that are used exclusively in the presence of people. Indeed, given the way the staff understands that these devices are actually used, limiting the regulation in such a way would severely limit its ability to do what it is intended to do − protect people from exposures to high levels of ozone emitted from these devices.

B. Definitions (Section 94801)

For the purposes of clarification and brevity within the proposed regulation order the intended meanings of a number of terms are provided in Section 94801. Several acronyms are defined for state and federal agencies and entities. Specific terms of importance to the appropriate application of the proposed regulation order are explicitly defined to avoid ambiguous interpretation.

C. Emission Standard (Section 94802)

Section 94802 outlines the specific ozone emission standard for IACD offered for sale within the state of California. The proposed regulation stipulates that all IACD manufactured for use in California in occupied spaces 12 months after the effective date of this regulation would need to be certified under the requirements of this regulation. Additionally, no IACD could be offered for sale within the state of California that produces an ozone emission concentration in excess of 0.050 ppm nine months after the effective manufacture date. This ozone emission concentration is consistent with the federal ozone emissions limit, as required by Section 41986

of the HSC. Verification of the ozone emission concentration of the IACD would be attained via certification by ARB, following the procedures described in Section 94804, discussed below. All of the IACD certified as complying with the 0.050 ppm ozone emission standard also would be required to satisfy the labeling and mark requirements described in Section 94806. All IACD would need to continue to meet the ozone emission standard in order to continue sale within California.

D. Exclusions and Exemptions (Section 94803)

Two classes of IACD are excluded or exempt from compliance with the ozone emission standard, as detailed in Section 94803. These exemptions would be for the use of IACD for industrial applications and for devices that are an integrated component of a central heating, air conditioning, or ventilation system. The following describes the qualifications and rationale of each exemption in greater detail.

There are several industrial applications that utilize ozone for a variety of purposes, most as an oxidant alternative to chlorine. Drinking water, wastewater and sewage treatment applications use ozone for purification. The pulp and paper industry use ozone for bleaching purposes, in addition to wastewater treatment. In certain circumstances ozone is used to increase the shelf-life of perishable food stuffs. Ozone is also used for odor control in several industries, and is used in the remediation of fire, smoke, and mold damage. Given the diversity of ozone use as an alternative oxidant we propose to provide an exemption for industrial applications that satisfy the “industrial use” definition specified in Section 94801. Indoor air cleaning devices that are manufactured, advertised, marketed, and used solely for industrial use would be eligible for exemption from the proposed regulation, provided these IACD are marketed and sold only through industrial supply outlets or businesses. Additionally, these IACD would have to be prominently labeled as “Solely for industrial use. Potential health hazard: emits ozone.” in order to satisfy the requirements for exemption. Any potential workplace exposure from such exempt IACD would fall under the authority of the California Department of Industrial Relations (Cal/OSHA). These exemptions may be reconsidered in the future if future information indicates they pose a risk to public health.

Indoor air cleaning devices that are a physically integrated component of a central heating, air conditioning or ventilation system, commonly referred to as “in-duct” devices, would be exempt from meeting the ozone emission standard. The primary reason for exemption of these IACD is the lack of relevant ozone emissions and exposure data from this type of device, and the need for a different test method. However, if future data show the ozone emissions from such devices pose a risk to public health, regulation measures would be proposed.

E. Certification Requirements (Section 94804)

The proposed regulation would require all IACD sold in California for use in occupied spaces to be certified by the ARB, except for devices qualifying for exemption under Section 94803 above. To attain certification, the IACD manufacturer is required to submit an application for consideration to ARB. Alternatively the application may be submitted by a professional or certification organization on the manufacturers’ behalf, provided the required information and appropriate signatures are included. If the IACD is deemed compliant with the proposed regulation, ARB will issue an Executive Order of certification for the IACD, allowing for sale within California.

The certification application would require information about the IACD manufacturer, the applicant (if different from the manufacturer), the IACD to be certified, other models in the model group covered, and the IACD test information. The format for submission of the certification application information is presented in Appendix D. Application materials would be required to be submitted together as a single submission. If some of the requested certification information is not available or not applicable it must be indicated in the application. The ARB Executive Officer could waive the requirement to provide such information for certification if they concur with the judgment of the applicant.

Certification applications would initially be reviewed by ARB for completeness. A written notice would be provided within 30 days of receipt indicating if the 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. Upon receiving certification approval, the IACD model and its associated group models, if any, would be added to a list of certified IACD that would be maintained on the ARB website. ARB staff would strive to process certification applications as quickly as possible, because the ARB understands the implications of a slow approval process for manufacturers.

Indoor air cleaning devices using only mechanical filtration for pollutant removal would be exempt from the testing requirement for the ozone emission standard, based on their known *de minimis* ozone emissions. Mechanical filtration achieves pollutant removal via physical barrier methods by forcing air through a filter medium. Due to the absence of an electrical discharge the potential for ozone production is minimal. Verification of qualification for the mechanical filtration exclusion would be made by the ARB Executive Officer based on information provided by the certification applicant. The information required for verification includes the product design specifications, a description of the air cleaning performance technology employed, and a block diagram or schematic of the IACD. Indoor air cleaning devices qualifying for this exclusion are still required to submit the information for certification, including certification for electrical safety according to ANSI/UL Standard 507 or any ANSI/UL Standard that addresses electrical safety for mechanical filtration air cleaners that succeeds Standard 507. Any IACD certified to Standard 507 prior to the enactment of the proposed regulation are eligible for certification without additional testing, provided they continue to comply with Standard 507 requirements. Mechanical filtration IACD are still required comply with the labeling requirements described in Section 94806 and be certified by ARB.

Following certification the IACD must maintain compliance with the requirements of this regulation. Notification must be provided to ARB, within 30 days, if at any time a certified IACD or indoor air cleaner model group fails follow-up testing under ANSI/UL Standard 867 or 507 protocols. Additionally, ARB staff may at any time purchase a certified device and evaluate its compliance with the regulation requirements. If at any time an IACD or indoor air cleaner model group is found to be non-compliant with the regulation requirements, their certification may be revoked. The ability to revoke certification for a non-compliant device ensures that ARB has the necessary authority to adequately protect the public from unnecessary ozone exposures from IACD.

F. Test Method (Section 94805)

Section 94805 details the test methods proposed to be used for verification of compliance with the ozone emission standard described in Section 94802. For the purpose of

compliance with the requirements of this regulation it is necessary to examine only one model of IACD within a model group, as defined in Section 94801, if a model group exists, to verify compliance with the test methods. The allowance for IACD model groups will limit unnecessary testing of IACD that may have non-performance related differences such as aesthetic modifications (i.e., color), several different brand names, or other similar cosmetic differences.

ANSI/UL Standards 867 and 507 are the test methods that would be used to determine compliance with the requirements of this regulation. Both are available from http://www.comm-2000.com. The ANSI/UL Standard 867 will be used to evaluate both the ozone emissions and electrical safety for all applicable IACD. Indoor air cleaning devices that are verified as mechanical-filtration only devices will be evaluated for electrical safety using ANSI/UL Standard 507, or any ANSI/UL Standard that addresses electrical safety for mechanical filtration air cleaners that succeeds Standard 507, and ozone emissions testing would not be required for certification. Inclusion of the electrical safety testing requirement for compliance with this regulation would provide protection to consumers by ensuring that any IACD design modifications to meet the ozone emissions limit do not compromise the integrity and fire safety of the device.

Ozone emissions from IACD would be determined following the test conditions outlined in the 2007 revision to Section 37 of ANSI/UL Standard 867. As the standard revision process is taking place in parallel to the development of this regulation, the following discussion of the ozone test method is based on the revision draft released for public comment on June 22, 2007. While changes to the released draft are expected, ARB staff anticipate that they will be small with little impact on the determined ozone emission. A copy of the June 22, 2007 Standard revision is provided in Appendix E. The revisions to Section 37 of Standard 867 are proposed by UL to provide clarification of the ozone emissions test protocol described in Section 37 in order to minimize variability among laboratories and to address uncertainties in the original language of Section 37. Briefly this test measures the ozone emissions of the IACD at a distance of 2 inches from the device over a period of 24 hours within a test chamber. ARB staff feel that by following the revised Section 37 and the 2 inch measurement location, any potential for extremely high near-source ozone exposures from IACD, as discussed in Section IV.D., would be minimized for the assured protection of public health. This is very important as several IACD examined by ARB staff emitted ozone in excess of 1 ppm at this distance, illustrating the substantial risk for extremely high near-source exposure levels. Since the emission test is conducted for a period of 24 hours, any ozone accumulation in the room will be ascertained in a manner consistent with the FDA regulation.

There are several important changes specified in the proposed revision of Section 37 of ANSI/UL Standard 867. A notable change to the ozone emission test procedure is the manner in which the background ozone concentration is determined. Accurate determination of the background ozone levels is essential. Previously, the pre- and post-test background measurements were averaged and then subtracted from the highest concentration measured during the IACD device test to calculate the ozone emission concentration. The previous language of Section 37 allowed for varied interpretation regarding when the pre- and post-test background measurements were to be performed, potentially allowing high ozone emitting IACD to pass the 0.050 ppm emission restriction (Niu *et al*., 2001a,b; Chen *et al.*, 2005; Siegel, 2005). The revised Section 37 now stipulates that the background measurement is to be performed in the test chamber immediately prior to the start of the IACD emission testing. Additionally, the proposed revision stipulates that none of the background measurements can exceed 0.005 ppm. These additional specifications for the background measurements should prevent high

ozone emitting devices from meeting the 0.050 ppm emission limit due to differences in interpretation of test details.

Other changes in the proposed Section 37 revision pertain to the test chamber. The majority of the changes to the test chamber were aimed to reduce variability in the ozone emissions determined by different laboratories. Test chambers may be constructed from stainless steel or any other non-porous and non-reactive material provided the chamber is able to attain the specified performance characteristics. These performance characteristics include verifying an ozone half-life of 16 ± 1 minutes, an air exchange rate between 0–0.35 ACH, and an air supply system capable of providing particulate-free, VOC-free, and ozone-free air. By tightening the specifications of the test chamber, the proposed revisions to Section 37 would substantially reduce inter-laboratory variability which is essential to avoid certified devices later failing a compliance test if tested by another laboratory.

Other notable revisions include the following:

- If the ozone emission of the first device exceeds 0.030 ppm, compliance with the emissions concentration limit will be verified by testing a second unit of the same model.
- The device will be operated for a 72 hour run-in period prior to emissions testing.
- The average of five consecutive measurements taken 60 seconds apart must not exceed 0.050 ppm.
- The maximum ozone emission location would be determined and used for the location of the monitoring inlet.
- Devices with multiple operation settings would be tested on each setting, or for continuous dials, on the high, medium and low settings.
- IACD containing ozone-monitoring circuitry must meet the emission limit with and without the circuitry engaged, unless its reliability has been demonstrated under specified tests.

For compliance with this regulation testing to determine the ozone emissions and electrical safety of IACD must be performed by an independent laboratory currently recognized as a Nationally Recognized Testing Laboratory (NRTL) by the U.S. OSHA. The laboratory must have NRTL status to complete the ANSI/UL Standard 507 and revised Standard 867 testing in their entirety. Such a NRTL may also utilize a Program #2 independent laboratory per the March 9, 1995 OSHA Federal Register Notice 60: 12980-12985 for Section 37 ozone testing required in this regulation. Prior to performing testing for this regulation, laboratories must also pass an ARB audit. The ARB audit would include an initial paper evaluation of the laboratories' Standard Operating Procedures (SOPs). Once the laboratories' SOPs are deemed acceptable, ARB staff may conduct an on-site inspection to verify the test chamber and instrumentation configurations, as well as to observe the successful attainment of the test conditions specified in the proposed revisions to Standard 867. Upon satisfactory completion of the ARB audit, laboratories may begin testing for certification submission.

G. Labeling and Safety Mark Requirements (Section 94806)

Any IACD subject to this regulation that does not qualify for exemption from this regulation would be required to display the proper label on the product packaging prior to sale within California. Medical devices would be labeled to comply with federal law by satisfying the requirements of Section 801.415 of Title 21 of the Code of Federal Regulations (see Appendix F), and state "ARB certified". For non-medical devices the label would be displayed upon completion of the requirements of Section 94804 and approval for certification by ARB.

Dimensions of the label would be at least 1 inch by 2 inches and would contain the text “This air cleaner complies with the federal ozone emissions limit. ARB certified”.

Indoor air cleaning devices that qualify for exemption to this regulation would likewise be required to display the appropriate exemption label on their packaging and in specified advertising. Any IACD for non-industrial use in occupied spaces that is advertised or sold via the Internet or mail catalogs and lacks ARB certification under Section 94804 would be required to display an advisory warning stating “Device does not meet California requirements, cannot be shipped to California.” in a prominent place on all Internet webpages, catalog pages and related materials for marketing and sale of the device. The inclusion of associated marketing materials, especially Internet-related items, in the labeling requirements is necessary as many IACD are obtained from Internet shopping, and consumers need to be aware of potential dangers that certain IACD may pose prior to their purchase, and whether or not the device under consideration complies with California regulations.

All IACD sold in California and subject to this regulation would be required to display the appropriate electrical safety certification or listing mark on the product. The mark must be consistent with the ANSI/UL Standard 867 requirements of the appropriate NRTL safety certification organization for devices required to undergo ozone emission testing. Indoor air cleaning devices meeting the requirements as “mechanical-filtration only” devices would be required to display the certification mark for Standard 507, or for any electrical safety standard for air cleaners that succeeds Standard 507. The combination of package labels, sales materials labels and the certification marks help assure consumers that their IACD is in compliance with this regulation.

H. Notice to Distributors, Retailers, and Sellers (Section 94807)

Within 12 months of the effective date of this regulation, all IACD manufacturers would be required to provide ARB with documentation indicating the manufacturer has provided all of its known distributors, retailers, and sellers with true and accurate copies of the final regulation order approved by ARB and the California Office of Administrative Law. Accepted documentation of an electronic notification will include a copy of the email and the contact information for each email address. Accepted documentation of a mailed notification will include a paper copy of the materials mailed and the associated mailing list and contact information. Any new distributors, retailers and sellers that become known to the manufacturer after the initial notification must be provided the same required materials, with their contact information provided to ARB. Additionally, manufacturers are required to submit the contact information for all of their known California distributors, retailers and sellers. Failure to comply with this provision may result in the rejection or revocation of ARB certification.

I. Recordkeeping Requirements (Section 94808)

The manufacturers, distributors, retailers, sellers and test laboratories would be required to maintain production, quality control, sales, or testing records for products that are sold, supplied, offered for sale, introduced into commerce, or manufactured for sale within the state of California, for at least three years. These records must be made available upon request to ARB. Such a request would be made only for enforcement purposes. Requested recorded information may be kept confidential if necessary.

J. Rejection, Revocation, Recall, and Penalties (Section 94809)

Failure to comply with any provision of the proposed regulation order could result in the denial of a certification application or having certification suspended or revoked. If a non-compliant device is found, the Executive Officer may order the products involved be recalled and replaced with compliant devices. In the event of a violation with an article of the proposed regulation, all other penalties authorized by law apply as well.

In enforcing this regulation, ARB's Enforcement Division inspectors will visit retail, wholesale, Internet outlets and distributors to ensure that air cleaners available for sale in California meet certification and labeling requirements. Periodically, air cleaners would be purchased and submitted to a laboratory for testing to ensure that they are in compliance with the ozone emission standards in Section 94805 of the regulation. Potential violations would be investigated, Notices of Violation (NOV) would be issued, and appropriate civil or administrative action could be taken by the Air Resources Board to enforce NOVs issued under this regulation. Civil penalties could be imposed as provided in Health and Safety Code sections 42402 *et seq*. Criminal cases may be referred to the appropriate prosecuting agency and would be subject to penalties under Health and Safety Code sections 42400 *et seq*.

K. Severability (Section 94810)

Each section and subsection of the proposed regulation is an independent entity. If any portion of the regulation is found to be invalid, the remainder of the regulation would continue to apply in full force and effect. Thus, each article is deemed severable.

VI. Economic Impacts

A. Summary

The potential economic impacts of the regulation will primarily be cost increases to most manufacturers to certify air cleaners, i.e., to meet testing and labeling requirements. Approximately 60 manufacturers and their distributors may be affected. For most manufacturers of OGs and a few manufacturers of BP devices, this certification also will require redesign of some products to meet ozone emission limits. The potential economic impact for most manufacturers is estimated to be insignificant relative to total sales and profits. However, some smaller manufacturers of OG and BP devices may be impacted over the short-term. The potential economic impacts on distributors, retailers, and consumers, are estimated to be minimal, except for those distributors whose suppliers choose not to provide a compliant product. The potential fiscal impact on ARB is about $175,000 per fiscal year after approval of the regulation. The fiscal impact on other state agencies and local agencies is expected to be insignificant. The potential impact in California on jobs, business competitiveness, and business creation, elimination, or expansion is expected to be insignificant.

B. Affected Businesses and Agencies

The proposed regulation will affect the manufacturers, distributors, and sellers of portable air cleaners used or intended for use in occupied spaces if the products are marketed for sale in California. Staff estimate that 61 manufacturers may be affected, and that their

combined annual California sales averaged approximately $40,000,000 per year from 2003-2006, as discussed in the following section.

Only a few of the manufacturers are based in California: three large manufacturers (Jarden Consumer Solutions, Sharper Image, and Biotech Research), and at least three smaller manufacturers (Aqua Sun Ozone International, Zojirushi America Corporation, Wein Products). A large majority of the actual manufacturing is done under contract with manufacturers in Asia, according to industry representatives.

ARB is the only state or local agency directly affected by this proposed regulation. Other state agencies such as the California Department of Public Health and some local health agencies such as health departments and district attorneys are not expected to be affected.

C. Potential Impacts on Businesses

1. Manufacturers

Industry-wide information on the number of air cleaner manufacturers, the number of models to be certified and the likely cost of redesign and certification is not currently available. Consequently, ARB staff sent a confidential market survey and a follow-up survey to all major manufacturers of portable air cleaners, and to known manufacturers of ozone generators. The survey asked about annual sales volume, retail price mark-ups, the number of models to be certified, the number of employees, and sales distribution channels. It also asked about the expected costs to redesign products, conduct ozone and safety tests, and label the products affected by the regulation. Only six manufacturers responded to these ARB requests for information. Nearly all of the responses supplied information on sales volumes, distribution channels, and employee numbers, but not on the number of models to be certified and the expected costs.

Detailed, comprehensive listings of all manufacturers and models of air cleaners sold in California are not available. Therefore, to estimate the number of manufacturers affected and the number of models that will require certification under the regulation, ARB staff used available sources of information on air cleaner models on the market, including the following:

- The list of ozone generator models on the ARB website (ARB, 2006c).
- The final report and data from a statewide survey of residential air cleaner use (Piazza *et al.*, 2006).
- The listing of portable air cleaner models, brands, and their Clean Air Delivery Rates (CADR) by the Association of Home Appliance Manufacturers (AHAM, 2007).
- The websites of various manufacturers.

Based on the information indicated above, ARB staff estimated that a total of 61 manufacturers have current models of air cleaners that would need to be certified in the first year (Year 1) after the effective date of the regulation (see Table VI-1). Eight of those manufacturers are considered “large share” manufacturers, based on their share of the California market from survey data by Piazza *et al.* (2006).

Staff also estimated that the California sales of air cleaners in 2003-2006 averaged about $40,000,000 per year. This estimate is based on household purchase data from the California survey by Piazza *et al.* (2006). This estimate is consistent with estimated California

sales of $41,000,000 for 2006, derived from an interpolation of national estimates of $275,000,000 in 2003 and $485,000,000 in 2013 (Freedonia, 2004), after adjusting for California's relative population size of 12% of the national population. Freedonia (2004) estimated that the U.S. market would grow by 76% from 2003 to 2013.

a. Number of Models to Be Certified

The following definitions of types of air cleaners were used to distinguish among different levels of ozone emissions and the resultant certification costs:

- Ozone Generators (OG): devices that intentionally produce ozone.

- By-Product (BP) Devices: devices that produce ozone as a by-product of their air cleaning technology. BP High Emitter Devices are BP devices that produce ozone emission concentrations near or above the UL 867 standard.

- Mechanical-filtration Devices (M): devices that only use filtration with a physical barrier, and non-electronic techniques; they produce *de minimis* ozone emissions.

Based on the available information indicated above, ARB estimated that a total of 215 models of air cleaners will need to be certified in the first year (Year 1) after the effective date of the regulation (Table VI-1). A total of 61 manufacturers would be affected; 53 (87%) are small businesses.

The results shown in Table VI-1 are listed for the three general types of portable air cleaner technologies. Each type of air cleaner is also broken down into Large Share and Small Share, based on the brand prevalence (market share) in the California survey data (Piazza *et al.*, 2006). Brands were combined when they had the same manufacturer, based on the CADR list and product websites. Staff assumed all models other than those with only cosmetic differences such as color or minor features would require certification. Staff also assumed that older models that are currently in retail and distribution channels, but no longer produced, will be phased out by the time the regulation is in effect. Note that the CADR directory lists a total of about 30 manufacturers of BP or Mechanical devices, while the California survey (Piazza *et al.*, 2006) indicates about 40 manufacturers after subtracting those brands made by the same manufacturer. This difference is attributed to the fact that not all manufacturers are AHAM members with CADR listings.

The total number of models to be certified was estimated by multiplying the average number of models per manufacturer (Column B) by the number of manufacturers in the category (Column C). The overall total number of models was estimated to be 215 models: 42 OG models, 94 BP models, and 79 Mechanical models. As seen in Table VI-1, the estimated average numbers of models were similar among manufacturers in the same market share category. The Large Share manufacturers were estimated to produce 6-8 models on average, while Small Share manufacturers were estimated to produce 3 models on average. The available lists of manufacturers and models are not completely comprehensive, so these estimates may be an underestimate for the current market. Additional details on how the estimates in Table VI-1 were developed are presented in Appendix G.

Table VI-1. Estimated Number of Air Cleaner Models to Be Certified, By Type of Air Cleaner

A Type of Air Cleaner	B Average # of Models per Manufacturer	C # of Manufacturers in Category	D Total # of Models to be Certified (B x C)
Ozone generators [a]			
Small share	3	10	30
Large share	6	2	12
Subtotal	NA [e]	12	42
By-product devices [b,c]			
Small share	3	22	66
Large share	7	4	28
Subtotal	NA	26	94
Mechanical devices [b,c,d]			
Small share	3	21	63
Large share	8	2	16
Subtotal	NA	23	79
Total	**NA**	**61**	**215**

Notes:

a. The number of models per ozone generator (OG) manufacturer was compiled from ARB (2006). The number of OG manufacturers was compiled from Piazza *et al.* (2006).
b. The number of By-Product (BP) device manufacturers and market share are from a California statewide survey (Piazza *et al.*, 2006, Appendix B, and brand name data). Brands made by the same manufacturer were identified using the CADR directory list (AHAM, 2007). For mechanical devices, the number of models was estimated using the same approach described above for BP devices.
c. Older models that are currently in retail and distribution channels but are no longer produced are assumed to be phased out by the time the regulation is in effect.
d. Assumes that about half of the models from small share producers that are on the CADR list are currently marketed in California and are considered mechanical devices.
e. NA: not applicable.

b. Cost of Certification to Typical Manufacturers

The cost to manufacturers to comply with this regulation will vary widely, depending on the type of air cleaner and the number of models produced by the manufacturer. First, estimates were developed for the initial costs per model for typical manufacturers to redesign, test ozone emissions, and label their products (Table VI-2). The BP category was broken into two categories – High Emitters and Low Emitters – because of potential differences in certification

costs. A range of initial costs for a single model was obtained from test laboratories currently performing the UL 867 and UL 507 tests and from AHAM, and staff used the mid-points of the cost ranges. The assumptions for the estimates in columns A, B, and C are provided in the footnotes to Table VI-2.

The sum of these costs per model is shown in Column D of Table VI-2. The Total Initial Cost per manufacturer ranges from $14,500 to $51,500 per model. In Column E, the initial costs were annualized, assuming a 5% discount rate over 5 years, to estimate the real cost over the product life. A product life of 5 years is typically used for research activities and equipment, so it is an appropriate time period for air cleaner redesign, testing, and labeling. The Years 1-5, Annualized Initial Cost, shown in Column E of Table VI-2, ranges from $3,300 to $11,900 per model. The actual cost per model for Mechanical devices is expected to be much lower because most manufacturers in this category already have UL certification for electrical safety.

Table VI-2. Initial Certification Costs per Model

A Year 1 Redesign Cost ($/model)	B Year 1 UL Testing ($/model) [a]	C Year 1 UL Labeling ($/model) [b]	D Total Initial Cost ($/model) (A+B+C)	E Years 1-5, Annualized Initial Cost ($/yr) [c]
OG				
20,000	14,000	17,500	51,500	11,900
BP High Emitter				
10,000	12,000	10,000	32,000	7,400
BP Low Emitter				
0	10,000	10,000	20,000	4,600
Mechanical				
0	4,500	10,000	14,500	3,300

Notes:

a. Assumptions: UL ozone test costs for UL 867 Clarification Sec. 37 protocol, at 3 settings, no second units tested.
   OG cost: 2 ozone pre-tests ($2,000 each), plus 1 UL 867 test ($10,000), totals $14,000.
   BP High Emitter: 1 ozone pretest ($2,000), plus 1 UL 867 test ($10,000), totals $12,000.
   BP Low Emitter: 1 UL 867 test ($10,000).
   Mechanical: $4,500 for UL 507 certification, if needed (most are already certified); no ozone tests.

b. OG: estimated range 5,000 - $30,000, midpoint $17,500. BP and mechanical: estimated range $5,000 - $15,000, midpoint $10,000.

c. Total Initial Cost discounted at 5% over Years 1-5. Rounded to the nearest $100.

In Table VI-3a, the potential costs for manufacturers were estimated using the annualized initial costs, plus ongoing costs due to model turnover. Model Turnover Costs in Years 2-5 (Column C) were estimated by assuming 10% of the models on average would be replaced by new models that required testing and labeling only.

Table VI-3a. Typical Costs to Manufacturers

Total Cost per Model			Typical Cost per Manufacturer			
A Year 1 Initial Cost ($/model) (Table VI-2)	**B Years 1-5, Annualized Initial Cost per Model ($/yr) (Table VI-2)**	**C Years 2-5, Model Turnover Cost per Model [a] ($/yr)**	**D Average # of Models per Mfr (Table VI-1)**	**E Years 1-5 Total Cost per Mfr ($) [b] D x (5B+4C)**	**F Annual Average Cost per Mfr ($/yr) (E / 5)**	**G Years 2-5 Total Turnover Cost per Mfr ($) (4xCxD)**
OG						
Small Share						
51,500	11,900	3,200	3	217,000	43,400	38,400
Large Share						
51,500	11,900	3,200	6	434,000	86,800	76,800
BP - High						
Small Share						
32,000	7,400	2,200	3	137,000	27,400	26,400
Large Share						
32,000	7,400	2,200	7	321,000	64,200	61,600
BP - Low						
Small Share						
20,000	4,600	2,000	3	93,000	18,600	24,000
Large Share						
20,000	4,600	2,000	7	217,000	43,400	56,000
Mechanical[c]						
Small Share						
14,500	3,300	1,500	3	68,000	13,600	18,000
Large Share						
14,500	3,300	1,500	8	180,000	36,000	48,000

Notes:

a. Assumption: 10% model turnover per year; only testing and labeling needed. Ongoing costs in Years 2-5 = (B + C from Table VI-2) x 10%. Rounded to nearest $100.
b. Includes annualized costs and ongoing costs. Rounded to nearest $1,000.
c. Most manufacturers of Mechanical devices would experience lower costs because most already have Standard 507 certification.

In addition, Table VI-3a shows the Years 1-5 Total Cost per Manufacturer in Column E for each category of manufacturer. The Years 1-5 Annualized Initial Cost in Column B was multiplied by 5 years, and the Year 2-5 Model Turnover Cost in Column C was multiplied by 4 years. The sum of these two values was then multiplied by the Average Number of Models per

manufacturer in Column D to yield the Years 1-5 Total Cost per Manufacturer in Column E. This value was then divided by 5 years to yield the Annual Average Cost per Manufacturer (Column F).

In general, the estimated Years 1-5 Total Costs per Manufacturer range from $68,000 to $434,000. The total costs are greatest for the OG group, followed in declining order by the BP High Emitter group, the BP Low Emitter Group, and the Mechanical group. As expected, the total costs estimated for the Small Share manufacturers in all categories are about ½ of the total costs of the Large Share manufacturers. These differences are largely due to different costs for redesign and labeling and the number of models to be certified. The estimated Annual Average Cost per Manufacturer ranges from $13,600 to $86,800. To the extent that the manufacturer passes on these costs to the consumer, the impact on the manufacturer will be less than projected here.

Smaller businesses will likely be impacted more by the increased costs for product certification. The Annual Average Cost for Large Share manufacturer was estimated to be about $36,000 to $86,800, as shown in Table VI-3a. These costs are insignificant relative to annual sales for manufacturers in this group, which are estimated to reach $50-120 million worldwide. For Small Share manufacturers, the Annual Average costs were estimated to be about $13,600 to $43,400 per year, while their sales were estimated to be $500,000 or less per year. However, because air cleaners appear to have a profit markup on the order of 40-60% added to their costs, the actual economic impact of the regulation is expected to be relatively insignificant for typical Small Share manufacturers, as well. In addition, the annual costs would decline rapidly after Year 5, reflecting only the ongoing costs from model turnover.

Table VI-3b shows the breakdown of the total initial costs and annual ongoing costs per manufacturer in the 5 years after the regulation is adopted. The total initial cost per manufacturer was calculated by multiplying Years 1-5 Annualized Initial Cost per Model by the Number of Models and by 5 years. The annual ongoing cost per manufacturer was calculated by multiplying Years 2-4 Annual Turnover Costs per Model by the Number of Models. As shown in Column E, the total initial costs for a small business (represented by Small Share Manufacturers) ranged from $50,000 to $179,000, depending on the type of indoor air cleaner. For a typical business (represented by Large Share Manufacturers), the total initial costs ranged from $132,000 to $357,000. As shown in Column F, the total ongoing costs were estimated to range from $5,000 to $10,000 for small businesses, and $12,000 to $19,000 for typical businesses.

The maximum potential impact of certification costs on the profits of manufacturers is shown in Table VI-4. The Annual Sales per Manufacturer (Column B), as estimated above, were multiplied by 0.5, assuming a 50% markup on costs. Next, the Average Annual Cost per Manufacturer (Column D) from Table VI-3a was adjusted for a 40% reduction in taxes to estimate the After-Tax Cost per Manufacturer (Column E). This value was then divided by the annual profits (Column C) to estimate the Percent Decrease in Profitability for each category of manufacturers (Column F).

Table VI-3b. Total Initial and Ongoing Costs per Manufacturer

A Type of Air Cleaner Mfr	B Number of Models per Mfr (Table VI-1)	C Years 1-5, Annualized Initial Cost per Model ($/yr) (Table VI-3a)	D Years 2-5, Annual Turnover Costs per Model ($/yr) (Table VI-3a)	E Years 1-5 Total Annualized Initial Cost per Mfr($) (5xBxC) [a]	F Years 2-5 Annual Turnover Costs per per Mfr ($/yr) [a] (BxD)
OG					
Small Share	3	11,900	3,200	179,000	10,000
Large Share	6	11,900	3,200	357,000	19,000
BP High Emitter					
Small Share	3	7,400	2,200	111,000	7,000
Large Share	7	7,400	2,200	259,000	15,000
BP Low Emitter					
Small Share	3	4,600	2,000	69,000	6,000
Large Share	7	4,600	2,000	161,000	14,000
Mechanical					
Small Share	3	3,300	1,500	50,000	5,000
Large Share	8	3,300	1,500	132,000	12,000

Notes:
a. Rounded to nearest $1,000.

The estimates of maximum decrease in profitability range from 0.1 to 10.4%, as shown in Table VI-4. The weighted average, based on the number of manufacturers in each category, is a 0.6% decrease in profitability. Only two categories have more than a 5% decrease in profitability: the Small Share manufacturers in the OG and BP High Emitter categories are estimated to have maximum profit decreases of about 10% and 7%, respectively. This may produce a potential for significant adverse impact for some Small Share Manufacturers if they are unable to pass the cost increase on to consumers. In conclusion, because of the low (0.6%) estimated average decrease in manufacturer profitability, staff does not expect the regulation to have a significant impact on the long-term profitability of most manufacturers, although there may be short term adverse impacts on some of the Small Share manufacturers to the extent they are unable to pass cost increases on to consumers.

Table VI-4. Potential Impact on Profits of Manufacturers

A Type of Air Cleaner	B Annual Sales per Mfr ($/yr)	C Annual Profits per Mfr ($/yr) (0.5 x B) [a]	D Annual Average Cost per Mfr ($/yr) (Table VI-3a)	E After-Tax Cost per Mfr ($/yr) (0.6 x D) [b]	F % Decrease in Profitability (E/C x 100) [c]
OG					
Small Share	500,000	250,000	43,400	26,000	10.4
Large Share	50,000,000	25,000,000	86,800	52,100	0.2
BP High Emitter					
Small Share	500,000	250,000	27,400	16,400	6.6
Large Share	50,000,000	25,000,000	64,200	38,500	0.2
BP Low Emitter					
Small Share	500,000	250,000	18,600	11,200	4.5
Large Share	50,000,000	25,000,000	43,400	26,000	0.1
Mechanical					
Small Share	500,000	250,000	13,600	8,200	3.3
Large Share	50,000,000	25,000,000	36,000	21,600	0.1
				Weighted Average [d]	**0.6**

Notes:

a. Calculation assumes a 50% retail markup.

b. Calculation assumes that the combined state and federal taxes are at the highest rate of 40%, reducing the after-tax cost to 60% of the pre-tax cost.

c. Rounded to the nearest 0.1%.

d. Calculated by 1) dividing the number of manufacturers in each category of Table VI-2 by 61, the total number of manufacturers, to yield the fraction of all manufacturers for that category of manufacturers; 2) splitting the BP category into 20% High Emitters and 80% Low Emitters; and 3) multiplying this fraction by the % Decrease in Profitability (Column F) for each category, and averaging all categories.

c. Cost to All Manufacturers

In order to estimate the total cost of the regulation for all manufactures combined, the total costs for all types of air cleaners were estimated for Years 1-5 (Table VI-5).

For each category of air cleaner, the Years 1-5 Annualized Cost (Column C) was multiplied by 5 years, and the Year 2-5 Model Turnover Cost per Model (Column D) was multiplied by 4 years. The sum of these two values was then multiplied by the Average Number of Models per category of air cleaner type (Column B). This yields the Years 1-5 Total Industry Costs, shown in Column E. In addition, the BP models were apportioned into two categories: 20% were estimated to be High Emitters, and 80% were estimated to be Low Emitters. This apportionment is based on an estimated number of ionizer and photocatalytic oxidation models with ozone emissions that may exceed the UL 867 limit of 0.05 ppm.

Table VI-5. Total Potential Cost to All Manufacturers, Years 1-5

A Type of Air Cleaner [a]	B # of Models (Table VI-1)	C Year 1 Annualized Cost per Model ($/yr) (Table VI-3a)	D Year 2-5 Model Turnover Cost per Model ($/yr) (Table VI-3a)	E Year 1-5 Total Industry Cost ($), [b] B x (5C+4D)	F Year 1-5 Average Industry Cost ($/yr), [b] (E / 5)
OG	42	11,900	3,200	3,036,600	607,300
BP High Emitter	19	7,400	2,200	870,200	174,000
BP Low Emitter	75	4,600	2,000	2,325,200	465,000
Mechanical	79	3,300	1,500	1,777,500	355,500
TOTAL INDUSTRY COSTS				**8,000,000**	**1,600,000**

Notes:
a. Assumed that 20% of By-Product devices are high emitters, and 80% are low emitters.
b. Rounded to nearest $100. Totals rounded to nearest $100,000

Column E values were divided by 5 to estimate the Years 1-5 Average Industry Cost per Year, as shown in Column F. The Year 1-5 Total Industry Costs based on the sum for all types of air cleaners, was estimated to be $8,000,000. The Total Average Industry Cost is estimated at $1,600,000 per year over the first 5 years (Column F). The annual average would decline rapidly after Year 5 because only the model turnover costs would be a factor.

2. Distributors and Retailers

Economic impacts on distributors and retailers as a whole in California are expected to be insignificant, but may be significant for small distributors and retailers of some OG brands. Some OG manufacturers have indicated that they will provide products that meet California certification requirements, so their distributors and retailers should not be affected significantly unless there is a temporary shortage of product. Some small distributors and retailers may decide to discontinue the sales of these products in California, especially for the Small Share manufacturers of OGs, because the manufacturing cost impacts for OGs are high compared to the other types of air cleaners. For the distributors and retailers of OGs that are 1- or 2-person businesses, impacts from the regulation may be substantial if their manufacturers decide not to certify air cleaners for the California market.

Ozone generators are distributed much differently than BP and Mechanical devices. For example, California survey results indicate that 26% of OG owners report purchasing their unit

from an independent distributor, 24% at a retail store, 19% from the Internet, and 29% from "somewhere else" (primarily "over the phone") (Piazza *et al.*, 2006). In contrast, 64% of BP owners report purchasing their units at a retail store, and 15% report purchasing via the Internet (Piazza *et al.*, 2006). Staff estimate some OG manufacturers sell as much as 80 to 100% of their units through independent distributors.

For BP and Mechanical devices the increased costs to manufacturers are expected to be relatively insignificant, and should not affect distributors and retailers unless there is a temporary shortage of product. In addition, for all types of air cleaners, the proposed sell-through period will allow manufacturers to sell existing inventory or perhaps continue selling it in other states. This sell-through provision would minimize any potential impacts of the regulations on distributors and retailers.

D. Potential Impacts on Consumers

The actual impact of the proposed regulation on consumers will depend on how much the manufacturers pass on their cost increases and profit markup to the consumer via price increases. The lower bound of the potential impacts on consumers would be the case where the manufacturers do not pass on any of the increased costs. This would result in no cost impact to consumers. The upper bound of the potential impact on consumers would be the case where manufacturers pass on all of their cost increases plus a profit markup, as discussed below. However, price increases may lead to reduced sales, which would impact the profitability of the manufacturers, and lead manufacturers to reduce or drop their price increases.

The upper bounds of the potential economic impacts on consumers in California were estimated by calculating the potential impacts on retail prices (Table VI-6). First, the Average Number of Units Sold per Year in California (Column A) was calculated using the 2003-2006 sales data by air cleaner category from the California survey (Piazza *et al.*, 2006) averaged over 3.5 years. The median sales prices in column B also were taken from the California survey. The Average Industry Cost for all manufacturers per year (Column C) for each category was taken from Table VI-5, and adjusted for a 50% profit markup added to the manufacturers' costs (Column D). This adjusted cost was then divided by the Average Number of Units Sold per Year (Column A), to yield the Average Price Increase per Unit (Column E).

The results shown in Table VI-6 indicate that the Average Price Increase per Unit (Column E) would potentially be $11 to $16. This assumes that the manufacturers pass on all of their costs, add a 50% profit markup, and average the cost over 5 years. This price increase of $11 to $16 translates into a Percent Increase in Median Sales Price (Column F) of 5% to 12%. The 5% increase in median sales price for the OG and BP categories does not appear to be a significant impact on the consumer. The 12% increase in median sales price for the Mechanical category appears to be potentially significant; however, many manufacturers of Mechanical air cleaners already have UL certification and would not need to have additional UL electrical safety testing, so their actual price increase would be much less than 12%. Therefore, the actual impact of the proposed regulation is expected to be insignificant to consumers, even if the manufactures pass on their cost and profit markup to the consumer.

The total potential cost to consumers in California, shown in Column G of Table VI-6, is $12,100,000 in the first five years after the regulation is approved. This cost is calculated as the product of the number of units sold per year, the price increase per unit, and 5 years. This cost

also represents the maximum total statewide cost to individuals, assuming that manufacturers pass on all of their costs to consumers and add an estimated 50% profit markup.

Table VI-6. Potential Cost to Consumer

A Avg. # of Units Sold per Year in CA, 2003-2006 (units/yr) [a]	B Median Retail Price ($/unit) [b]	C Average Industry Cost: All Mfrs ($/yr) (Table VI-5) [c]	D Average Industry Cost with 50% Markup ($/yr) [d] (1.5 x C)	E Average Price Increase per Unit ($/unit) [e] (D / A)	F % Increase in Median Retail Price (E/B x 100)	G Total Cost to Consumer, Years 1-5 ($) [f] (5xAxE)
OG						
55,600	300	607,300	911,000	16	5	4,600,000
BP						
74,400	250	639,000	958,500	13	5	4,800,000
Mechanical						
49,900	90	355,500	533,300	11	12	2,700,000
TOTAL						12,100,000

Notes:

a. Based on California data on percent of households buying OG between 2003 and mid-2006, averaged over 3.5 yr (Piazza *et al.*, 2006). Rounded to nearest 100.
b. Based on California data for (Piazza *et al.* 2006).
c. From Table VI-5. For BP devices, the sum of the total costs for BP high & low emitter manufacturers from Table VI-5 is used here to obtain an overall cost for BPs. Rounded to nearest $100.
d. Assumption: 50% profit markup added to manufacturers' cost increases. Rounded to nearest $100.
e. Manufacturers will probably absorb these costs because their customers are price-sensitive and the manufacturers' markup is currently about 40-60%.
f. Cost to consumers represents the total statewide cost to individuals over 5 years. Rounded to the nearest $100,000.

E. Potential Impacts on Employment

Portable air cleaner manufacturers are included in the category of small electrical appliance manufacturing industry (North American Industry Classification System, Code 33521), which includes establishments engaged in manufacturing small electric appliances and electric house wares, household-type fans, household-type vacuum cleaners, and other electric household-type floor care machines. According to the 2006 U. S. Census Bureau (2006a,b), California employment in this industry category was 182 jobs in 2004, or about 2 percent of the national employment in the industry. This also represents only about 0.01 percent of the total manufacturing jobs in California. These employees working in 18 establishments generated about $6,300,000 in payroll, accounting for less than 0.01 percent of total California manufacturing payroll in 2004. Ten establishments had four employees or less; the rest had five or more employees each. These data show that the contribution of industries such as the indoor

air cleaner industry to the California economy is very small, and the proposed regulation would have no significant impact on the economy.

F. Potential Impacts on Business Competitiveness

The proposed regulation would have no noticeable impact on the ability of California manufacturers to compete with manufacturers of similar products in other states. This is because all manufacturers that produce indoor air cleaning devices for sale in California are subject to the proposed regulation regardless of their location. In addition, the proposed regulation is expected to cause a negligible increase in the retail price of indoor air cleaning devices which is unlikely to dampen the demand for these products in California.

G. Potential Impacts on California State or Local Agencies

For FY 2008-9 and FY 2009-10, ARB anticipates that one additional staff position ($125,000) and $50,000 in contract funds will be needed each year for ongoing work to enforce the regulation after approval of the regulation. The total amount needed will be $175,000 per year. This assumes the current ARB estimate of $125,000 per year for an Air Pollution Specialist staff position.

Other state agencies such as the Department of Public Health and local agencies such as local health departments and district attorneys are not expected to be impacted by the proposed regulation.

H. Business Creation, Elimination, or Expansion

The proposed regulation is likely to have a small impact on the status of the manufacturing of indoor air cleaning devices in California. Most manufacturers are located outside of California. Only a few of these manufacturers are based in California: two Large Share manufacturers (Sharper Image and JCS/THG), and two Small Share manufacturers (Aqua Sun Ozone International and Wein Products). It is likely that some of the Small Share manufacturers will drop out of the California market because of the cost associated with the proposed regulation, especially for those OG manufacturers that focus primarily on water purification and only minimally on air purification. Some small distributors and retailers may also decide to discontinue the sales of these products in California. However, we do not expect the impact on California businesses to be significant because indoor air cleaning devices usually account for only a small share of products carried for sale by these businesses, or the products of some manufacturers may already meet UL 867 ozone limits.

Businesses that perform testing and certification for these products, however, may experience an increase in demand for their services.

I. Other Possible Economic Impacts

No other major economic impacts of the regulation are expected. Because the costs to individual manufacturers, distributors, and retailers are estimated to be insignificant or very small, staff does not expect any significant impacts on the number of California jobs or the air cleaner market in California. Two of the Large Share BP manufacturers are based in California

– Sharper Image and JCS/THG – but the impact on their California jobs and market should be insignificant because they have a large worldwide market and their products are manufactured in Asia. One of the Small Share manufacturers of OGs, Aqua Sun Ozone International, is based in California, but because they also manufacture water purification products, the proposed regulation should not force this company out of business.

J. Costs and Benefits of Alternatives to the Regulation

Staff considered three alternatives to the proposed regulation (See subsection II.B). The no-action alternative is not viable because AB 2276 requires ARB to regulate the emissions of ozone from indoor air cleaners, and the health impacts of exposures to high levels of ozone are substantial. The two action alternatives considered by staff are: 1) use a different test method; and 2) allow dual-purpose devices, i.e., those with an optional mode for producing much higher levels of indoor ozone for use in an unoccupied space. Compared to the proposed regulation, the alternative of using a different test method would take more time and ARB staff resources to develop, so it would increase costs to ARB and could result in a failure to meet the legislatively mandated schedule. It also could increase the costs to some manufacturers because many of them already obtain UL 867 certification and would have to switch to another test method. This alternative would not provide any discernible benefit to businesses or consumers.

The dual-purpose device alternative would increase the risk of public exposures to very high levels of indoor ozone, and hence, increase the risk of the resultant health impacts and medical costs. Because a dual-purpose device poses such a substantial health risk, this alternative would require stringent surveillance to prevent misuse of the product. This would increase ARB's costs to enforce the labeling, advertising, and sales provisions of the regulation and to improve consumer education. This alternative would not produce any substantial benefits; ozone treatment for indoor mold or odor problems is already available through commercial services.

VII. Environmental Impacts

A. Summary of Environmental Impacts

The proposed regulation is expected to protect public health by reducing human exposure to, and the health impacts of, ozone from IACD. The proposed regulation is also expected to provide public health benefits by reducing human exposures to chemical reaction products of indoor ozone such as formaldehyde, a known human carcinogen, as well as ultrafine particles and other irritant compounds. In consideration of the data analyses performed herein, staff has determined that no significant adverse environmental impacts should occur as a result of adopting this proposed regulation. This chapter describes the potential impacts that the proposed regulation may have on the environment.

B. Legal Requirements

The California Environmental Quality Act (CEQA) and ARB policy require that an analysis be performed to determine the potential adverse environmental impacts of proposed regulations. To meet this requirement, ARB must assess the extent and severity of reasonably foreseeable environmental impacts, and respond (in writing) to all significant environmental

issues raised in the public review period and at the Board hearing. Presently, ARB's regulatory program is certified by the Secretary of Resources (cf. Public Resources Code §21080.5), which allows ARB to include an environmental analysis in the ISOR instead of preparing an environmental impact report or negative declaration. Written responses to significant environmental issues raised by the public will be included in the Final Statement of Reasons (FSOR) for the proposed regulation. Public Resources Code §21159 requires that the environmental analysis prepared by ARB include analyses of the following "reasonably foreseeable" items:

- Impacts of the methods of compliance.
- Feasible mitigation measures.
- Alternate means of compliance with the proposed regulation.

With respect to mitigation measures, CEQA requires state agencies to identify and adopt feasible mitigation measures that would minimize any significant adverse environmental impacts described in the environmental analysis.

C. Foreseeable Environmental Impacts

1. Reduced Exposure to Ozone and Public Health Impacts

As discussed in Chapter IV.D, staff estimates that over 500,000 Californians are currently exposed routinely to indoor ozone concentrations above the 8-hour CAAQS of 0.070 ppm due to the use of IACD in their homes. Nearly one-third of these persons (161,000) are estimated to be exposed to indoor ozone concentrations of 0.201-0.400 ppm, three to five times greater than the CAAQS. As discussed in Chapter IV.A, controlled exposure studies of healthy and asthmatic human subjects over 1-8 hours have shown that exposure to ozone concentrations of 0.08 ppm or more can produce significant adverse effects on pulmonary function, and causes lung inflammation, tissue damage, and airway hyperresponsiveness. These adverse health effects were observed in substantial fractions of the subjects.

The proposed regulation is expected to reduce indoor ozone exposures from the use of indoor air cleaners to below 0.050 ppm, which is well below the 8-hour CAAQS and the ozone concentrations found to have significant effects in the controlled clinical studies of humans. Therefore, staff expects the proposed regulation to produce a public health benefit by preventing exposures to high concentrations of ozone and the resultant adverse health effects.

2. Other Potential Environmental Impacts

Ozone reacts chemically with terpenes, common fragrance compounds found in cleaning products and deodorants, to produce formaldehyde, a known human carcinogen and Toxic Air Contaminant, as well as ultrafine particles, and other airborne irritant compounds (Nazaroff and Weschler, 2004; Nazaroff *et al.*, 2006). Relatively low levels of indoor ozone (below the CAAQS) can produce indoor levels of these pollutants that may pose a substantial health risk. The proposed regulation would substantially reduce these health risks by greatly reducing ozone emissions from new IACD.

The ozone produced by IACD, and the chemical reaction by-products such as formaldehyde can eventually reach the outdoor air. However, the indoor ozone reacts quickly with indoor surfaces and indoor air pollutants, and the net amount of ozone and formaldehyde

that reaches the outdoor air is quickly diluted to very small concentrations in the outdoor air. Therefore, staff does not expect the proposed regulation to have a significant impact on outdoor air quality.

The proposed regulation does not include any requirements or effects on hazardous waste, water quality, bioaccumulation, or other significant adverse environmental impacts. Therefore, staff does not expect any adverse environmental impacts in these areas of concern.

D. Reasonably Foreseeable Feasible Mitigation Measures

Staff has concluded that no significant adverse environmental impacts would occur from implementing the proposed regulation. Thus, no mitigation measures would be needed.

E. Alternate Means of Compliance

As discussed in Chapters II.C and VI.J above, staff considered but did not recommend any alternate means of compliance. The alternative of using a different test method for ozone emissions is expected to cause a substantial delay and increased cost to business and ARB to develop the proposed regulation. This would result in a delay in achieving the pubic health benefits of the proposed regulation due to reduced ozone emissions and indoor exposures. The other alternate means of compliance was to allow dual-use devices, which produce very high ozone emission concentrations for mold and odor treatment, to be sold in California. This alternate is expected to produce only very limited potential benefits and would not outweigh the possible ozone exposure risks.

F. Environmental Justice

Environmental justice is a core consideration in ARB's efforts to provide clean air for all California communities (ARB, 2001). The proposed regulation, calling for emission concentration limits for ozone from portable indoor air cleaning devices, would not cause significant adverse impacts in any community. Rather, implementation of the proposed regulation would likely reduce exposures to ozone and its toxic by-products in all types of households, including those in low-income areas and ethnically diverse communities. Further, because the estimated increased cost of an air cleaner is $11-16 per unit, impacts on low income consumers are not expected to be significant.

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