



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (cwf)
FOLDER: K023830 - 314 pages
COMPANY: KES SCIENCE & TECHNOLOGY, INC (KESSCIETECH)
PRODUCT: PURIFIER, AIR, ULTRAVIOLET, MEDICAL (FRA)
SUMMARY: Product: AIROCIDE TI02

DATE REQUESTED: Aug 12, 2016

DATE PRINTED: Aug 12, 2016

Note: Printed





FEB 04 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Hayman, Jr.
President
KES Science & Technology, Incorporated
3625 Kennesaw North Industrial Parkway
Kennesaw, Georgia 30144

Re: K023830
Trade/Device Name: AiroCide TiO₂
Regulation Number: 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: II
Product Code: FRA
Dated: November 6, 2003
Received: November 18, 2003

Dear Mr. Hayman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Hayman

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Susan Runner, DDS, MA

Interim Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



Science & Technology, Inc.

3025 Kennessaw North Industrial Pkwy. Kennessaw, GA 30144 USA
PHONE (800) 627-4913 FAX (770) 425-0837 www.kstmst.com

January 31, 2003

Food and Drug Administration
Center for Devices and Radiological Health
(HFZ-308)
Office of Compliance
Information Processing and Office Automation Branch
9200 Corporate Boulevard
Rockville, MD 20850-4015

501(k) Notification

Dear Sir/Madam,

AiroCide TiO₂ INTENDED USE: Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc.

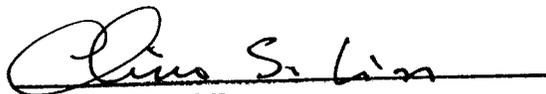
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023830



FEB 04 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Hayman, Jr.
President
KES Science & Technology, Incorporated
3625 Kennesaw North Industrial Parkway
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Sincerely yours,



Susan Runner, DDS, MA

Interim Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

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Center for Devices and

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Enclosure



Science & Technology, Inc.

3020 Kennesaw North Industrial Pkwy. Kennesaw, GA 30144 USA
PHONE (800) 627-4913 FAX (770) 425-0837 www.kesmist.com

January 31, 2003

Food and Drug Administration
Center for Devices and Radiological Health
(HFZ-308)
Office of Compliance
Information Processing and Office Automation Branch
9200 Corporate Boulevard
Rockville, MD 20850-4015

501(k) Notification *K023850*

Dear Sir/Madam,

AiroCide TiO₂ INTENDED USE: Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Chun S. Lim

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: *K023830*

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 18, 2002

KES SCIENCE & TECHNOLOGY, INC
3625 KENNESAW N. INDUSTRIAL PKY
KENNESAW, GA 30144
ATTN: JOHN HAYMAN, JR

510(k) Number: K023830
Received: 18-NOV-2002
Product: AIROCIDE TI02

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

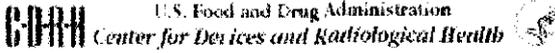
As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

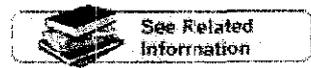
You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health



SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS



510(k) Number: K023830

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate **box**):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

RECEIVED
 2002 NOV 18 P 1:23
 FDA/CDRH/ODE/PMO

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	/	
Table of Contents.	/	
Truthful and Accurate Statement.	/	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	/	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	/	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	/	
Statement of Indications for Use that is on a separate page in the premarket submission.	/	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	/	

<http://www.fda.gov/cdrh/ode/checklist-f102.html>

11/1/2002

5157
 29
 H2
 II

510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	/	
Identification of legally marketed predicate device. *	/	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	/	
Class III Certification and Summary. **	X	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	X	
510(k) Kit Certification ***	X	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):	(no entry here)	(no entry here)
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		

<p>b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.</p>		
<p>c. A Declaration of Conformity with design controls that includes the following statements:</p>		
<p>A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.</p>		
<p>A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.</p>		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
<p>For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)</p>		
<p>For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]</p>		
<p>For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.</p>		
<p>For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data</p>		

will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of

the document.

Passed Screening Yes No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

Uploaded on January 29, 2002

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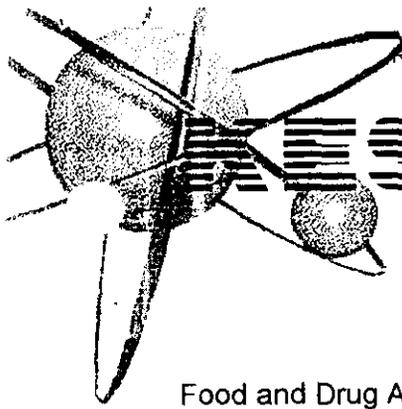
510(k) Overview

Section 510(k) of the Food, Drug and Cosmetic Act requires those device manufacturers who must register to notify FDA, at least 90 days in advance, of their intent to market a medical device. This is known as Premarket Notification - called PMN or 510(k). It allows FDA to determine whether the device is equivalent a device already placed into one of the three classification categories. Thus, "new devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified.

Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.

[Return to 510\(k\) Homepage](#)

(November 15, 1996)



Science & Technology, Inc.

Food and Drug Administration
Center for Devices and Radiological Health
(HFZ-308)
Office of Compliance
Information Processing and Office Automation Branch
9200 Corporate Boulevard
Rockville, MD 20850-4015

501(k) Notification

Dear Sir/Madam,

We understand that if we (KES Science & Technology, Inc.) are to make claims that our Air purifying system ("AiroCide TiO₂" - for photo catalytic removal of airborne pathogens) is suitable for many applications, including helping to protect people in medical settings, then we are required to complete the 510k process. We believe the AiroCide System will list as follows:

Device	Purifier. Air, Ultraviolet, Medical
Product Code	FRA
Device Class	2
510(k) exempt	NO
Regulation Number	880.6500

AiroCide TiO₂ INTENDED USE: Potential applications include removing and mineralizing airborne contaminations of pathogens *and/or harmful molds and volatile organic compounds* present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc. We assume this device would not be a primary defense (we assume that masks or air venting would be primary).

AiroCide CURRENT FIELD TESTING: In addition previously completed laboratory testing, we will be testing an AiroCide unit at the Fulton County, Georgia, Department of Health, in their sputum collection room. We have units currently in place in Erie, PA at the Hamot Medical Center in one of their operating rooms (to see if there is a reduction of CFU's during procedures). We have tested AiroCide in a mold-condemned residence, with positive results (see attached.) We have a registration number from EPA.

HOW THE AiroCide UNIT WORKS:

A) UVGI photons

B) Hydroxyl radicals

The unit pulls in air from the room and passes it through a reactor bed, which contains UVGI (Ultra Violet Germicidal Irradiation) plus Titanium Dioxide (TiO₂), which is a semiconductor photocatalyst. When the catalyst is irradiated with **photons** of less than 385 nm (the UVC light), the band gap energy is exceeded and an electron is promoted from the valence band to the conduction band. This process generates Hydroxyl radicals. **Hydroxyl radicals** and super-oxide ions are highly reactive species that oxidize volatile organic compounds (VOCs) adsorbed on the catalyst surface. They will also kill and decompose adsorbed bioaerosols. The process is referred to as heterogeneous photocatalysis or, more specifically, photocatalytic oxidation (PCO). In our test, the carbon atoms in the pathogens were radioisotope tagged. The Hydroxyl radicals mineralized the organisms (reduced the organics to non organic forms such as H₂O and CO₂). The CO₂ was found to contain the tagged Carbon (this also demonstrates that the catalyst is self cleaning)

Organisms That AiroCide Removes, Kills and/or Mineralizes:

AiroCide has been proven to kill **99.99998 %** of *Bacillus Thuringiensis* spores in one pass through its reactor. (*Bacillus Thuringiensis* is the most similar spore-forming bacterium to *Bacillus Anthracis* on the phylogenetic tree.) It scientifically follows that AiroCide will easily kill weaker or similar spores as well as the vegetative states of most all bacteria found in the areas of proposed application of AiroCide (as noted above in the section of this document "AiroCide INTENDED USE:")

To substantiate our above statement we note the following: According to Pennsylvania State University (W.J. Kowalski, PhD), highly regarded in the US as an expert in bio-terrorism "... To put this in perspective, this organism, in spore form, would require about 50 times the UV dose required to disinfect smallpox, tuberculosis, and *Legionella*. ..."

AiroCide System Description:

The Airocide unit is a 48" x 24" x 4" aluminum box, ETL-listed, which plugs into a standard 110 outlet (456 watt max power consumption). The AiroCide has 52 UVGI 8 watt bulbs and approximately 5 pounds of TiO₂ coated Rasching rings. Each unit processes approximately 15,000 cubic feet in 24 hours and mounts on the wall or ceiling. The only maintenance required is replacing the UVGI bulbs once per year.

We believe there are many uses for our system as it currently is engineered (for reducing airborne pathogens). We have been working with the researchers at the University of Wisconsin and with NASA (it is their technology) to quantify other potential prophylactic applications for our system

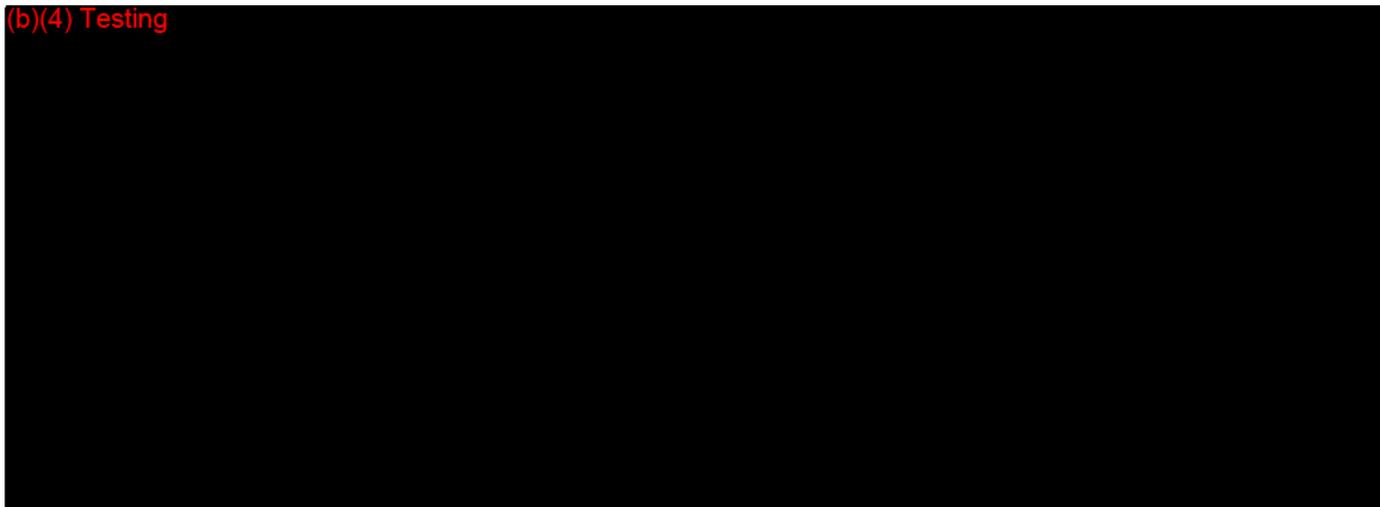
SUBJECT: AiroCide TiO₂

Synopsis: AiroCide TiO₂ utilizes two well-established scientific mechanisms to kill bacteria, mold, fungi, virus, spores, and to break down volatile organic compounds (VOCs). The first killing mechanism is (b)(4) lamps produce this light. These lamps produce billions of UVGI photons. The second killing mechanism is a photocatalytic reaction with TiO₂. This reaction occurs when photocatalytic TiO₂ coated rings are placed around and excited by the UVGI lamps. This photocatalytic reaction produces millions of hydroxyl radicals, which kill and/or mineralize bacteria, etc. These two scientific mechanisms have been proven to be effective pathogen killers by the University of Wisconsin and other University laboratories. In University of Wisconsin testing these two mechanisms demonstrated a 99.99998 % effective kill rate of B. thuringiensis spores (the very robust brother of B. anthrax spores). AiroCide TiO₂ reduces the concentration of bacteria, mold, fungi, spores, etc. in the air. A mold test was conducted in an abandoned trailer in Austin, Texas on May 27, 2002 by Michael A. Bokenkamp Certified Mold Inspector. The test results indicate an 85% reduction in mold spores with only one air turn with an AiroCide TiO₂ Unit.

Please find attached the following:

#1 FDA 2891 and a 2892 application for a new device dated October 29, 2002.

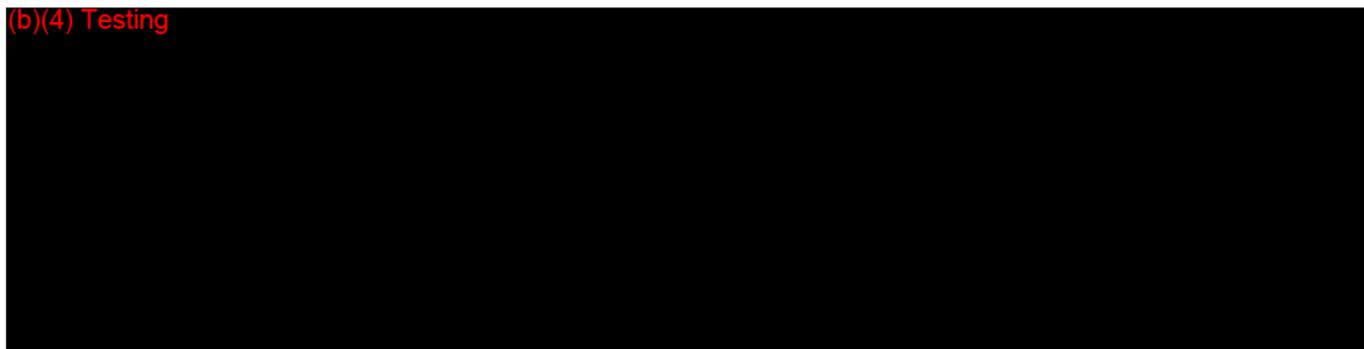
(b)(4) Testing



#5 AiroCide's ETL listing of certified products.

#6 An AiroCide Device Description and Specification sheet.

(b)(4) Testing



(b)(4) Testing

#10 Publication from the National Renewable Energy Laboratory Mineralization of Bacteria Cell Mass on a Photocatalytic Surface in Air from Vol 32 NO. 17 1998 / Environmental Science & Technology showing that E. coli was mineralized by TiO₂ to CO₂ and H₂O.

#11 Overview of Photocatalysis Chemistry

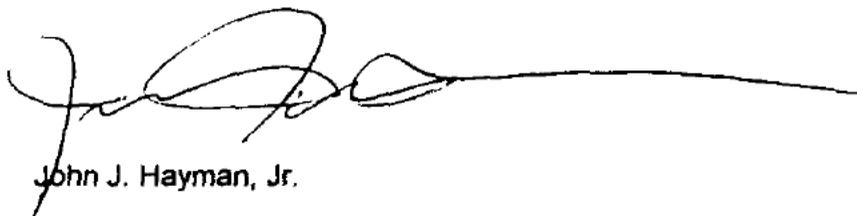
#12 National Renewable Energy Laboratory - Chemistry for Bioenergy Systems Outlines what science researchers have demonstrated regarding photocatalytic reactions. From http://www.nrel.gov/chemistry_bioenergy/chemistry.html

#13 Summary Internet document of Dr. Michael Leung's testing in a hospital operating room "...For comparison, the same test was performed with the photocatalytic converter disconnected. This showed filtration using only the HEPA filter reduced the bacterial count by just 5.4 per cent. Therefore, the immediate disinfection effect of the titanium dioxide filter led to the destruction of 46.6 per cent of airborne bacteria in one pass of air through the air purifier. ..." From <http://www.fhki.org.hk/hki09.htm>

#14 Summary of test data of an AiroCide TiO₂ conducted at the (b)(4) Testing on September 24, 2002 before the AiroCide TiO₂ was turned on and October 15, 2002 when the AiroCide TiO₂ was operating.

Please call or email me with any questions you may have.

Best regards,



John J. Hayman, Jr.

KES Science & Technology, Inc
President
KES Science & Technology, Inc.

Phone: 770-427-6500

Email: president@kesmist.com

www.kes-pro.com PDF files about the testing and operation of the Airocide are available at this site.

CDRH SUBMISSION COVER SHEET

Date of Submission: 11-6-02

FDA Document Number:

Section A		Type of Submission		
PMA Original Submission <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	PMA Supplement <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	PDP <input type="checkbox"/> Presubmission Summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	510(k) Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional Information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Report Amendment	Meeting <input type="checkbox"/> Pre-IDE mtg. <input type="checkbox"/> Pre-PMA mtg. <input type="checkbox"/> Pre-PDP mtg. <input type="checkbox"/> 180-Day mtg. <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	Class II Exemption <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission Describe Submission:

RECEIVED
 2002 NOV 18 P 1:24
 FDA/CDRH/OCE/PMO

Section B Applicant or Sponsor				
Company/Institution Name: <u>KES SCIENCE & TECHNOLOGY, INC.</u>		Establishment registration number:		
Division Name (if applicable):		Phone number (include area code): <u>770-427-6500</u>		
Street Address: <u>3625 KENNESAW NORTH INDUSTRIAL PARKWAY</u>		Fax number (include area code): <u>770-425-0837</u>		
City: <u>KENNESAW</u>	State/Province: <u>GEORGIA</u>	Zip code: <u>30144</u>	Country: <u>USA</u>	
Contact Name: <u>JOHN HAYMAN, JR.</u>				
Contact Title: <u>PRESIDENT</u>		Contact e-mail address: <u>president@kesmist.com</u>		

Section C Submission Correspondent (if different from above)				
Company/Institution Name:		Establishment registration number:		
Division name (if applicable)		Phone number (include area code):		
Street Address:		Fax number (include area code):		
City:	State/Province:	Zip Code:	Country:	
Contact Name:				

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number:

Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name: KES SCIENCE & TECHNOLOGY, INC.		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): 770 427-6500	
Street address: 3625 KENNESAW NORTH INDUSTRIAL PARKWAY		FAX number (include area code): 770 425-0837	
City: KENNESAW	State/Province: GEORGIA	Zip code: 30144-1234	Country: USA
Contact name: JOHN HAYMAN, JR.			
Contact title: PRESIDENT			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution Name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title		Contact e-mail address:	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title		Contact e-mail address:	

Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: <input type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement
1 FRA	2	3	4	
5	6	7	8	

510(k) Number	Trade or Proprietary or model name	Manufacturer
1 9000546	1 BIO-FIGHTER UV LIGHT	1 DUST FREE, INC
2 9031477	2 KLEEN AIR-KING II	2 ADIRONDACK PURIFICATION
3 9034618	3 CAP300 ULTRAVIOLET	3 ABATEMENT TECHNOLOGIES
4 9029939	4 SECOND WIND	4 MONAGAN ENT., INC
5 1648585	5 RX AIR 3000	5 CLEAN AIR RESEARCH & ENV. INC
6	6	6

Section F Product Information - Applicable to All Applications

Common or usual name or classification name:

Trade or proprietary or model name	Model Number
1 Airocide TiO ₂	1 TiO ₂
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: Laboratory Testing Animal Trials Human Trials

Section G Product Classification - Applicable to All Applicants

Product code: FRA	C.F.R. Section 880.6500	Device Class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel:		
Indications (from labeling):		

Section D1

Reason for Submission – PMA,PDP, or HDE

- New Device
- Withdrawal
- Additional or Expanded Indications
- Licensing Agreement
- Change in design, component, or specification:
 - Software
 - Color Additive
 - Material
 - Specifications
 - Other (specify below)
- Location Change:
 - Manufacturer
 - Sterilizer
 - Packager
 - Distributor
- Processing Change:
 - Manufacturing
 - Sterilization
 - Packaging
 - Other (specify below)
- Labeling Change:
 - Indications
 - Instructions
 - Performance Characteristics
 - Shelf Life
 - Trade Name
 - Other (specify below)_
- Report Submission:
 - Annual or Periodic
 - Post Approval Study
 - Adverse Reaction
 - Device Defect
 - Amendment
- Response to FDA correspondence:
 - Request for applicant hold
 - Request for removal of applicant hold
 - Request for extension
 - Request to remove or add manufacturing site
- Change in Ownership
- Change in correspondent
- Other Reason (specify):

Section D2

Reason for Submission - IDE

- New device
- Addition of institution
- Expansion/extension of study
- IRB certification
- Request hearing
- Request waiver
- Termination of study
- Withdrawal of application
- Unanticipated adverse effect
- Notification of emergency use
- Compassionate use request
- Treatment IDE
- Continuing availability request
- Change in:
 - Correspondent
 - Design
 - Informed consent
 - Manufacturer
 - Manufacturing process
 - Protocol – feasibility
 - Protocol – other
 - Sponsor
- Response to FDA letter concerning:
 - Conditional approval
 - Deemed approval
 - Deficient final report
 - Deficient progress report
 - Deficient investigator report
 - Disapproval
 - Request extension for time to respond to FDA
 - Request meeting
- Report Submission:
 - Current investigator
 - Annual progress
 - Site waiver limit reached
 - Final
- Other reason (specify):

Section D3

Reason for Submission – 510(k)

- New Device
- Additional or expanded indications
- Other reason (specify):
- Change in technology
- Change in design
- Change in materials
- Change in manufacturing process

Table of Contents

Form FDA 2892 Device Listing dated November 7, 2002
Form FDA 2891 Initial Registration of Device Establishment

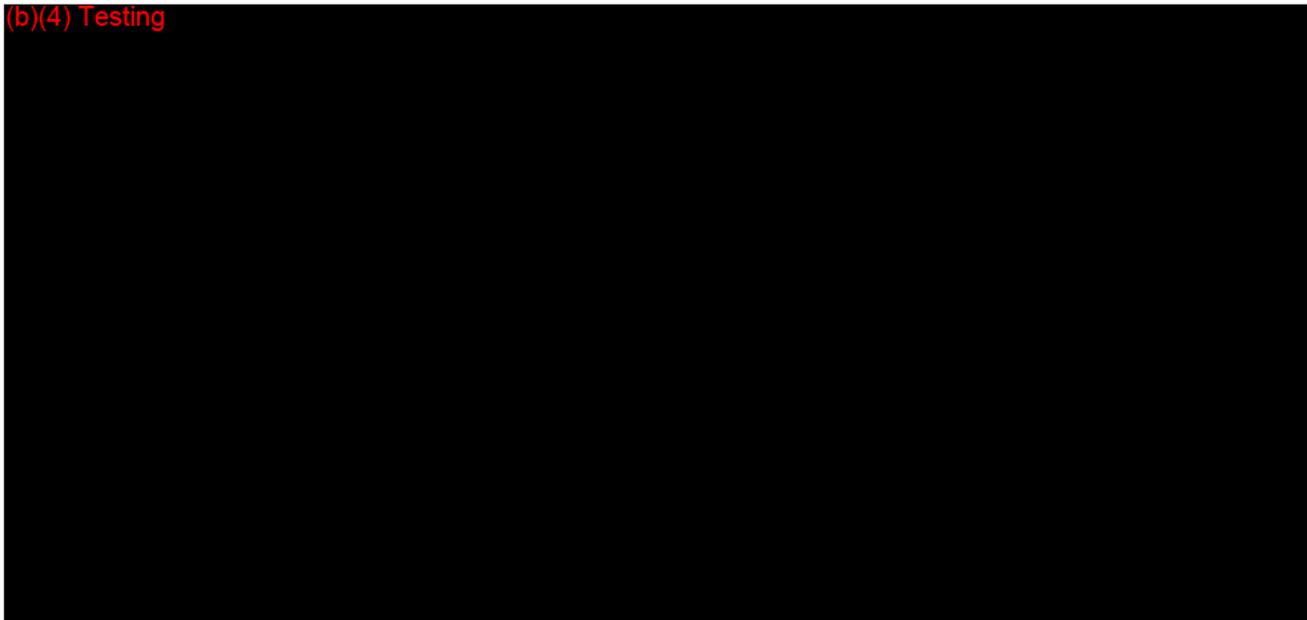
Predicate Devices (for Classification Name-Purifier, Air, Ultraviolet, Medical Device Class 2, Product Code FRA, Regulation 880.6500, Medical Specialty - General Hospital)

- 1-3 Bio-Fighter UV Light
- 4 Kleen Air-King
- 5-9 Cap300
- 10-18 Second Wind
- 19-21 RXAIR3000

Description

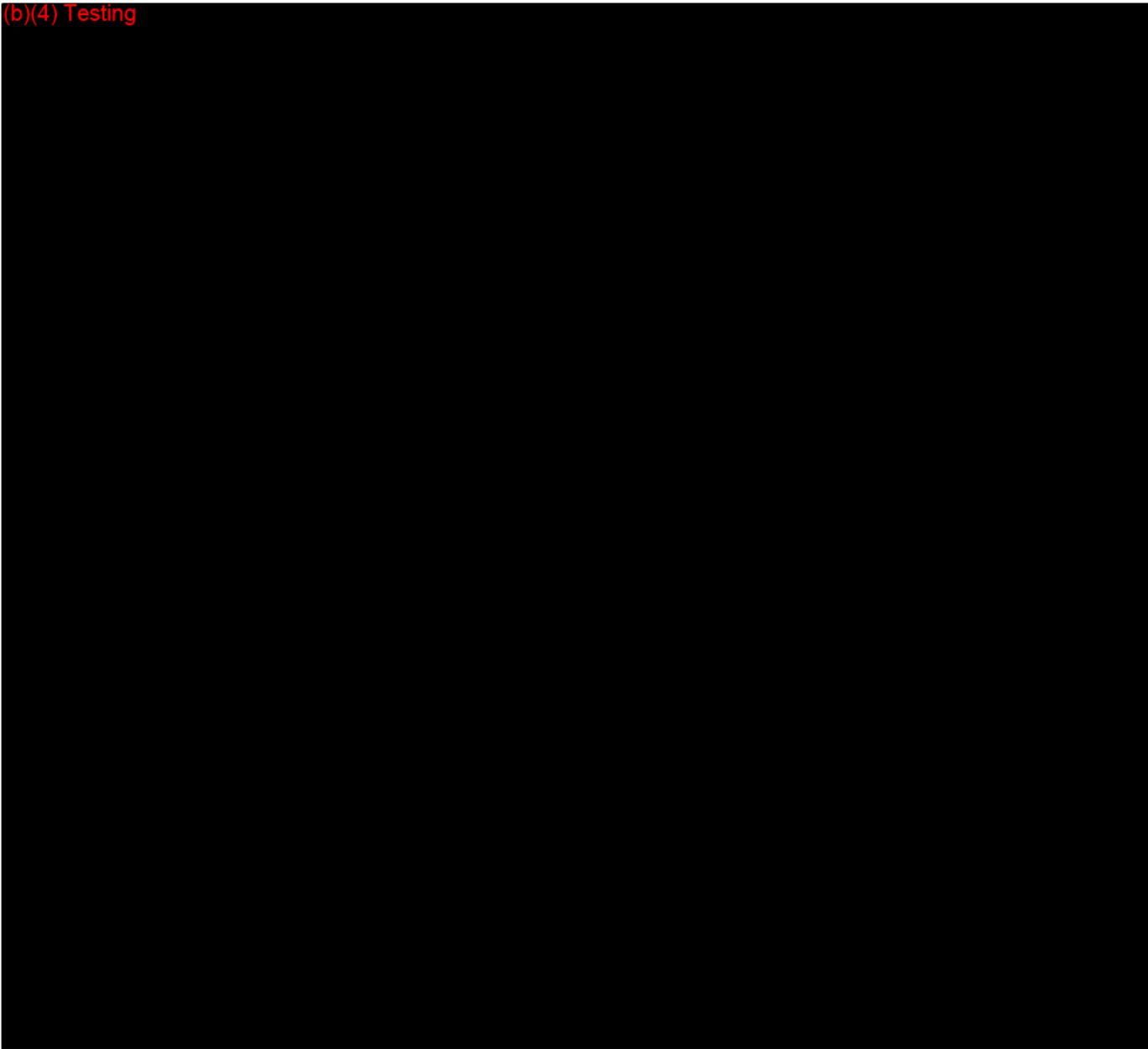
- 22 Indications for Use Form
- 23-26 501(K) notification letter with supporting documents (following)

(b)(4) Testing



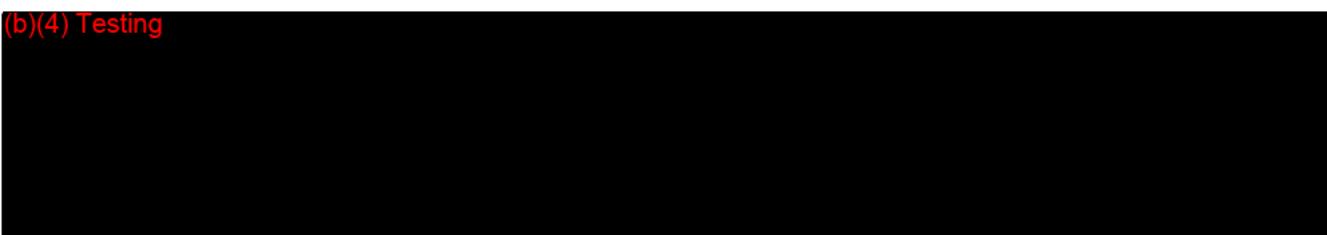
182 An AiroCide Device Description and Specification sheet.

(b)(4) Testing



202-204 Summary Internet document of Dr. Michael Leung's testing in a hospital operating room "...For comparison, the same test was performed with the photocatalytic converter disconnected. This showed filtration using only the HEPA filter reduced the bacterial count by just 5.4 per cent. Therefore, the immediate disinfection effect of the titanium dioxide filter led to the destruction of 46.6 per cent of airborne bacteria in one pass of air through the air purifier. ..." From <http://www.fhki.org.hk/hki09.htm>

(b)(4) Testing



Test Data

- 207 Truth and Accurate Statement
- 208 Pre-market Notification Statement

- 209-254 AiroCide DATA

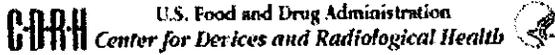
Labeling

- 255 Labels used on AiroCide TiO₂
- 256 ETL Authorization to Mark
- 257-259 Owner's Manual and Installation Instructions (included in shipping carton)

Specifications

- 260

AiroCide's ETL listing of certified products.



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- [CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)

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Device Listing Database

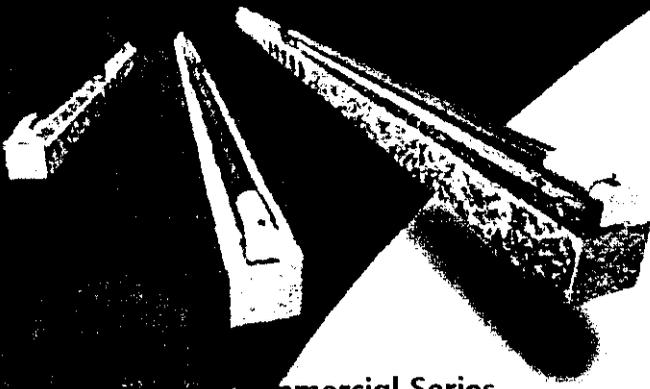
Proprietary Device Name: BIO-FIGHTER UV LIGHT
Common/Generic Device Name: AIR DUCT MOUNTED UV-C LIGHT FIXTURE (VARIOUS MODELS)
Classification Name: PURIFIER, AIR, ULTRAVIOLET, MEDICAL
Device Class: 2
Product Code: FRA
Regulation Number: 880.6500
Medical Specialty: General Hospital
Owner/Operator: DUST FREE, INC.
Owner/Operator Number: 9000546
Registered Establishment Name: DUST FREE, INC.
Establishment Registration Number: 1651838
Date of Listing: 10/12/01
Listing Status: Active
Establishment Operations: Manufacturer

Database Updated 11/5/2002

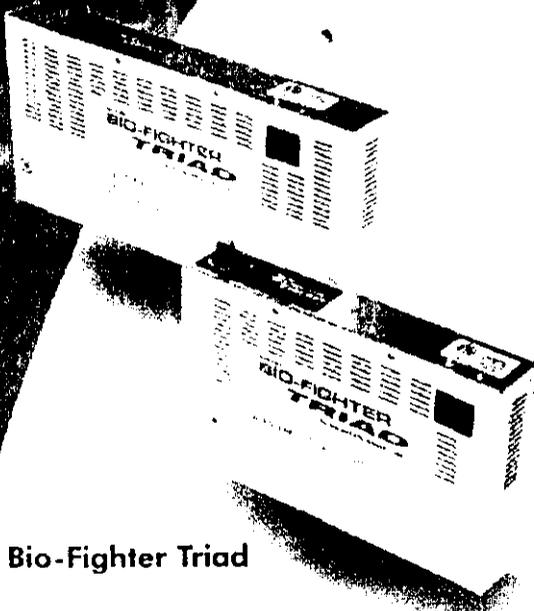
Records processed under FOIA request

BIO-FIGHTER[®]

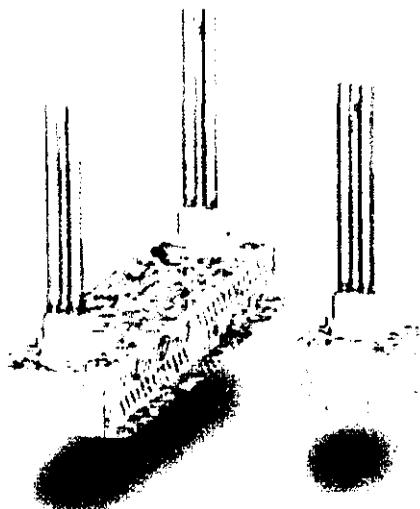
Germicidal Ultraviolet Lights



Commercial Series



Bio-Fighter Triad



Bio-Fighter Nomad 2 & Nomad

A solution for Microbial Contaminants in HVAC systems.

Dirty Socks Syndrome. Sick Building Syndrome. These are some of the names given to mold and bacteria problems in HVAC systems. Germicidal light (UV-C) is a very cost effective method of combatting bacteria, viruses, yeasts, and molds. In fact, UV-C can actually inactivate these microorganisms. The potential benefits are many; increased HVAC coil efficiency, lower maintenance costs, improved indoor air quality, and affordability.

For over 70 years, UV-C has been an effective tool in neutralizing harmful pathogens. Many of the molds, bacteria, and fungi that cause odors and problems in your air handling system, can be decreased with the installation of UV-C light.

Features and Benefits

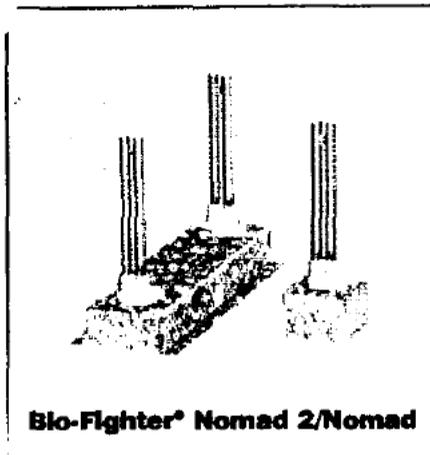
- Medical studies prove the effectiveness of UV-C light.
- Available for residential, commercial, and industrial applications.
- Assists in the prevention of mold growth on HVAC coils, allowing them to operate at peak efficiency.
- Neutralizes many bacteria, viruses, fungi, yeasts, and molds.
- Inexpensive to operate. Only pennies per day.
- High output, long life UV-C bulbs.
- Great for homes, restaurants, offices, hospitals, day care centers, etc.
- Surface/airborne microbial control applications.
- Low maintenance and reduced costs.
- Longest fixtures available on the market.

 **DUST FREE[™]**
www.dustfree.com

BIO-FIGHTER®

Germicidal Ultraviolet Lights

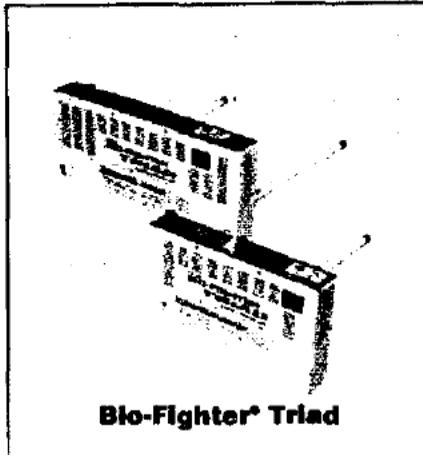
- Nomad/Nomad 2
- Triad
- Commercial Series



Bio-Fighter® Nomad 2/Nomad

The Nomad and Nomad 2 installs almost anywhere inside the HVAC system. Either Nomad model utilizes a high-output tube design in conjunction with a high power ballast to produce increased levels of UV-C energy. An excellent one year warranty on chassis and electrical.

- High-output, low pressure, twin-tube bulb design.
- Perfect for surface microbial control applications.
- Single or dual bulbs.
- 9" or 16" bulb lengths.



Bio-Fighter® Triad

The Triad offers high UV-C output for surface or airborne microbial control applications. Features include dual safety devices to reduce the risk of accidental exposure to UV-C light, improved construction and appearance, limited lifetime warranty, and ETL safety agency listing. The Triad is optionally available with odor reducing bulbs.

- ETL safety agency listing.
- Limited lifetime warranty.
- Single and dual bulb options.
- 16" or 20" bulb lengths.



Bio-Fighter® Commercial Series

The Commercial Series provides a solution for irradiating large commercial cooling coils. Reduce maintenance costs by using one Commercial Series in place of several smaller UV-C fixtures. Available in lengths up to five feet. An excellent one year warranty on chassis and electrical.

- High-output Magnum bulbs.
- Available in lengths up to five feet.
- Multiple fixtures are easily wired in series.
- Polished aluminum reflector increases UV-C radiance.

Part #	Description	Base Dimensions	Weight	Volts	Current (Ma)	Microwatts at 1 meter	Ozone Generation	Average Tube Life
04400	Nomad 9D	3.5"L x 3.5"W x 2.5"H	2.20 lbs.	120/230	380	90	None	9000 Hours
04401	Nomad 16D	7"L x 3.5"W x 3.125"H	3.75 lbs.	120/230	700/450	190	None	9000 Hours
04966	Nomad 2D9	17"L x 5.875"W x 2.125"H	5.35 lbs.	120/230	760	180	None	9000 Hours
04967	Nomad 2D16	17"L x 5.875"W x 2.125"H	7.60 lbs.	120/230	1400/900	380	None	9000 Hours
04404	Triad 1S 16"	6.75"L x 11"W x 2"H	4.50 lbs.	120/230	750	375*	Optional	9000 Hours
04405	Triad 1S 20"	6.75"L x 11"W x 2"H	4.50 lbs.	120/230	750	375*	Optional	9000 Hours
04407	Triad 2S 16"	6.75"L x 14"W x 2"H	6.75 lbs.	120/230	750	750*	Optional	9000 Hours
04408	Triad 2S 20"	6.75"L x 14"W x 2"H	6.75 lbs.	120/230	750	750*	Optional	9000 Hours
04910	Commercial 3ft.	34.125"L x 2"W x 3.16"H	5.90 lbs.	220	800	230	Optional	9000 Hours
04911	Commercial 4ft.	46"L x 2"W x 3.16"H	7.00 lbs.	220	800	320	Optional	9000 Hours
04912	Commercial 5ft.	62.125"L x 2"W x 3.16"H	7.55 lbs.	220	800	380	Optional	9000 Hours

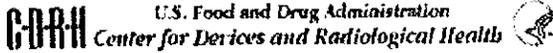
*Microwatt output measured at 12", 50", 24" x 24" duct, 750 CFM.

All specifications subject to change without notice.



PO Box 519
 Royse City, TX 75189
 1-972-635-9564

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3



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Device Listing Database

Proprietary Device Name: KLEEN AIR-KING II (OZONE GENERATOR0

Common/Generic Device Name: KLEEN AIR-KING II (OZONE GENERATOR0

Classification Name: PURIFIER, AIR, ULTRAVIOLET, MEDICAL

Device Class: 2

Product Code: FRA

Regulation Number: 880.6500

Medical Specialty: General Hospital

Owner/Operator: ADIRONDACK PURIFICATION CO., INC.

Owner/Operator Number: 9031477

Registered Establishment Name: ADIRONDACK PURIFICATION CO., INC.

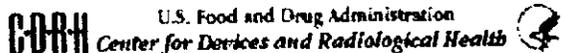
Establishment Registration Number: 1320485

Date of Listing: 08/07/97

Listing Status: Site Tentatively out of business

Establishment Operations: Manufacturer

Database Updated 11/5/2002



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Device Listing Database

Proprietary Device Name: CAP300 ULTRAVIOLIGHT

Common/Generic Device Name: CAP300

Classification Name: PURIFIER, AIR, ULTRAVIOLET, MEDICAL

Device Class: 2

Product Code: FRA

Regulation Number: 880.6500

Medical Specialty: General Hospital

Owner/Operator: ABATEMENT TECHNOLOGIES, LTD.

Owner/Operator Number: 9034618

Registered Establishment Name: ABATEMENT TECHNOLOGIES, LTD.

Establishment Registration Number: 3000135138

Date of Listing: 03/12/01

Listing Status: Active

Establishment Operations: Manufacturer

Database Updated 11/5/2002

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Two Steps for Better IAQ	Central Air Purifier Technologies	Central Air Purifier Products	FAQ	How to Purchase Central Air Purifiers	Home
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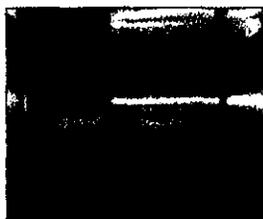
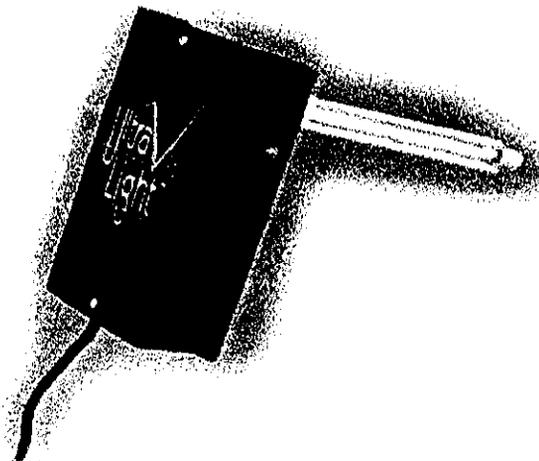
Central Air Purifiers

CAP300 UltraViolight™ Plus CENTRAL AIR PURIFIER

The UltraViolight Plus™ Central Air Purifier (CAP300-UVP1) is primarily designed for use in homes with microbial growth, VOC, humidity, moisture, or odor problems. Since this system does not provide particulate filtration, it is the perfect choice for homes that already have an upgraded HVAC particulate filtration unit such as the CAP100 or CAP100BP, or a competitive model. The UltraViolight Plus™ system features the same UV Plus lamp (germicidal UV and photolysis) used in the CAP100-UVP model.

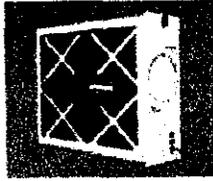
Place your mouse over arrows below for more information on each feature.

- ▶ Illuminated On/Off Switch
- ▶ High Output Lamp
- ▶ Easy Installation
- ▶ Safety First
- ▶ Full Duct Coverage
- ▶ Electrical Enclosure
- ▶ Lamp Mounting Gasket



The extra long lamp provides full duct coverage.

Go to CAP100 SERIES



CLICK HERE

Go To CAP600 Series



CLICK HERE

Two Steps for Better IAQ | CAP Technologies | CAP Products
CAP100 Series | CAP300 Series | CAP600 Series
FAQ | How to Purchase CAP Products | CAP Home



Two Steps for Better IAQ	Central Air Purifier Technologies	Central Air Purifier Products	FAQ	How to Purchase Central Air Purifiers	Home
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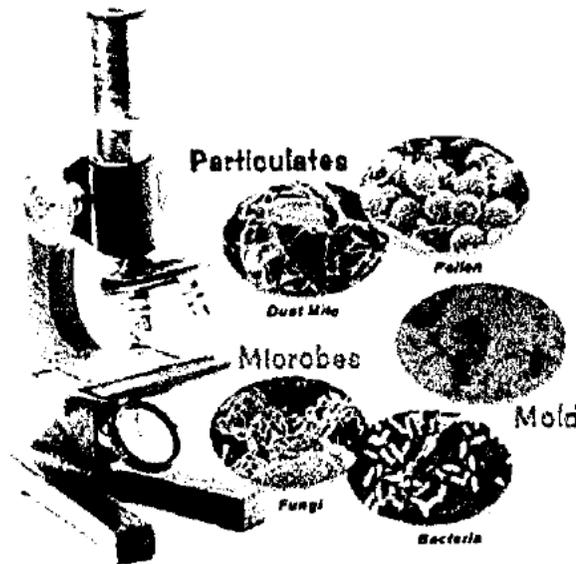
Central Air Purifiers

Central Air Purifiers

CAP TECHNOLOGIES

Each CAP model incorporates one or more of the following air purification technologies:

- Particulate filtration
- Odor and gas adsorption
- Ultraviolet germicidal irradiation (UVGI)
- Photolysis



Particulate Filtration

Particulate matter in indoor air exists in a wide range of particle sizes. Large, visible particles are most easily trapped by most filter media. These particles are too large to be respirable (breathed into the lungs), and are more of a housekeeping problem than a health threat, as they tend to drop out of the air and accumulate on surfaces. CAP100 series models utilize much higher efficiency particulate filters, designed to capture smaller (1 to 25 micron) particles which can pass right through most furnace filters, such as soot, very fine dust, dust mite and insect remains, pet dander, and pollens. The true HEPA (High Efficiency Particulate Air) filters in the CAP600 models, certified to a minimum efficiency of 99.97% at 0.3 microns, effectively capture even smaller microscopic particles and biological pollutants, such as tobacco smoke, bacteria, viruses, and mold and fungal spores.

Carbon Adsorption

Activated carbon filters are utilized in CAP600 series models to eliminate or reduce airborne gases and odors. This is done via a process known as adsorption, whereby the gaseous molecules of the contaminants are attracted to and chemically bond to the surface of the carbon. The amount of carbon required and the life of the carbon filter are determined by the concentration of gases and odors in the home. A special woven carbon filter media is typically sufficient for the light or moderate odor levels found in most homes. Heavy-duty granular carbon filters are available for homes with higher concentrations of odors from pets, cooking, or smokers. Special "triple blend" filters are available for removing certain gases and odors that are less effectively adsorbed by carbon.

Ultraviolet Germicidal Irradiation

Ultraviolet germicidal irradiation (UVGI) is a part of the spectrum of

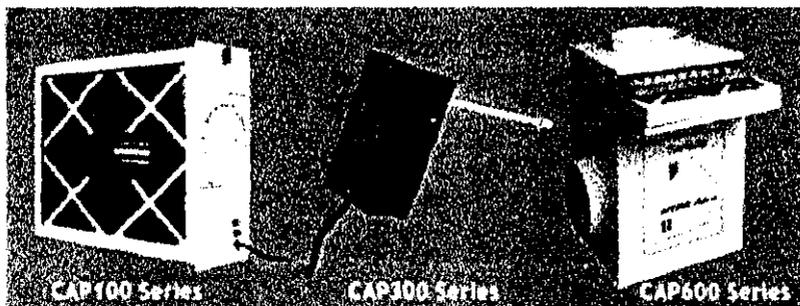
electromagnetic energy generated by the sun. UVGI can also be generated artificially with specially designed germicidal UV lamps. UVGI lamps have been used for more than 40 years to disinfect air in hospitals, and to reduce bacterial contamination in food storage and pharmaceutical facilities. UVGI "kills" microorganisms by destroying their DNA, and is most effective against bacteria and viruses. Now this proven microbial control technology is available for the residential market. All three CAP product series include models equipped with special UV Plus lamps that emit high output UVGI.

Photolysis

Molds, fungi, and other organisms are typically much more resistant to germicidal UV than bacteria and viruses, often requiring up to 100 times more exposure for an effective "kill" rate. The unique UV Plus lamps therefore also generate UV energy in a second wavelength range to produce a controlled amount of trivalent oxygen - also known as ozone - via a chemical oxidation reaction known as photolysis. Ozone is used throughout the world for numerous air and water purification and deodorization applications, such as purifying the bottled water we drink. This powerful oxidizer breaks down unpleasant odors, and provides increased effectiveness against molds and mold products.

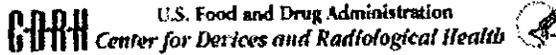
The return duct installation of CAP products also enables ozone to be used both safely and effectively. By utilizing the HVAC system as the "oxidation chamber", ozone can penetrate into the coil, drain pan, and other downstream system components that are particularly susceptible to mold and fungal growth without elevating ozone levels within the occupied living space.

Central Air Purification
Family of Products



[CLICK HERE](#)

Two Steps for Better IAQ | CAP Technologies | CAP Products
CAP100 Series | CAP300 Series | CAP600 Series
FAQ | How to Purchase CAP Products | CAP Home



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Device Listing Database

Proprietary Device Name: SECOND WIND
Common/Generic Device Name: SECOND WIND PINNACLE AIR PURIFIER; NOBLE AIR PURIFIER
Classification Name: PURIFIER, AIR, ULTRAVIOLET, MEDICAL
Device Class: 2
Product Code: FRA
Regulation Number: 880.6500
Medical Specialty: General Hospital
Owner/Operator: SELECT DESIGN LTD.
Owner/Operator Number: 9029939
Registered Establishment Name: MONAGAN ENT., INC.
Establishment Registration Number: 1320726
Date of Listing: 03/26/97
Listing Status: Active
Establishment Operations: Manufacturer, Specification Developer

Database Updated 11/5/2002



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1999

Mr. George C. Monagan
President
Monagan Enterprises, Incorporated
14247 Ridge Road
Albion, New York 14411

Re: K980745
Trade Name: First Breathe and Second Wind Air Purifier,
Ultraviolet HVAC Mounted
Regulatory Class: II
Product Code: FRA
Dated: January 9, 1999
Received: January 14 1999

Dear Mr. Monagan

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

Page 2 - Mr. Monagan

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K980745

Device Name: Second Wind Air Purifier/First Breath Air Purifier

*Ultraviolet
HVAC mounted*

Indications For Use

The Second Wind Air Purifier was designed to be used in an HVAC system, to improve the indoor air quality. The Second Wind air purifier is recommended to be used in conjunction with a media filter, humidifying device, proper controls to run the fan and the sealing of any ductwork.

The Second Wind air purifier may be, but not necessarily used in conjunction with a complete IAQ package. The use is for anyone concerned with his or her indoor air quality.

The unit is easily installed within the forced air furnace and/or the air movement device within a home or business.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(per 21 CFR 801.109)

Chun S. Lin
OR
(Division Sign-Off)

Over-The-Counter Use X

Division of Dental, Infection Control,
and General Hospital Devices

(Optional Format 1-2-96)

510(k) Number K 980745

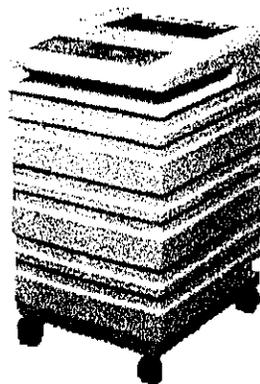


Model 3000

- Application** **Portable Air Purifier**
- Controls** **Manual**
- Air Flow** **600 to 800 CFM**
- Recommended Room size** **4,000 to 4,800 cubic feet**
- Efficiency** **To 99.99% @ 0.3 Microns**
- Power** **3.1 amps @ 110 volts 60 hz s/p**
- Dimensions** **21" W x 24" L x 35" H**
- Weight** **86 lbs.**
- Shipping Dimensions** **23" W x 26" x L 33" H**
- Shipping Weight approx.** **100 lbs.**

Specifications subject to change without notice.

3000m Manual
 Adobe acrobat format .pdf
 "approx download time 1 min at 28800"



Clean Air Research & Environmental Inc.
3227 Commander Drive - suite 101 - Carrollton, Texas 75006 - Phone (972) 233 2777 - Fax: (972) 233 0533

[Home](#)

sales@rxair.com



Air the way it was meant to be.....

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Photo-Catalytic Oxidation (PCO) The Technology

In order to fully understand PCO, we must first learn a little about the metal catalyst involved, Titanium in this case. Titanium has been stated as being a light, strong, and anti-corrosive. These characteristics are largely due to its unique, very thin barrier layer of oxidized film on its surface. This invisible surface layer, Titanium Oxide (TiO₂), is quite remarkable in the fact that it will if scratched or damaged, immediately restore itself in the presence of air or water. The TiO₂ film layer also has a high refraction ratio and when it is irradiated by UV light of less than 385nm, the band gap energy (the level of energy photons needed to be able to free electrons from their atomic bonds) is exceeded. What is created are electron/hole pairs, hydroxyl radicals (OH), thus attracting molecules, i.e. volatile organic compounds and bioaerosols, to the catalyst Titanium. The contaminants are oxidized by the reaction that takes place during the process due to the fact that the OH radicals need to attach themselves to something, and when they do they oxidize it to CO₂ and H₂O primarily.

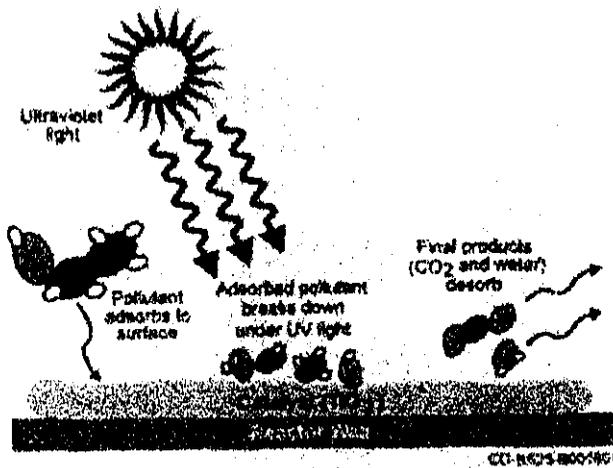


Diagram of the POC Process

A good analogy to think of when you are pondering the concept is electronic air cleaners. Electronic air cleaners work by charging the large dust particles passing through them with an electronic charge, either positive or negative. The particles are then collected on oppositely charged metal plates. With PCO, after the VOC's and bioaerosols are attracted to the titanium, they are come into contact with the OH radicals which change the contaminants molecular structure. PCO will kill and decompose absorbed bioaerosols, as well as toxic VOC's and the odors they produce.

As can be seen from these charts the oxidation power of OH radicals is second only to that of fluorine. Looking at the oxidation power of ozone we can determine that it is not as powerful an oxidant as singlet oxygen or OH radicals. Therefore an ozone generator, though a good method of oxidizing VOC's, is not as effective as singlet oxygen 1.78 or OH radicals 2.06 in oxidizing contaminants.

Advantages of Photo-Catalytic Oxidation

- ☉ High destruction efficiencies at room temperatures
- ☉ No chemical additives
- ☉ No residual ozone
- ☉ High oxidation yields for gas phase reactants and odors.
- ☉ Low energy requirements
- ☉ Complete oxidation of organics to CO₂ & H₂O is possible (VOC's and bioaerosols)
- ☉ Applies to a large number of organics (VOC's and bioaerosols)
- ☉ Works in humid conditions
- ☉ Long service life
- ☉ Low maintenance requirements
- ☉ Negligible pressure drop in duct system
- ☉ Low system cost
- ☉ Easy to install

Now that PCO technology can be integrated into new and existing heating, air conditioning, and ventilating systems everyone (even the most chemically sensitive) have an effective process for removing and destroying low-level indoor air pollutants including mold, bacteria, viruses, and fungi.

There have been numerous scientific studies, research and applications using PCO technology. The following are a few excerpts from some:

"One effective method to destroy dilute concentrations of organic and chlorinated organic pollutants in air is heterogeneous POC, which uses a semiconductor catalyst such as TiO₂ and near-UV radiation to decompose contaminants..." The large number and variety of chemicals successfully treated by PCO indicates potentially broad range of application."

John L. Falconer, Ph.D. Professor of Chemical Engineering Univ. of Colorado, Ph.D (Chemical Engineering), Stanford University 1974, B.E.S. (Chemical Engineering), The John Hopkins University, (1967)

"Photocatalysts for the destruction of indoor air pollutants, including VOC's and gaseous inorganic pollutants such as nitrous oxides, carbon monoxide, and hydrogen cyanide..." (Heller 1996). "Report test show the technology capable of rapidly destroying toxic components of tobacco smoke such as formaldehyde, acrolein and benzene." Taken from the American Lung Association webpage January 24, 2001

"...The PCO technique destroys pollutants in both air and water..."
NREL National Renewable Energy Laboratory

"...Carbon 13 labeled ethanol (CH₃(¹³C)H₂O) was absorbed on the catalyst and photocatalytically oxidized..."
Darrin S. Muggli; Sheldon A. Larson; John L. Falconer Journal of Chemistry 1996

"...The purpose of this study is to investigate the purification of air emissions contaminated with toluene via the heterogeneous photocatalytic oxidation (PCO) process..." "...Experimental results indicated that near to 100% conversion ratios of toluene are achieved for the initial 30-minute reaction period..."
Chung-Hsuang Hung Photocatalytic Decomposition of Toluene Under Various volatile organic compounds temperatures.

"...Photocatalytic oxidation (PCO), a relatively new technology, shows promise for economically controlling hazardous air pollutants and volatile organic compounds from smaller sources, such as waste water treatment plants, dry cleaning facilities, painting facilities, carbon regeneration plants, air-stripping towers, soil venting processes, hazardous waste incinerators, and municipal landfills..."
Melanie Louise Sattler, Method for Predicting Photocatalytic Oxidation Rates of Organic Compounds

"...Potential applications for using titania-based materials as photocatalysts include...Destroying volatile organic compounds (trichloroethylene, benzene, formaldehyde, etc.). Reducing air pollution in homes and industries such as dry-cleaners, painting booths, and printers..."
Marc A Anderson, Professor Water Chemistry Program and Material Science, University of Wisconsin

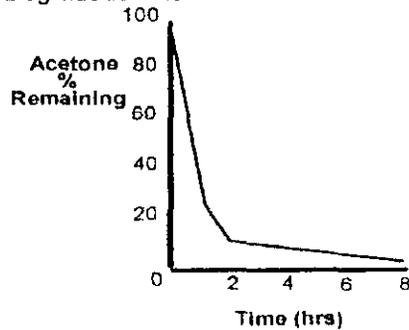
"...In addition to automobile exhaust cleaning, use of environmental catalysts such as titanium oxide photocatalysts

is rapidly growing for control of residential environments, e.g., antimicrobial activity and odor control..."
Katsunori Yogo, Masamichi Ishikawa, Interdisciplinary Department, Frontier Science Institute, Mitsubishi Research Institute, Inc.

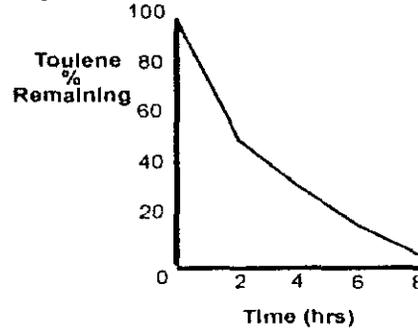
"...Titanium dioxide is therefore applied for deodorizing, by decomposing substances causing bad odor, and for prevention of air pollution by absorbing and oxidizing..."
Japan Chemical Week, August 26, 1999

Those are just a few examples of the vast research that has been and is being done on PCO technology, including Second Wind's own testing recently completed at the IAQ labs of the University at Waterloo on our own photocatalytic air purifiers. Please view the dramatic results of our testing on the following page.

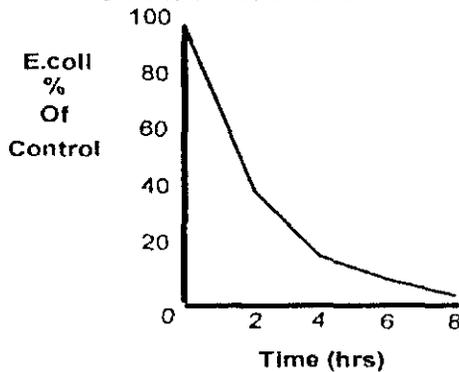
Degradation Kinetics of Acetone in UV



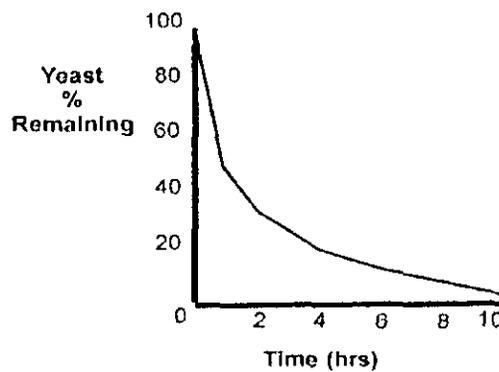
Degradation Kinetics of Toulene in UV



UV Inactivation of E.coli



UV Inactivation of Yeast

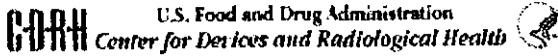


All of the information on these pages can be obtained for more in depth study. All references and test data are available on request.

COMPARATIVE SUMMARY OF AIR CLEANING TECHNOLOGY

	Second Wind PCO	Active Carbon Filter	HEPA Filter	Air Ozonation	Chemical Biocide	High Energy UV	Electro-static Filter
--	-----------------	----------------------	-------------	---------------	------------------	----------------	-----------------------

Captures Microorganisms	X	X	X				X
Destroys Microorganisms	X			X	X	X	
Creates No Hazardous Waste Products	X						
Generates no Ozone	X	X	X		X		
Captures High Molecular Weight VOCs	X	X					
Captures Low Molecular Weight VOCs	X					X	
Destroys High Molecular Weight VOCs	X			X		X	
Destroys High Molecular Weight VOCs	X						
Unlimited Capacity	X			X		X	X
Eliminates Organic Odors	X	X		X			
Low Pressure Drop	X			X	X	X	X
Low Maintenance Cost	X			X			X
Low Operating Cost	X			X			X



[510 \(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NIIRIC](#) | [Guidance](#) | [Standards](#)

Prototype - for testing only

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Device Listing Database

Proprietary Device Name: RXAIR 3000
Common/Generic Device Name: RXAIR 3000
Classification Name: PURIFIER, AIR, ULTRAVIOLET, MEDICAL
Device Class: 2
Product Code: FRA
Regulation Number: 880.6500
Medical Specialty: General Hospital
Owner/Operator: CLEAN AIR RESEARCH & ENVIRONMENTAL, INC.
Owner/Operator Number: 9011073
Registered Establishment Name: CLEAN AIR RESEARCH & ENVIRONMENTAL, INC.
Establishment Registration Number: 1648585
Date of Listing: 03/25/96
Listing Status: Active
Establishment Operations: Manufacturer

Database Updated 11/5/2002

1.1 General Description

Intended Use

The RxAIR is designed to circulate room air through the patented multistage HEPA filter to remove microbial airborne particulate. Contaminated air is therefore continuously purified by passing through the RxAIR filter. Twelve air changes per hour are easily achieved in an 18 ft x 20 ft room resulting in a continuous cleansing or “washing” of the room air. This is analogous to hand washing's effect on skin contamination and helps to control airborne particulates.

The effectiveness of the device is dependent upon room parameters such as room size, central heat and air, doors, windows, etc. Clean Air Research & Engineering consultants are available for detailed analysis of room parameters. As a general rule it is necessary to keep windows and doors closed for maximum effectiveness of the RxAIR unit.

The RxAIR is easily utilized in any room where air cleansing is desired, such as offices, classrooms, health care rooms, waiting rooms, and day care facilities. The technical support staff at RxAIR is available for consultation and support.

2.1 Controls and Indicators

Power Switch

Press to turn the unit on or off.

Blower Switch

Press to alternately select Hi or Low blower speeds.

On Indicator

HI / LOW Blower Indicators

Replace UV Bulb Indicator

Illuminates when the UV bulb requires replacement. See maintenance section.

Replace Filter Indicator

Illuminates when the filter requires replacement. See maintenance section.

6.1 Performance Specifications:

General

Filter	5 stage combination HEPA with UV
Air Changes per Hour	12 @ 4,000 cubic feet
Air Flow in C.F.M	48,000 on Hi / 36,000 on Low
Dimensions	21" W x 24" L x 35" H
Weight	84 lbs.
Chassis	Polyethylene
AC Power Requirements	110-125 volts RMS AC 3.5 amps

HEPA filter

- { **Certified HEPA filter- Minimum efficiency of 99.99% on 0.3 micron particles**
- { **Five stage filtration consists of:**
- { **1. External prefilter**
- { **2. Germistatic prefilter**
- { **3. RxTrete electrostatic prefilter**
- { **4. HEPA**
- { **5. Charcoal absorber**

UV-C Germicidal ultraviolet lamp

- { **8 watts**
- { **12" overall length**
- { **Ozone free quartz envelope**

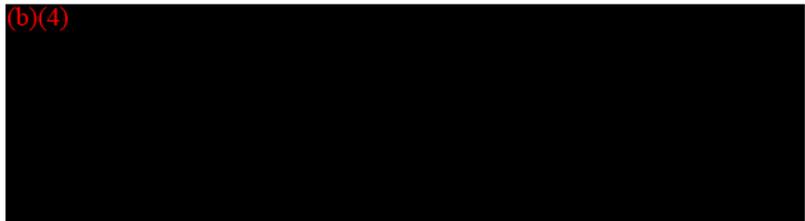
Safety

- { **AAMI Risk Currents: 0.1 ohms chassis to power ground connection, less than 100ua RMS measured from chassis to ground through standard AAMI load with AC power applied.**

Environmental Characteristics

- { **Operating Temperature:**
- { **Operating Humidity:**
- { **Storage Temperature:**
- { **Storage Humidity:**
- { **Operating Altitude:**

(b)(4)



Page 1 of 1

510(k) Number (if known): Ke23830

Device Name: AIROCIDE TiO₂

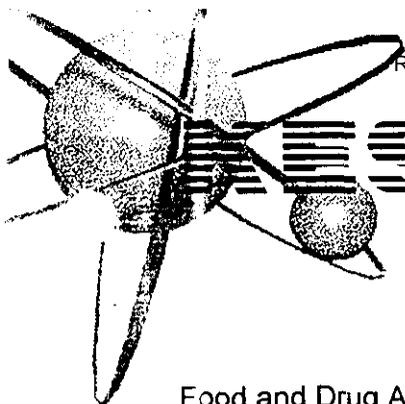
Indications For Use:

AiroCide TiO₂ INTENDED USE: Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc. We assume this device would not be a primary defense (we assume that masks or air venting would be primary).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)



Science & Technology, Inc.

Food and Drug Administration
Center for Devices and Radiological Health
(HFZ-308)
Office of Compliance
Information Processing and Office Automation Branch
9200 Corporate Boulevard
Rockville, MD 20850-4015

501(k) Notification

Dear Sir/Madam,

We understand that if we (KES Science & Technology, Inc.) are to make claims that our Air purifying system ("AiroCide TiO₂" - for photo catalytic removal of airborne pathogens) is suitable for many applications, including helping to protect people in medical settings, then we are required to complete the 510k process. We believe the AiroCide System will list as follows:

Device	Purifier. Air, Ultraviolet, Medical
Product Code	FRA
Device Class	2
510(k) exempt	NO
Regulation Number	880.6500

AiroCide TiO₂ INTENDED USE: Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc. We assume this device would not be a primary defense (we assume that masks or air venting would be primary).

AiroCide CURRENT FIELD TESTING: In addition previously completed laboratory testing, we will be testing an AiroCide unit at the Fulton County, Georgia, Department of Health, in their sputum collection room. We have units currently in place in Erie, PA at the Hamot Medical Center in one of their operating rooms (to see if there is a reduction of CFU's during procedures). We have tested AiroCide in a mold-condemned residence, with positive results (see attached.) We have a registration number from EPA.

HOW THE AiroCide UNIT WORKS:

A) UVGI photons

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B) Hydroxyl radicals

The unit pulls in air from the room and passes it through a reactor bed, which contains UVGI (Ultra Violet Germicidal Irradiation) plus Titanium Dioxide (TiO₂), which is a semiconductor photocatalyst. When the catalyst is irradiated with photons of less than 385 nm (the UVC light), the band gap energy is exceeded and an electron is promoted from the valence band to the conduction band. This process generates Hydroxyl radicals. Hydroxyl radicals and super-oxide ions are highly reactive species that oxidize volatile organic compounds (VOCs) adsorbed on the catalyst surface. They will also kill and decompose adsorbed bioaerosols. The process is referred to as heterogeneous photocatalysis or, more specifically, photocatalytic oxidation (PCO). In our test, the carbon atoms in the pathogens were radioisotope tagged. The Hydroxyl radicals mineralized the organisms (reduced the organics to non organic forms such as H₂O and CO₂). The CO₂ was found to contain the tagged Carbon (this also demonstrates that the catalyst is self cleaning)

Organisms That AiroCide Removes, Kills and/or Mineralizes:

AiroCide has been proven to kill 99.99998 % of *Bacillus Thuringiensis* spores in one pass through its reactor. (*Bacillus Thuringiensis* is the most similar spore-forming bacterium to *Bacillus Anthracis* on the phylogenic tree.) It scientifically follows that AiroCide will easily kill weaker or similar spores as well as the vegetative states of most all bacteria found in the areas of proposed application of AiroCide (as noted above in the section of this document "AiroCide INTENDED USE:")

To substantiate our above statement we note the following: According to Pennsylvania State University (W.J. Kowalski, PhD), highly regarded in the US as an expert in bio-terrorism "... To put this in perspective, this organism, in spore form, would require about 50 times the UV dose required to disinfect smallpox, tuberculosis, and *Legionella*. ..."

AiroCide System Description:

The Airocide unit is a 48" x 24" x 4" aluminum box, ETL-listed, which plugs into a standard 110 outlet (456 watt max power consumption). The AiroCide has 52 UVGI 8 watt bulbs and approximately 5 pounds of TiO₂ coated Rasching rings. Each unit processes approximately 15,000 cubic feet in 24 hours and mounts on the wall or ceiling. The only maintenance required is replacing the UVGI bulbs once per year.

We believe there are many uses for our system as it currently is engineered (for reducing airborne pathogens). We have been working with the researchers at the University of Wisconsin and with NASA (it is their technology) to quantify other potential prophylactic applications for our system

SUBJECT: AiroCide TiO₂

Synopsis: AiroCide TiO₂ utilizes two well-established scientific mechanisms to kill bacteria, mold, fungi, virus, spores, and to break down volatile organic compounds (VOCs). The first killing mechanism is (b)(4) lamps produce this light. These lamps produce billions of UVGI photons. The second killing mechanism is a photocatalytic reaction with TiO₂. This reaction occurs when photocatalytic TiO₂ coated rings are placed around and excited by the UVGI lamps. This photocatalytic reaction produces millions of hydroxyl radicals, which kill and/or mineralize bacteria, etc. These two scientific mechanisms have been proven to be effective pathogen killers by the University of Wisconsin and other University laboratories. In University of Wisconsin testing these two mechanisms demonstrated a 99.99998 % effective kill rate of *B. thuringiensis* spores (the very robust brother of *B. anthracis* spores). AiroCide TiO₂ reduces the concentration of bacteria, mold, fungi, spores, etc. in the air. A mold test was conducted in an abandoned trailer in Austin, Texas on May 27, 2002 by Michael A. Bokenkamp Certified Mold Inspector. The test results indicate an 85% reduction in mold spores with only one air turn with an AiroCide TiO₂ Unit.

Please find attached the following:

#1 FDA 2891 and a 2892 application for a new device dated October 29, 2002.

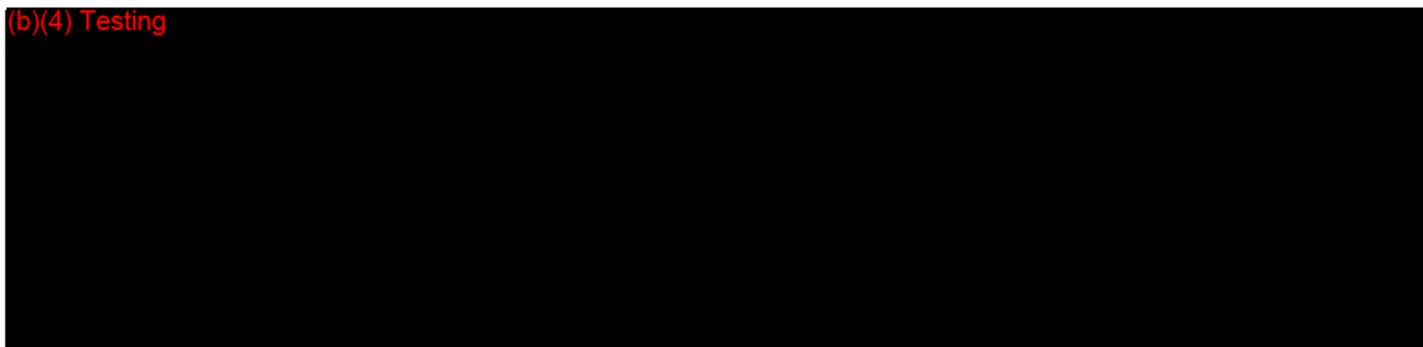
(b)(4) Testing



#5 AiroCide's ETL listing of certified products.

#6 An AiroCide Device Description and Specification sheet.

(b)(4) Testing



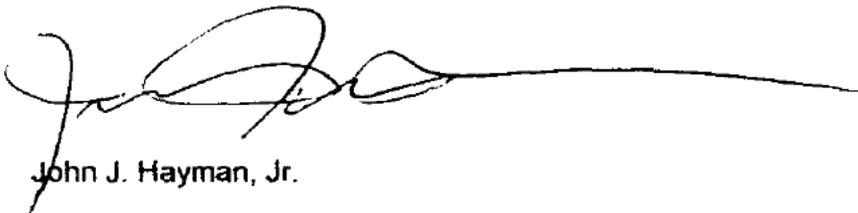
(b)(4) Testing

#13 Summary Internet document of Dr. Michael Leung's testing in a hospital operating room
"...For comparison, the same test was performed with the photocatalytic converter disconnected. This showed filtration using only the HEPA filter reduced the bacterial count by just 5.4 per cent. Therefore, the immediate disinfection effect of the titanium dioxide filter led to the destruction of 46.6 per cent of airborne bacteria in one pass of air through the air purifier. ..."
From <http://www.fhki.org.hk/hki09.htm>

(b)(4) Testing

Please call or email me with any questions you may have.

Best regards,



John J. Hayman, Jr.

KES Science & Technology, Inc
President
KES Science & Technology, Inc.

Phone: 770-427-6500
Email: president@kesmist.com

www.kes-pro.com PDF files about the testing and operation of the Airocide are available at this site.

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26

(b)(4) Testing

RE: Response to Definitions of Decon Device Performance Measures for Buildings

Dear Ms. Busher and Ms. Smith,

Per your request, please find enclosed a response for *definitions device performance measures for buildings* for the AiroCide product, which is produced and marketed by KES Science and Technology. The enclosed response has 3 appendices and will be supplemented in the next 45-60 days with the submission of the results from data presently being gathered in studies of 1) the AiroCide as a system and 2) the biological inactivation modalities operating within the device. Results from these studies will be submitted for publication in a peer-reviewed journal in the next 60 days. In addition, a presentation will be made at the forthcoming American Industrial Hygiene Association (AIHA) conference and exposition (June 1-6, 2002; San Diego, CA) with observations made from study #2 above. The presentation is entitled *Control of Bacterial Spores with UVGI and Photocatalysis* (<http://www.aiha.org/conf.html#abs>; Late Breaking Issues, Forum 240: Anthrax Remediation Issues).

I am submitting this report to Tetra Tech with the understanding of John Hayman, President of KES Science and Technology.

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Tes
ting

Sincerely,

(b)(4) Testing

Decon Definitions of the AiroCide
May 3, 2002

(b)(4) Testing

DEFINITIONS OF DECON DEVICE PERFORMANCE MEASURES FOR BUILDINGS

BUILDINGS

For this effort, building decontamination refers to the ability to destroy or remove biological agents from internal surfaces and air contained within. Buildings will require special consideration during the performance of decontamination operations, as a variety of surfaces are contained within a building (e.g. painted surfaces, carpet, ceiling tile, fabrics, wood, glass, etc.), as well as the presence of ventilation systems and other complications. This presents a significant challenge to all decontamination technologies.

To effectively compare building decontamination technologies, a specific example building will be used. This example building has two floors totaling 40,000 square feet of floor surface area. The building contains an HVAC system. It is assumed that *Bacillus anthracis* spores are distributed throughout the building at varying concentrations. The building contents are a combination of porous and non-porous materials, and contain various other items, such as electronics, papers, and personal items. This model is designed to test the performance of various decontamination devices under these circumstances.

The technology considered can address structural items, HVAC, electronics, papers, and personal items in total or any one separately.

PREFACE -- A Short Narrative on the Operational Character of the AiroCide:

The AiroCide device is designed to remove airborne particulates, microbiologicals (e.g., spores of *Bacilli*) and gaseous compounds via several treatment modalities operating concurrently. These modalities are described herein. In its present configuration, the AiroCide treatment device can be mounted to a ceiling, wall or other interior surface of a building. The AiroCide device contains an internally mounted fan. During operation, the fan will cause a local negative pressure differential between room air near the fan inlet and that downstream of the fan. In so doing, room air will be entrained into the AiroCide. The AiroCide is operated as a single-pass treatment device. The media within the AiroCide is designed to remove or immobilized the airborne biologicals entrained into the device. Once immobilized onto the surface of the media within the AiroCide, two treatment modalities operate concurrently to inactivate and oxidize the biologicals.

Decon Definitions of the AiroCide
May 3, 2002

1.0 BIOLOGICAL EFFICACY GOAL

Ability of the decontamination system to limit the effectiveness of biological agents during all environmental conditions, either by agent neutralization or removal. Assume normal conditions will consist of a variety of reasonably clean surfaces (plastic, fabric, painted, etc.) and moderate temperature and humidity.

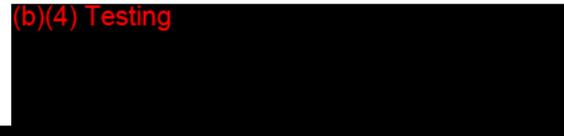
- 1.1 **Effectiveness Measure.** Ability to destroy/remove spores to a specified level on all surfaces, components, or air. Examines the technology to determine the likely end-state of the decontamination effort.

The AiroCide treatment device has been empirically examined for its removal efficiency based on performance testing of the full system. A report was prepared (December, 2001) describing the performance testing and is attached to this document as **Appendix A**. A summary of the testing is provided here:

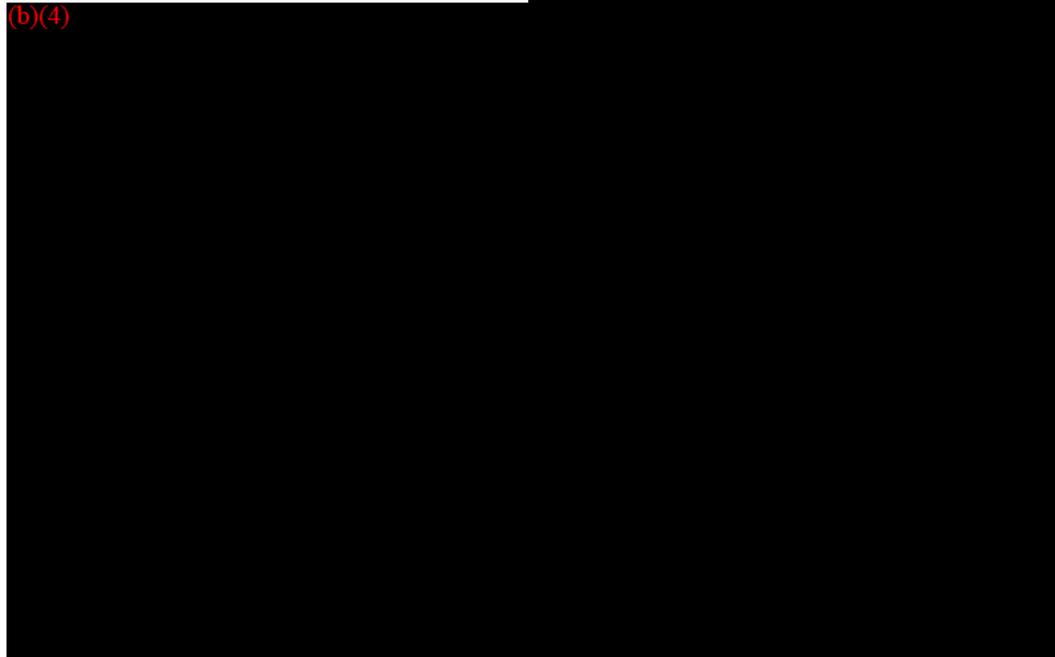
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Decon Definitions of the AiroCide
May 3, 2002

(b)(4) Testing

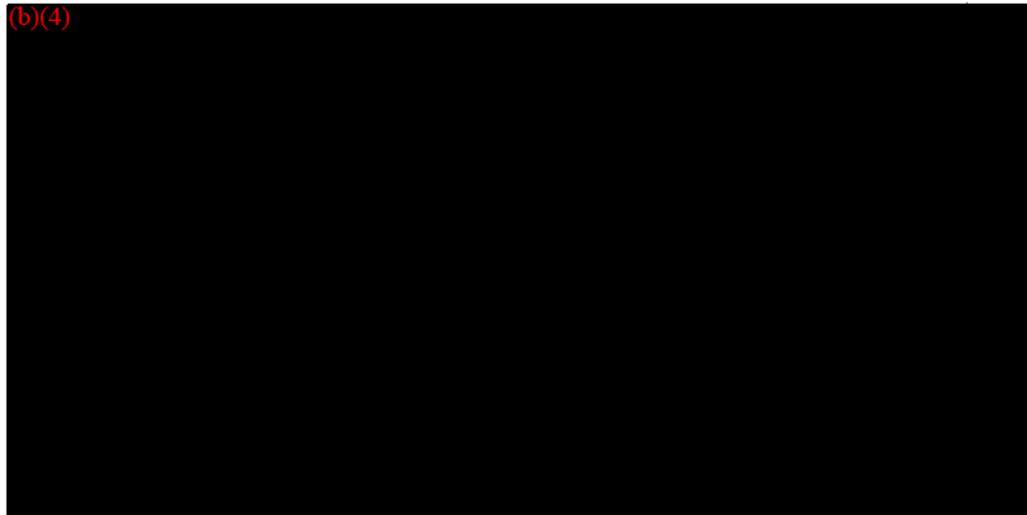
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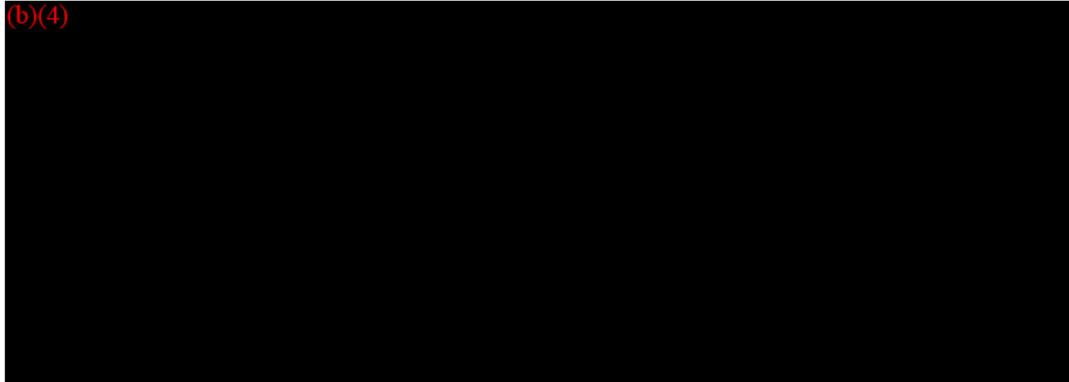
1.2 **Environmental Conditions Measure.** Effectiveness under a wide range

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1.3 **Penetration Measure.** Effectiveness of decontaminant/system on a

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Decon Definitions of the AiroCide
May 3, 2002

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- 1.4 **Scientific Confidence and Validation/Verification.** The confidence in equipment and supporting material used in the process (evaluated as a system).

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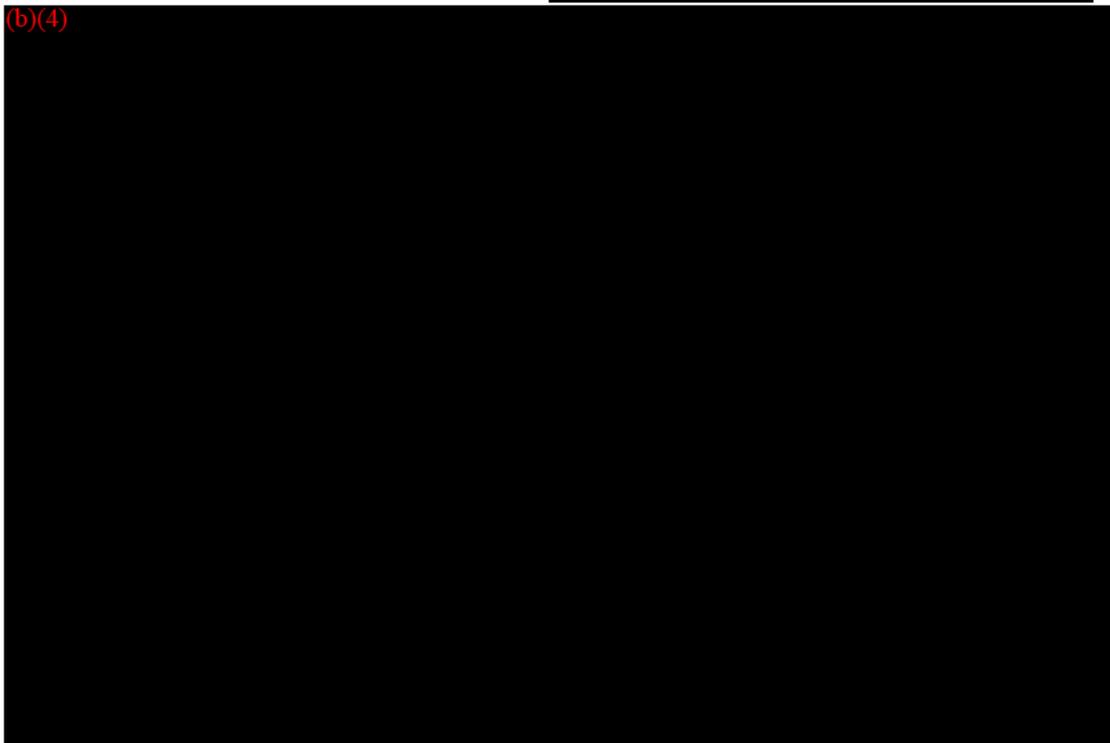
LDGI Rate Constants for Respiratory Pathogens.

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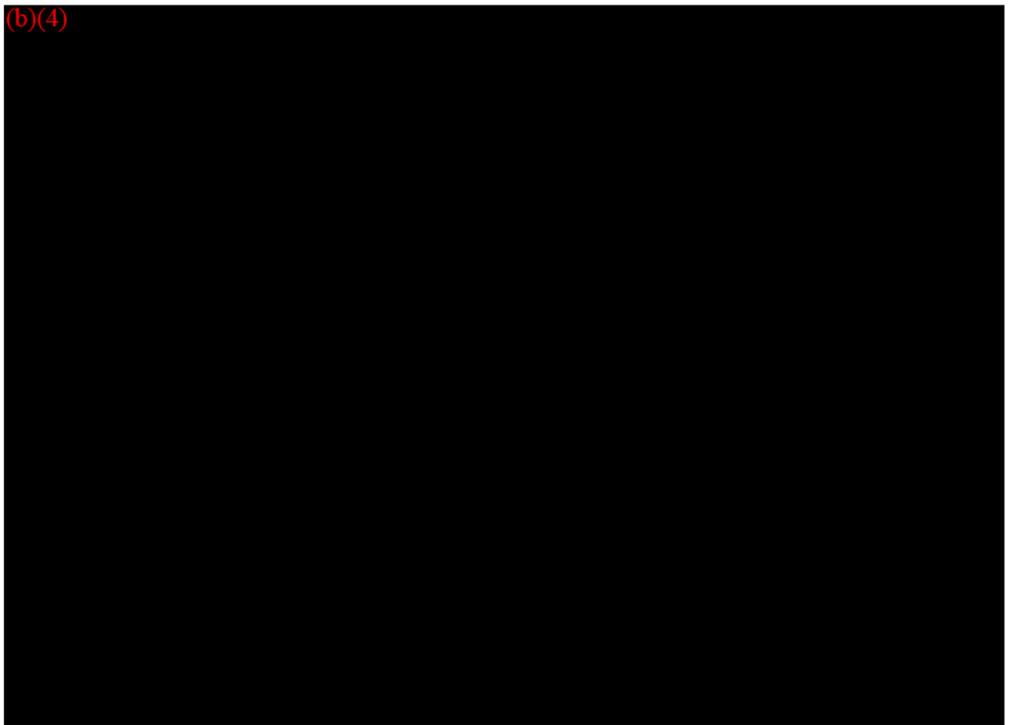
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Decon Definitions of the AiroCide
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Indoor air quality problems can originate from airborne particulates, gaseous compounds and bioaerosols. Bioaerosols of importance in indoor air include a large variety of the fungi, bacteria, viruses, mycotoxins, and endotoxins. The impact of bioaerosols on indoor air quality is considered significant and has been reviewed [6], [7], [8]. Transmission of bioaerosols via airborne

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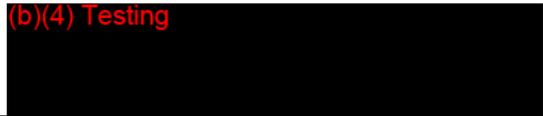
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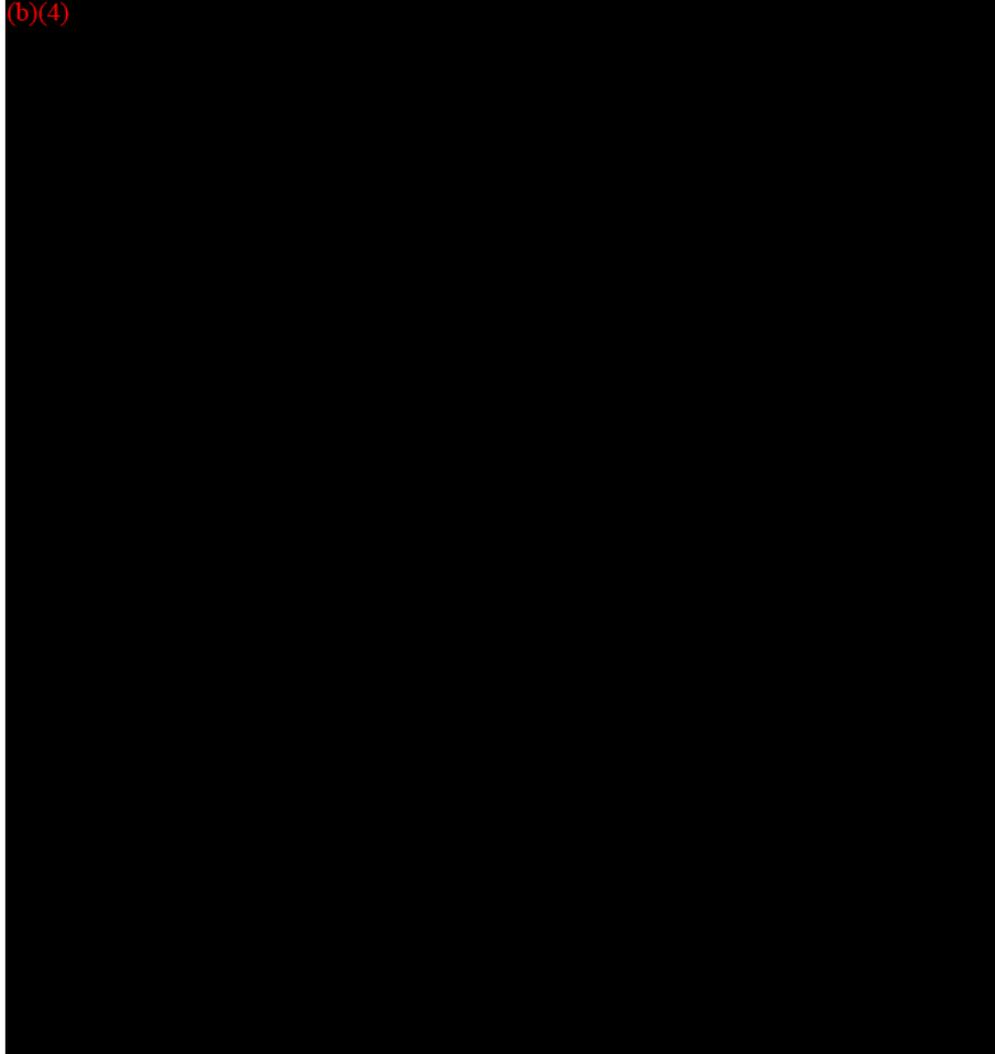
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May 3, 2002

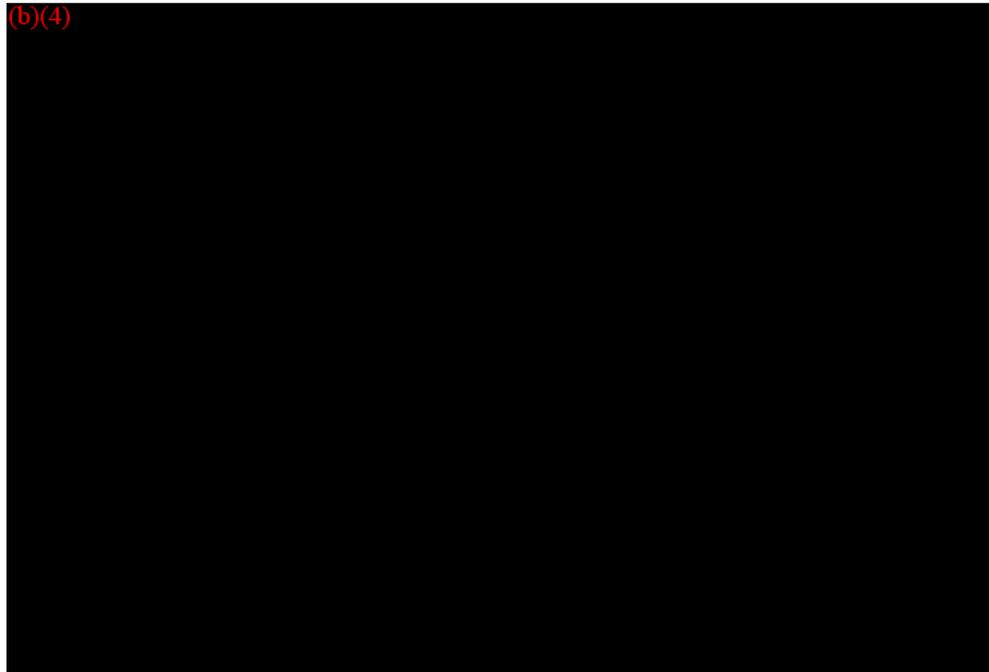
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The application of non-ionizing radiation energy has been demonstrated for disinfecting bacteria, fungi, and spores of bacteria, protozoa, oocysts, and helminth eggs [25]. Najdovski et al. [26] investigated the application of microwaves (b)(4) at power

(b)(4)

A current study at the University of Wisconsin – Madison (Tompkins, Principal Investigator) examines the sporicidal effect of illuminating thin-film titania with near-UV radiation using spores of *B. subtilis* as a model organism. *B. subtilis* is selected because it is non-pathogenic, is a spore-former, and has a phenotype similar to *B. anthracis* [32]. This work also examines the sporicidal effect of

Decon Definitions of the AiroCide
May 3, 2002

combing microwave irradiation with photocatalysis. *B. subtilis* can be considered as an optimum indicator bacterium for microwave sterilization studies [33].

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(b)(4) Testing

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Decon Definitions of the AiroCide
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2.0 OPERATIONAL IMPACT GOAL

Effect of decontaminant/system on decontamination effort and operations for buildings, components, or items.

2.1 Capacity Measure. Effective area or volume that can be neutralized

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[Redacted]

2.2 Material Compatibility Measure. Damage caused to materials, equipment, electronics, structure, etc. as a direct result of the decontamination effort.

The AiroCide is a flow through treatment device that processes air entrained into it. Processed air is exhausted from the device at a flow rate equal to that entering it or about ~ (b)(4) [Redacted].

2.3 Post-Decon Detection Measure. Potential to cause false negative responses on biological agent detection equipment (i.e. decontamination technology leaves behind residue that masks or interferes with post-decon analysis). Assumes a growth-based assay.

The AiroCide will not leave behind residue that interferes with post-decon analysis. The AiroCide is a self-contained treatment device that does not emit media, except for the air entrained into it and processed therein. The processed air exhausted from the device will contain substantially less biological contaminants as a result of the media within the AiroCide immobilizing these biologicals.

2.4 Total Time Measure. Total time required to conduct decontamination operations in example building. Time/rate includes set-up, processing (may include single or multiple pass), equipment acquisition, and teardown.

The efficacy of the AiroCide treatment device depends on the residence time required to inactivate the immobilized biological agents. Measures of the residence time needed for inactivation are based on two laboratory studies:

Glass Slide Study: Results are forthcoming and to be presented to Tetra Tech in next 45-60 days.

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Decon Definitions of the AiroCide
May 3, 2002

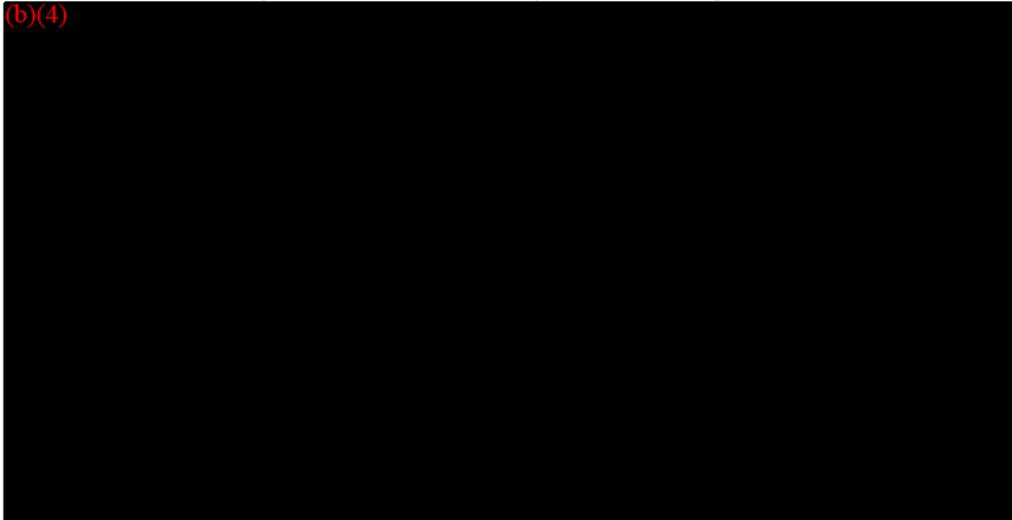
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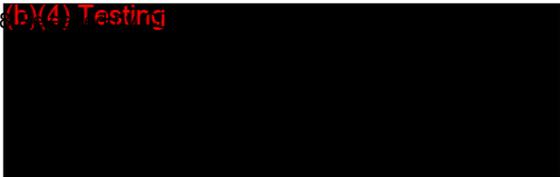
Full-scale AiroCide Device Study: Results are forthcoming and to be presented to Tetra Tech in next 45-60 days.

- 2.5 **Reuse Measure.** Ability of device to be decontaminated, returned to service, or designed for single use.
The AiroCide treatment device is designed to operate continuously (24 hours – 7 days/wk) provided it remains powered – although the duty cycle can be adjusted to the needs and desires of the operator. The AiroCide contains two components that directly influence performance – the

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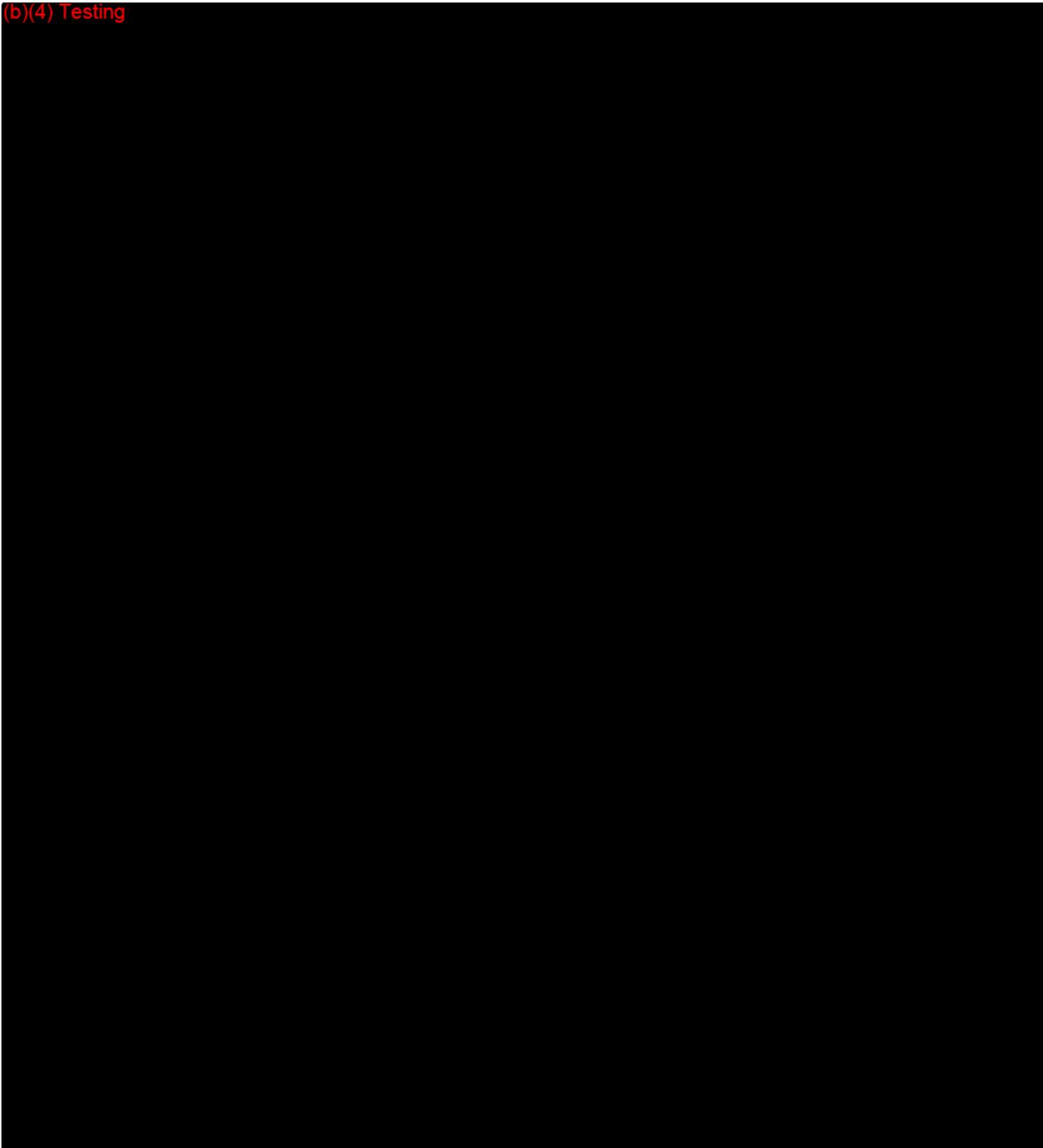
Decon Definitions of the AiroCide
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3.0 LOGISTIC IMPACT GOAL

Effect of the decontaminant/device on support and logistical systems.

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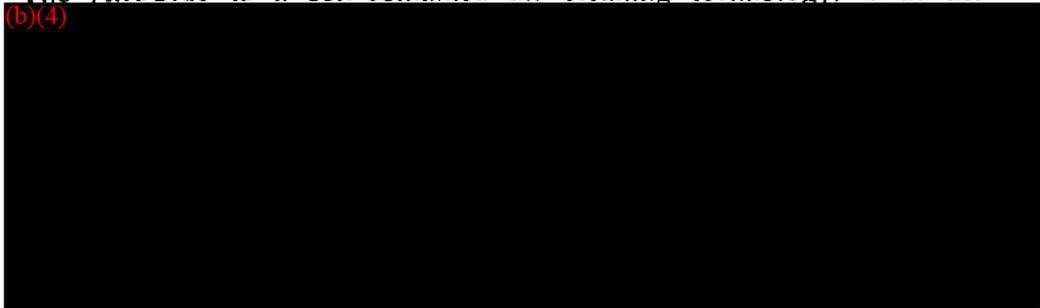


4.0 SAFETY, HEALTH AND ENVIRONMENTAL GOAL

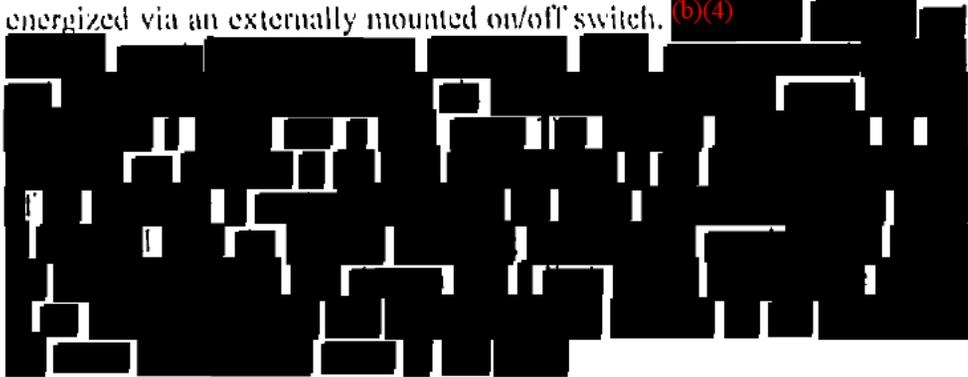
Ability of the user to operate the device or use the decontaminant without being injured, suffering any side effects from it, or negatively impacting the environment in which the decontaminant is used.

- 4.1 **Personnel Hazard Measure.** Potential health hazard (acute or chronic) to decontamination site personnel from operation of the device (e.g. chemical, shock, electrical hazards, radiation exposure, explosion potential, etc). Assumes that decon site personnel are wearing appropriate protection clothing, masks, and gloves.

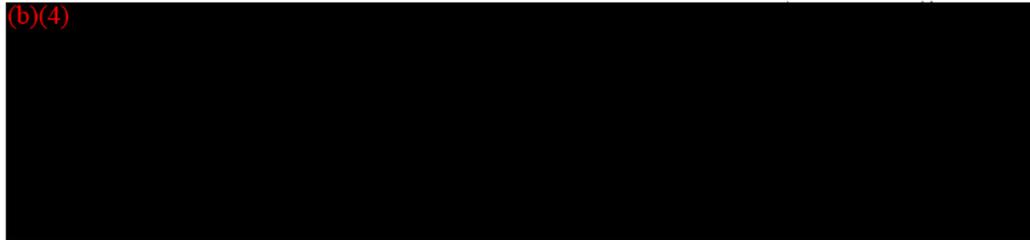
The AiroCide is a self-contained air cleaning technology. With the (b)(4)



The AiroCide is powered by inserting a power cord (18-2 with ground) into a 120-VAC electrical source, i.e., wall outlet. The AiroCide is energized via an externally mounted on/off switch. (b)(4)



The UVGI light sources used in the AiroCide have the spectral (b)(4)



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Decon Definitions of the AiroCide
May 3, 2002

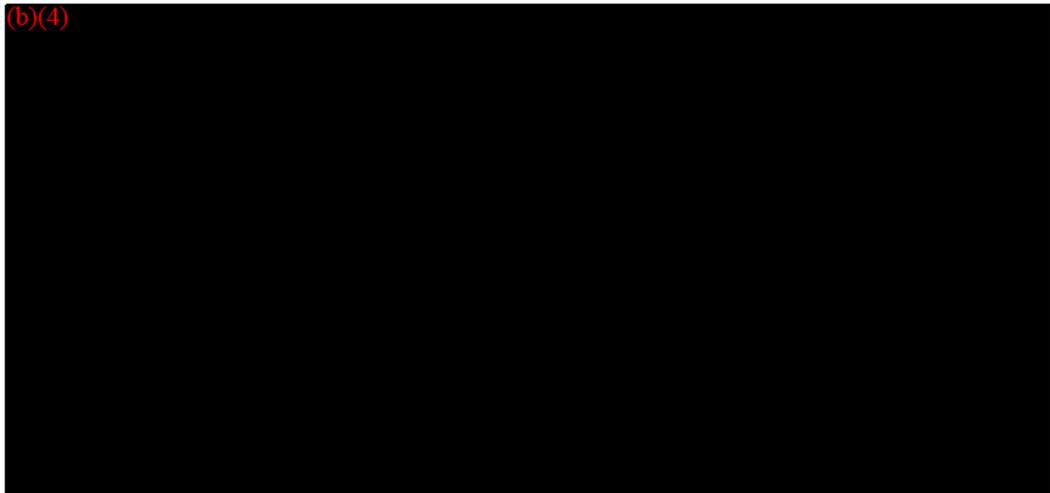


Germicidal spectral output



Figure 1. Spectral irradiance of UVGI light sources in AiroCide.
(For reference to the figure above, UV-C: 285 nm below, UV-B: 285-315 nm, UV-A: 315-400 nm; Visible: 400 nm - 700 nm.)

- 4.2 **Environmental Hazard Measure.** Degree of environmental hazard or impact associated with direct contact of decontaminant device or decon by-products or residual.



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44

Decon Definitions of the AiroCide
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- 4.3 **Public Health Hazard Measure.** Potential health hazard (acute or chronic; severe, serious health effects) to the public (building occupants, visitors, and/or community) resulting from operation of the device (e.g. chemical, radiation exposure, explosion potential, etc).

The *Hazards Identification* section of the MSDS (Appendix C) indicate the following human health effects: contact with eyes may cause irritation; contact with skin may cause minor irritation; nuisance dust may be generated; no toxicity is expected if ingested. The carcinogenicity information states that none of the components of the photocatalyst are known carcinogens, although NIOSH considers TiO₂ to be a potential occupational carcinogen. However, the photocatalyst is immobilized onto the surface of glass supports. Indeed the photocatalyst is sintered at high temperature (b)(4) to the borosilicate glass supports so that it remains adherent to the glass supports. In this way, the photocatalyst will remain within the AiroCide and not be entrained into the effluent (or exhaust) air,

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(b)(4) Testing



December 1, 2001

Appendix A

John Hayman
President
KES Science and Technology
3625 Kennesaw North Ind. Pkwy.
Kennesaw, GA 30144
(800) 627-4913

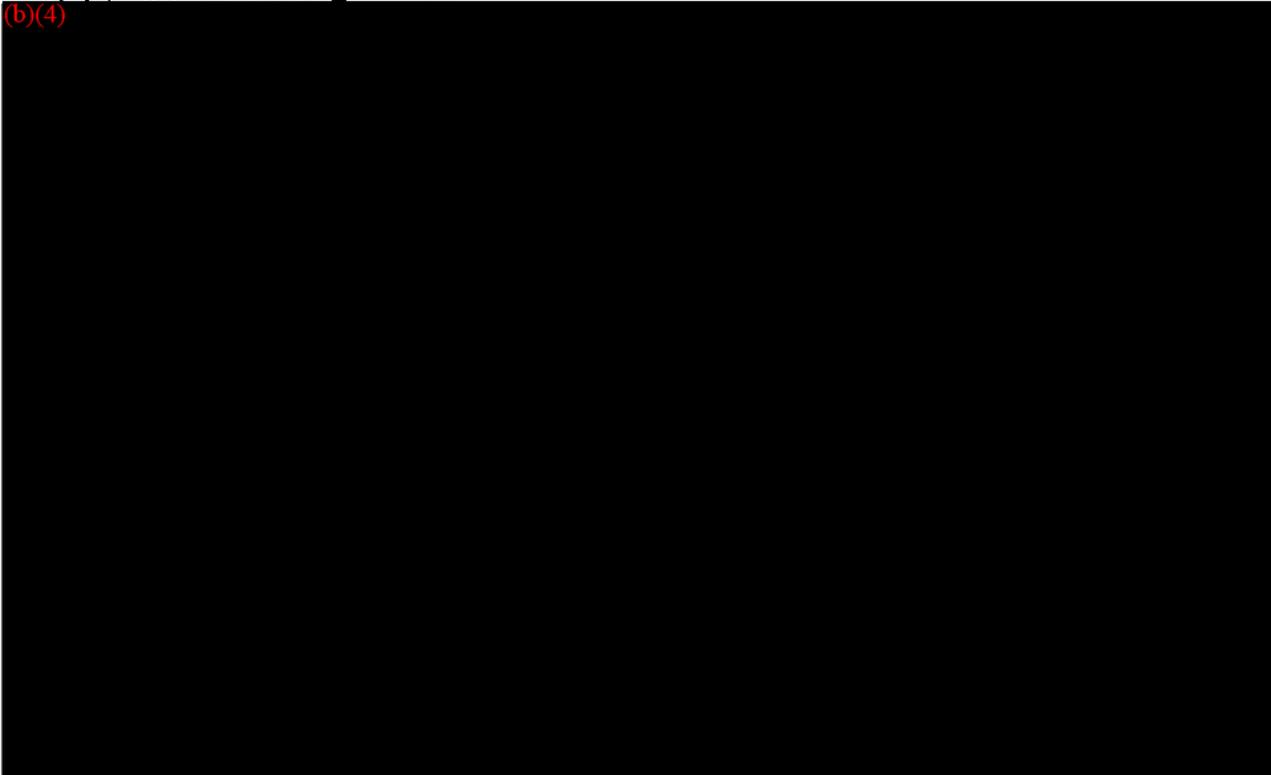
RE: Performance of AiroCide in Controlling Bacterial Spores

Dear President Hayman,

Please find below the results from testing the AiroCide device (KES Science and Technology; Kennesaw, GA) as a technology for controlling air-borne concentrations of bacterial spores. The figures numbered below are found in the Appendix.

Experimental Testing Results

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(b)(4) Testing

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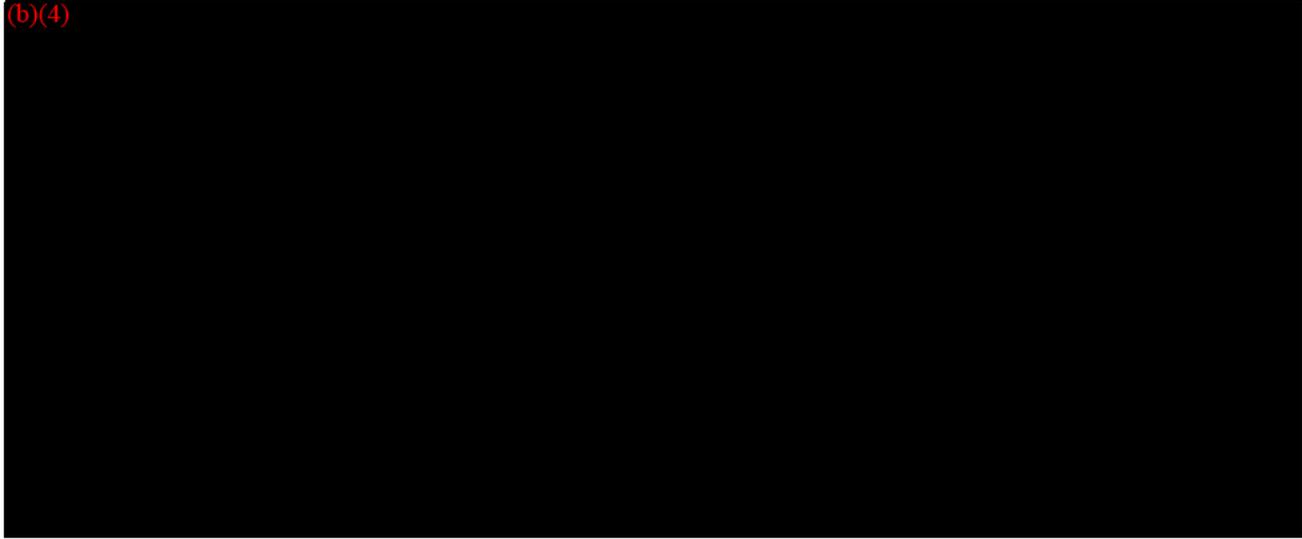
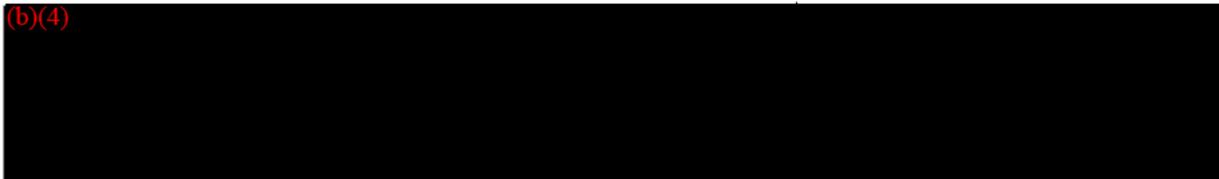
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Table 1 Experimental Results

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(b)(4) Testing



Appendix

Group 2

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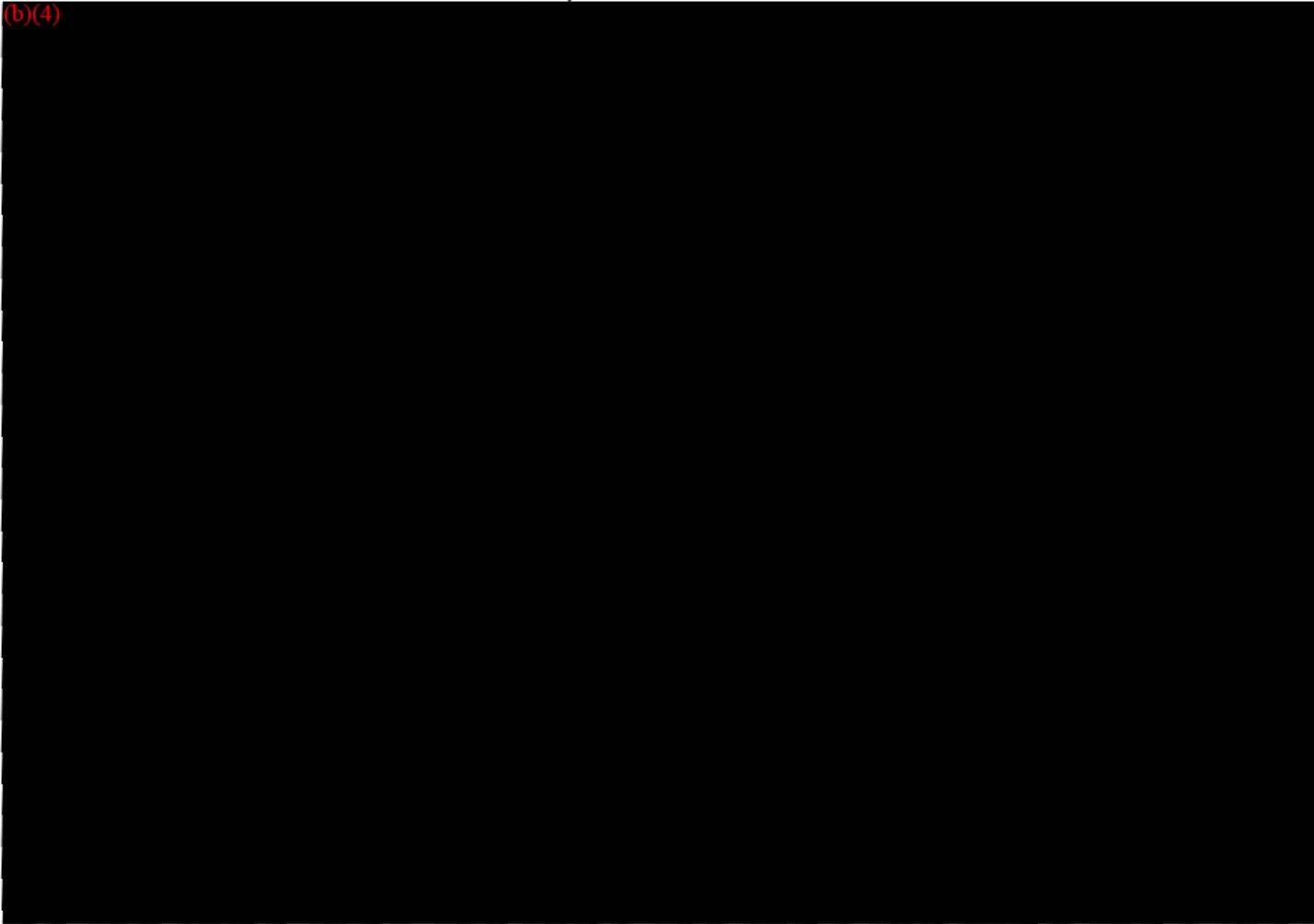


Figure 1 – Phylogenetic tree of genus *Bacillus*. Note group similarity between *B. anthracis* and *B. thurengiensis*.

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(b)(4) Testing



Figure 2 - Suspension of *B. thuringiensis* spores in nebulizer.



Figure 3 - Experimental set-up. Air from compressed air cylinder aerosolizes suspension of *B. thuringiensis* spores.

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(b)(4) Testing



Figure 4 – Experimental set-up. Spores fill a Plexiglas chamber positioned over the inlet to AiroCide unit.



Figure 5 - Experimental set-up. Exit of AiroCide device displaying energized UV lamps .



Figure 6 – Experimental set-up. Petri dishes at exit of AiroCide ; in position to capture exhaust from the AiroCide .

(b)(4) Testing



Figure 7 Petri dishes in incubator room.



Fig. 8 Mass-measured initial inoculum of (b)(4)

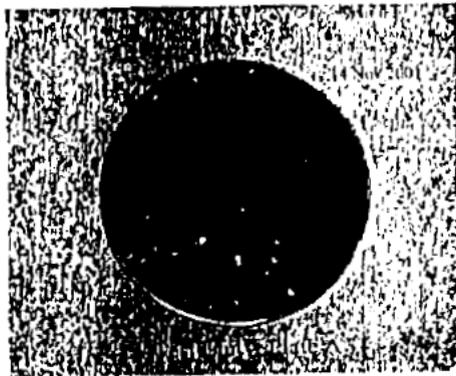


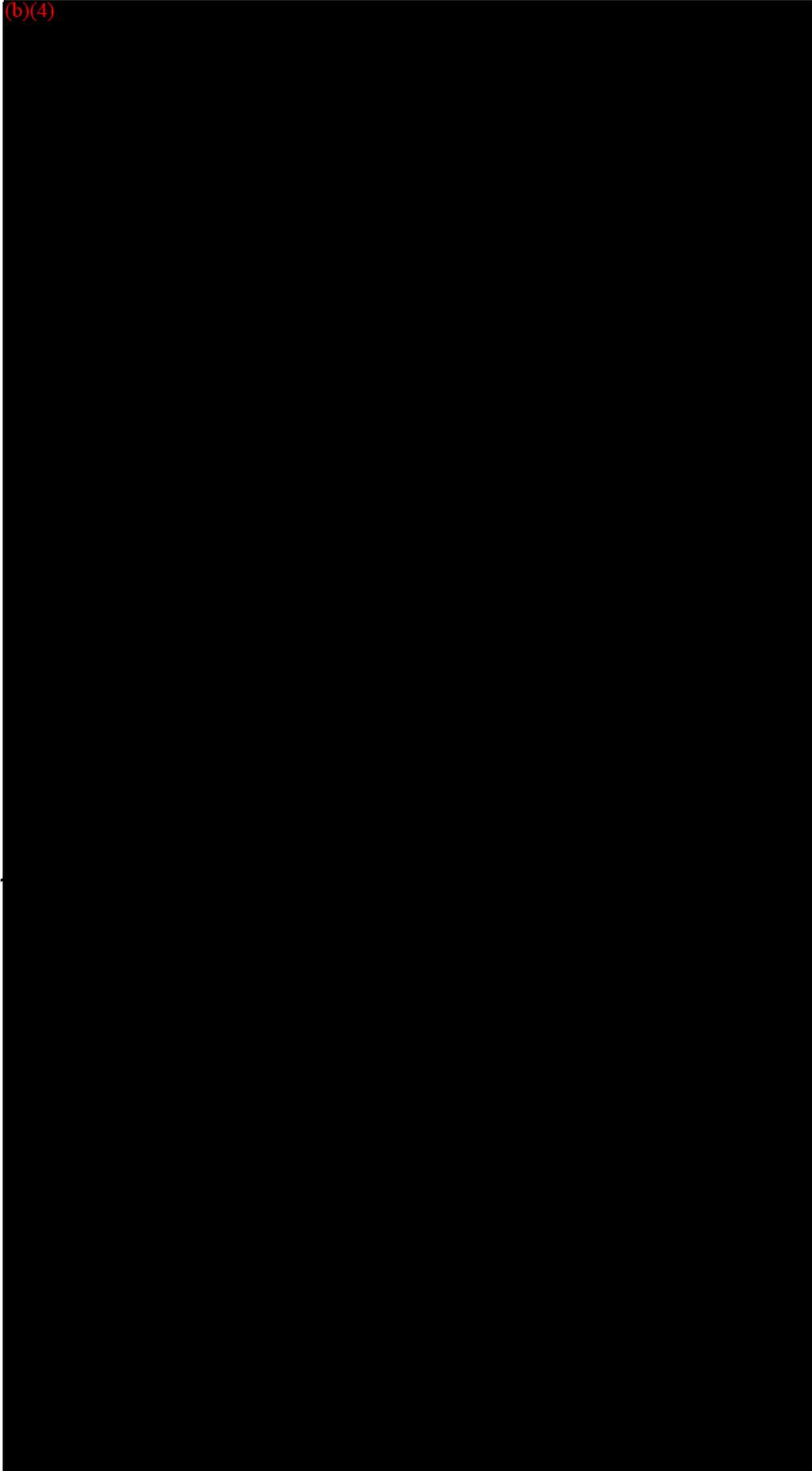
Fig. 9 Example of CFUs on Petri dish.

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Appendix B

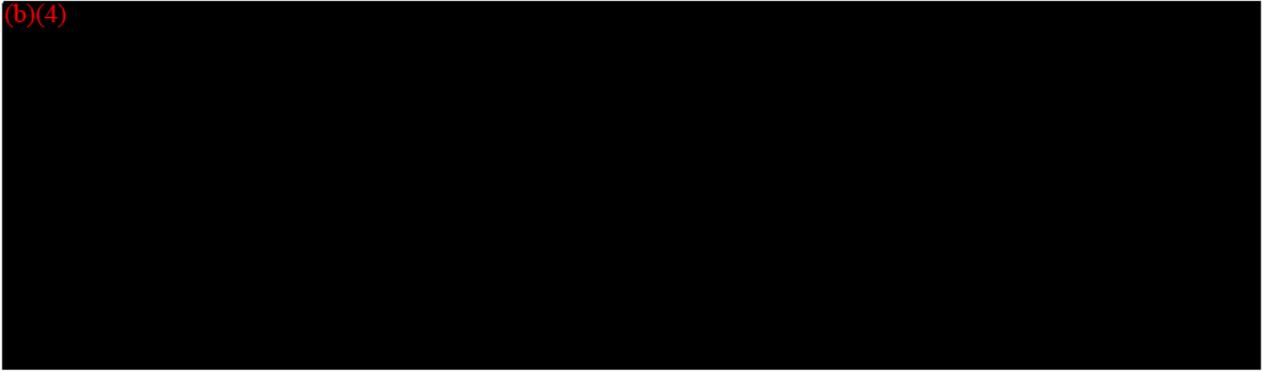
ASHRAE Research Project 1134-RP

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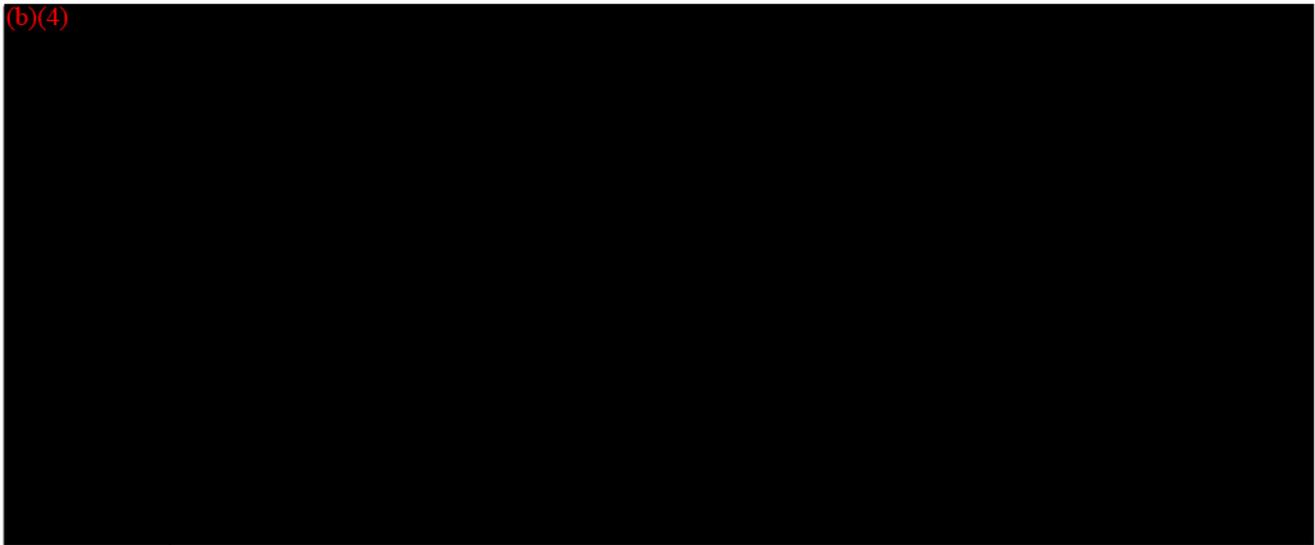
Preface

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Acknowledgements

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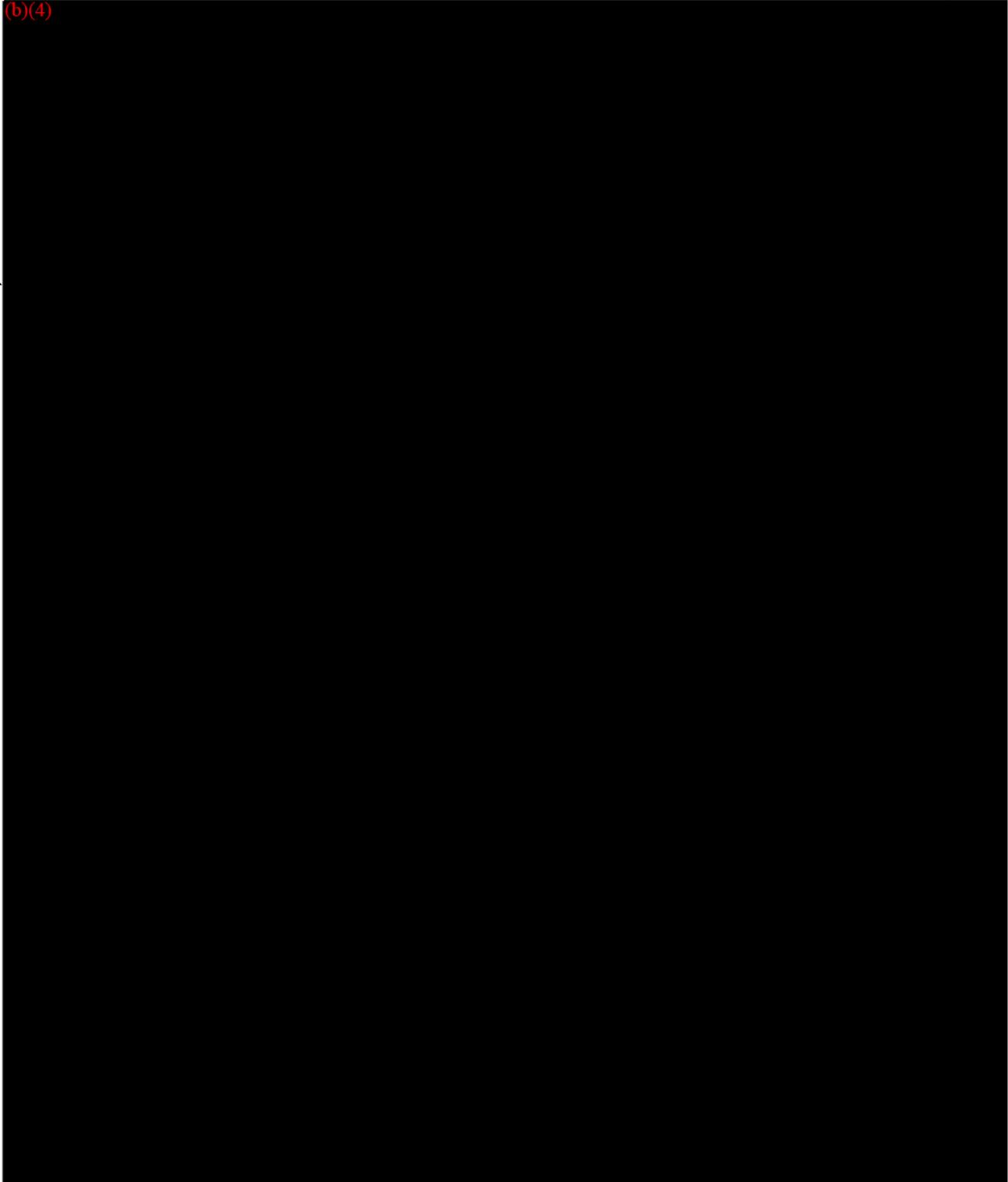


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EXECUTIVE SUMMARY

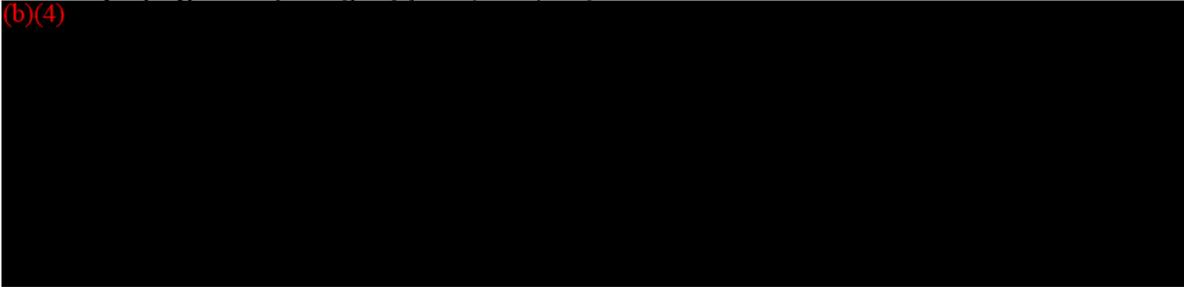
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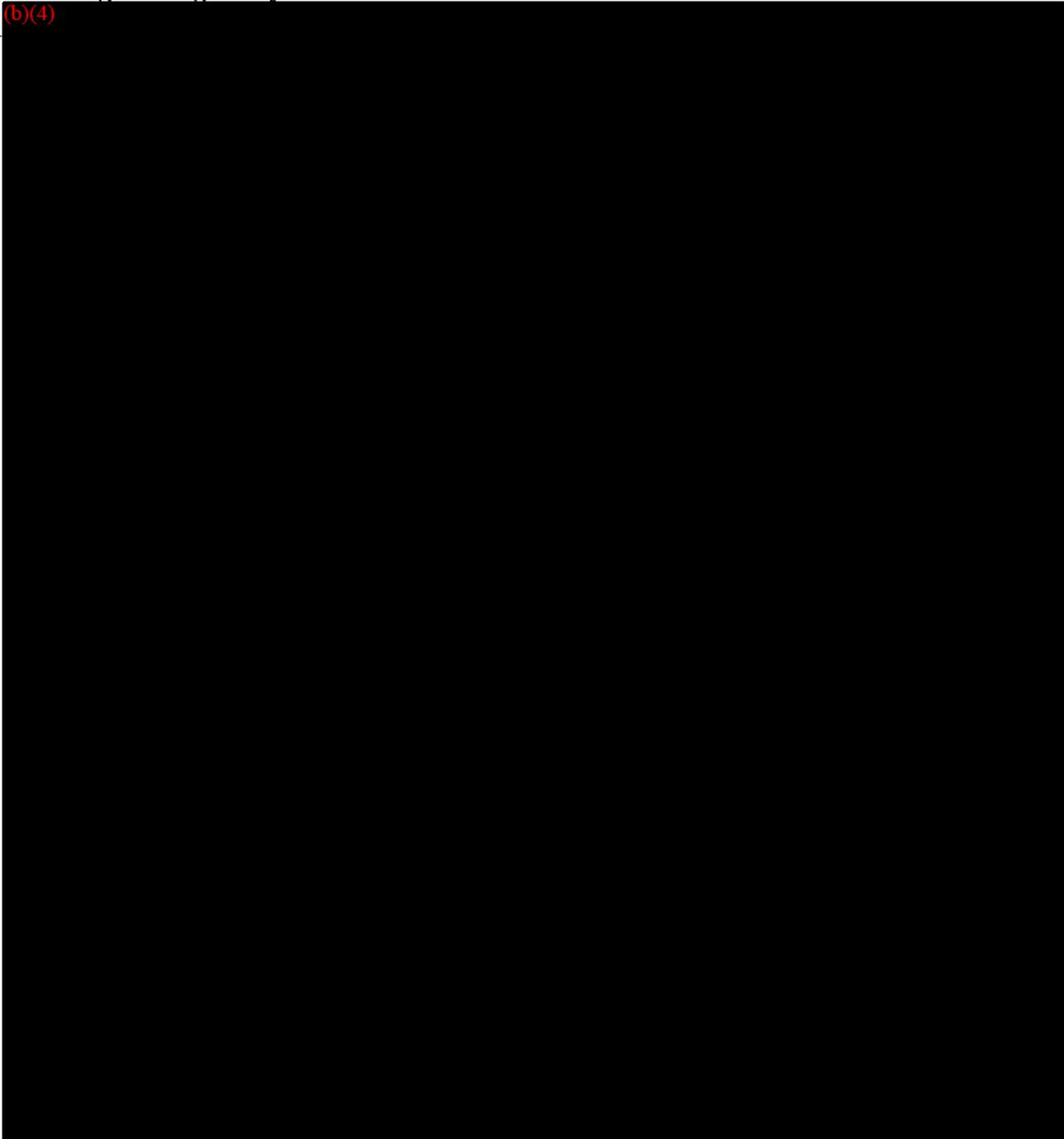
Catalyst Life/Fouling. Catalyst deactivation has been demonstrated with several

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2. Engineering Analysis

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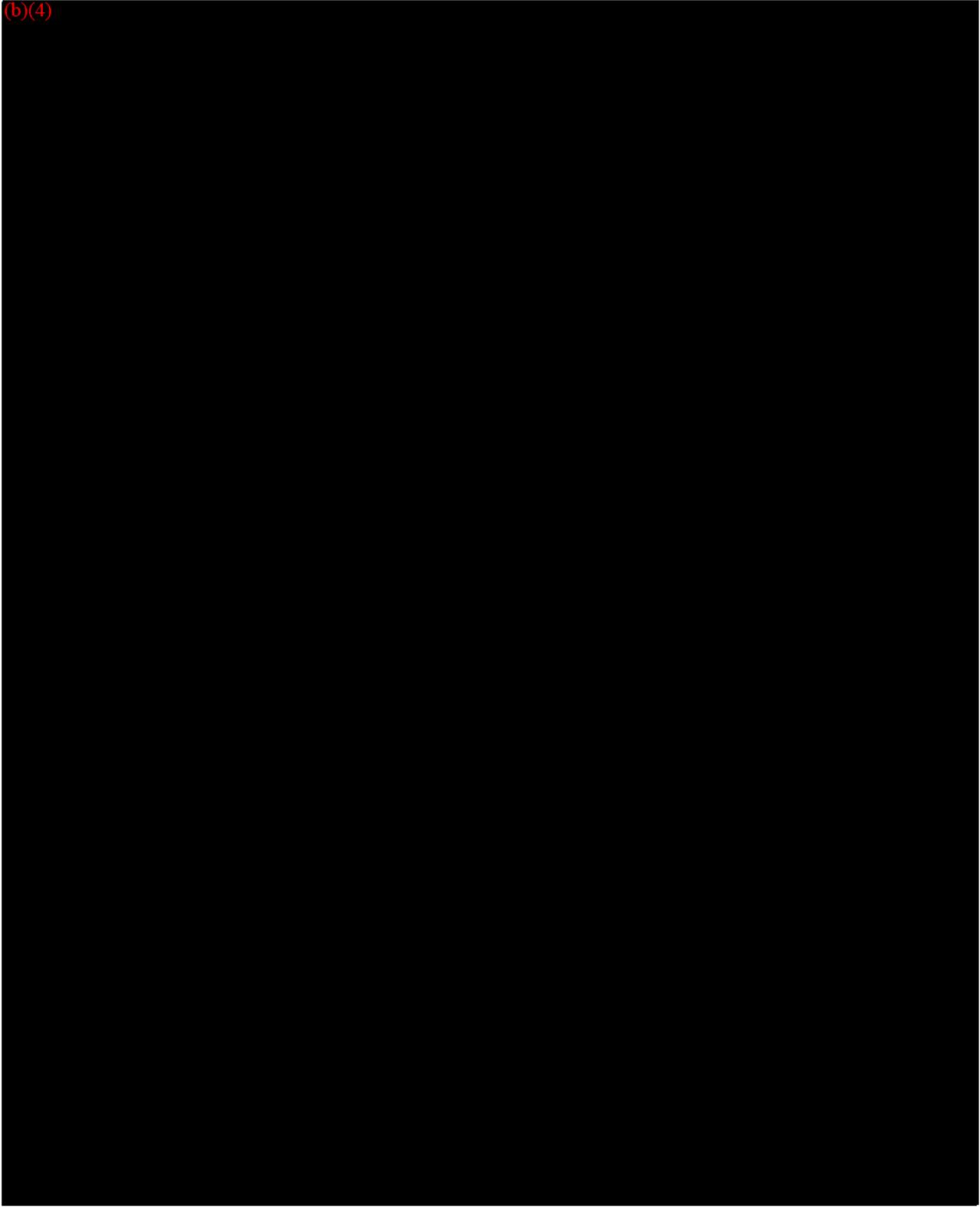
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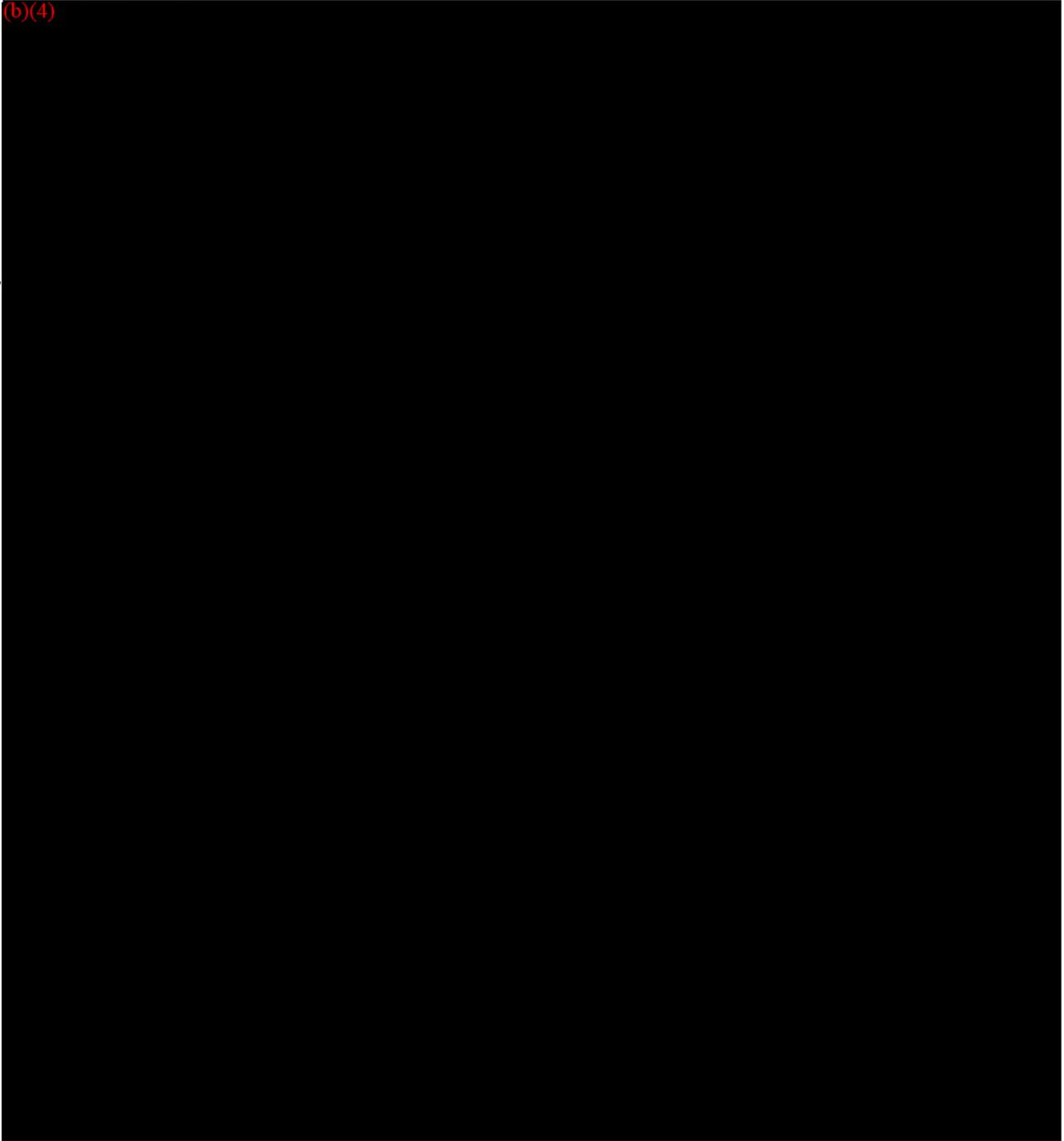
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3. Future Work

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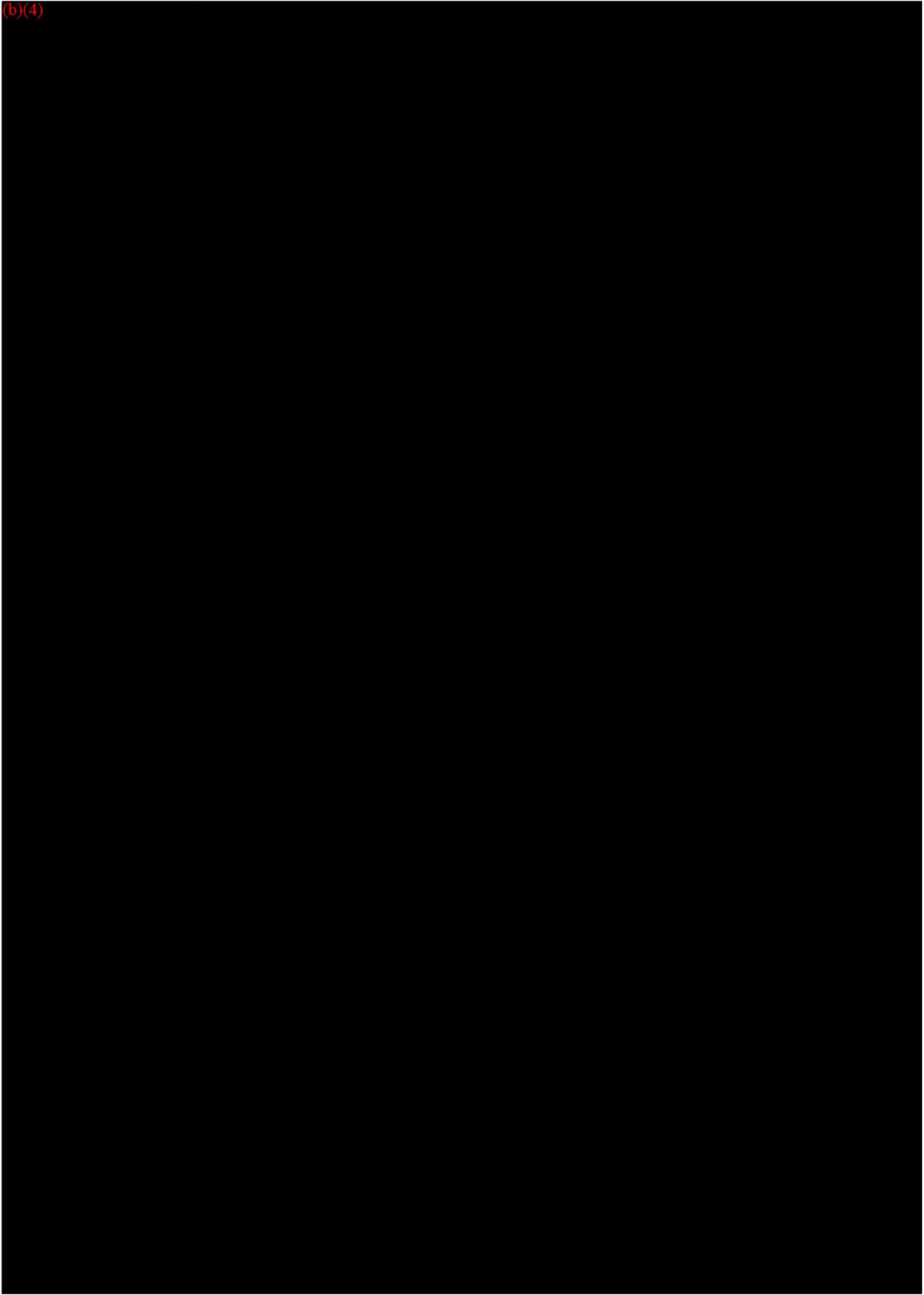
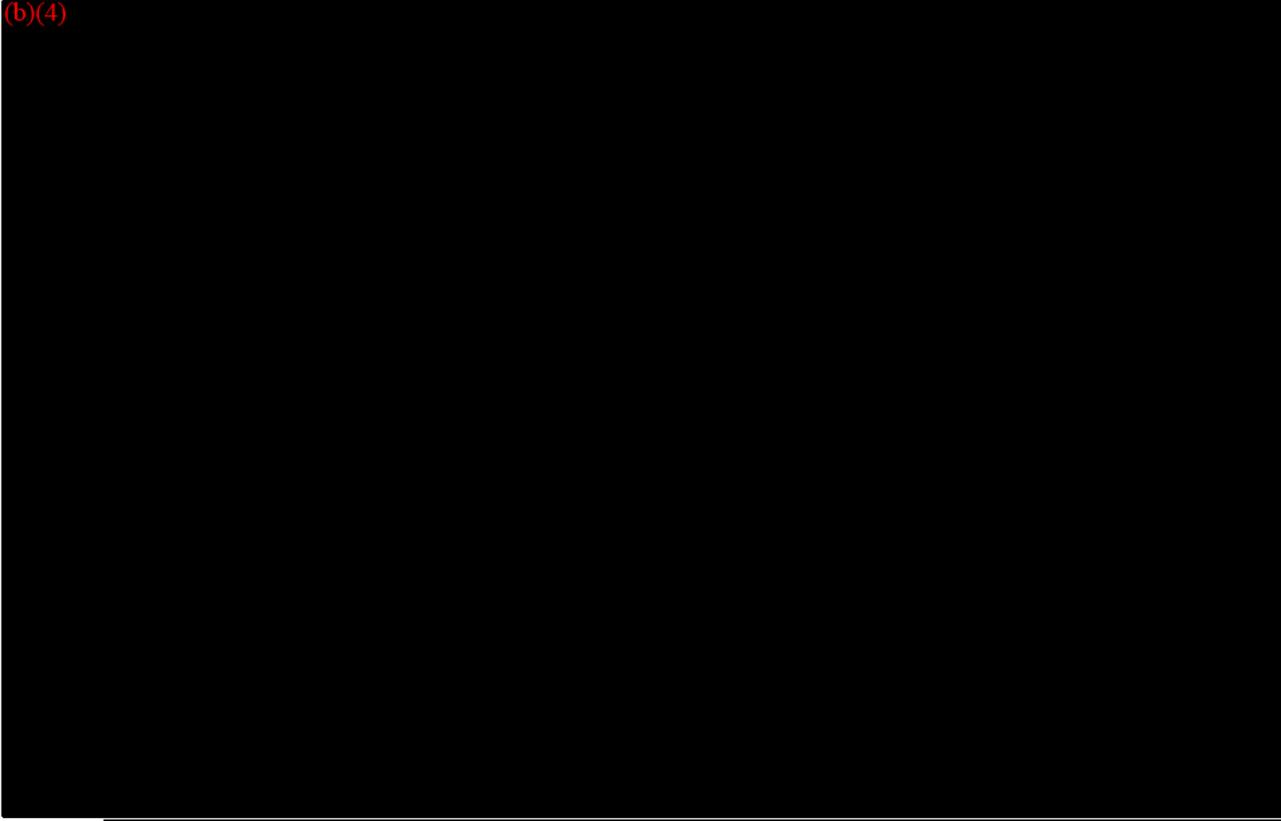


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Approximately 300 references in heterogeneous gas-phase photocatalysis were obtained in written form from numerous journals including

Applied Catalysis
Applied Catalysis B-Environmental
Bulletin of the Chemical Society of Japan
Catalysis Letters
Catalysis Reviews – Science and Engineering
Catalysis Today
Chemical Engineering Science
Chemistry Letters
Chemosphere
Electrochemical and Solid State Letters
Environmental Science and Technology
Industrial and Engineering Chemistry Research
Journal De Physique IV

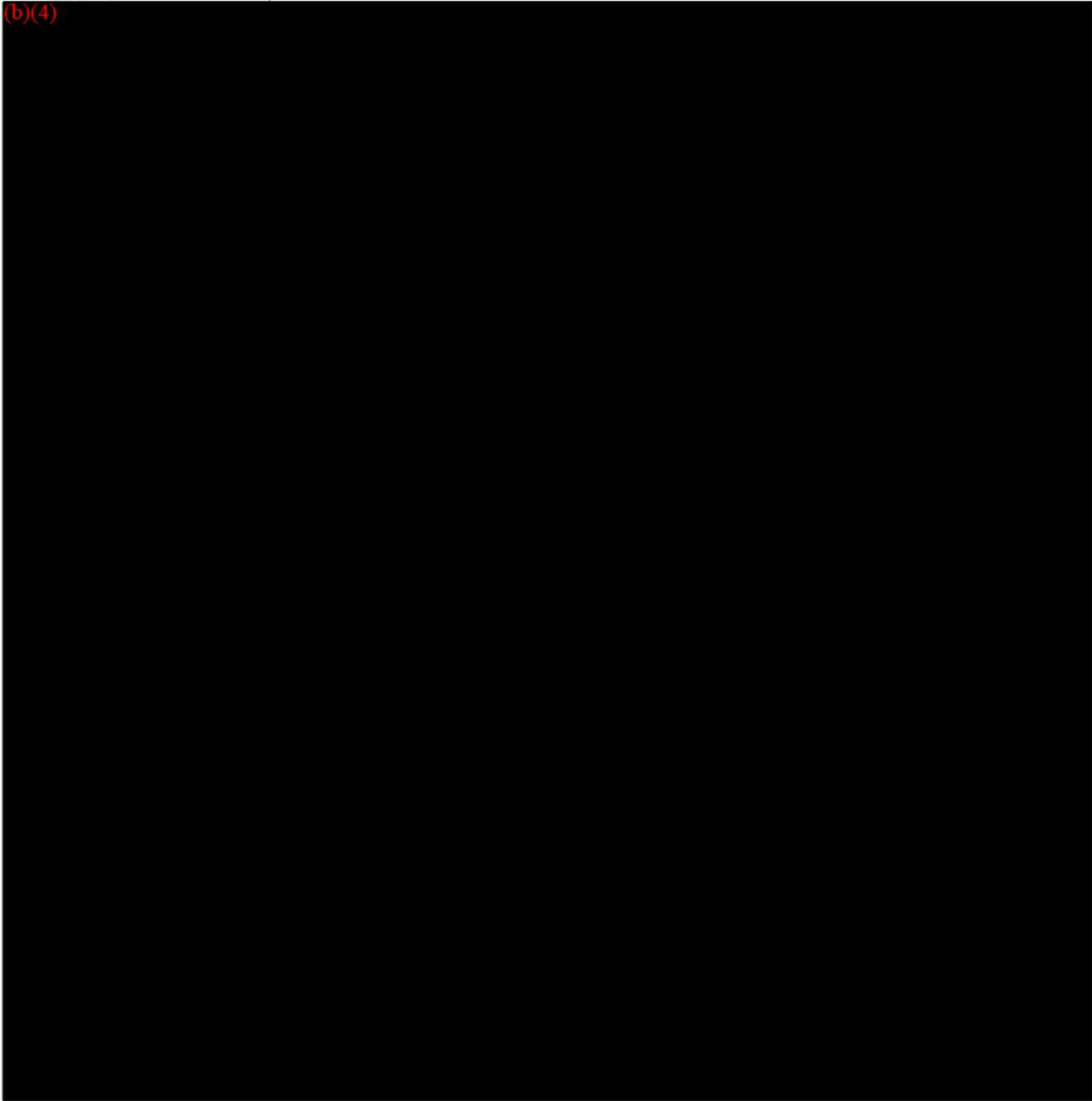
Journal of Catalysis
Journal of Molecular Catalysis
Journal of Photochemistry and Photobiology
Journal of Photochemistry And Photobiology A-Chemistry
Journal of Photochemistry and Photobiology B-Biology
Journal of Physical Chemistry
Journal of Physical Chemistry A
Journal of Physical Chemistry B
Journal of the Air & Waste Management Association
Journal of the American Chemical Society
Journal of the Chemical Society – Faraday Transactions
Journal of the Japan Institute of Metals
Langmuir
New Journal of Chemistry
Physical Chemistry Chemical Physics: PCCP
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Thin Solid Films
Water Research

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Background

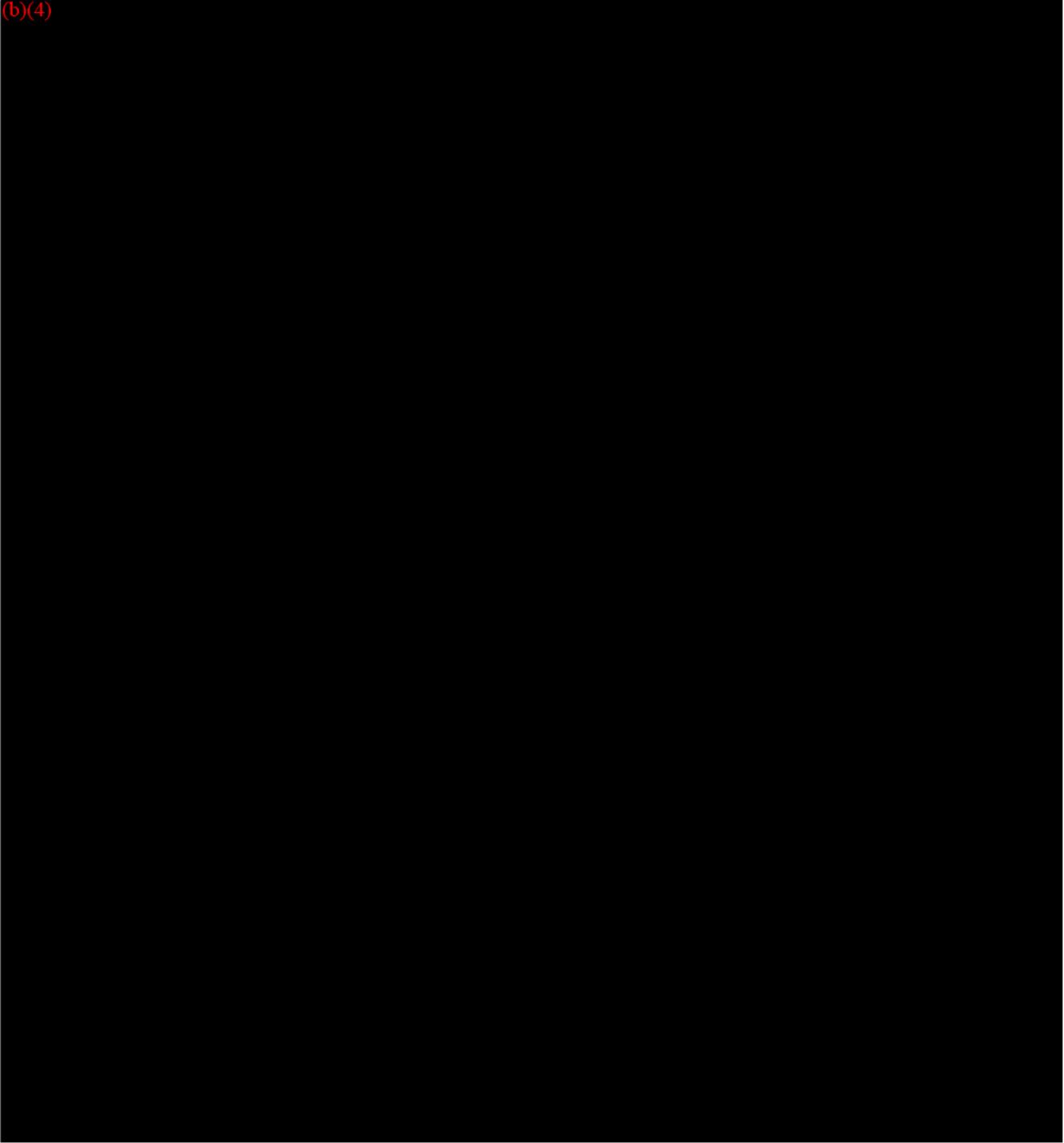
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1.0 LITERATURE REVIEW

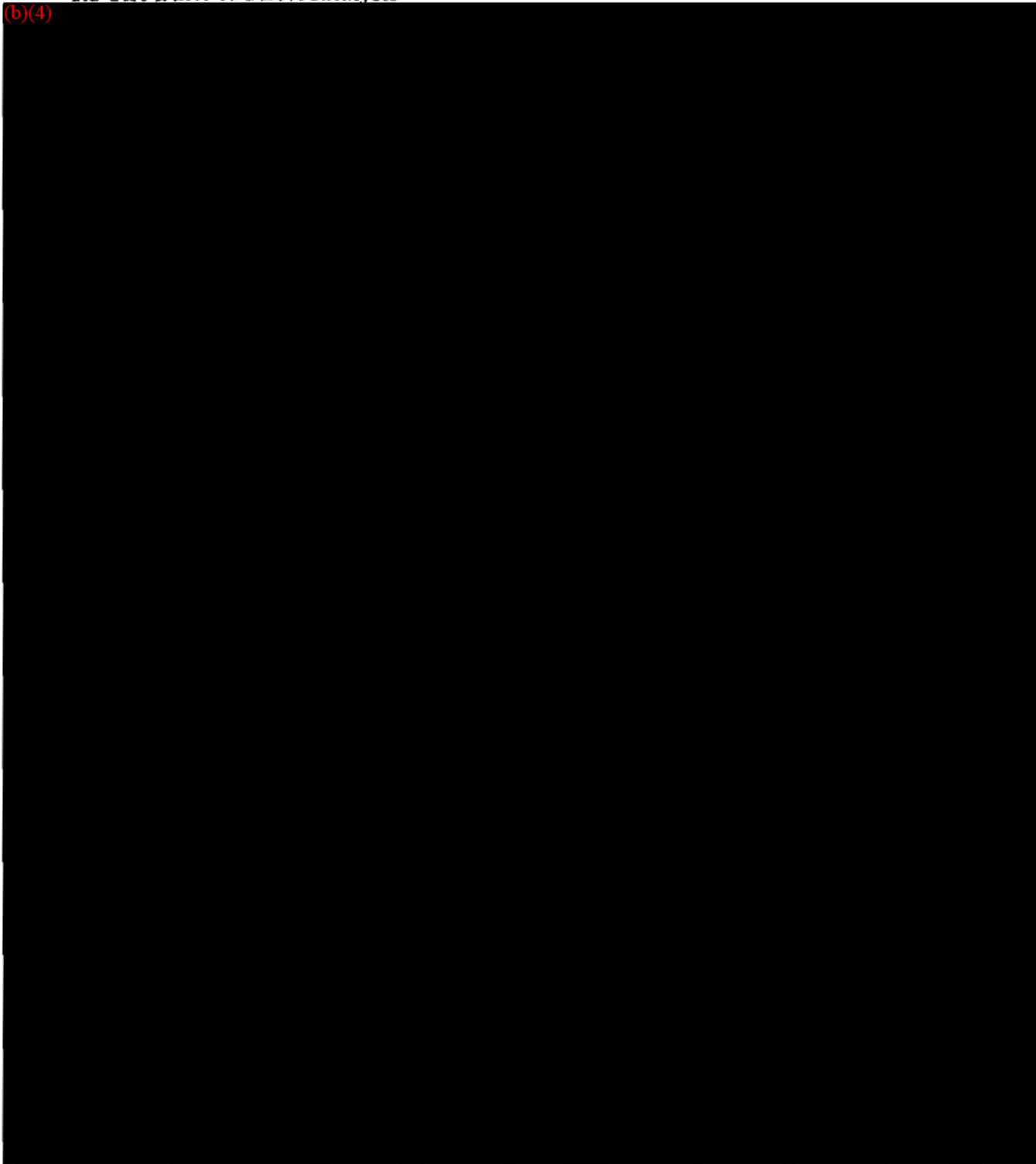
1.1 Photocatalytic Oxidation

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1.2 The Basis of Photocatalysis

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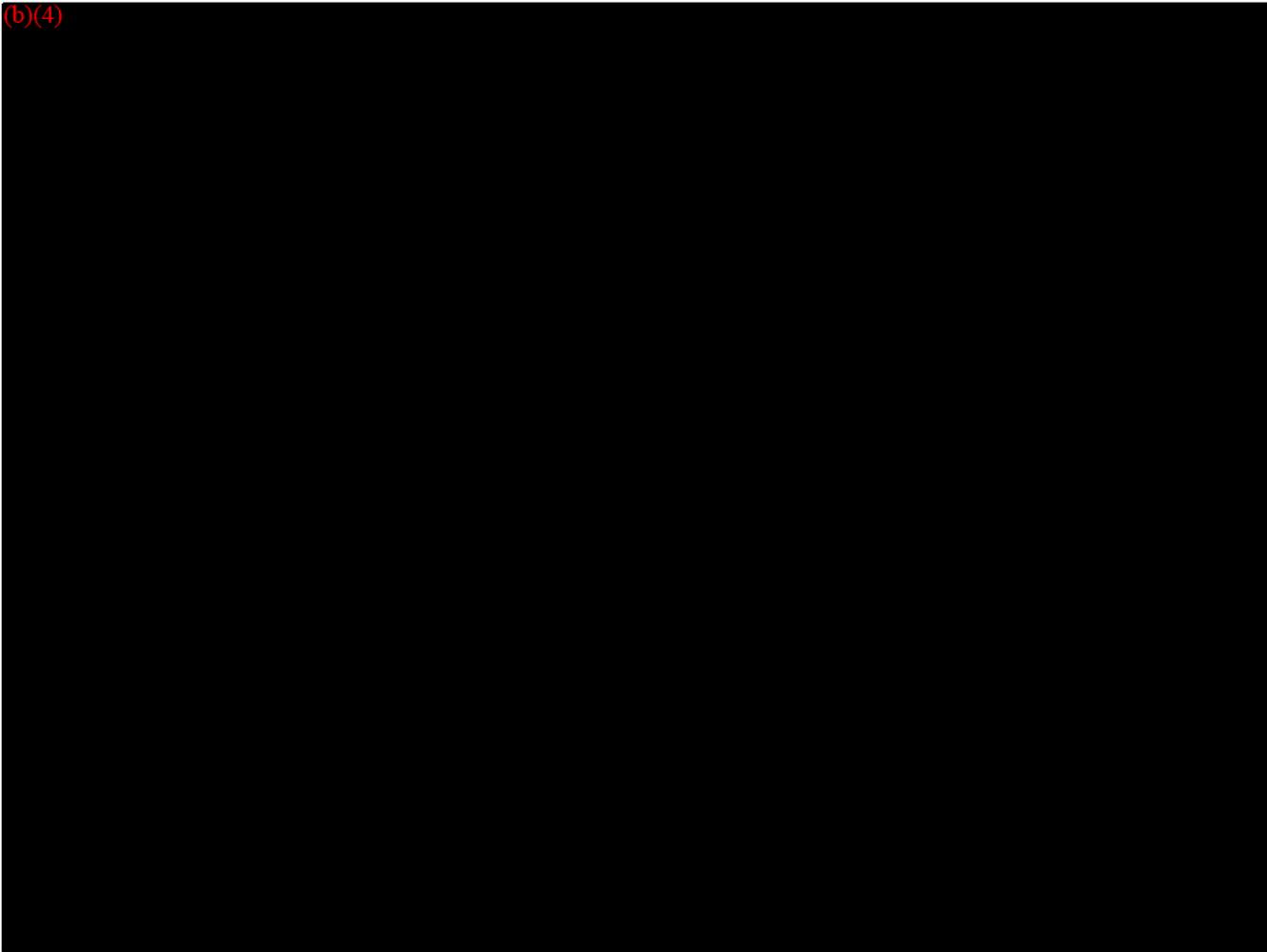


(b)(4)



Figure 1.1 Schematic of photocatalytic process at particle level

(b)(4)

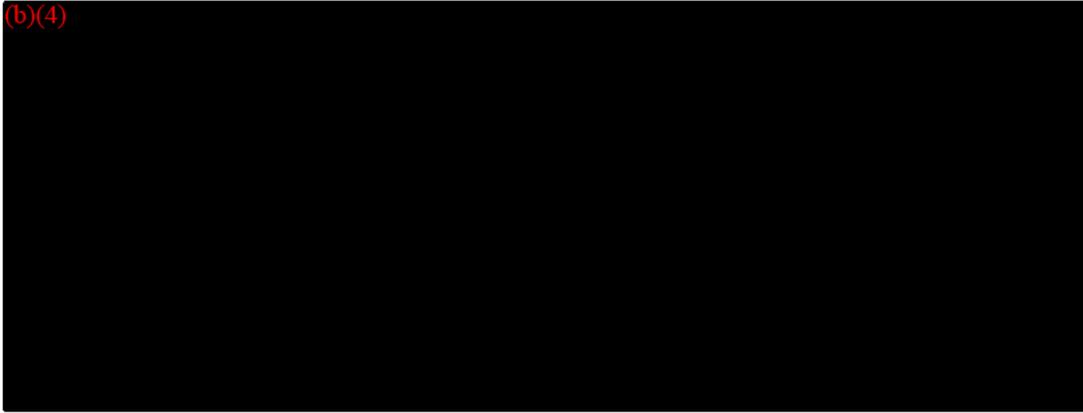


111

(b) (b)(4)

(c)

(d)



1.3 Light Source Character

(b)(4)



1.4 Photocatalytic Oxidation of Gas-Phase Compounds

(b)(4)

1.4.1 Compounds Studied**1.4.1.1 Organic Compounds**

(b)(4)

Survey of Literature

- 1,1,1-trichloroethane (CHCl₂CH₂Cl)** – d’Hennezel & Ollis (1997), d’Hennezel (1998), Isidorov et al. (1997)
- 1,3-butadiene (H₂C:CHHC:CH₂)** – Obee & Brown (1995)
- 1,4-dioxane (OCH₂CH₂OCH₂CH₂)** – d’Hennezel and Ollis (1997), d’Hennezel (1998)
- 1-butanol (CH₃(CH₂)₃OH)** – Peral and Ollis (1992), Blake and Griffin (1988)
- 1-butene (C₄H₈)** – Cao et al. (1999)
- 2-hexene (C₆H₁₂)** – Ohno et al. (1998)
- 2-propanol (isopropanol, C₃H₈O)** – Ait-Ichou et al. (1985), Alberici and Jardim (1997), Bickley et al. (1973), Cunningham and Hodnett (1981), Larson et al. (1995), Ohko et al. (1997), Ohko et al. (1998), Wentworth and Chen (1994)
- acetaldehyde (CH₃CHO)** – d’Hennezel & Ollis (1997), Obuchi et al. (1999), Ohko et al. (1998), Sauer and Ollis (1996), Shifu et al. (1998), Sopyan et al. (1994), Sopyan et al. (1996)
- acetic acid (CH₃CO₂H)** – Muggli and Falconer (1999), Sclafani et al. (1988)
- acetone (CH₃COCH₃)** – Alberici and Jardim (1997), Peral and Ollis (1992), Sauer and Ollis (1996), Shifu et al. (1998), Vorontsov et al. (1997), Vorontsov et al. (1999), Yu et al. (1998), Zorn et al. (1999)
- benzene (C₆H₆)** – Atkinson and Schmann (1989), d’Hennezel and Ollis (1996), d’Hennezel and Ollis (1997), d’Hennezel et al. (1998), Einaga et al. (1999), Fu et al. (1995), Ibusuki and Takeuchi (1986), Jacoby et al. (1996), Larson and Falconer (1997), Luo and Ollis (1996), Sauer et al. (1995), Seuwen and Warneck (1994), Sitkiewitz and Heller (1996)
- butyraldehyde (CH₃(CH₂)₂CHO)** – Peral and Ollis (1992)
- carbon dioxide (CO₂)** – Anpo et al. (1995)
- carbon monoxide (CO)** – Anderson et al. (1996), Vorontsov et al. (1997a, 1998b)
- chloroform (CHCl₃)** – Alberici and Jardim (1997), Alberici et al. (1998)

dichloromethane (CH₂Cl₂) – Alberici et al. (1998)
diethyl ether ((C₂H₅)₂O) – Vorontsov et al. (1997b)
dimethoxymethane (C₃H₈O₂) – Alberici and Jardim (1997)
dimethylmethylphosphonate (DMMP, (CH₃)₂CH₃PO₂) – Obee and Satyapal (1998)
ethanol (C₂H₅OH) – Cunningham et al. (1974), Kennedy and Datye (1998), Muggli et al. (1996), Muggli et al. (1998), Nimlos et al. (1996), Sauer and Ollis (1996), Vorontsov et al. (1997b)
ethylene (H₂C:CH₂) – Fu et al. (1996a), Obee and Hay (1997), Sirisuk et al. (1999), Yamazaki et al. (1999), Zorn et al. (2000)
formaldehyde (HCHO) – Noguchi et al. (1998), Obee (1996), Obee & Brown (1995), Peral & Ollis (1992)
iso-octane ((CH₃)₂CH(CH₂)₄CH₃) – Alberici and Jardim (1997)
isopropyl alcohol ((CH₃)₂CHOH) – Brinkley & Engel (1998a); Brinkley & Engel (1998b)
isopropylbenzene (C₉H₁₂) – Alberici and Jardim (1997)
methane (CH₄) – Dreyer et al. (1997), Okabe et al. (1997)
methanol (MeOH, CH₃OH) – Alberici and Jardim (1997), d'Hennezel & Ollis (1997), Liu et al. (1985)
methyl acrylate (CH₂:CHCOOCH₃) – d'Hennezel & Ollis (1997)
methyl chloroform (C₂H₃Cl₃) – Alberici and Jardim (1997)
methyl ethyl ketone (MEK, CH₃COCH₂CH₃) – Alberici and Jardim (1997), d'Hennezel & Ollis (1997)
methyl isopropyl ketone (C₅H₁₀O) – Alberici and Jardim (1997)
methyl tert-butyl ether ((CH₃)₃COCH₃) – d'Hennezel & Ollis (1997)
methylene chloride (CH₂Cl₂) – Alberici and Jardim (1997), d'Hennezel & Ollis (1997)
m-xylene (C₈H₁₀) – Peral and Ollis (1992)
propene (C₃H₆) – Pichat et al. (1979)
propionaldehyde (C₂H₅CHO) – Takeda et al. (1995), Takeda et al. (1997)
pyridine (C₅H₅N) – Alberici and Jardim (1997), Sampath et al. (1994)
t-butyl methyl ether (C₅H₁₂O) – Alberici and Jardim (1997)
tetrachloroethylene (PCE, Cl₂C:CCl₂) – Alberici et al. (1998), Alberici and Jardim (1997), Hung & Yuan (1998), Li et al. (1998)
toluene (C₆H₅CH₃) – Blanco et al. (1996), d'Hennezel et al. (1998), Ibrahim and de Lasa (1999), Li et al. (1998), Luo and Ollis (1996), Méndez-Román & Cardona-Martínez (1998), Obee (1996), Obee & Brown (1995)
trichloroethylene (TCE, CHCl:CCl₂) – Alberici et al. (1998), Alberici and Jardim (1997), Annapragada et al. (1997), Buechler et al. (1999), Driessen et al. (1998a, 1998b, 1998c), Dibble and Raupp (1990), Dibble and Raupp (1992), Hung and Marinas (1997a, 1997b), Hwang et al. (1998), Kim et al. (1996), Kim et al. (1998), Liu et al. (1997), Luo and Ollis (1996), Nimlos et al. (1993), Phillips and Raupp (1992), Wang et al. (1998a, 1998b, 1998c), Yamazaki-Nishida et al. (1993), Yamazaki-Nishida et al. (1995), Yamazaki-Nishida et al. (1996)
vinyl acetate (CH₃COOCH:CH₂) – d'Hennezel & Ollis (1997)
xylene – Blanco et al. (1996), d'Hennezel and Ollis (1997)
Investigations of multiple VOCs – Lichtin et al. (1996)

Detailed Descriptions of Select Organic Compounds

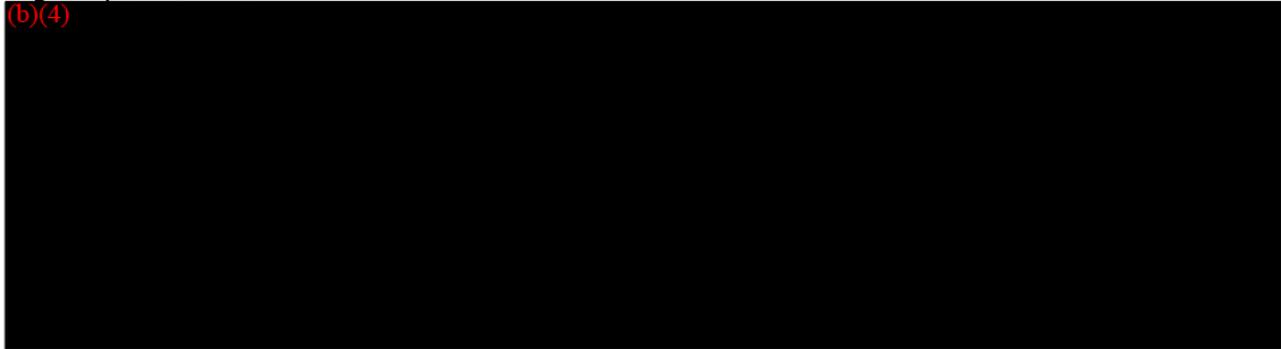
Toluene:

(b)(4)



Carbon dioxide:

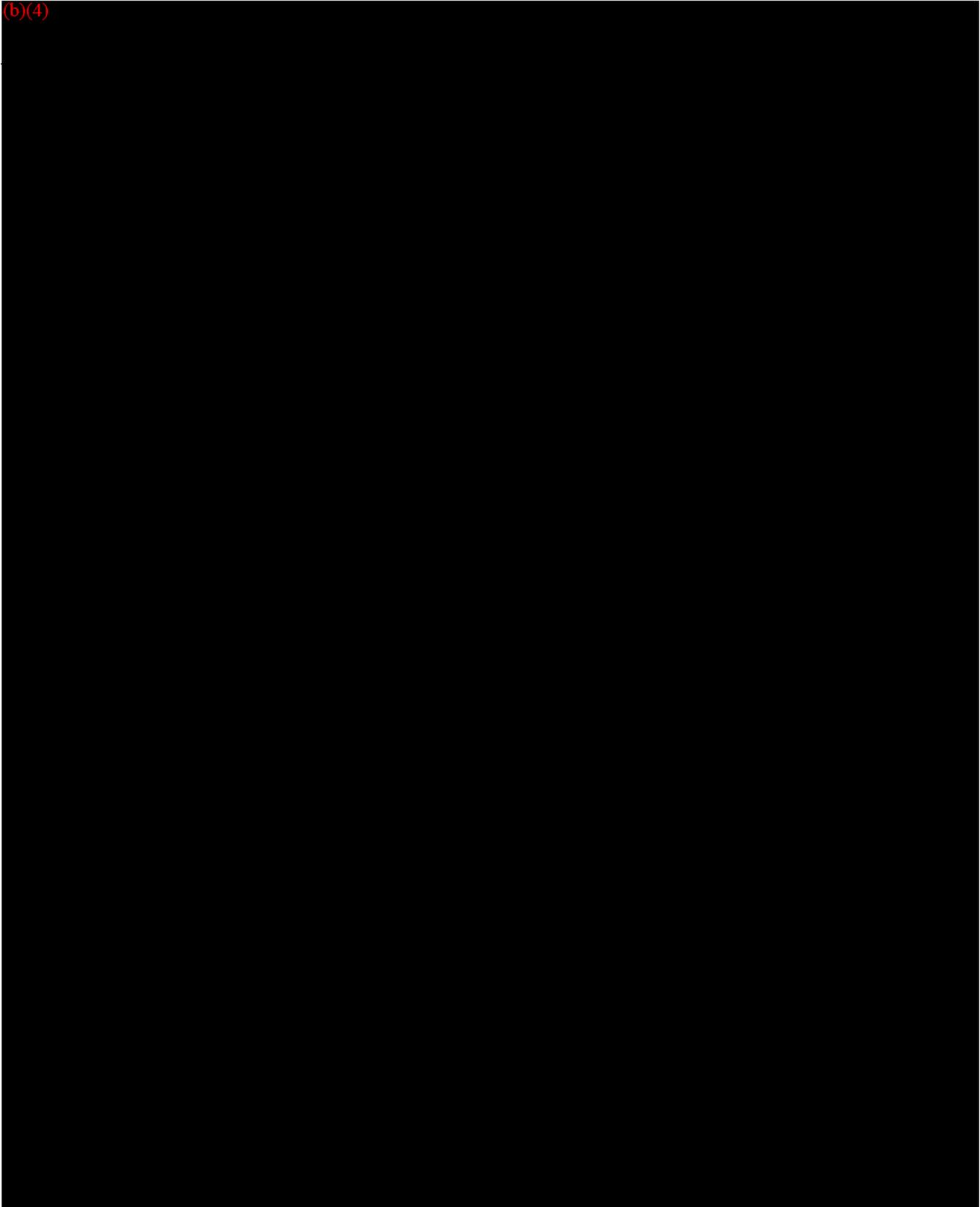
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19

(b)(4)



116
69

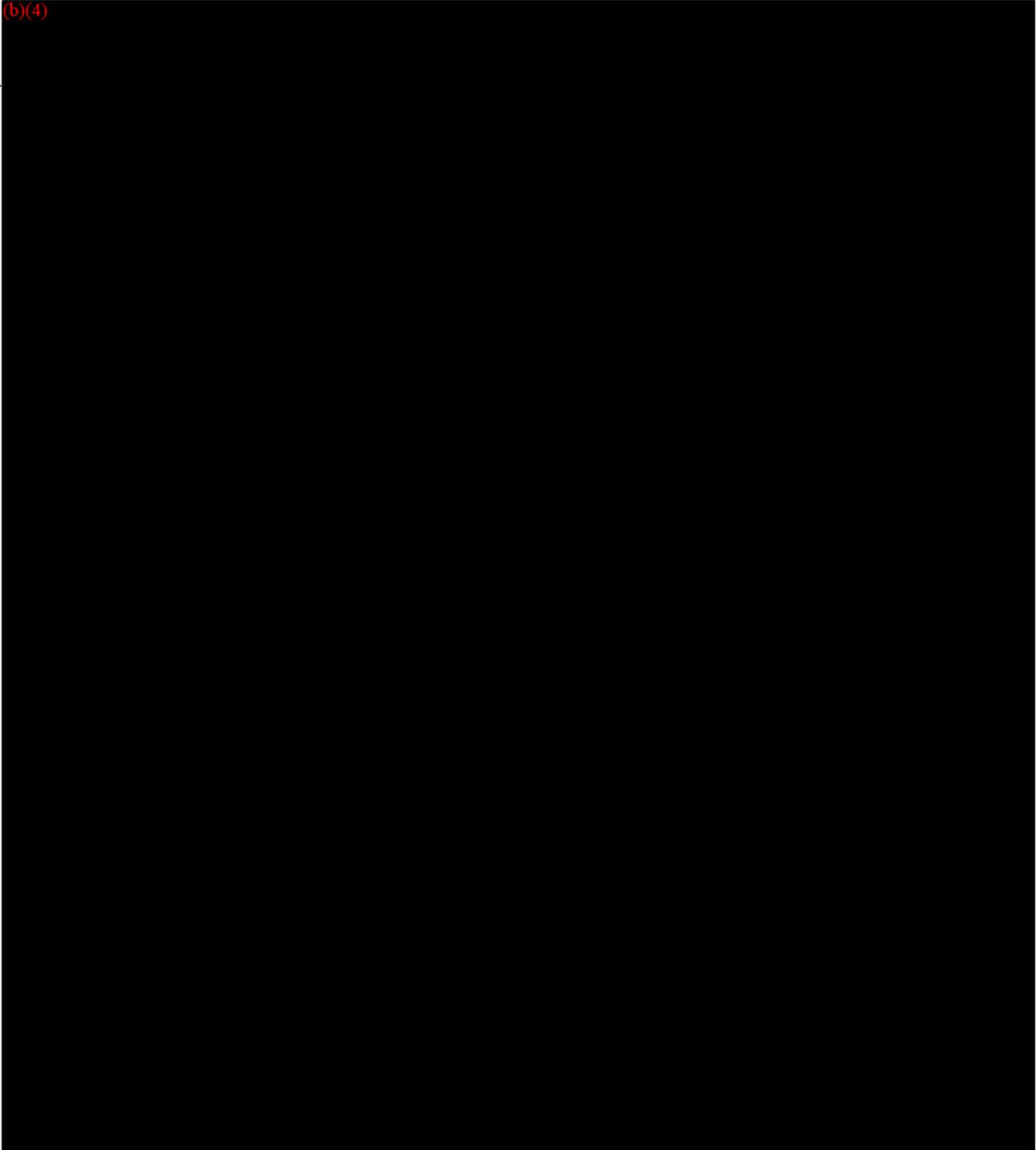
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ASHRAE 1134-RP

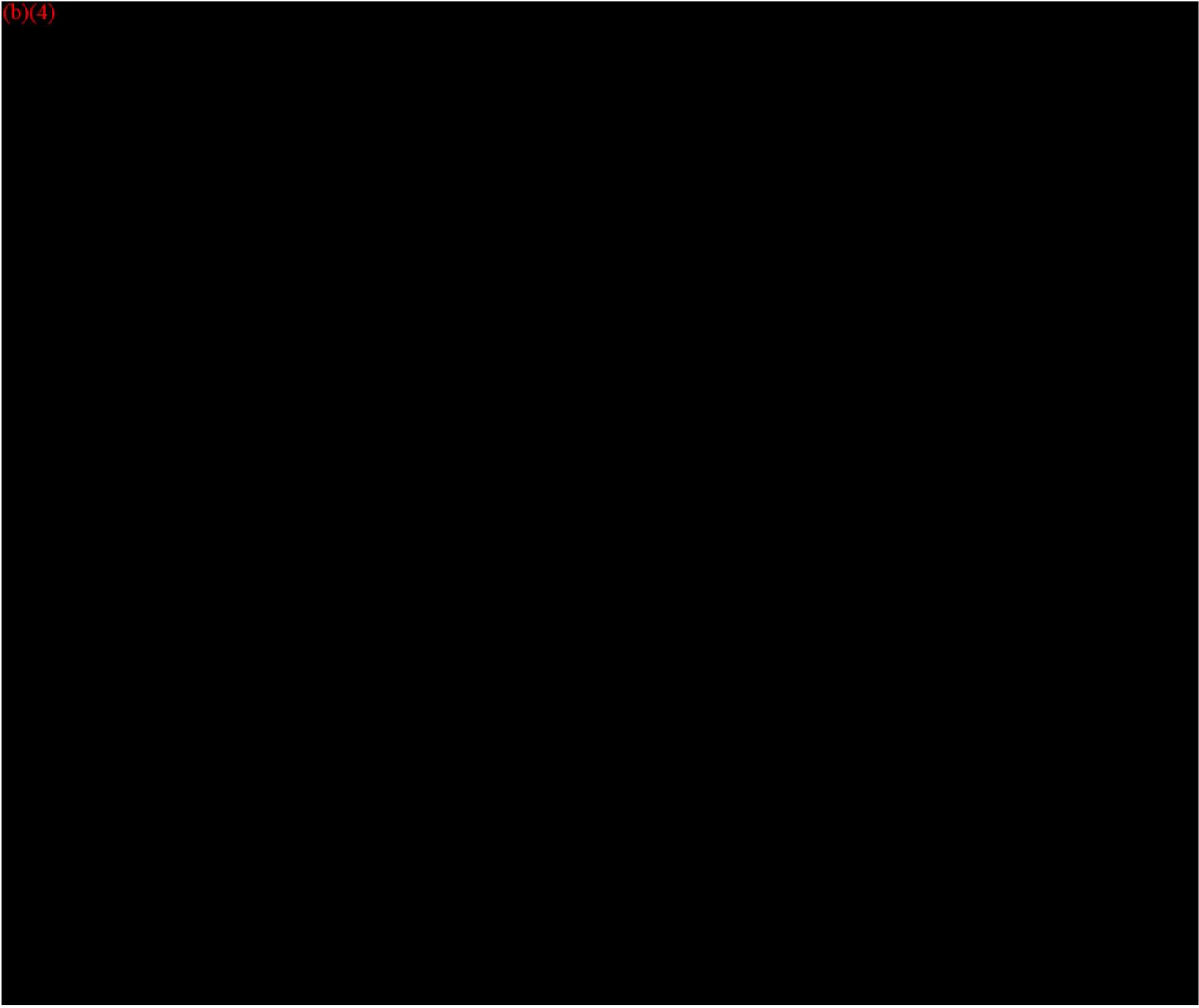
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118
71

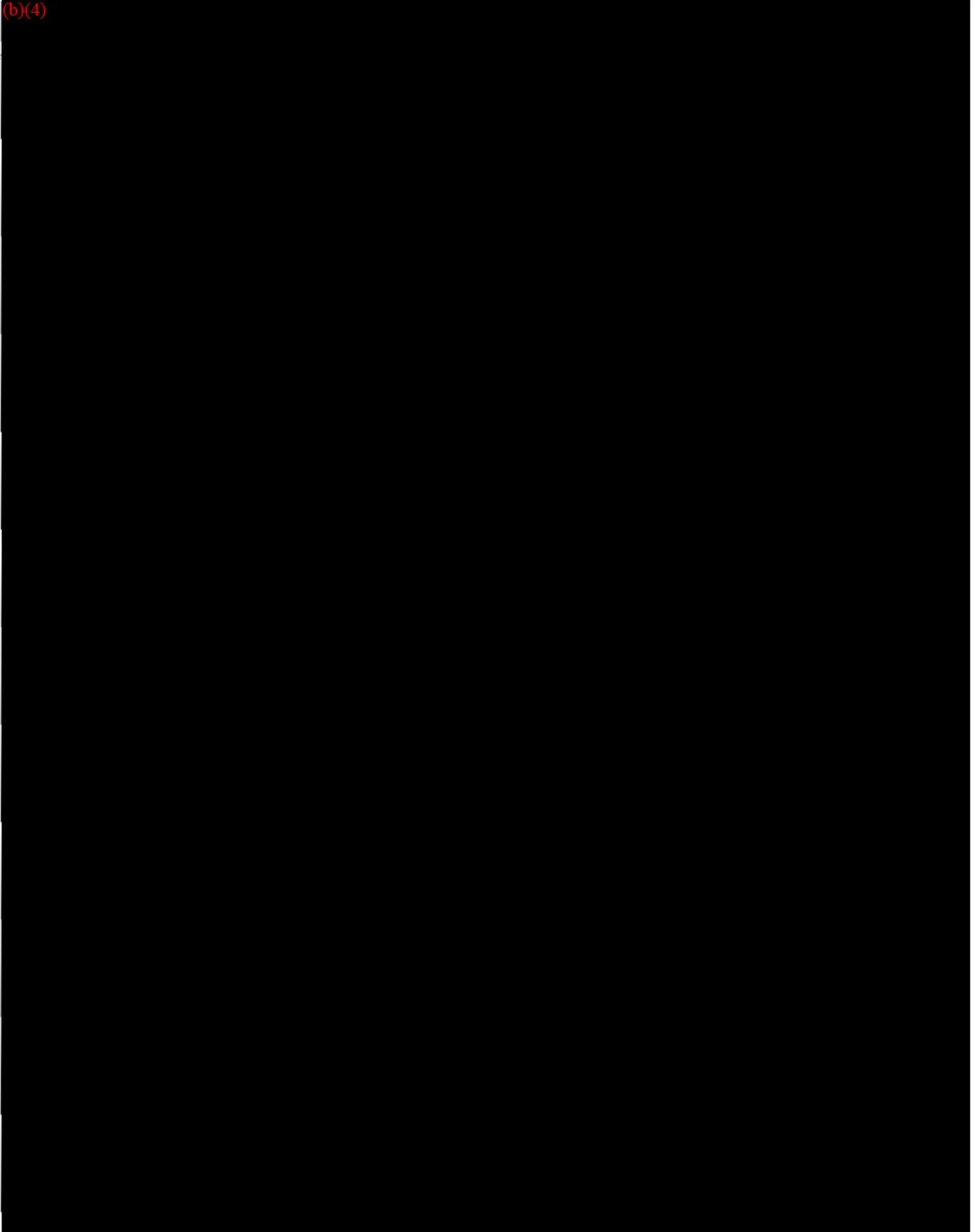
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23

(b)(4)



120
73

(b)(4)

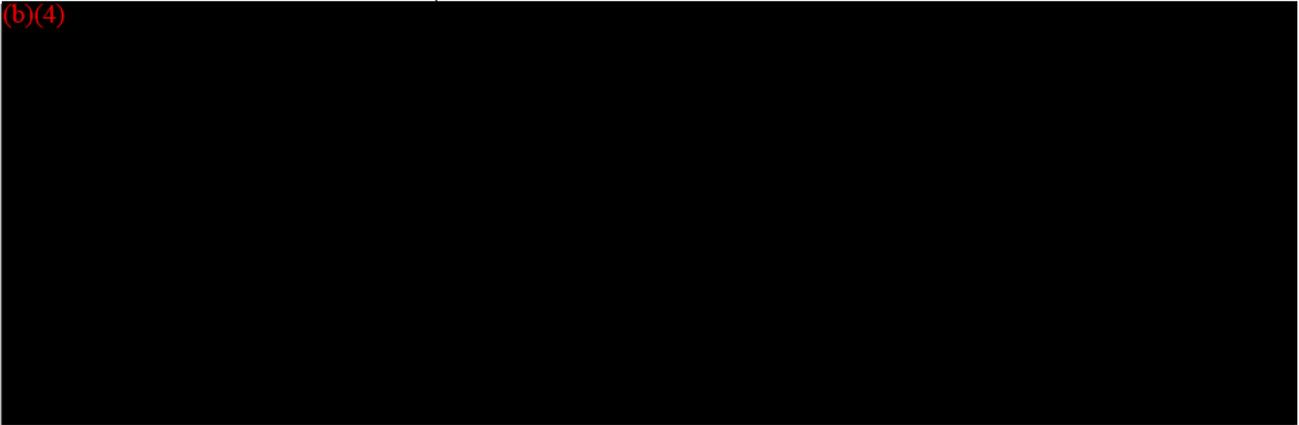
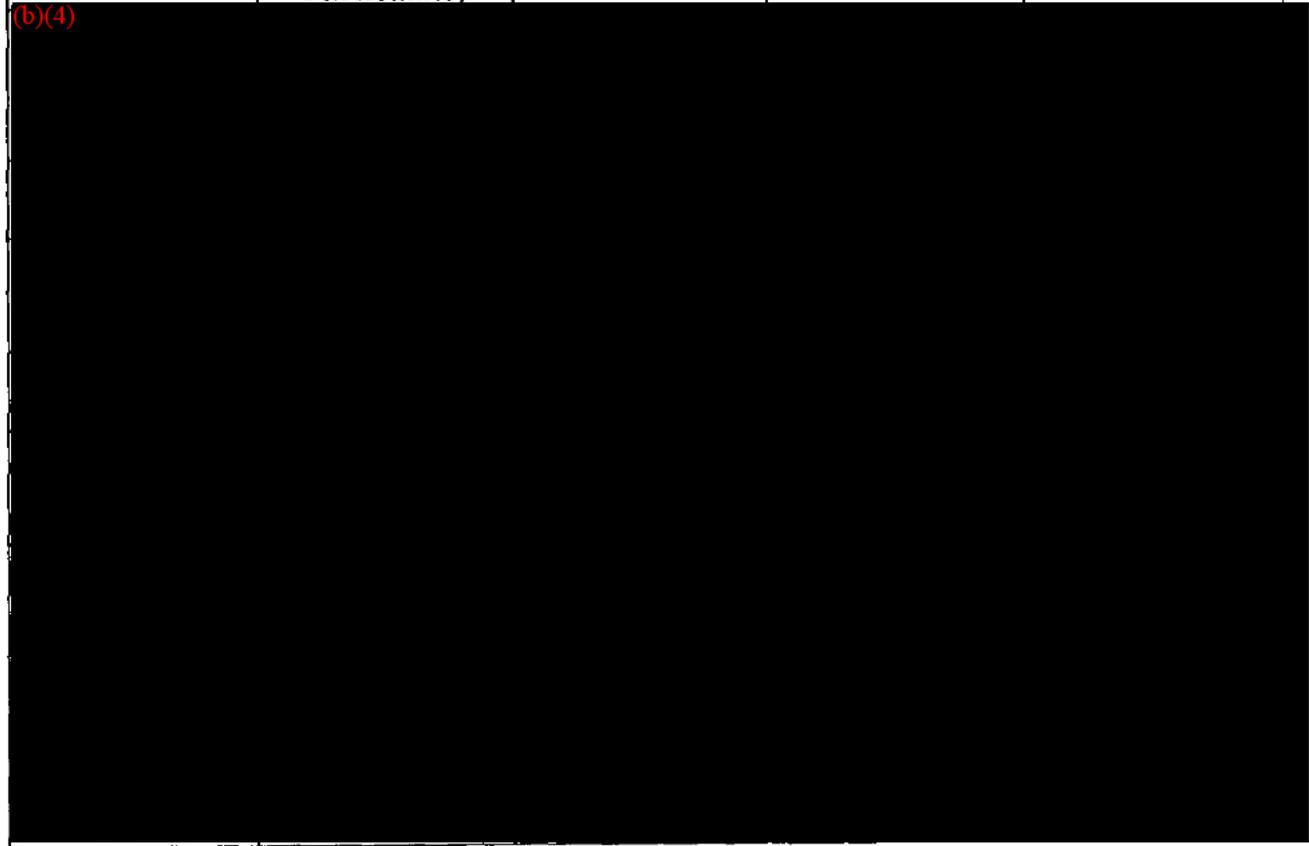


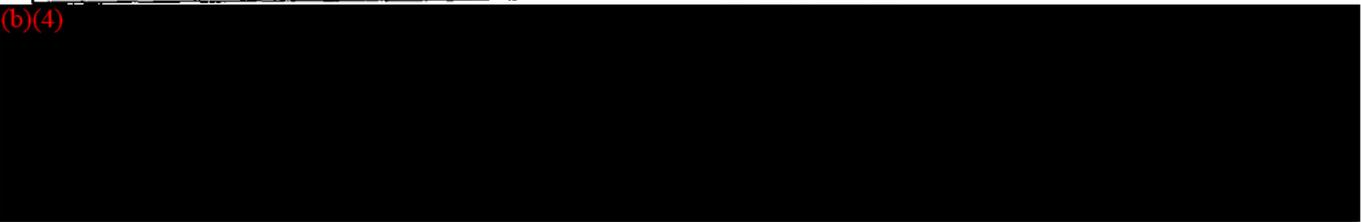
Table 1.2 Some photocatalyst formulations.

Semiconductor Photocatalyst	Form (Powder / Thin-film / Particulate)	Supported?	Catalyst Source	Reference
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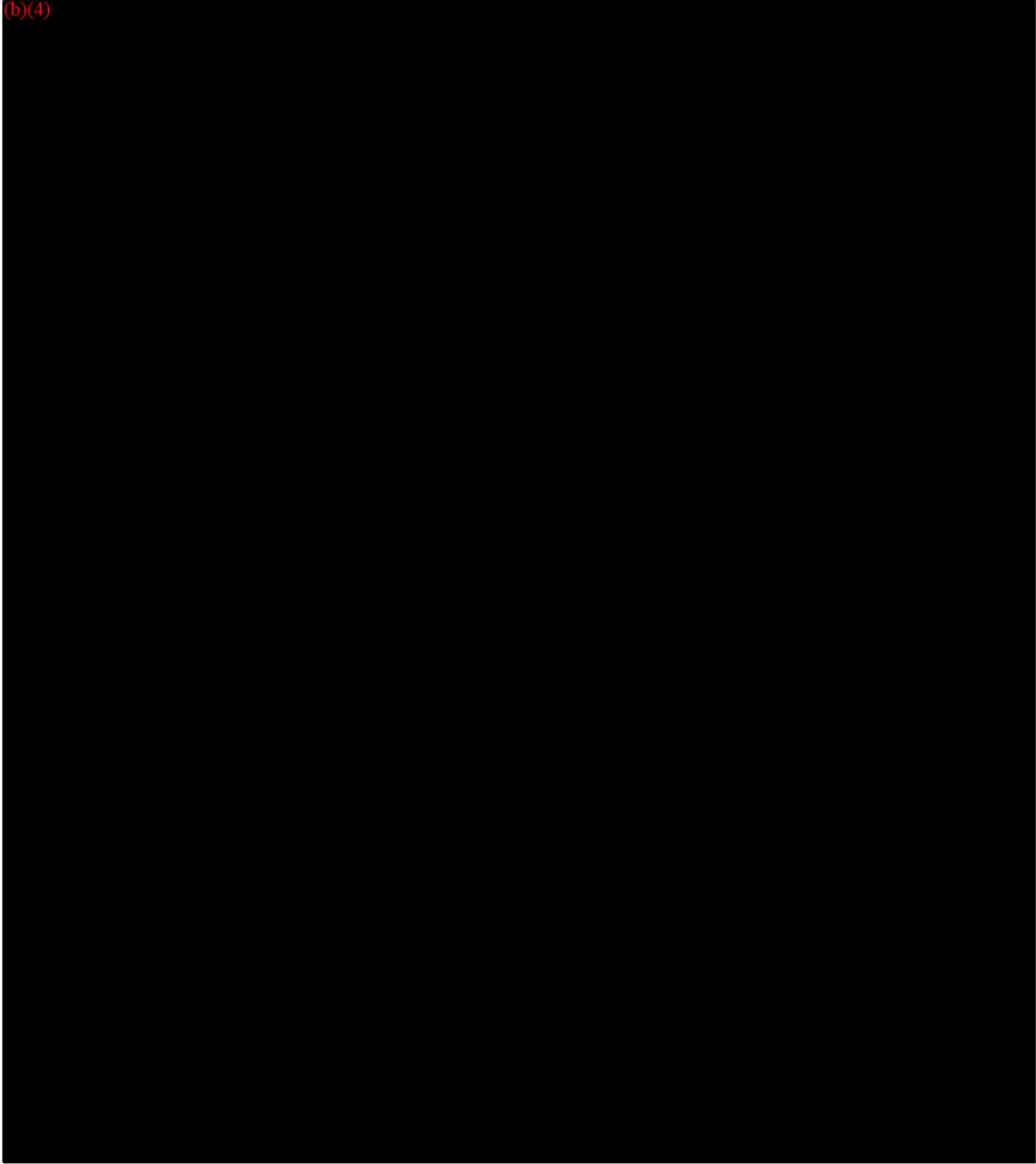
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25

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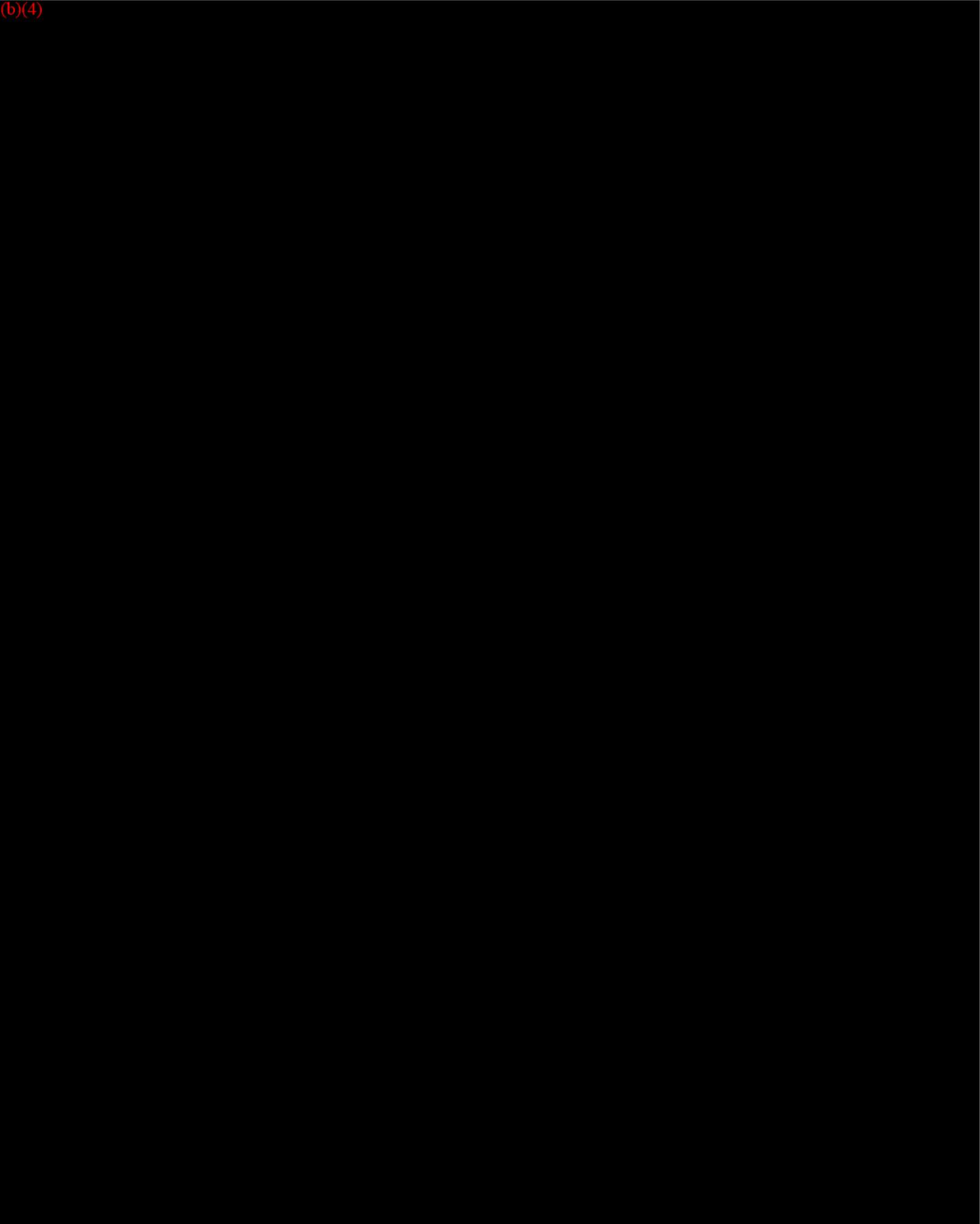


122
75

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26

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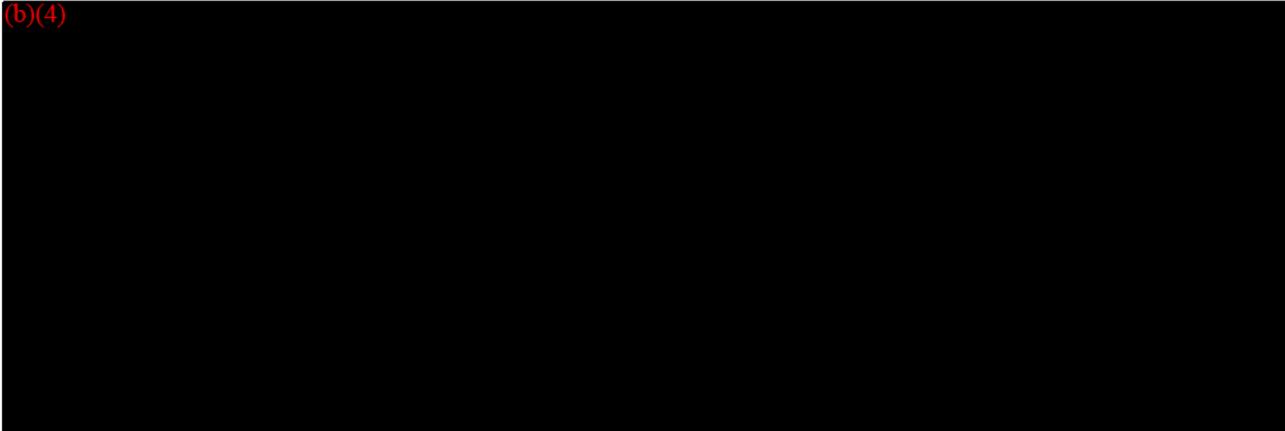


123

ASHRAE 1134-RP

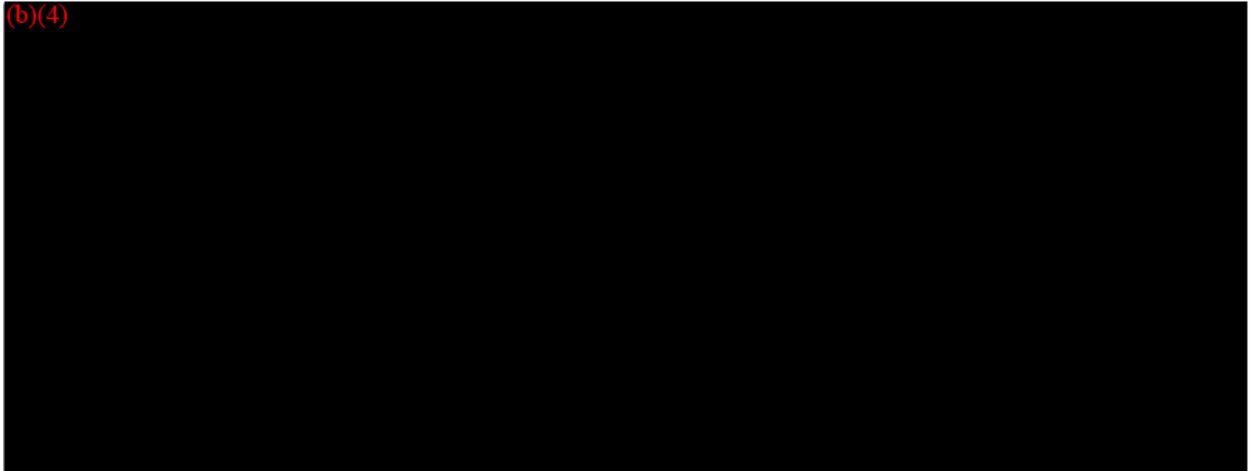
27

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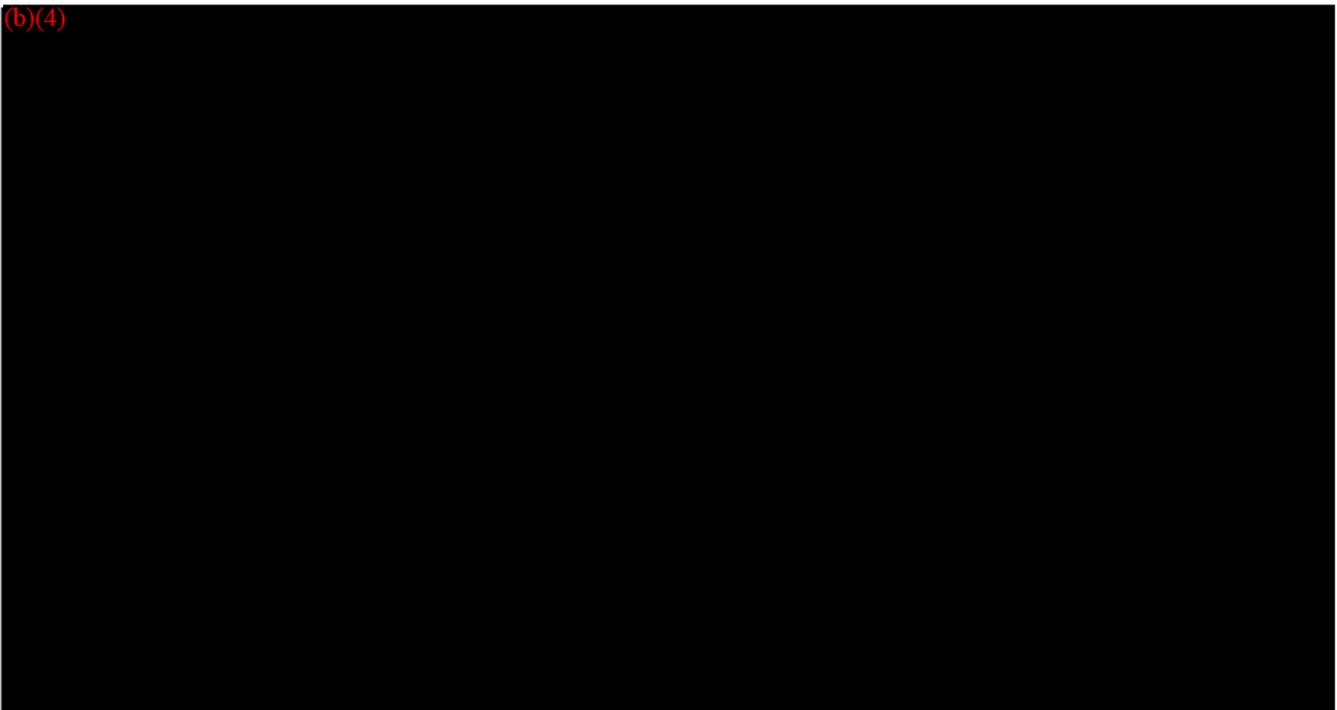


deprotonation

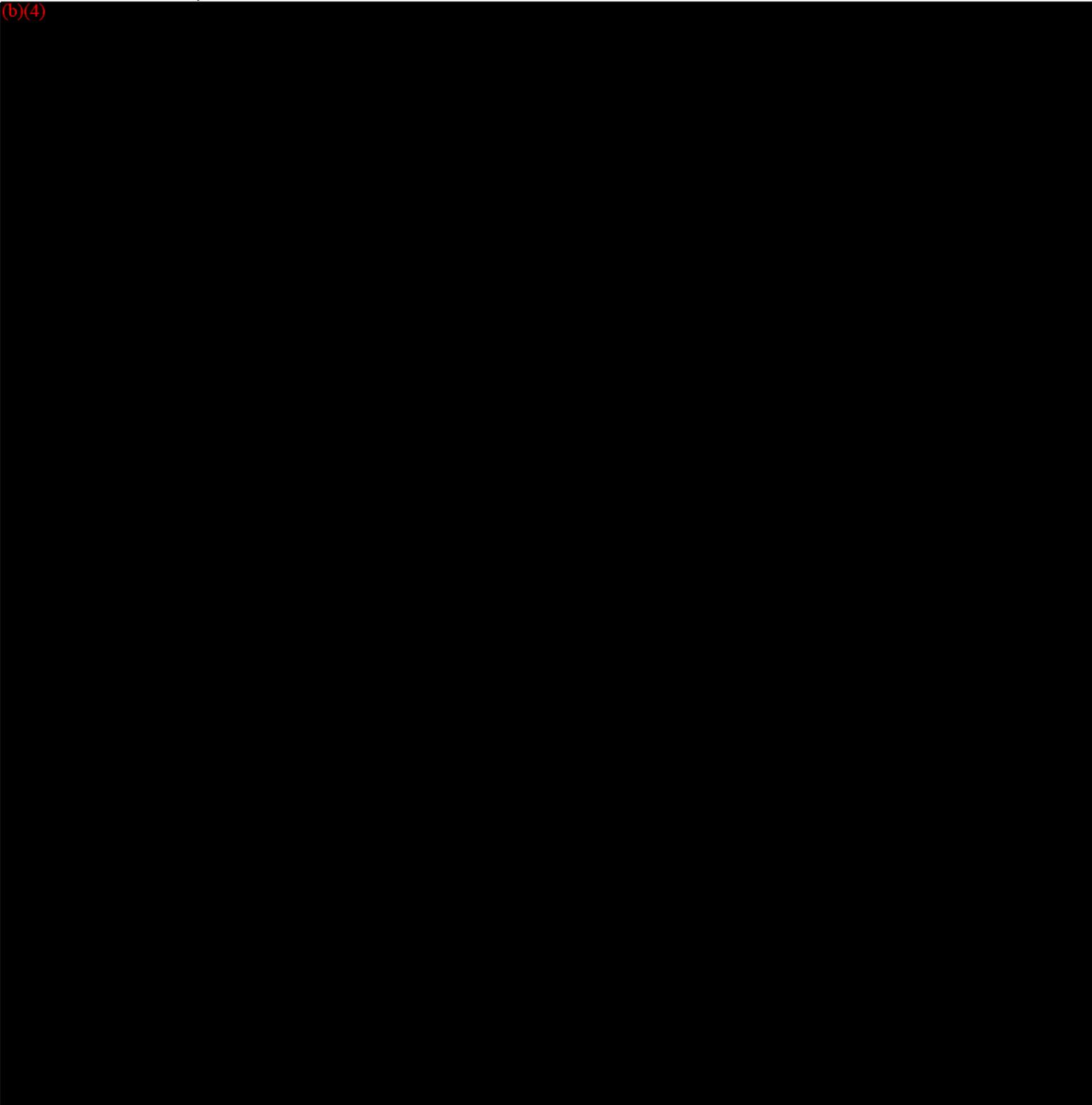
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(b)(4)



(b)(4)



125

Table 1.3 Photocatalytic Reaction Metrics

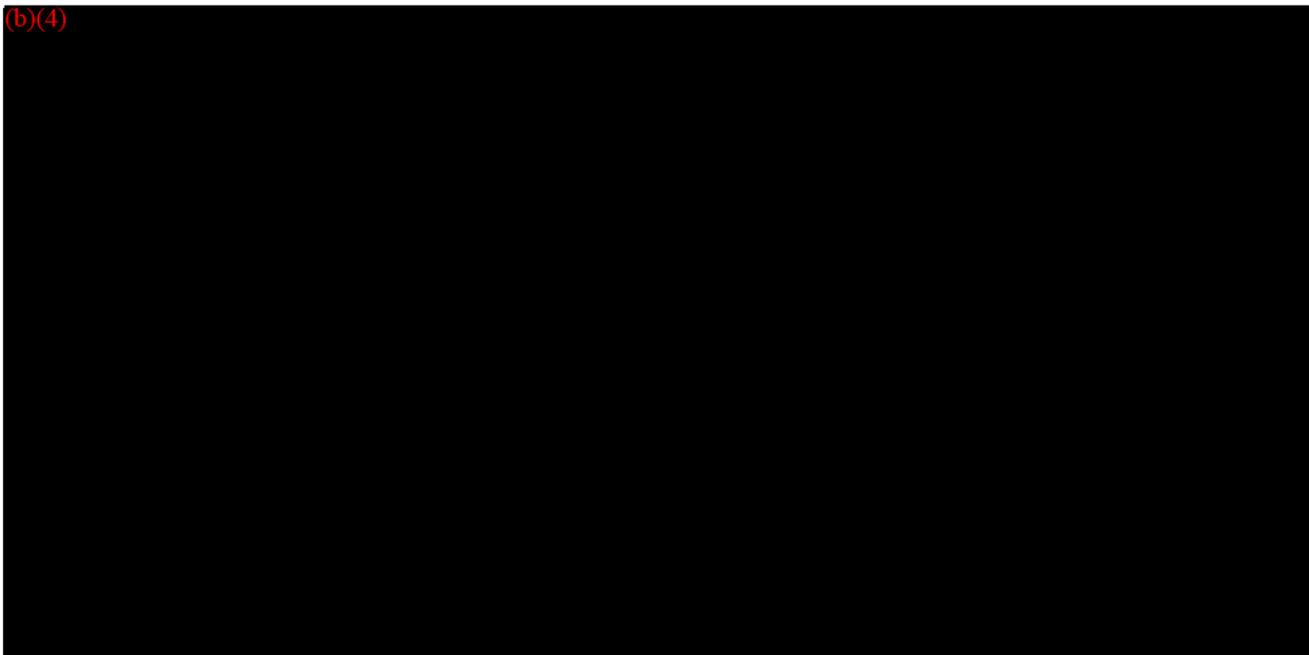
Compound	Observed Reaction Rates	Reaction Order (Rate Constant)	Reaction Mechanism Presented?	% Conversion	Reference
(b)(4)					

(b)(4)

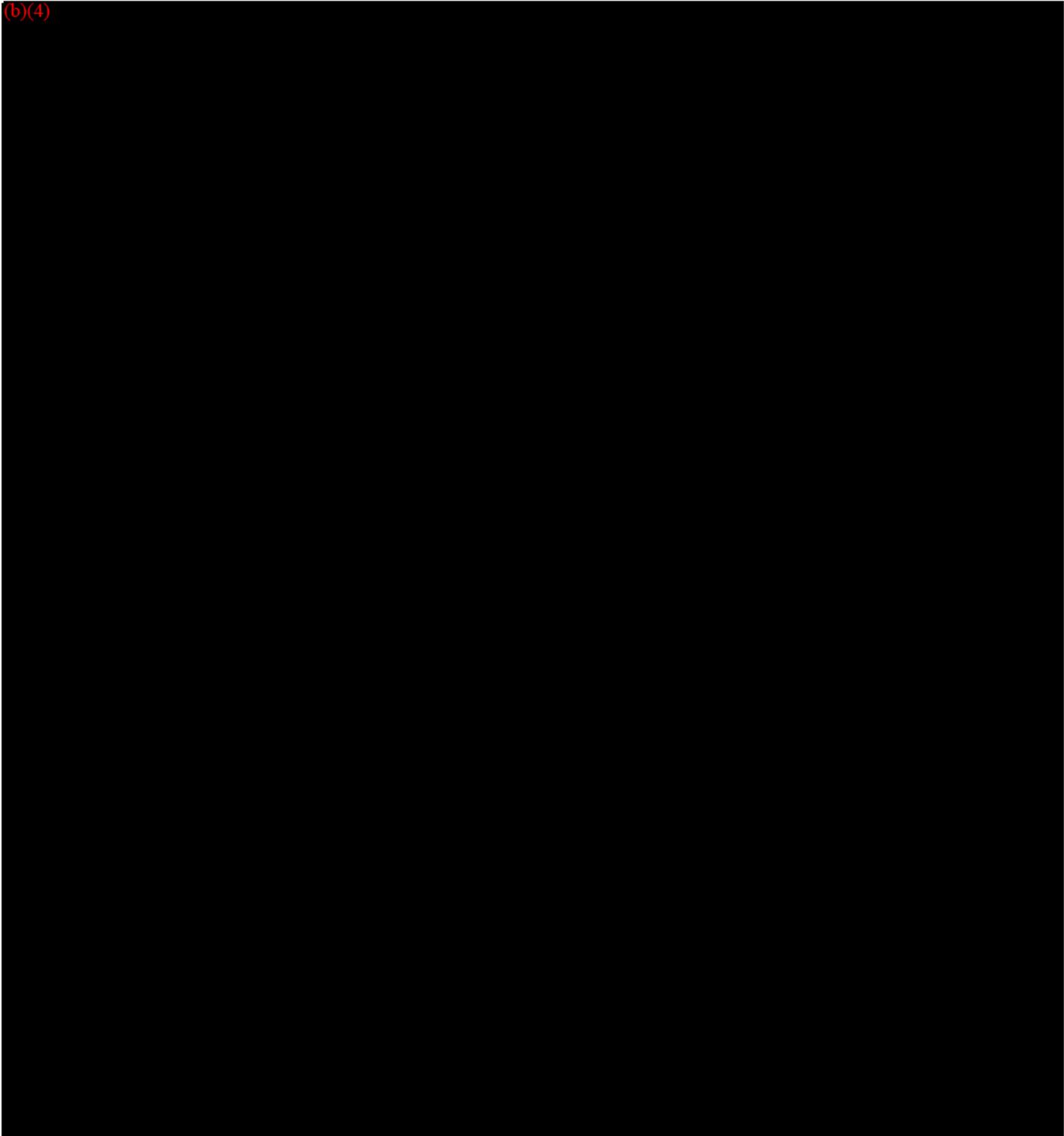




**Figure 1.2 Diagram of powder layer photocatalytic reactor.
Design employed by Teichner's group (Formenti et al. 1971).**



(b)(4)



(b)(4)

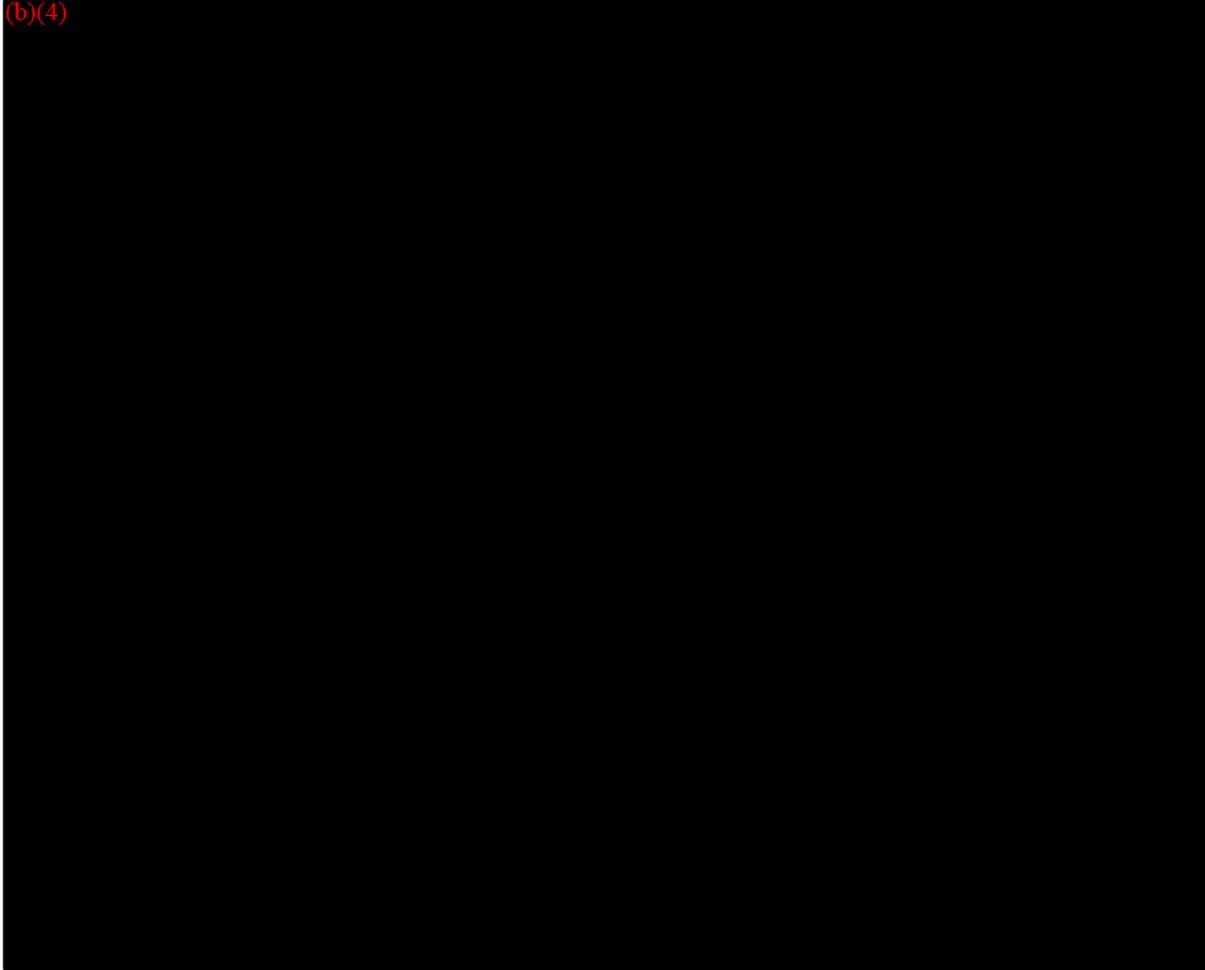
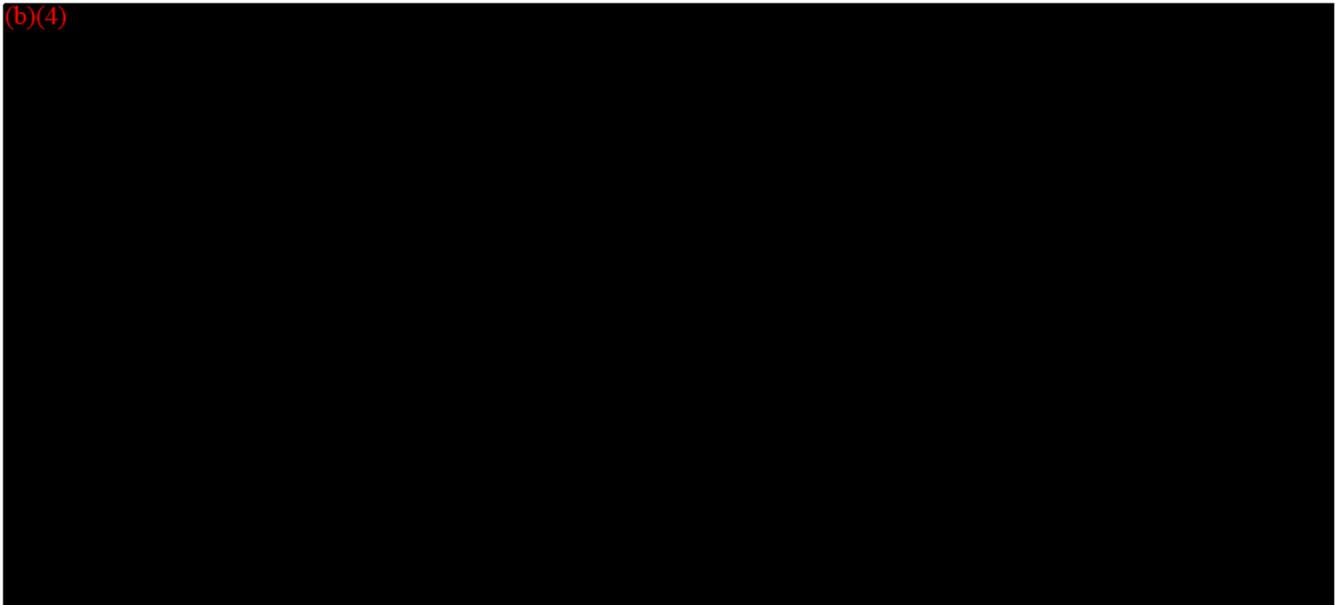
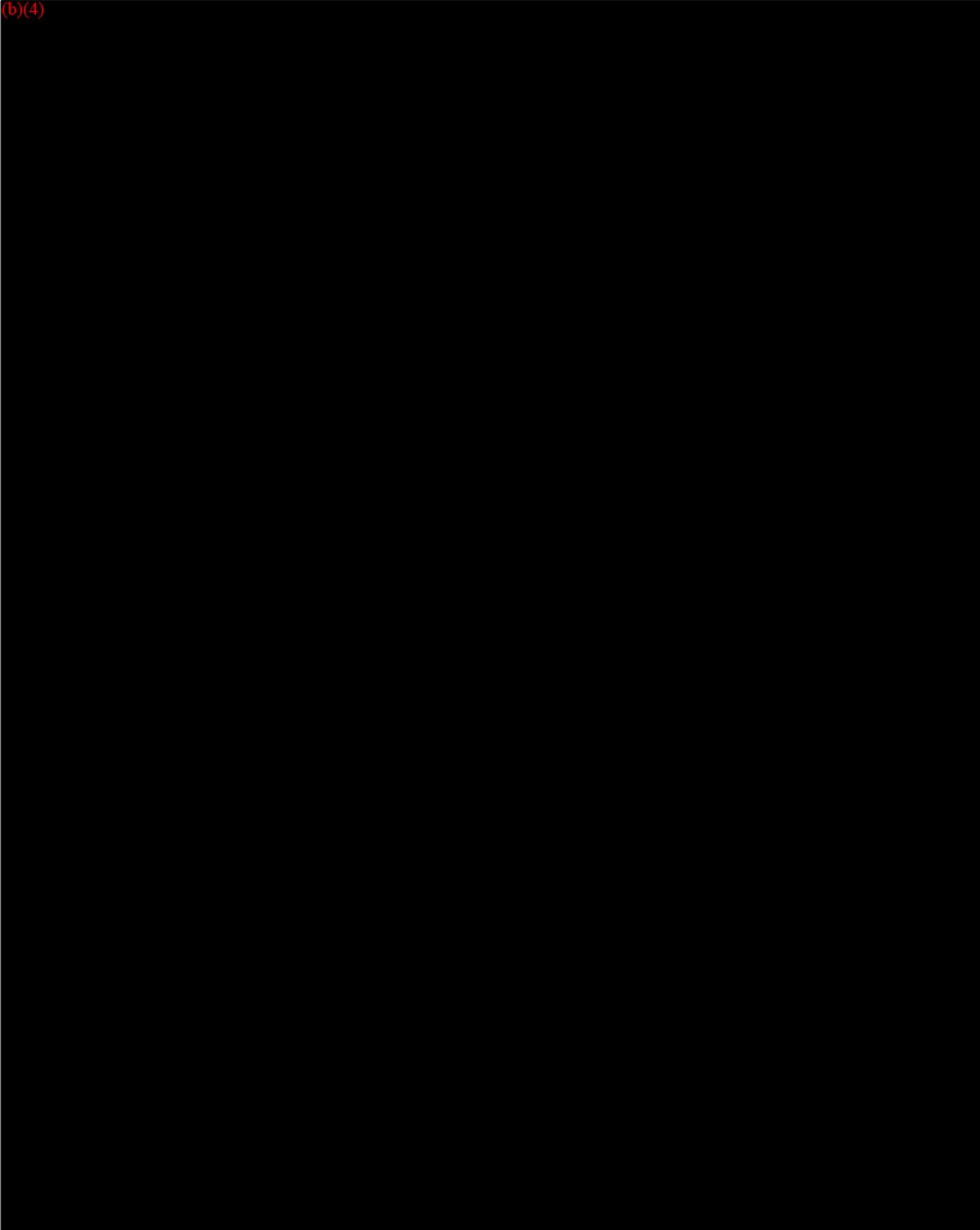


Figure 1.3 Transport reactor used by Ayoub (1986). d_o is lamp outer diameter, d_i is reactor inner wall outer diameter, and D_i is reactor outer wall inner diameter.

(b)(4)



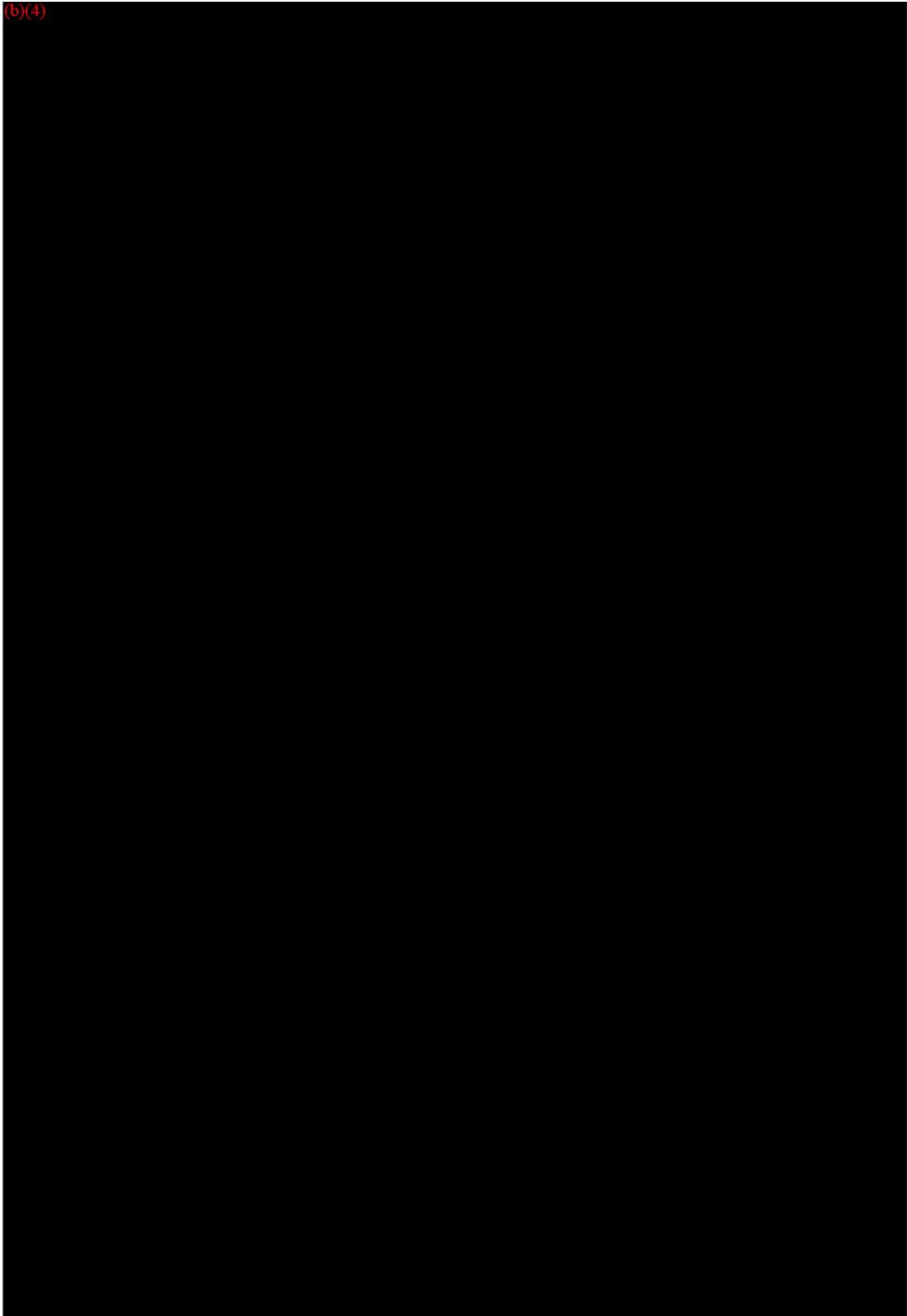
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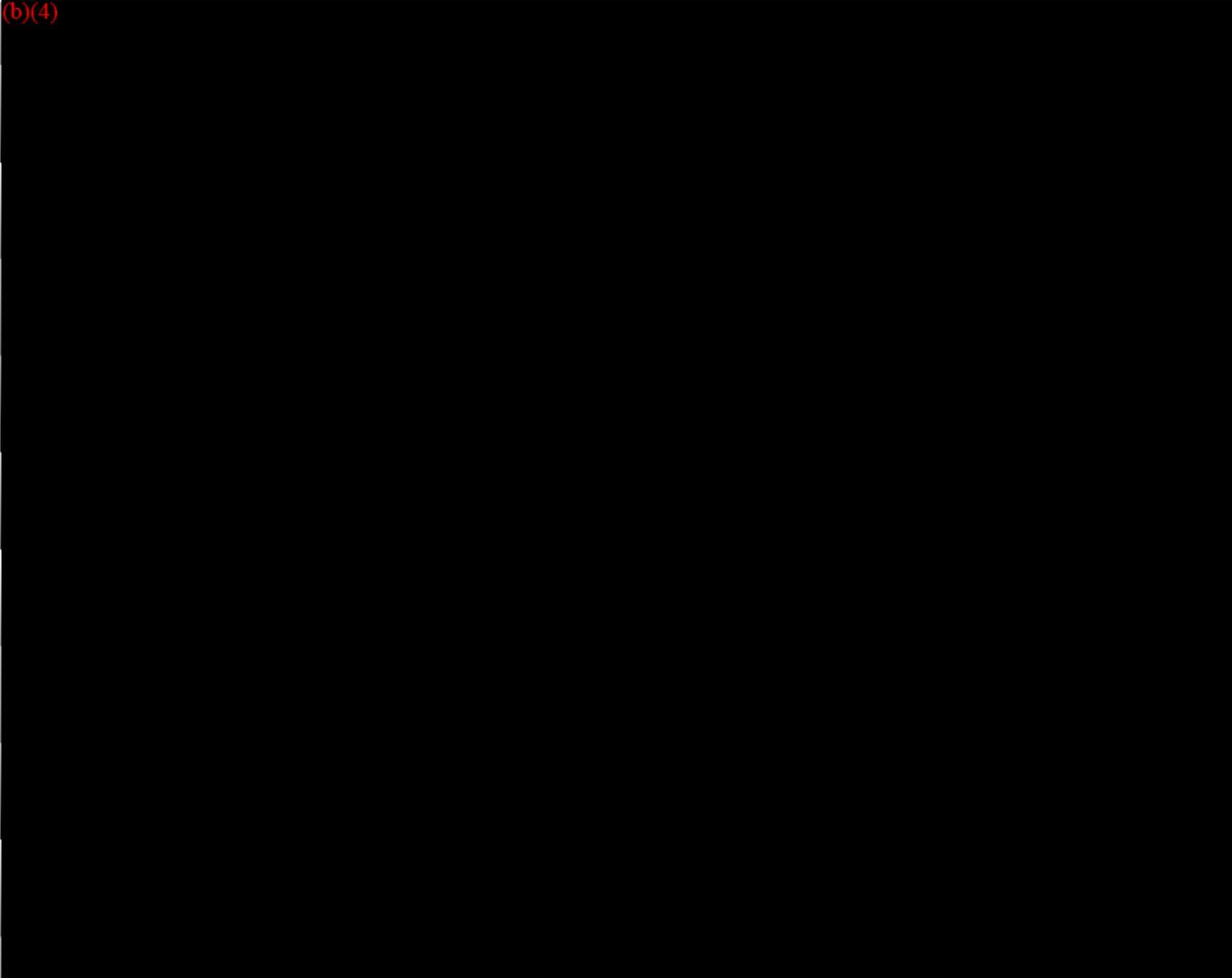
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32
85

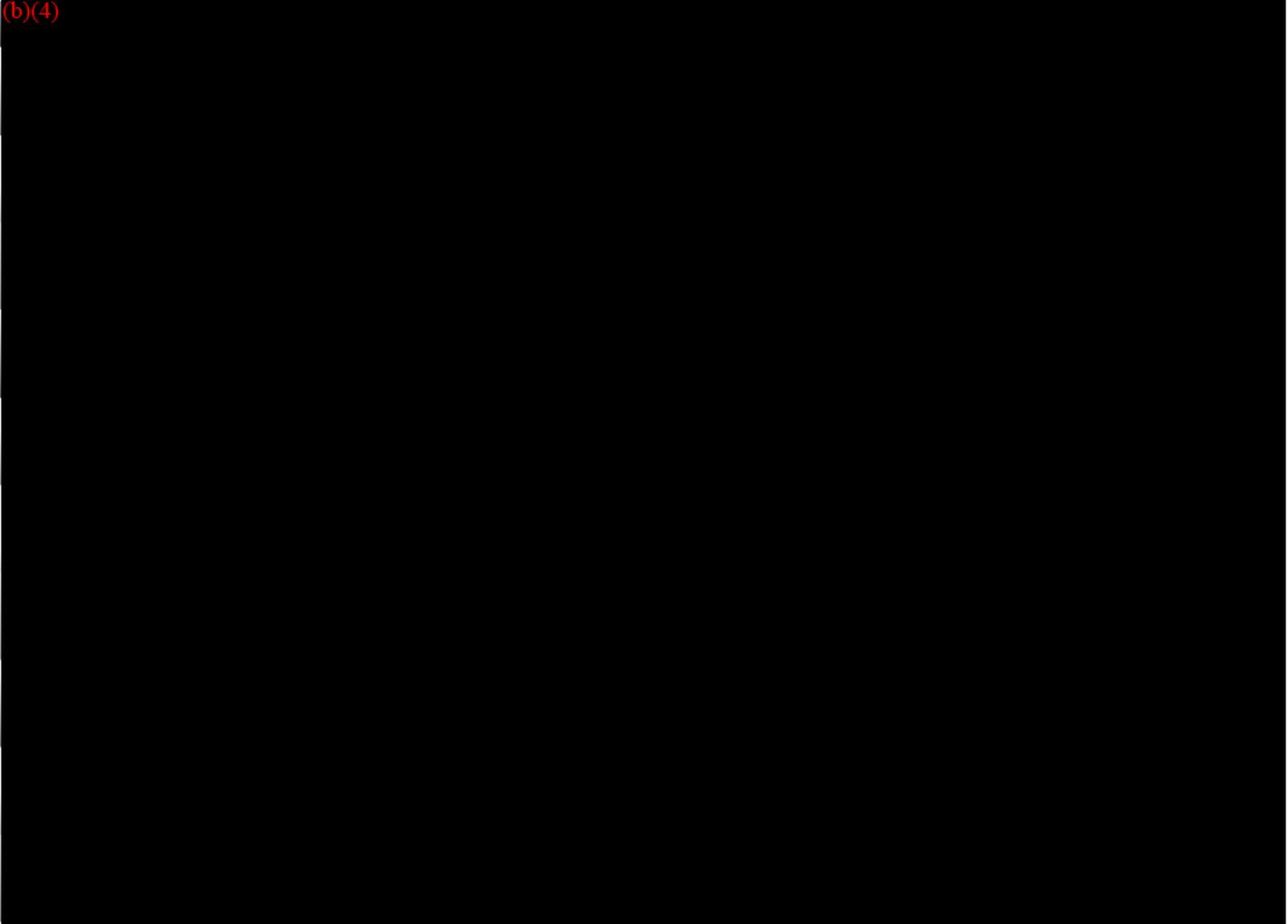
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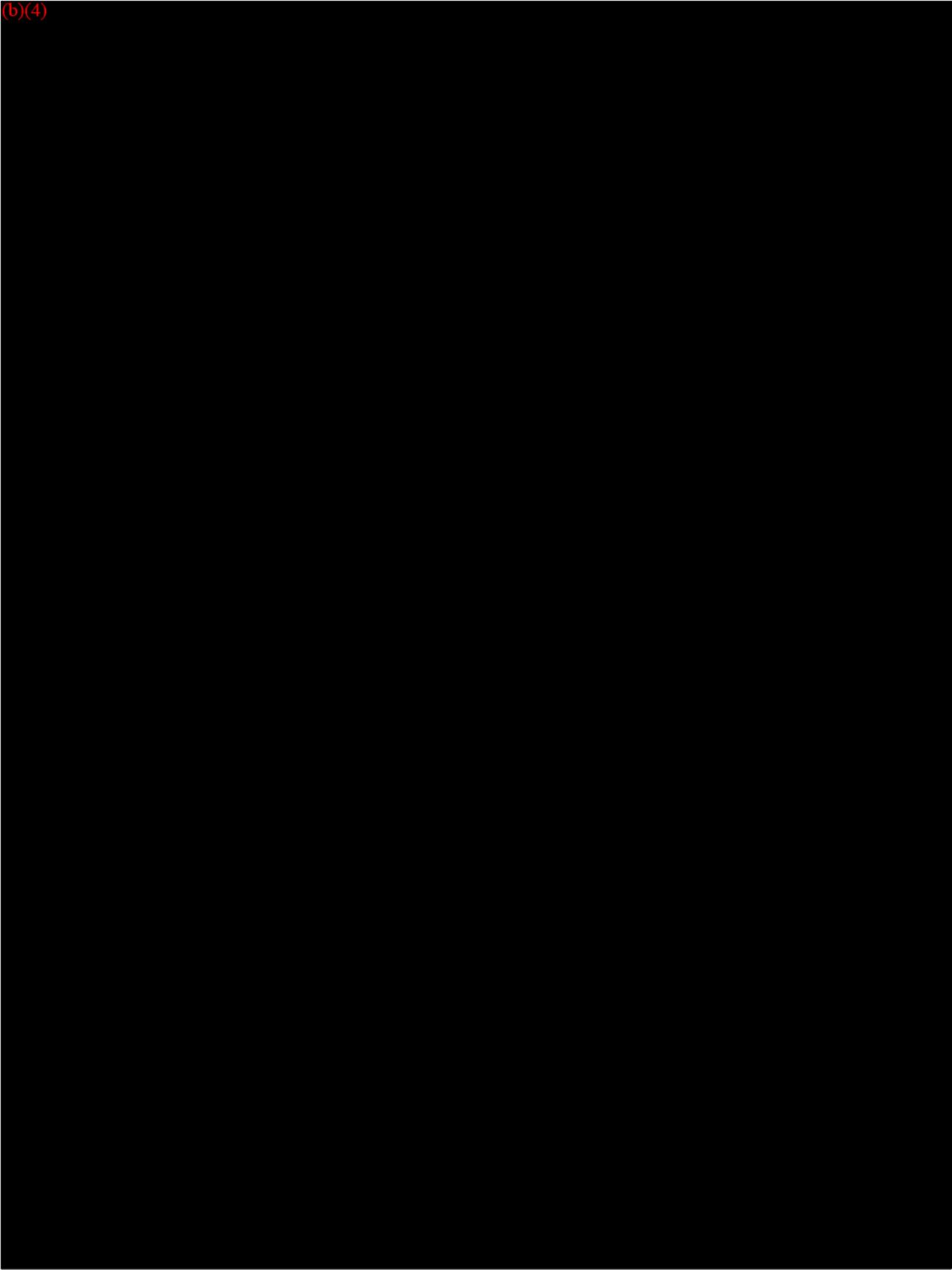
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134

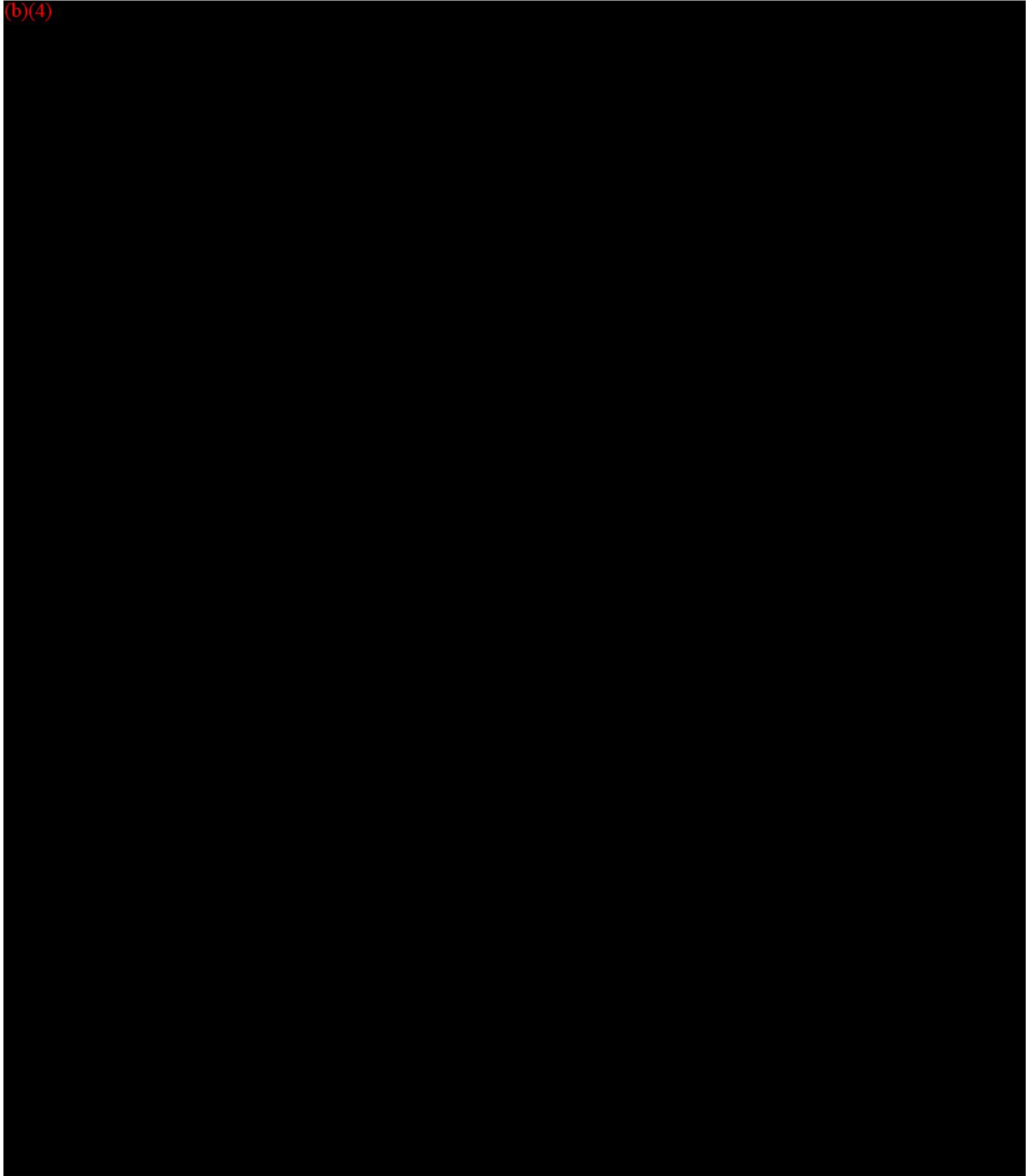
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135

(b)(4)



(b)(4)

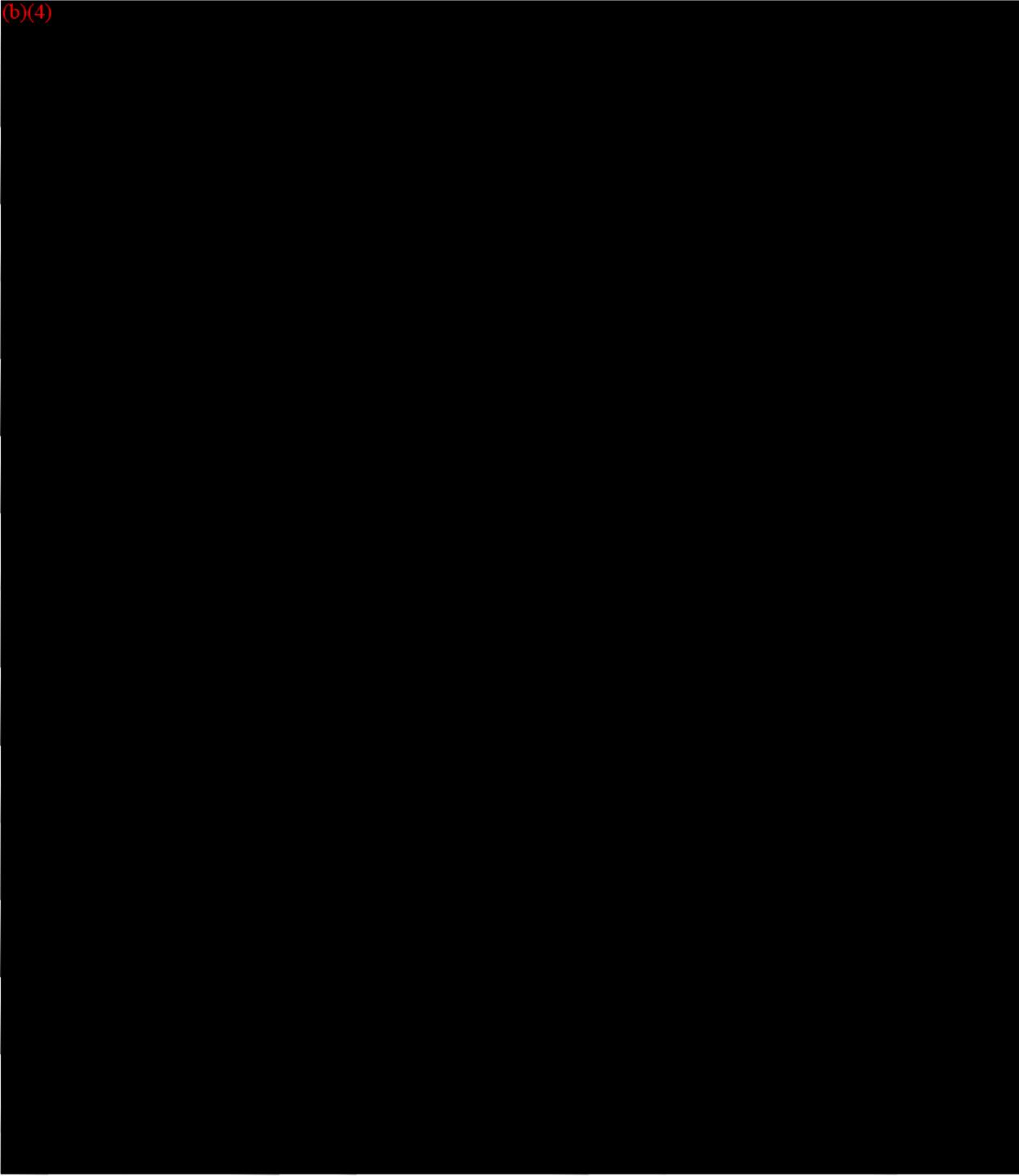
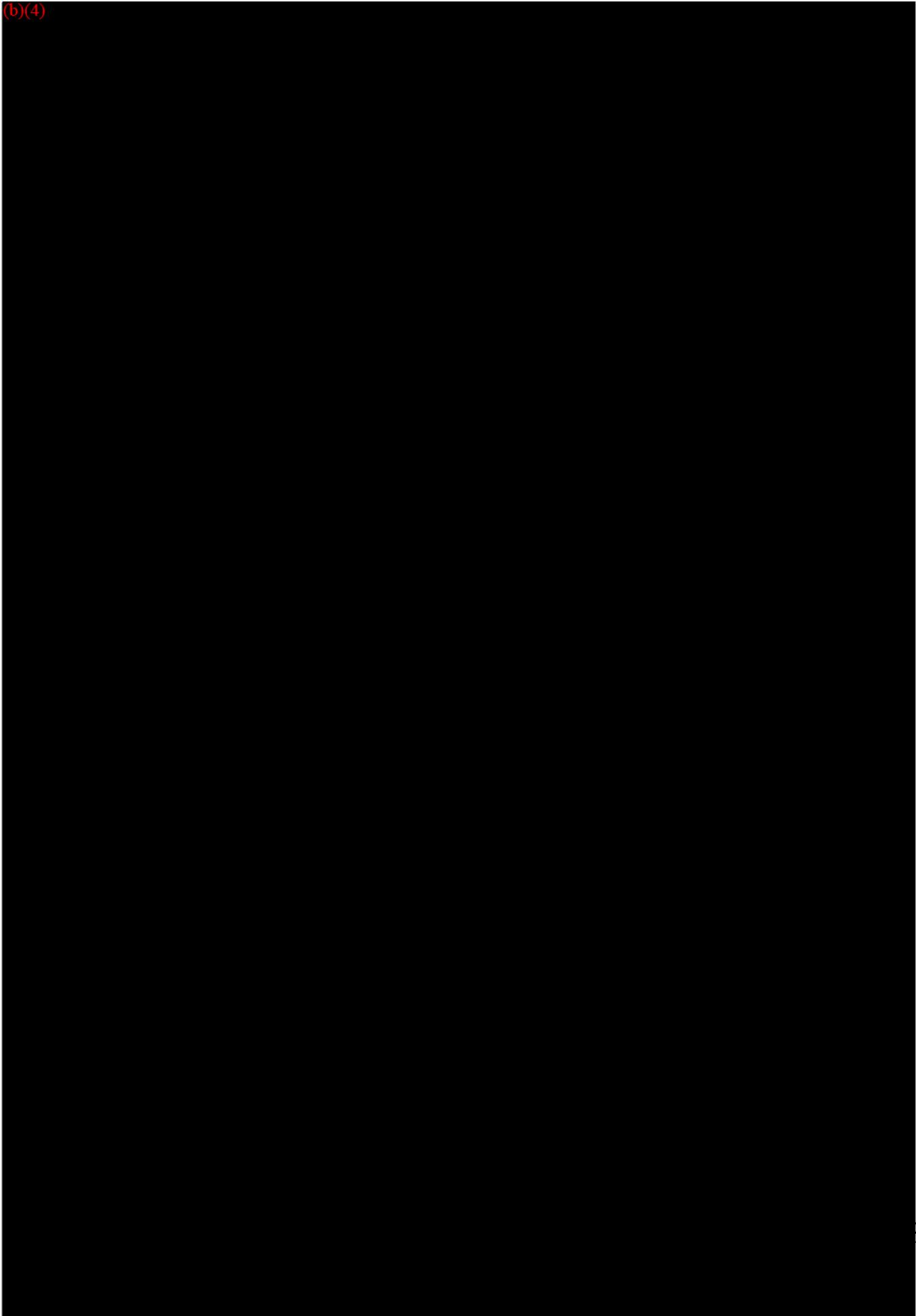


Figure 1.8 Time history of fluorescent light source irradiation – (a) 4 W (F4T5BL) and (b) 8 W (F8T5BL). Surface measurements (I_s) are shown.

ASHRAE 1134-RP

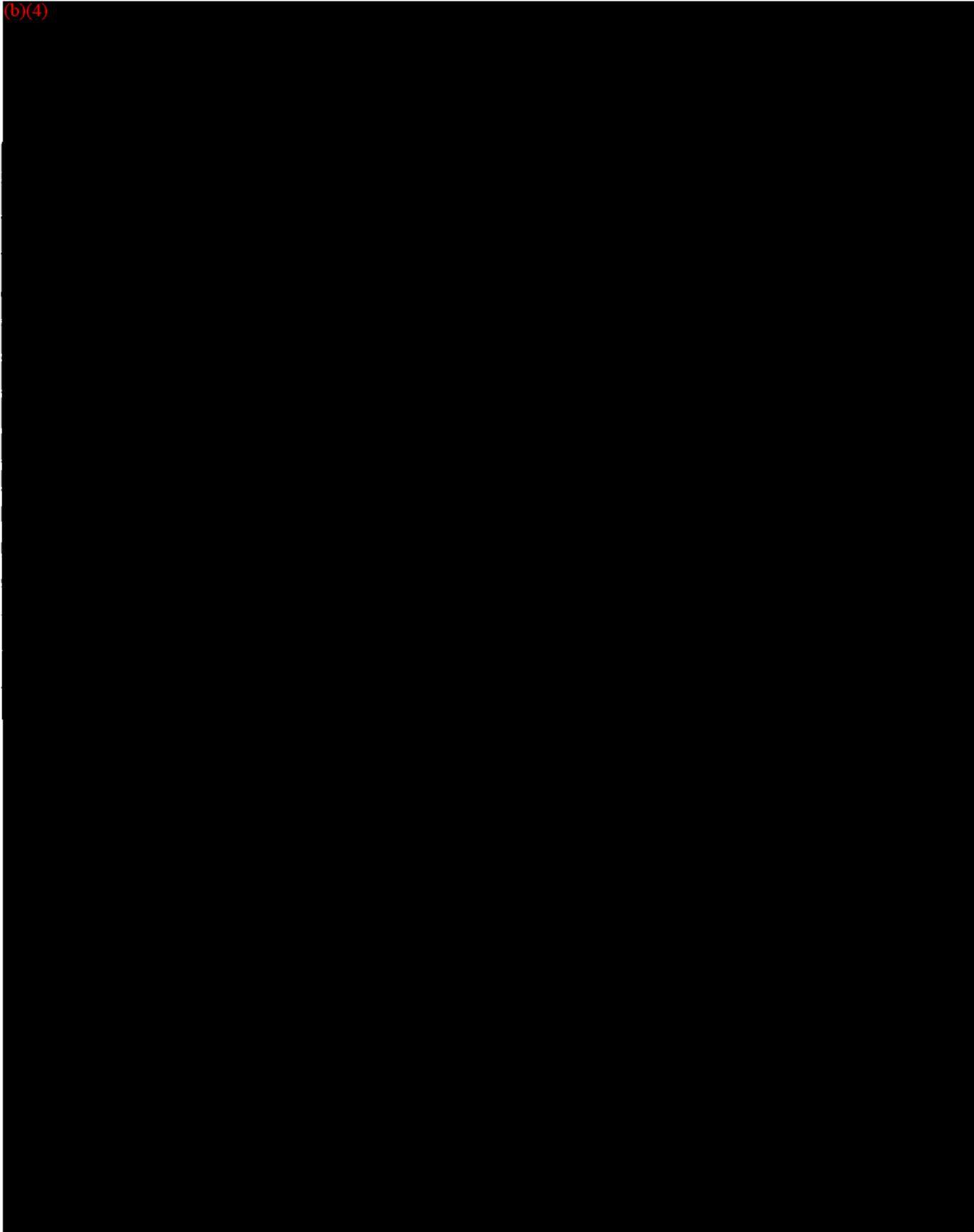
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38
91

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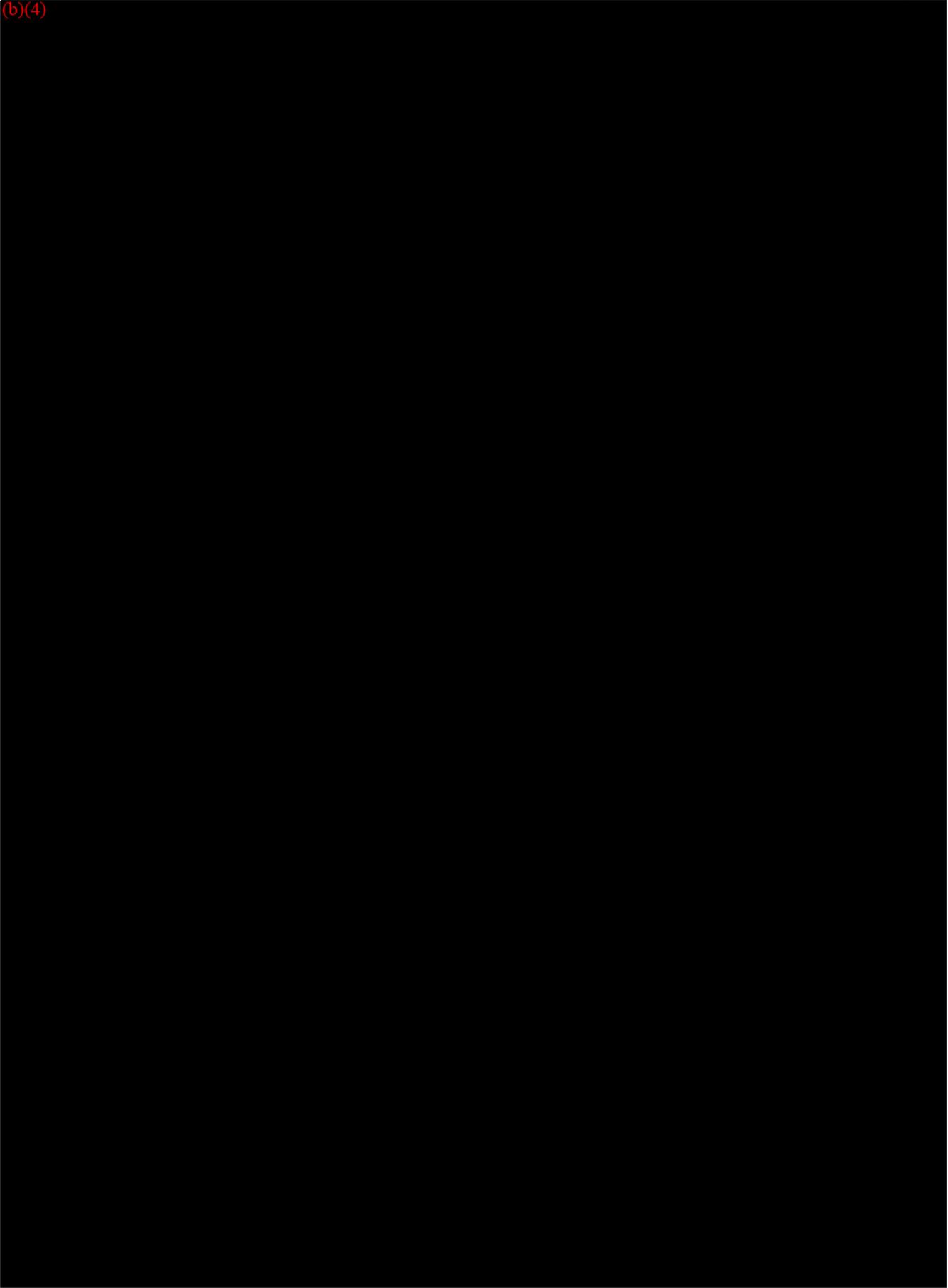


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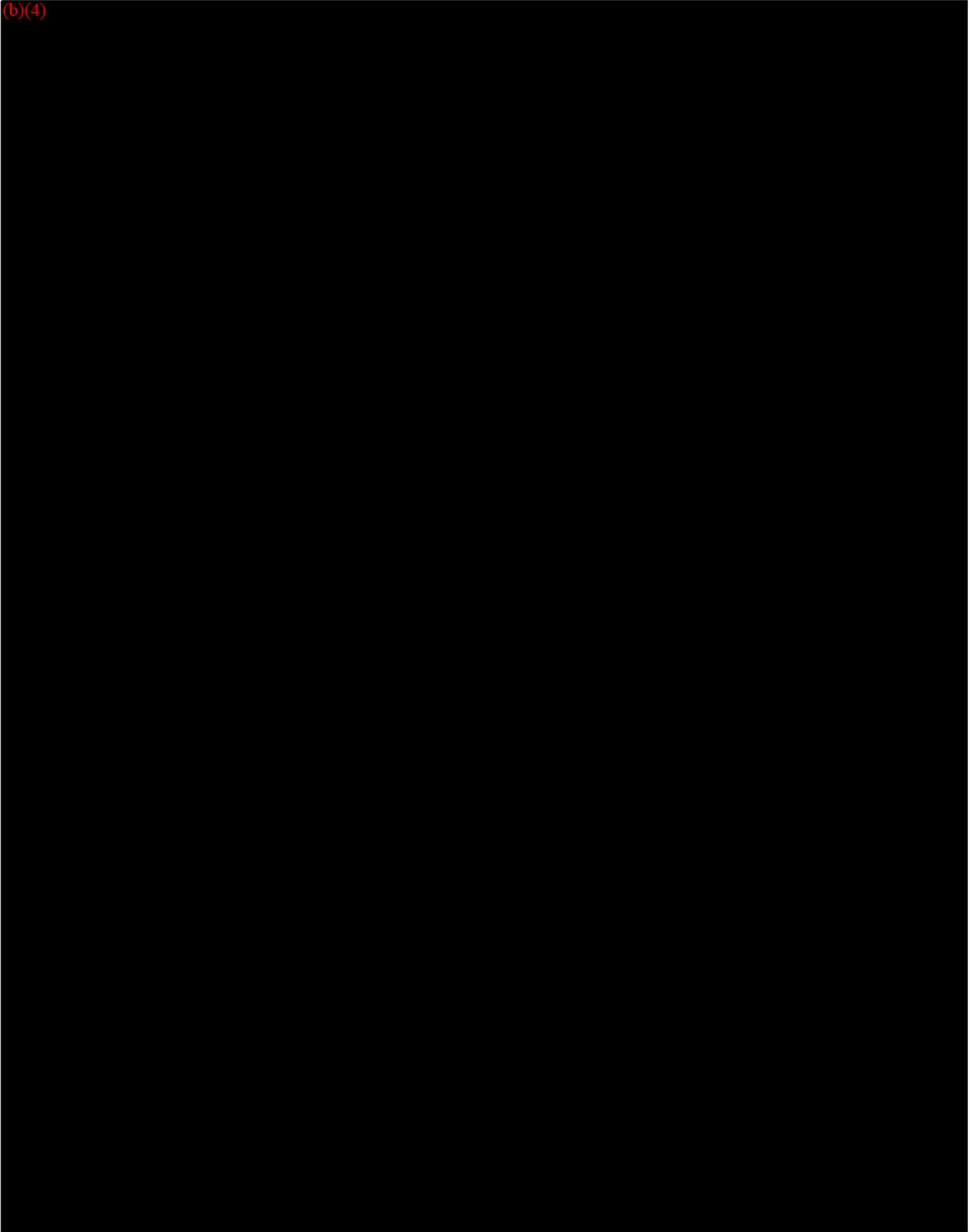
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140

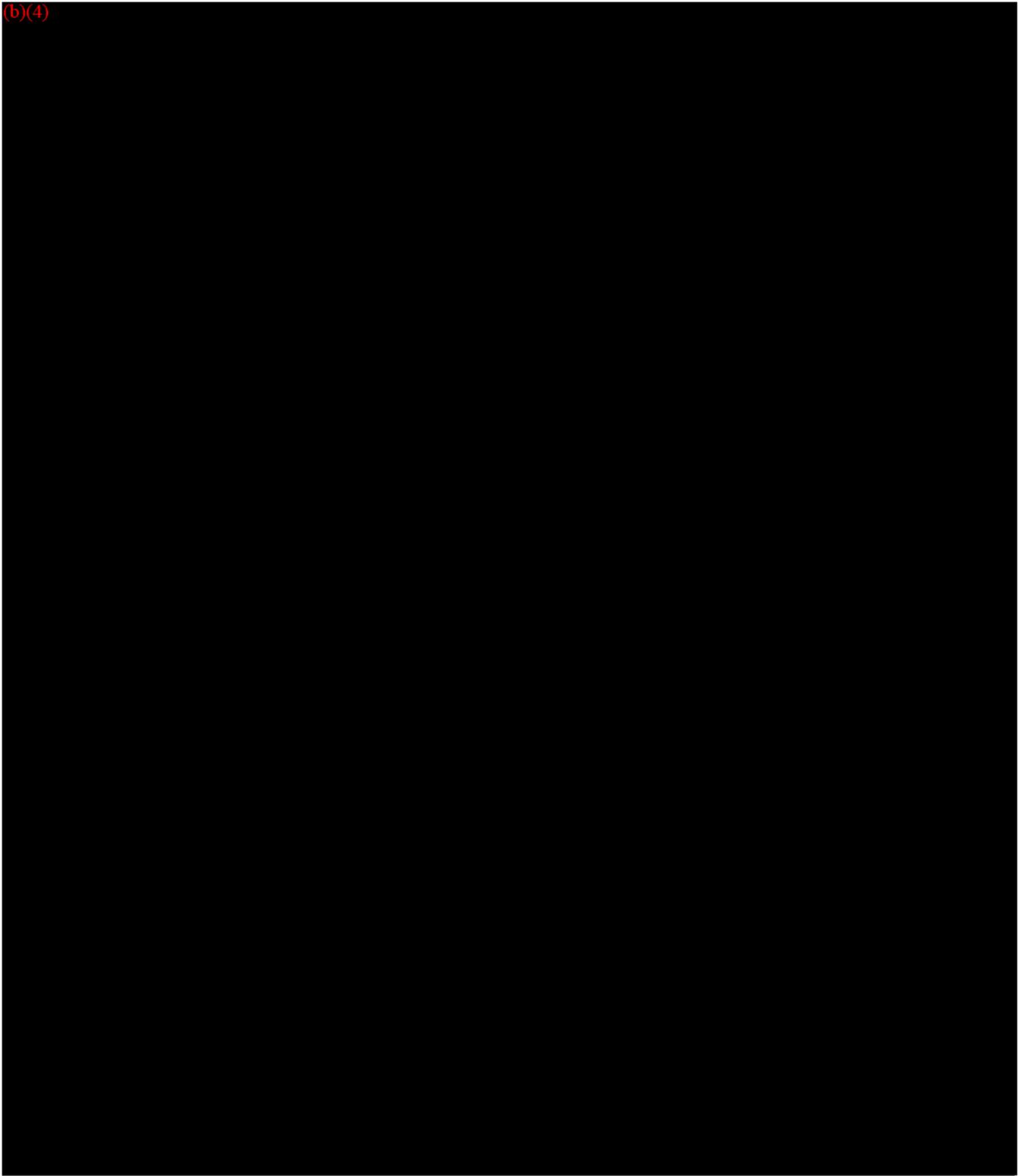
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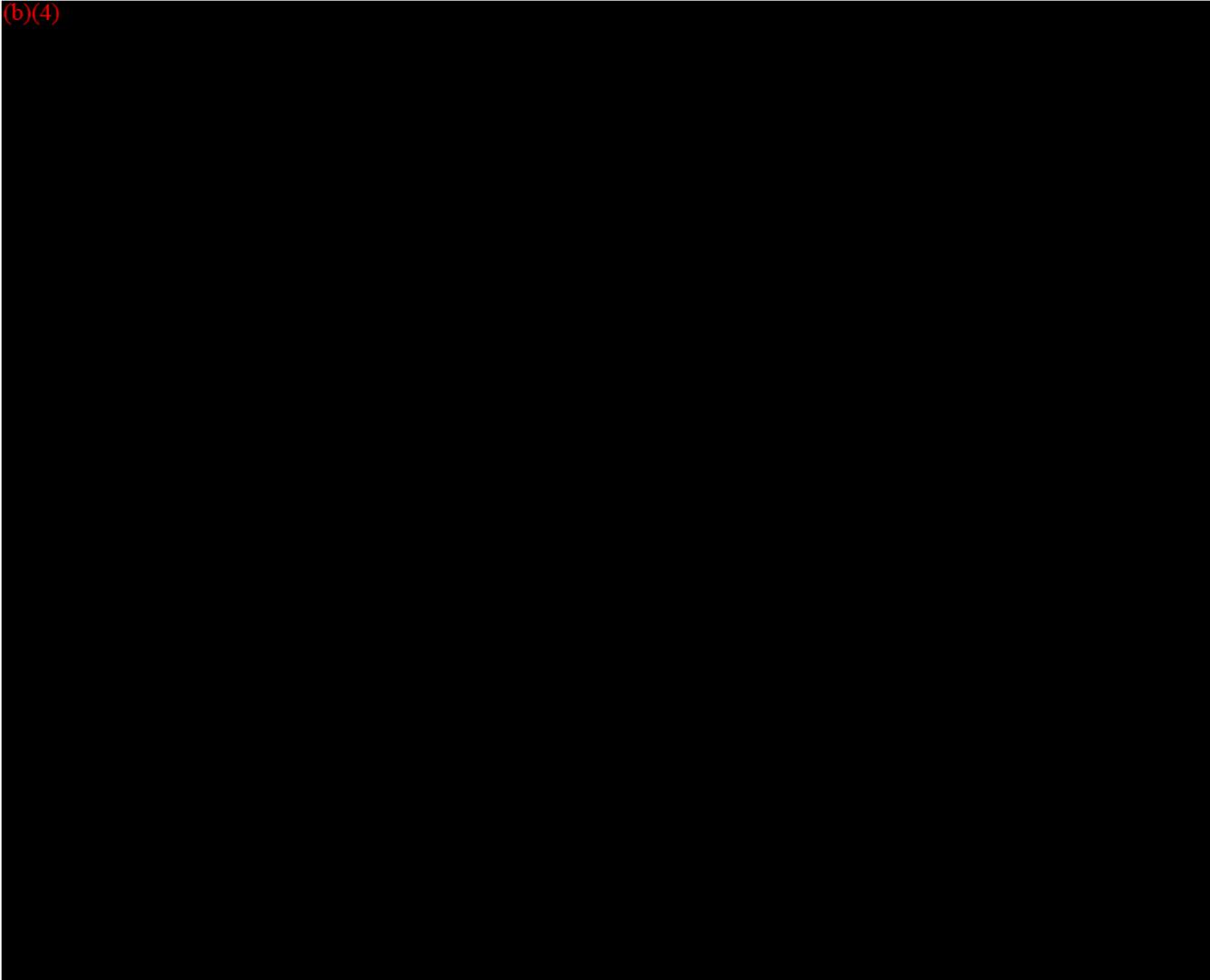
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142
95

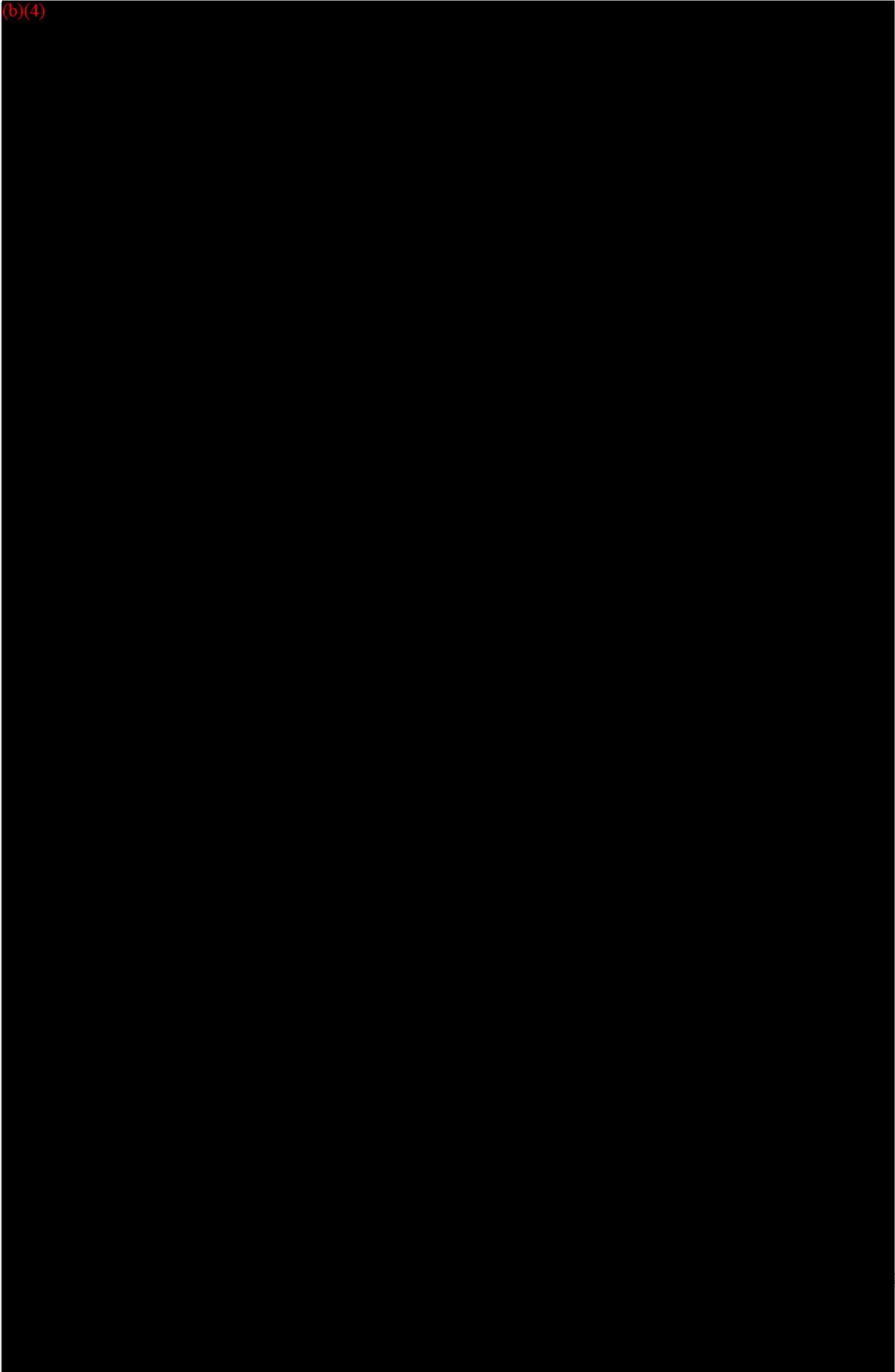
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47

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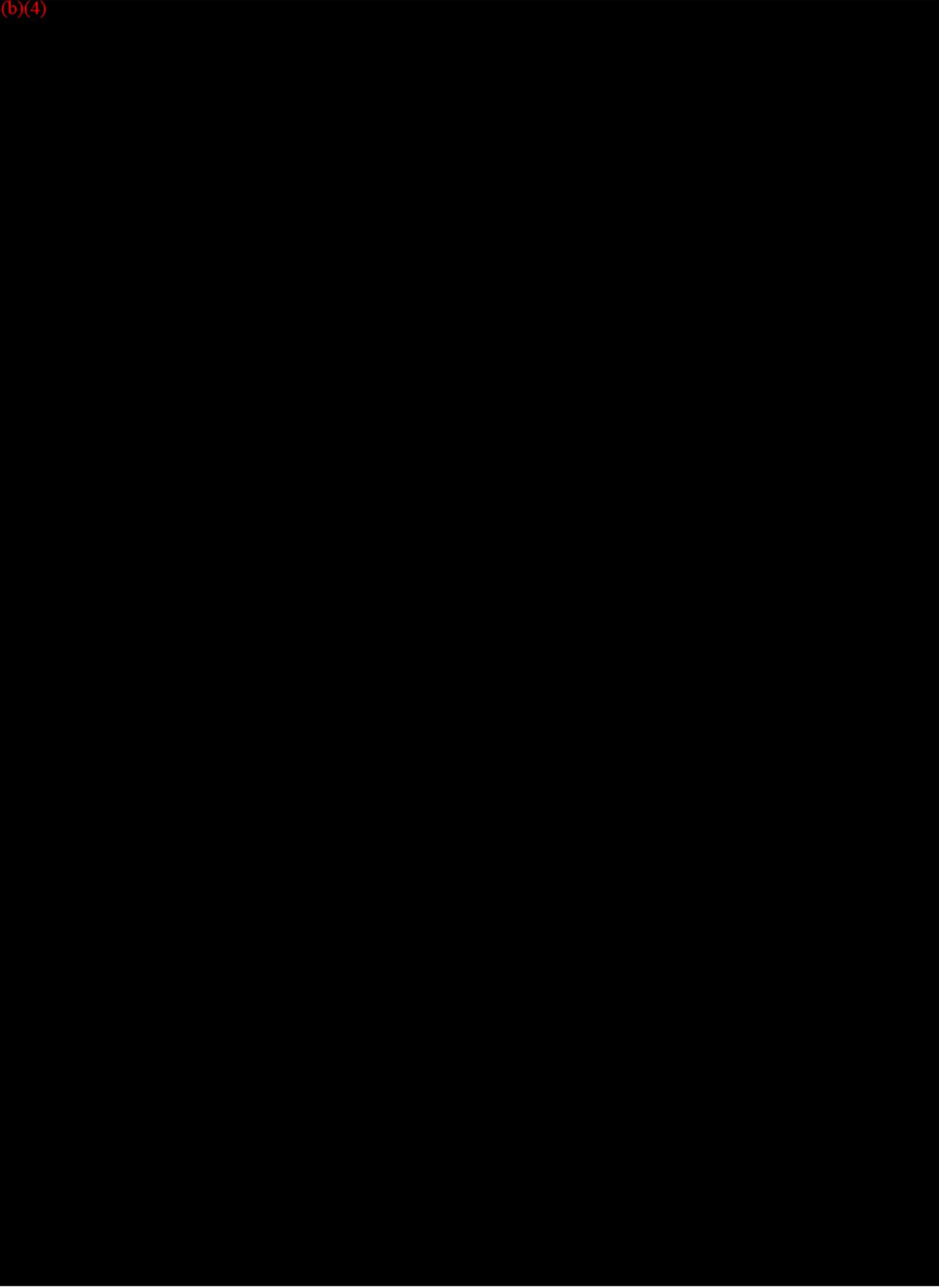


4
97

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48

(b)(4)

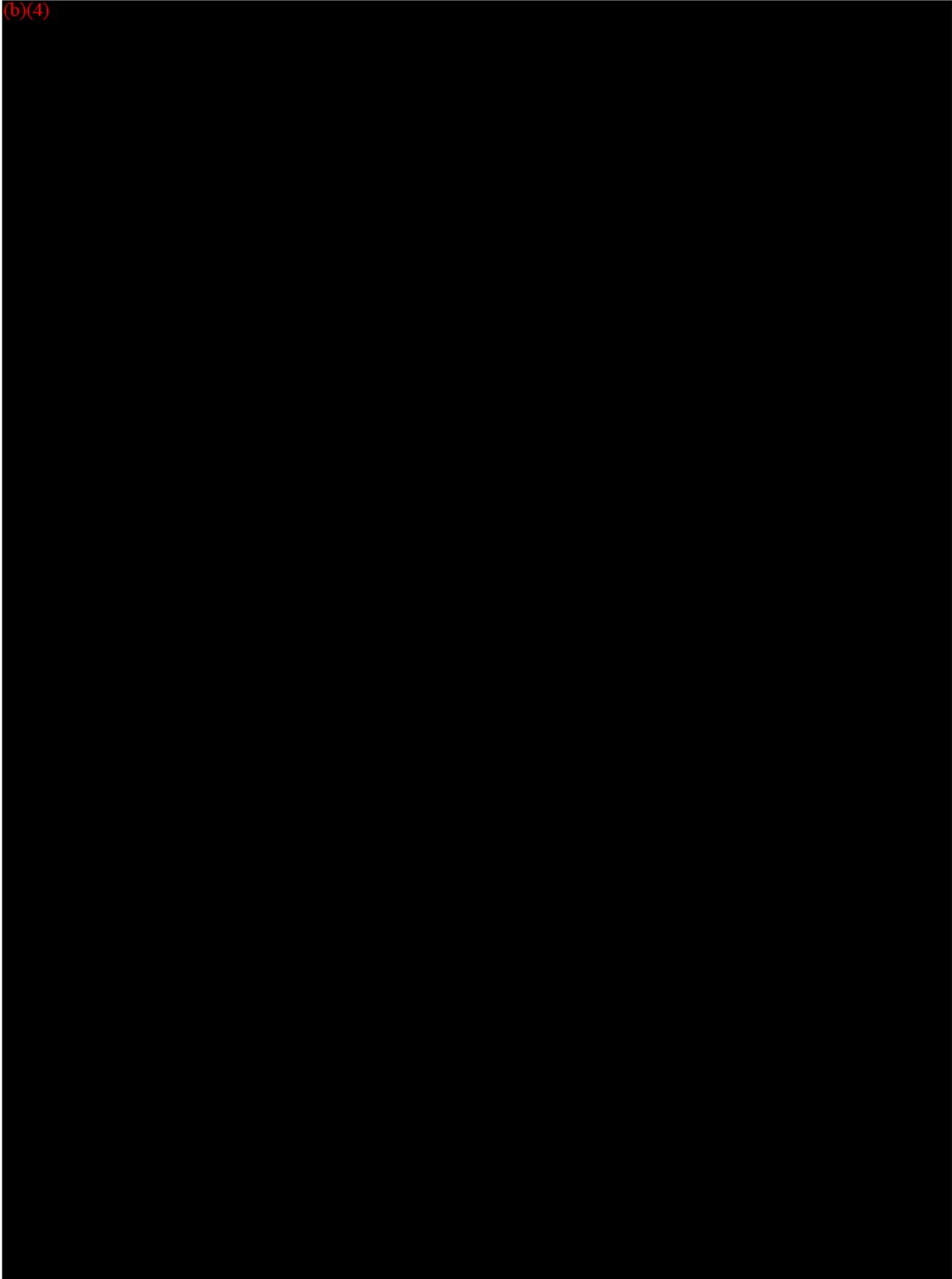


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ASHRAE 1134-RP

49

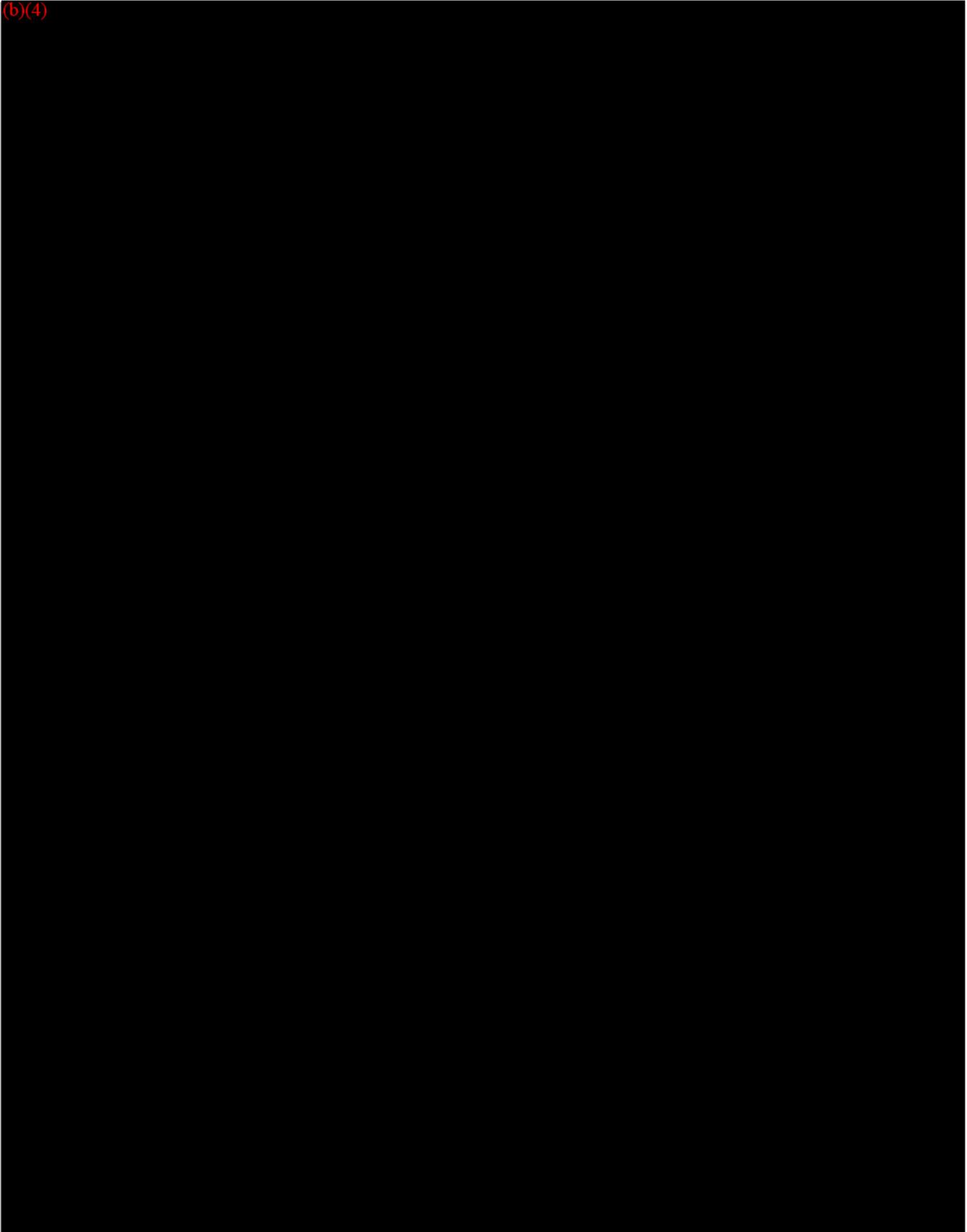
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ASHRAE 1134-RP

50

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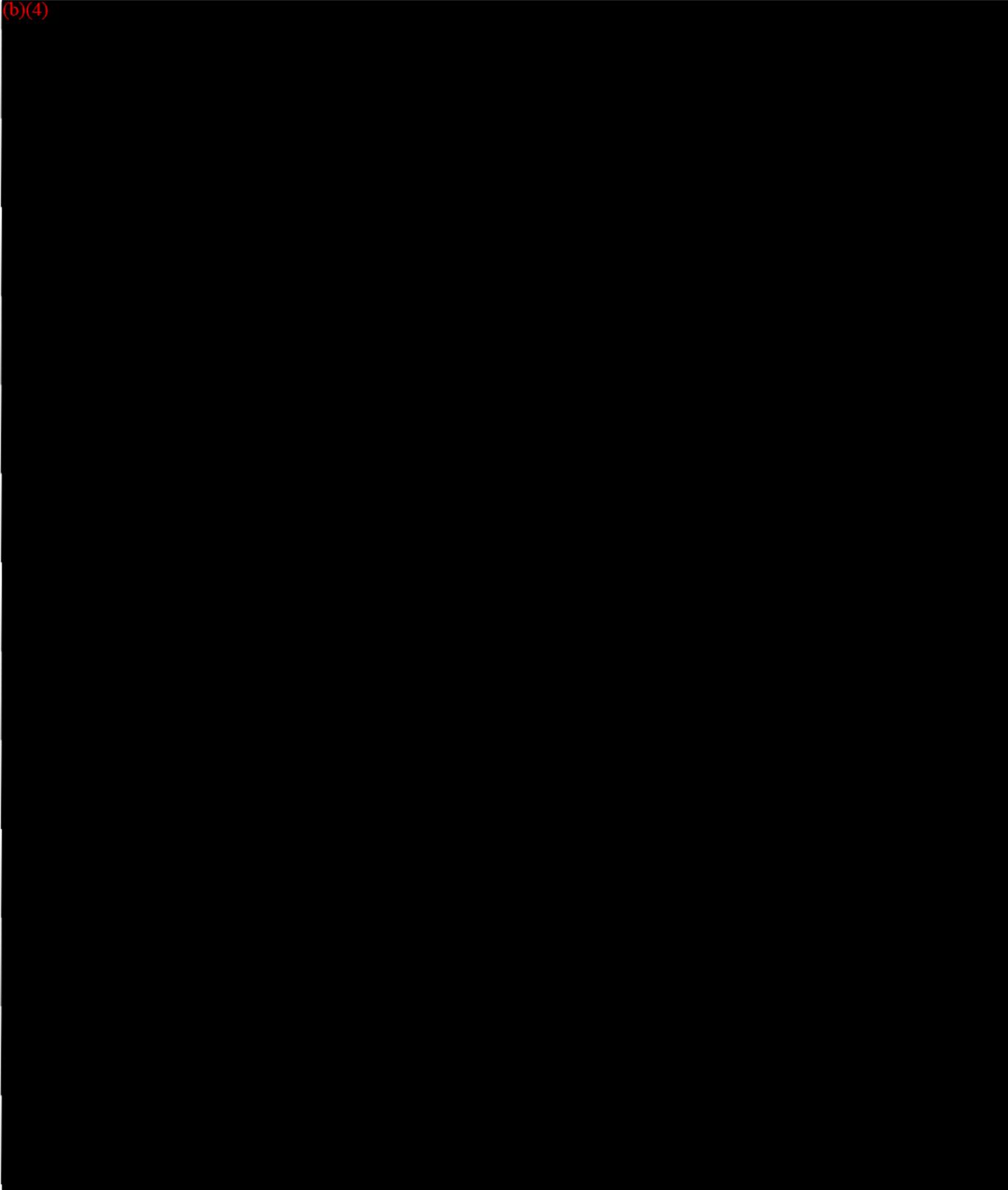


147

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51

(b)(4)



148

101

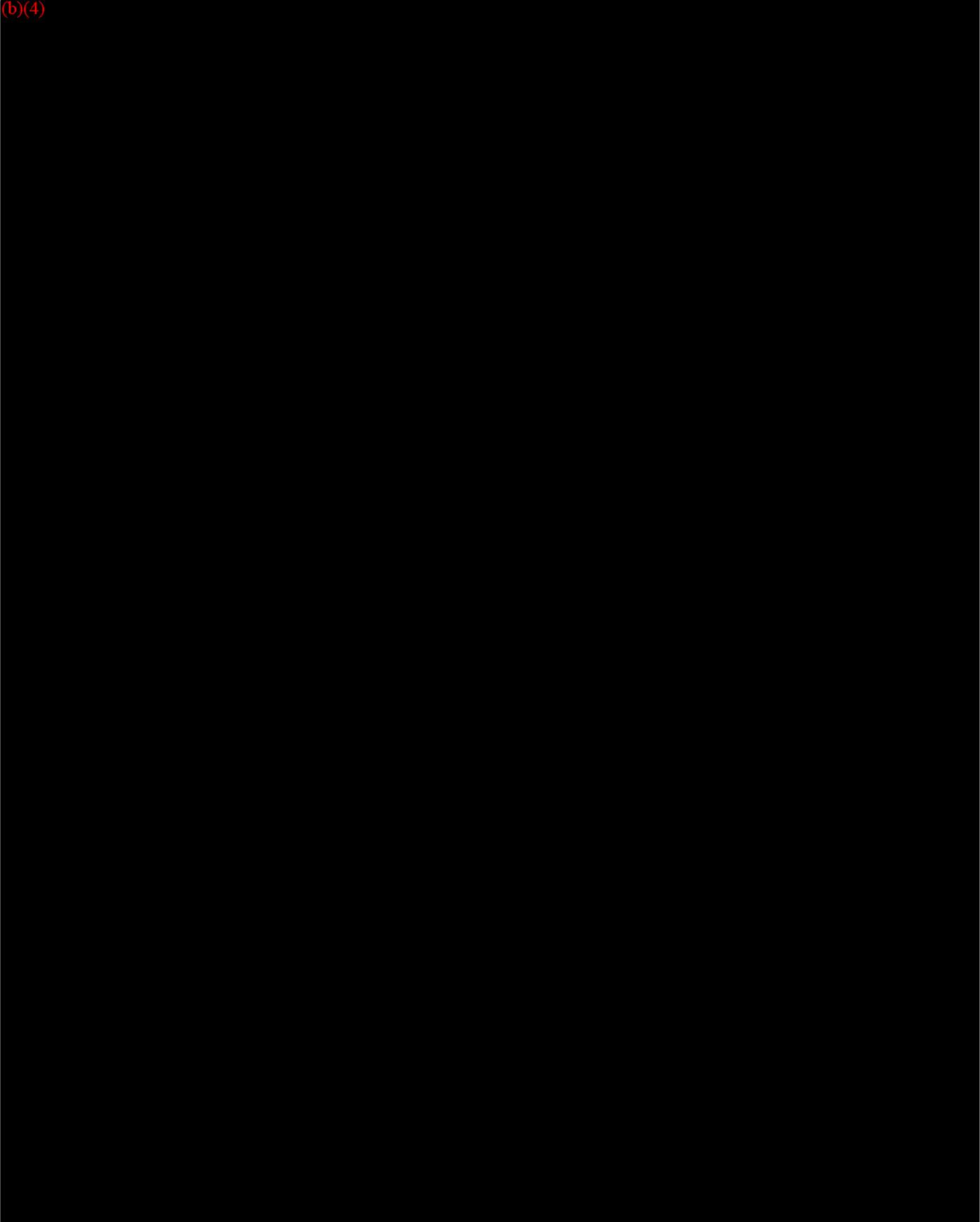
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ASHRAE 1134-RP

53

(b)(4)



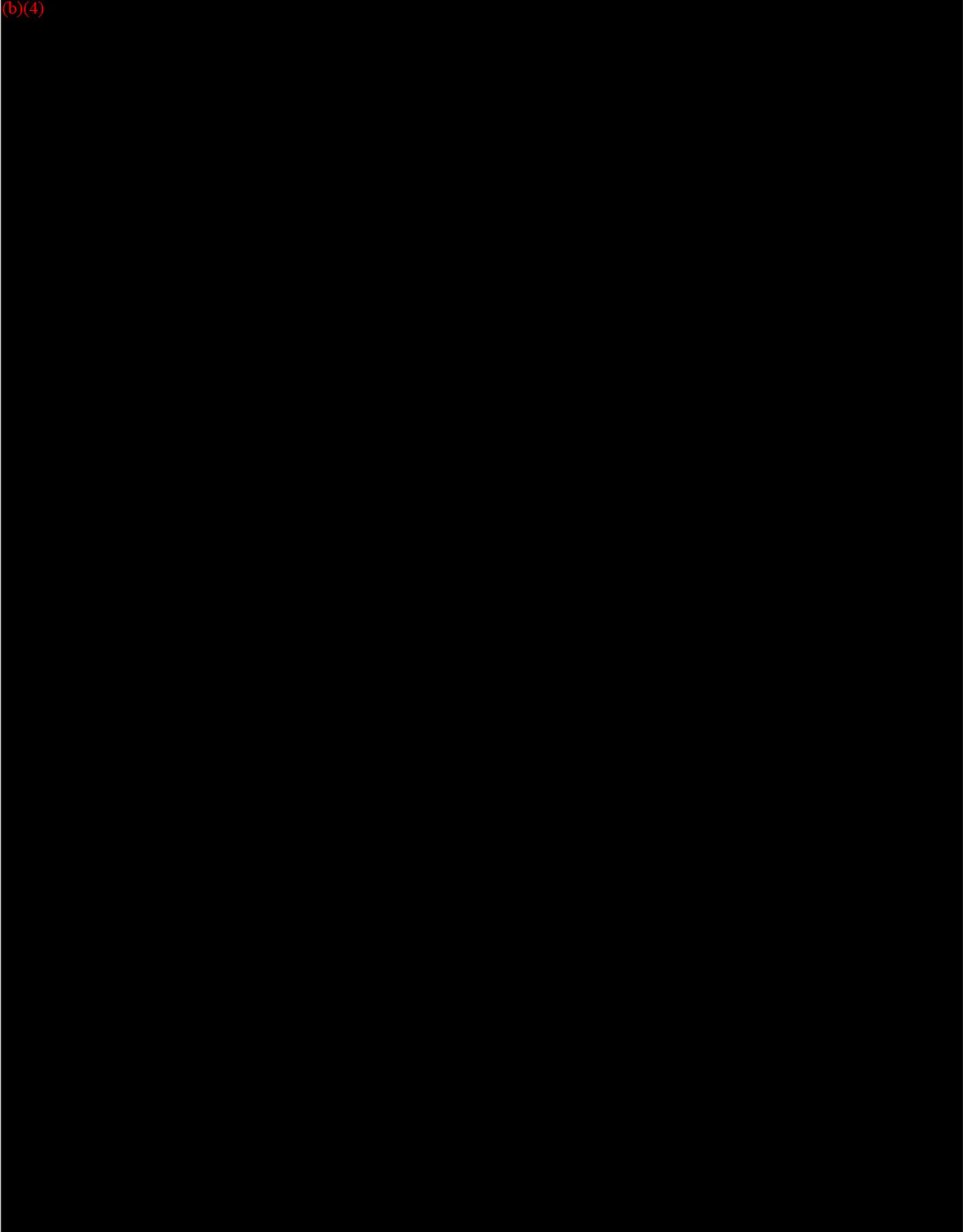
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103

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54

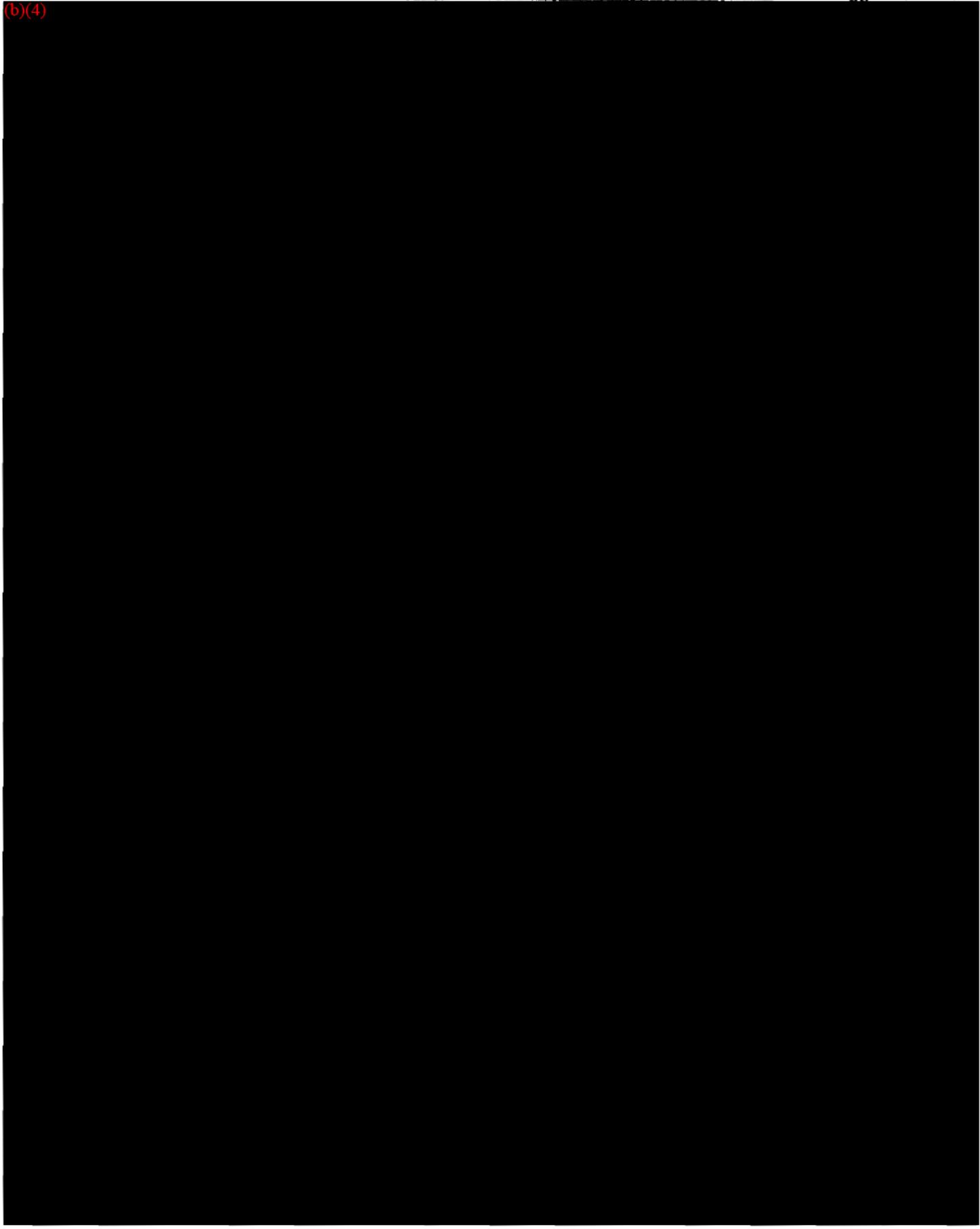
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ASHRAE 1134-RP

56

(b)(4)



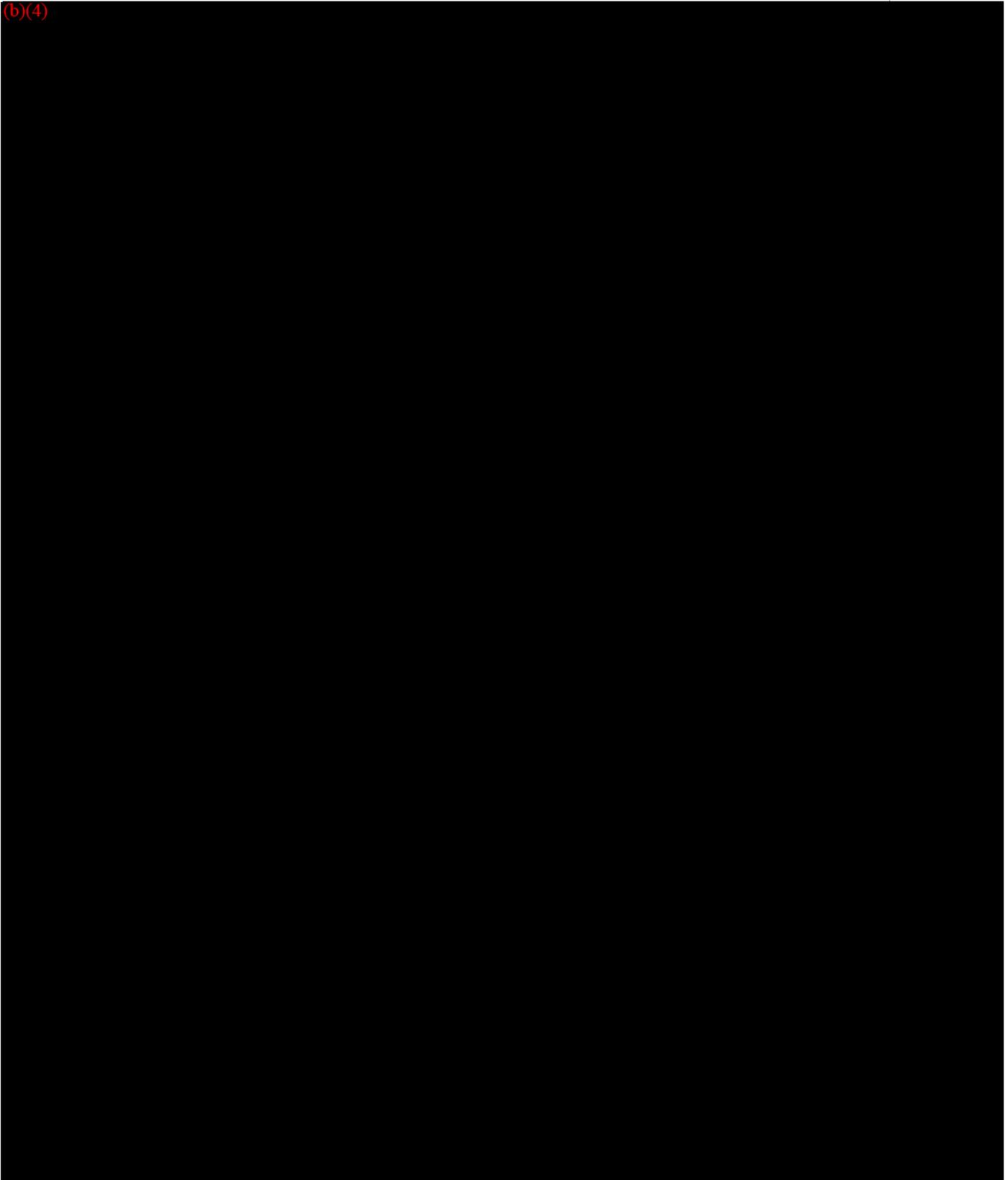
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105

ASHRAE 1134-RP

55

(b)(4)

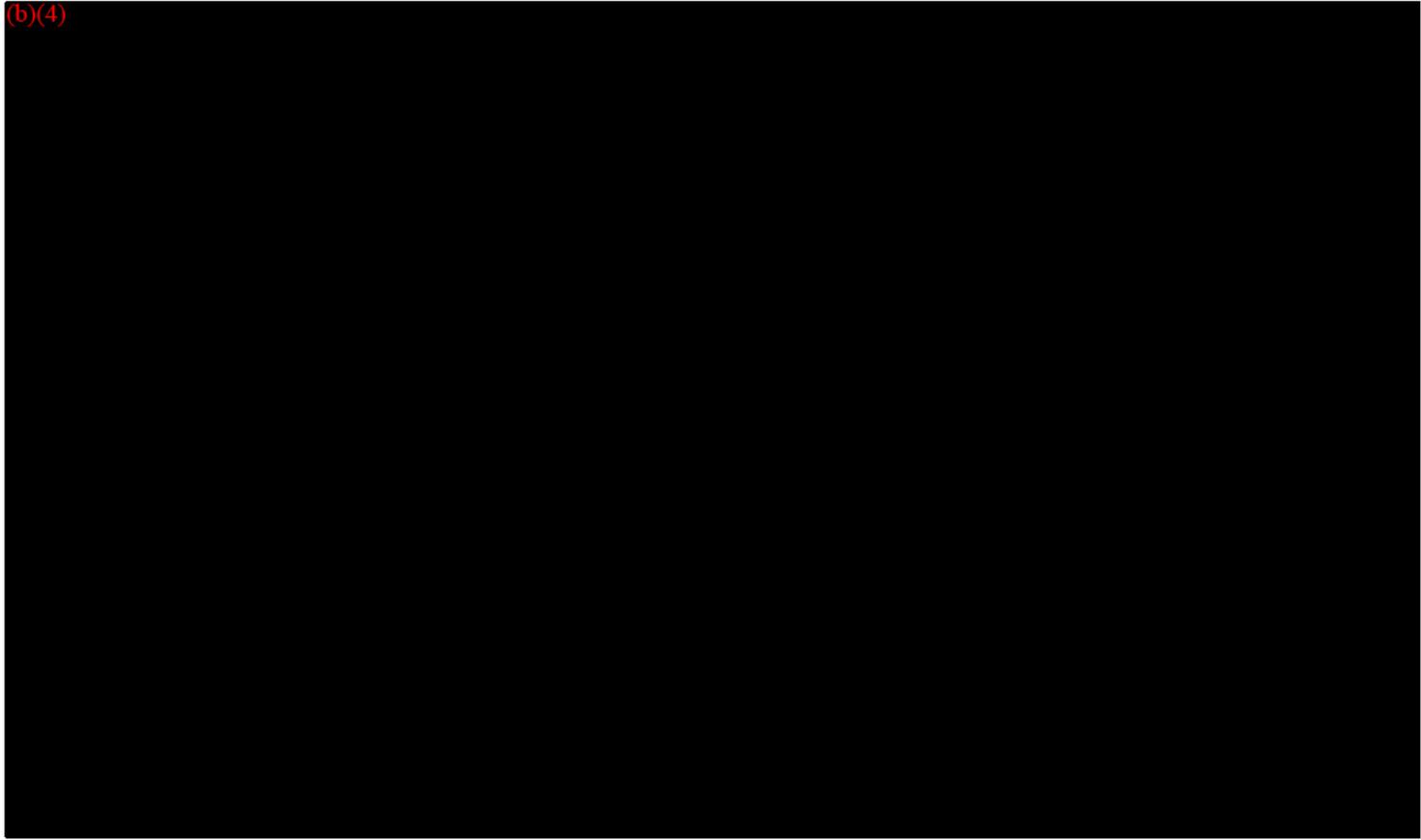


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ASHRAE 1134-RP

57

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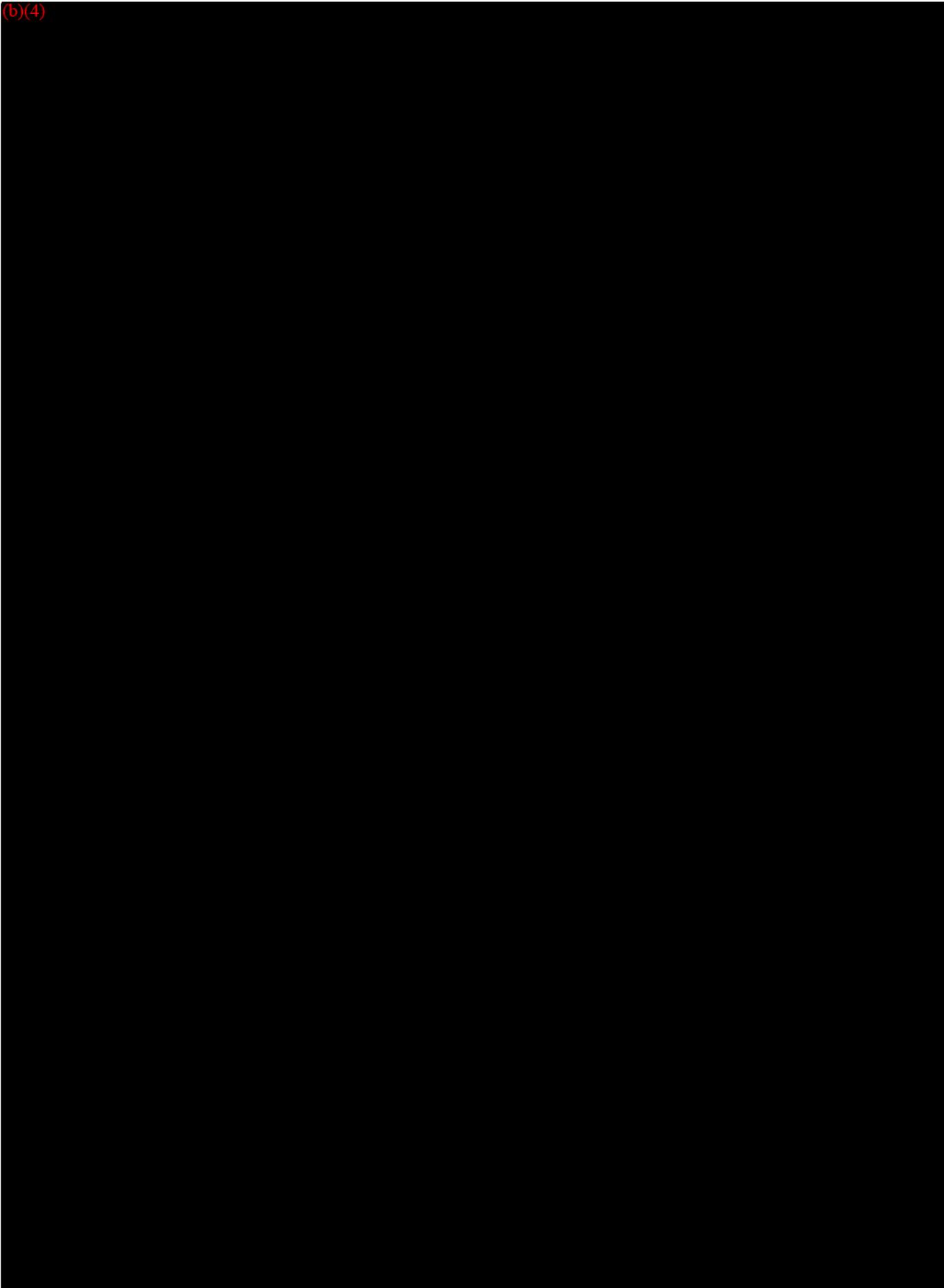


154
107

ASHRAE 1134-RP

58

(b)(4)

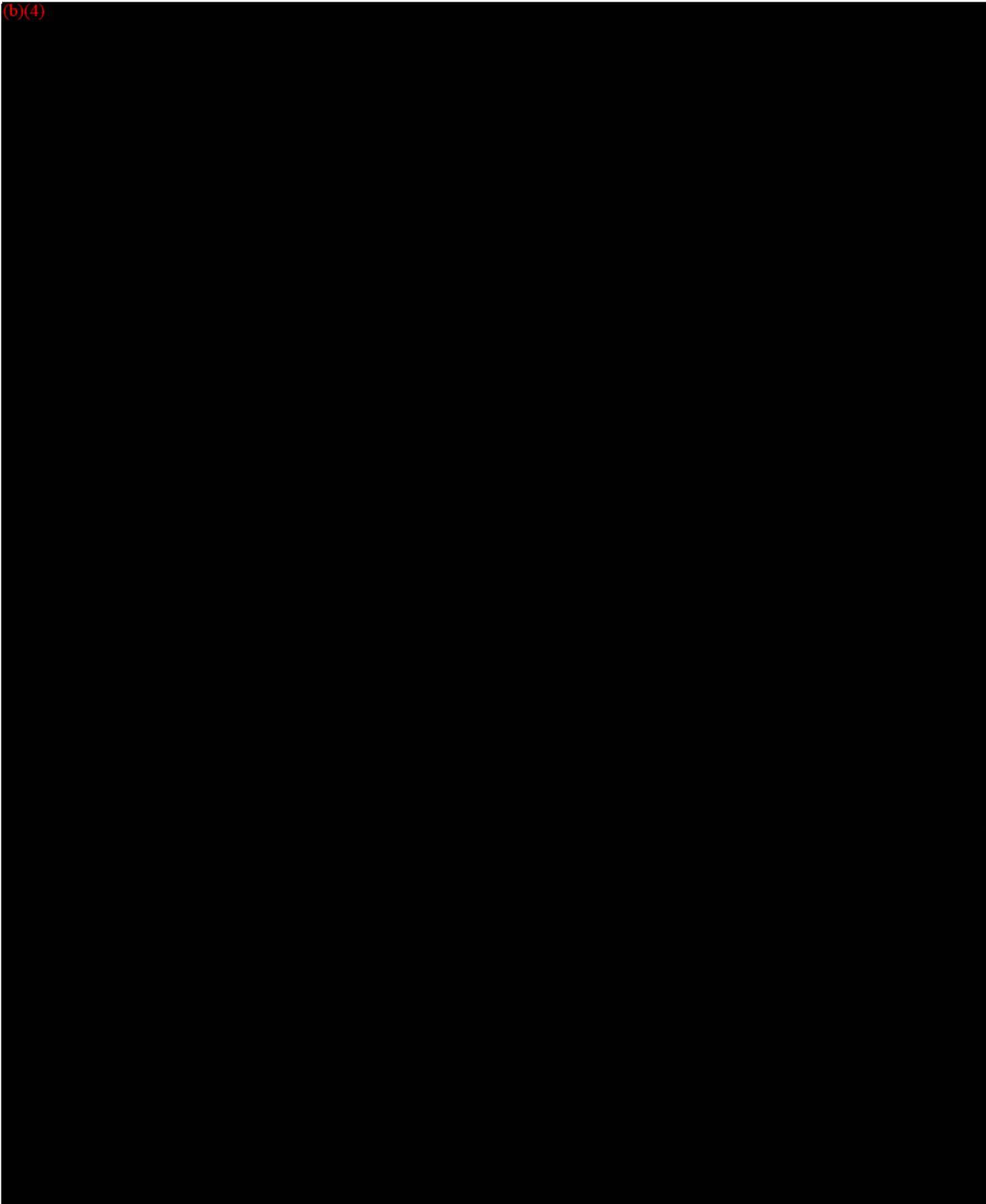


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ASHRAE 1134-RP

59

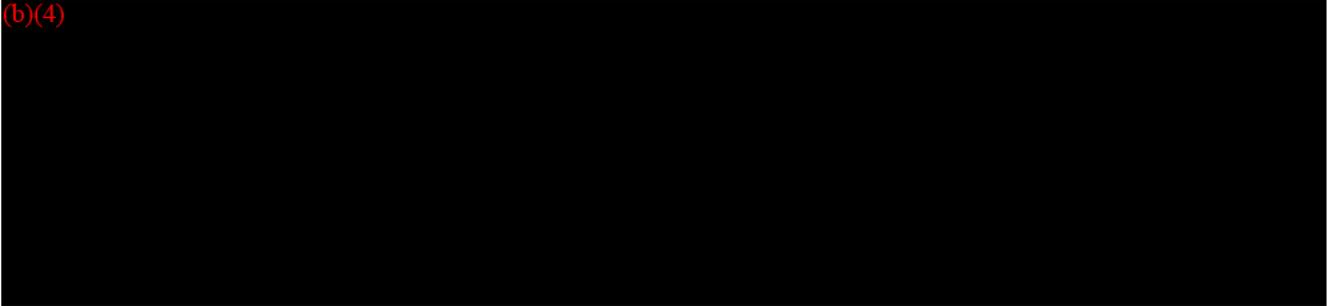
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ASHRAE 1134-RP

60

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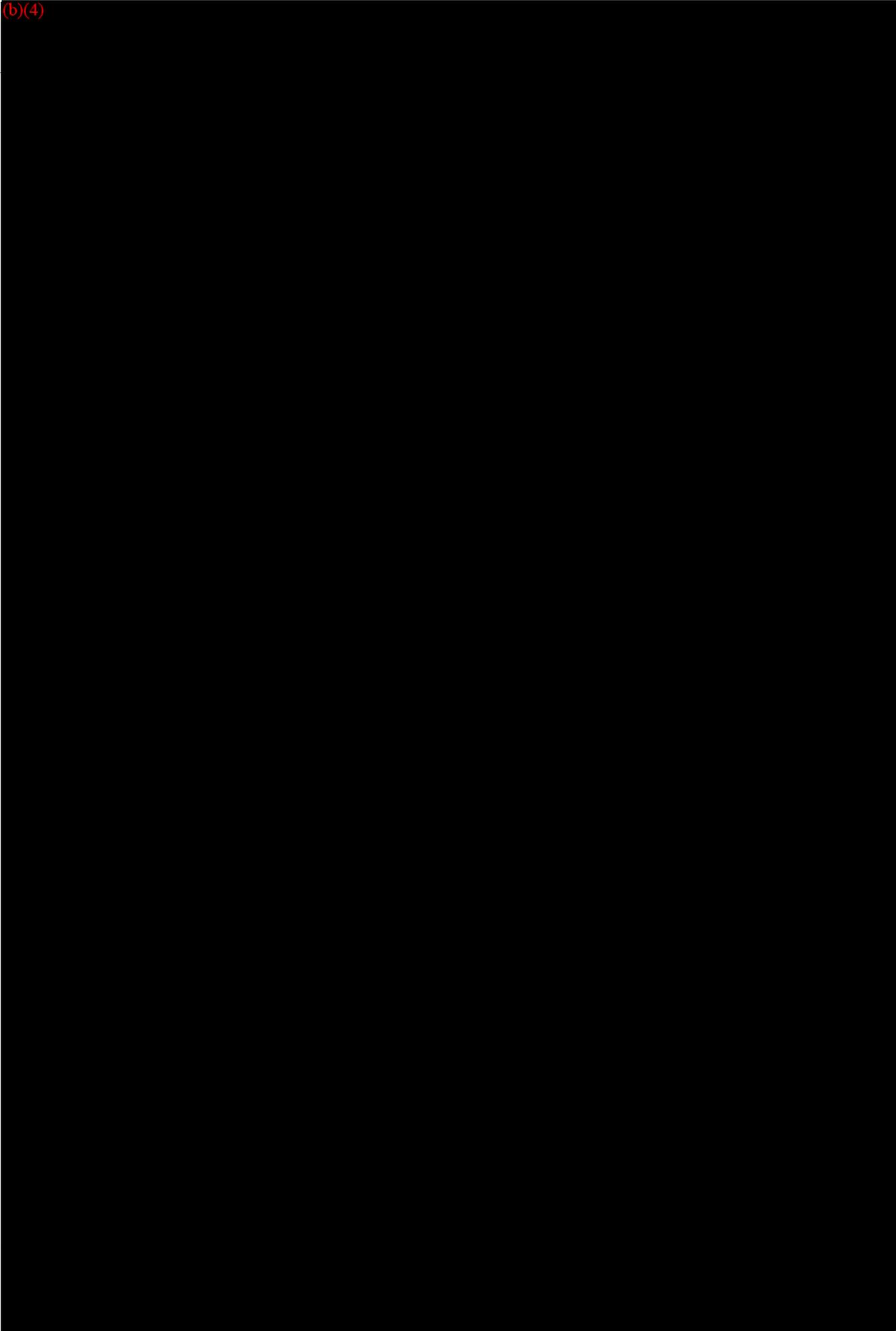


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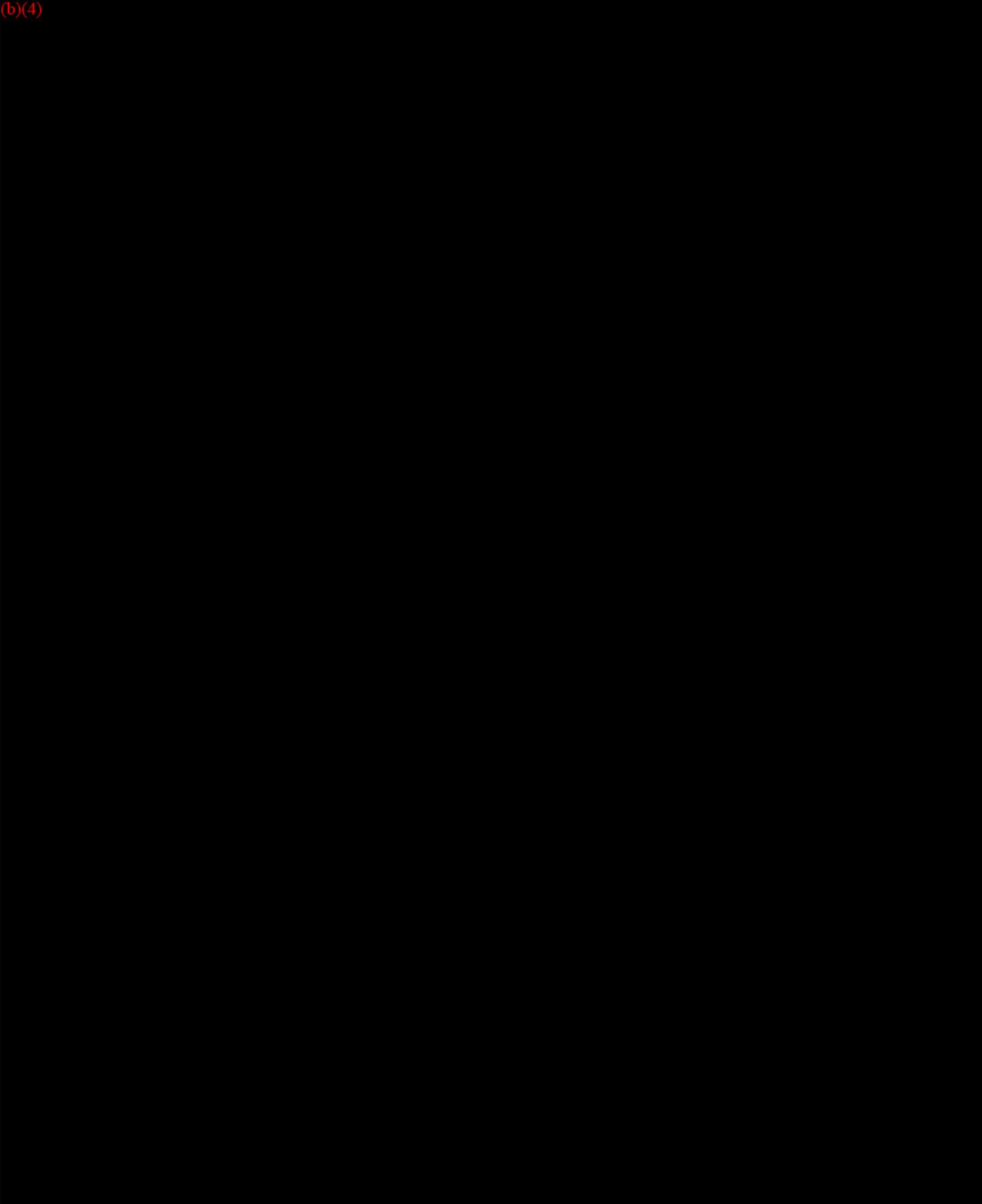
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62

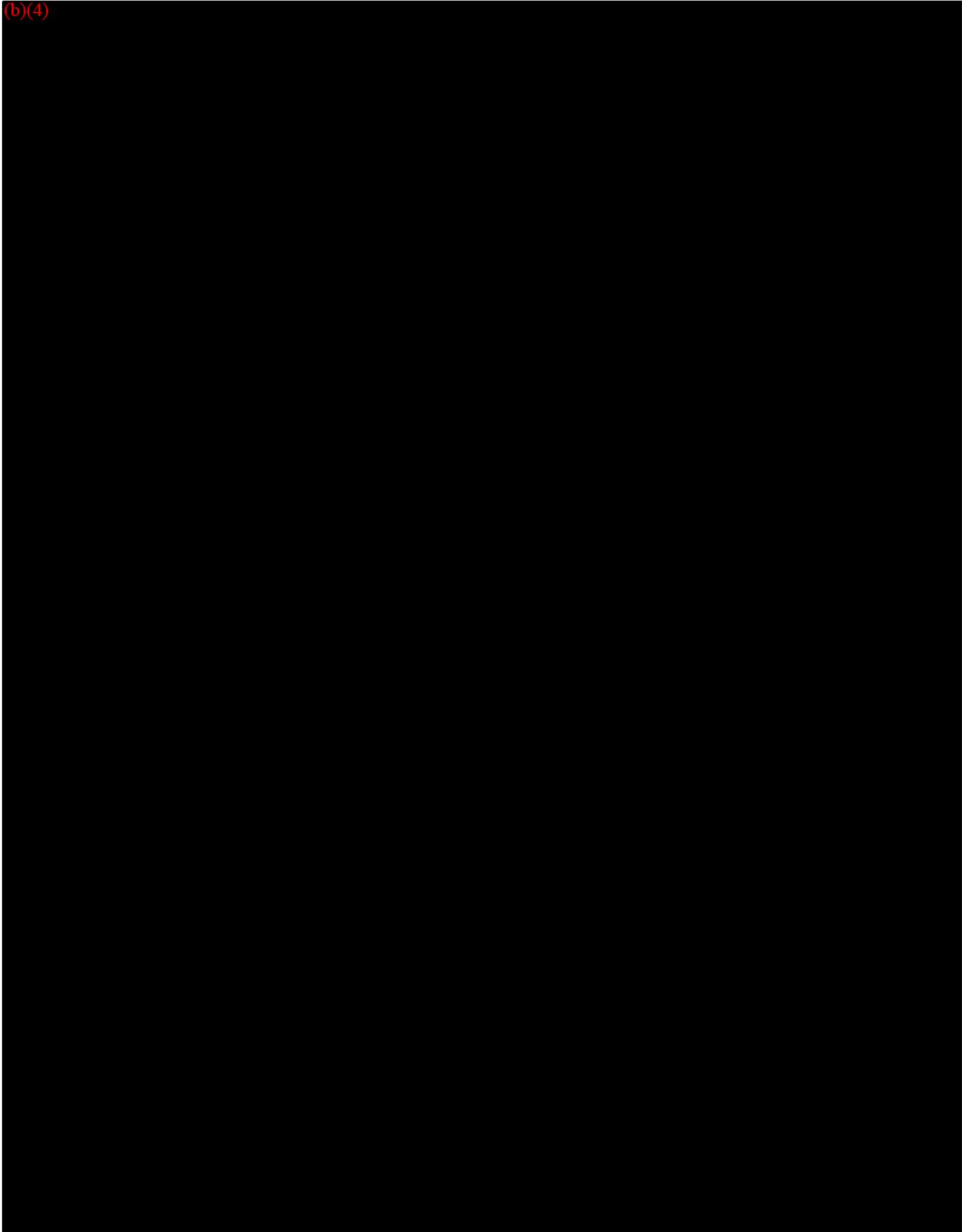
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ASHRAE 1134-RP

63

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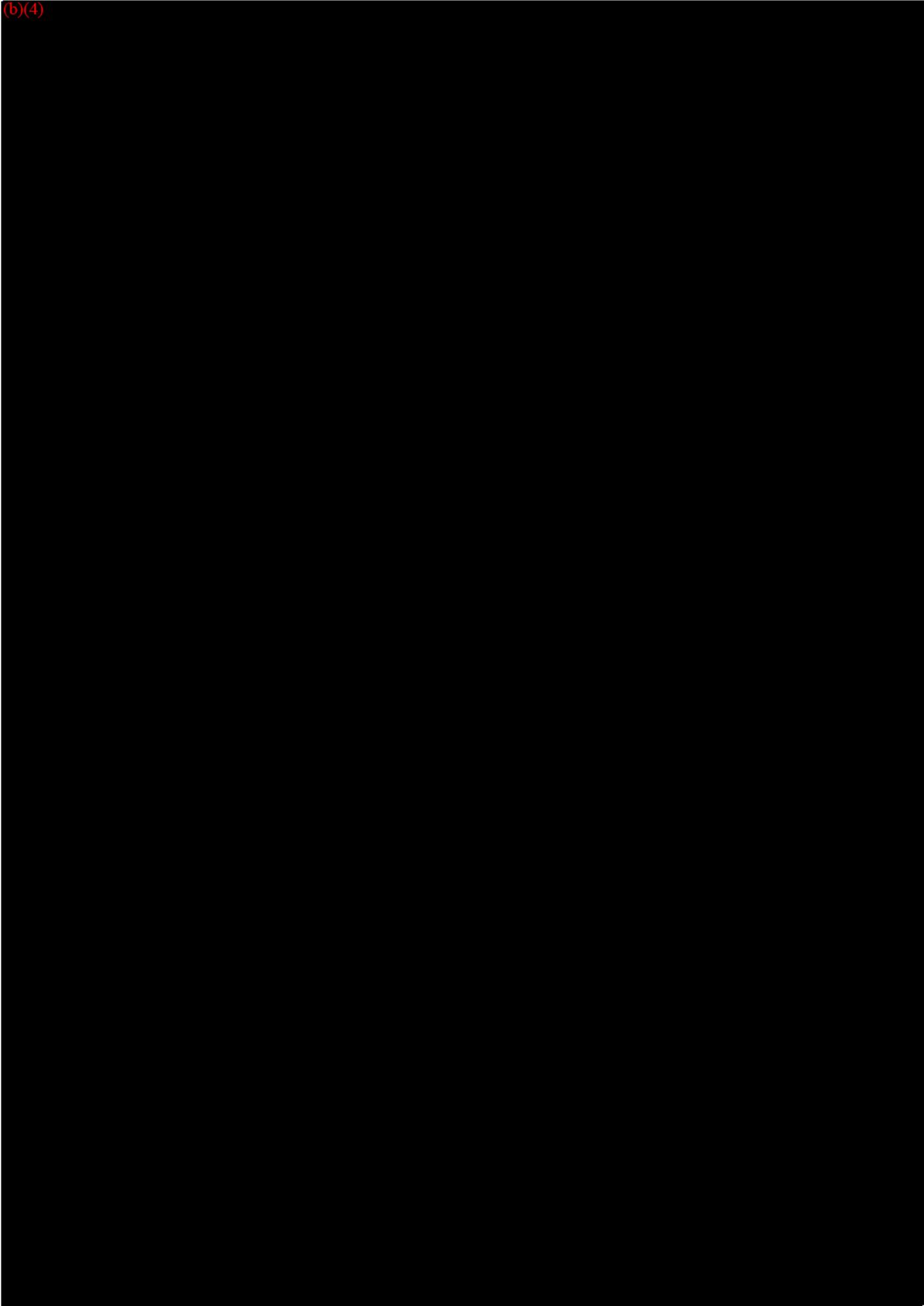


160
113

ASHRAE 1134-RP

64

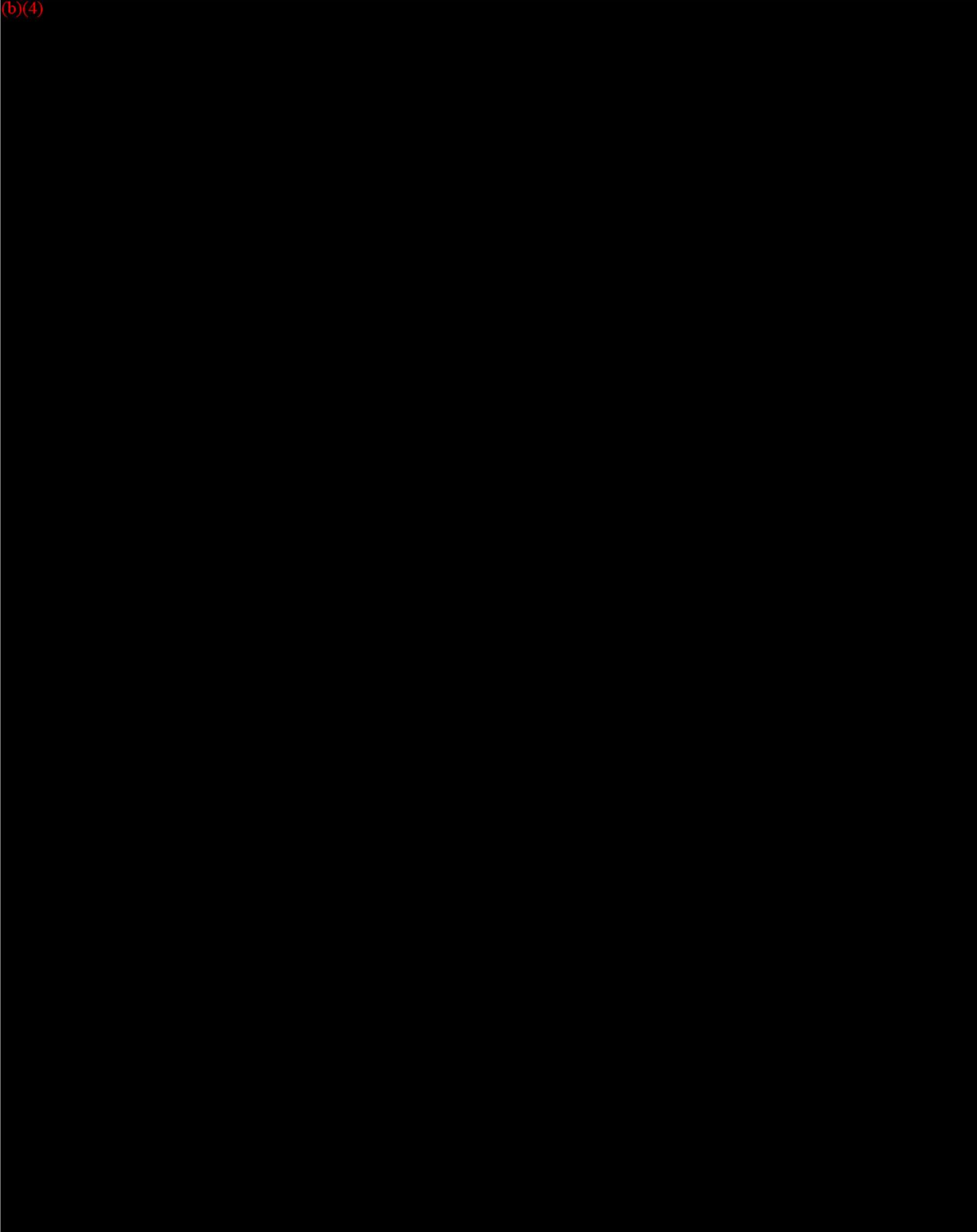
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ASHRAE 1134-RP

65

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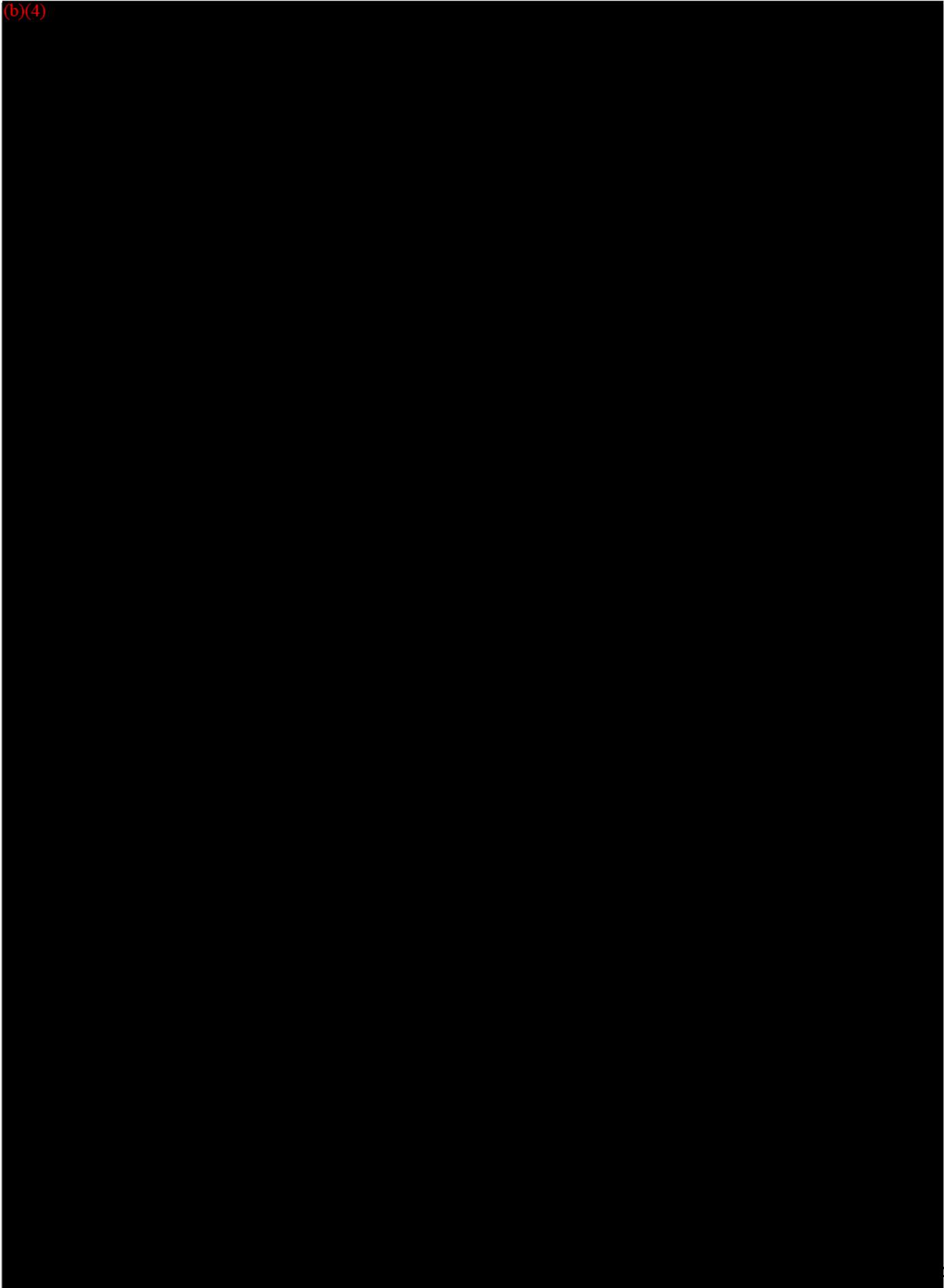


115

ASHRAE 1134-RP

66

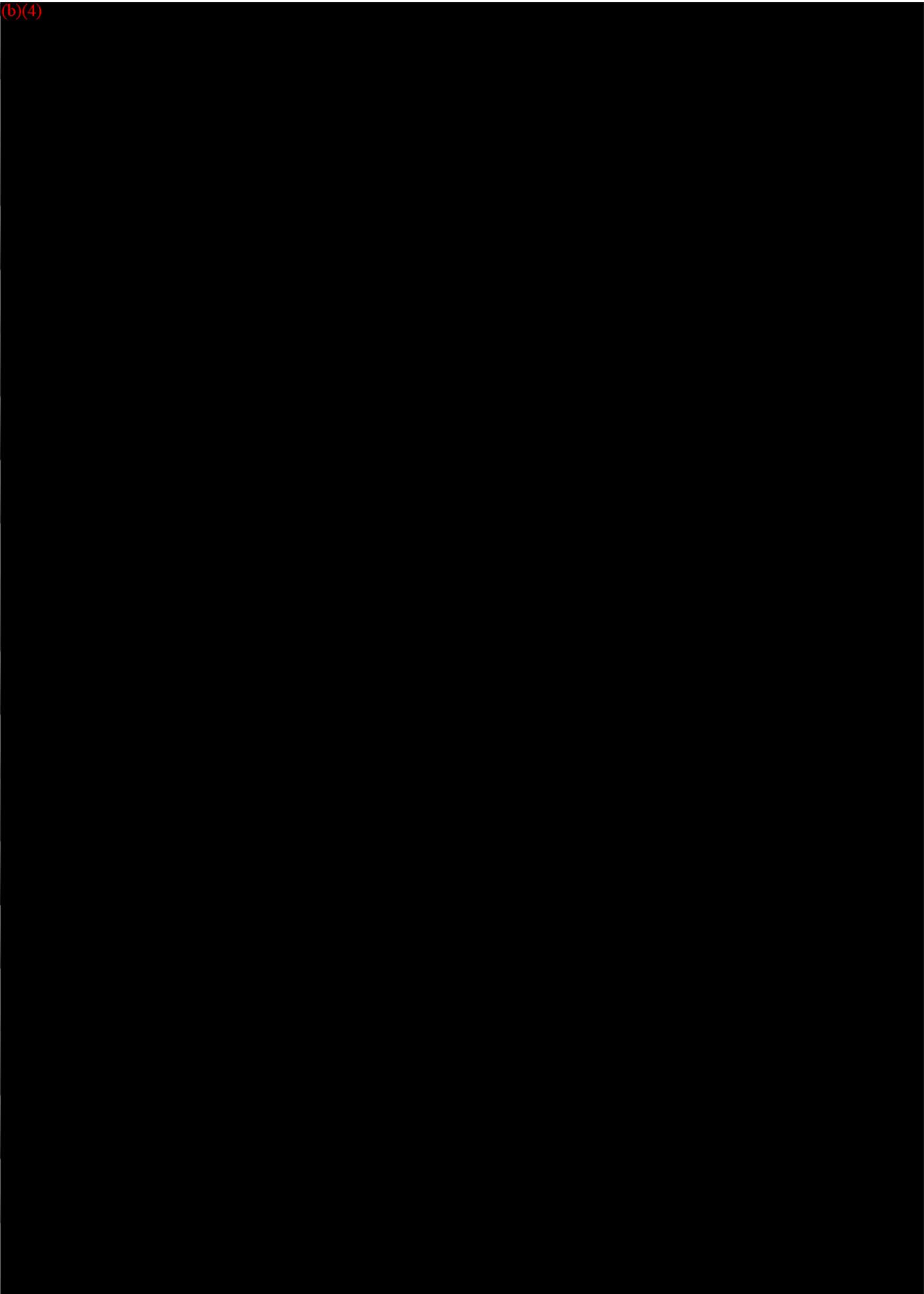
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67

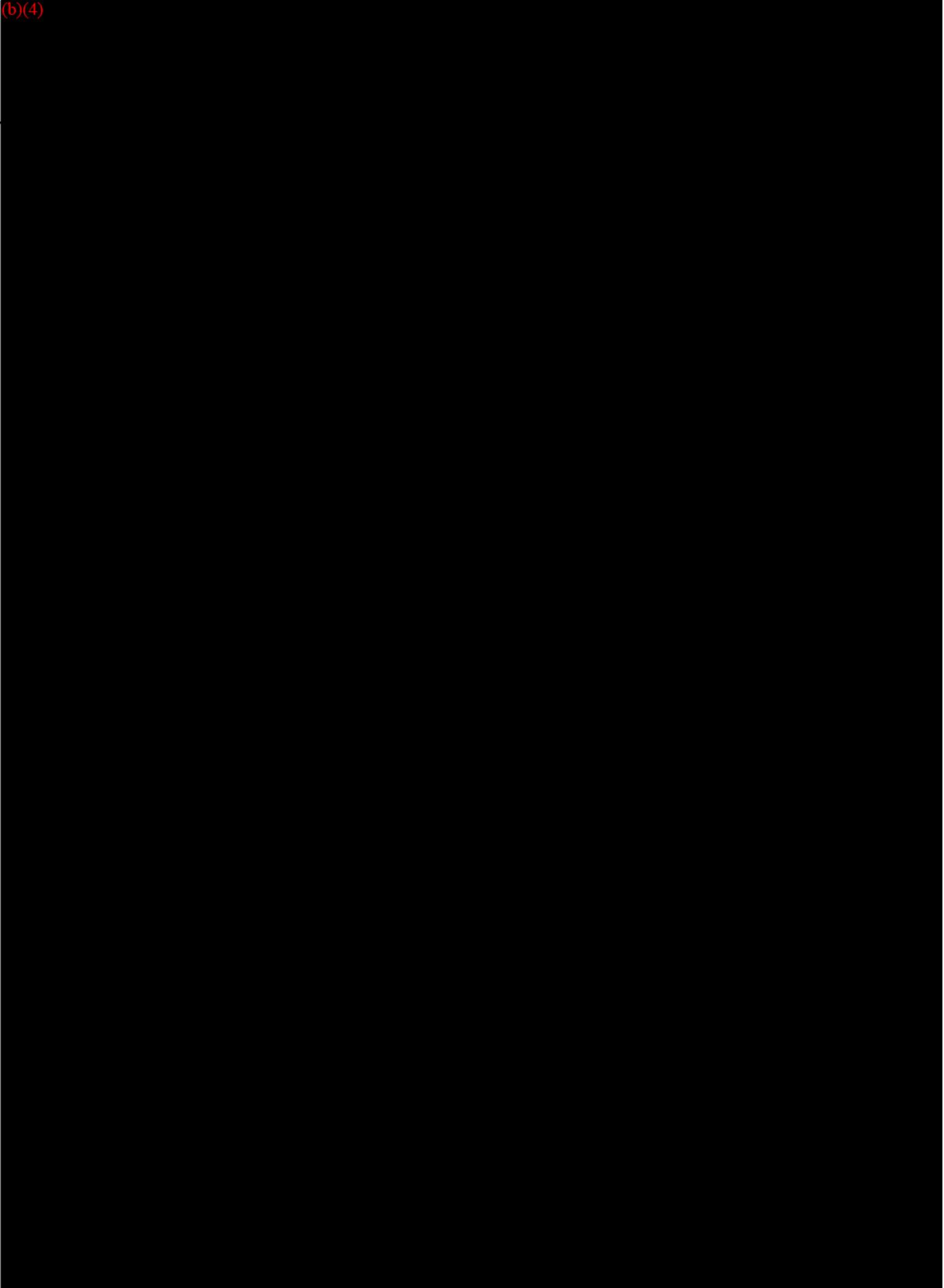
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68

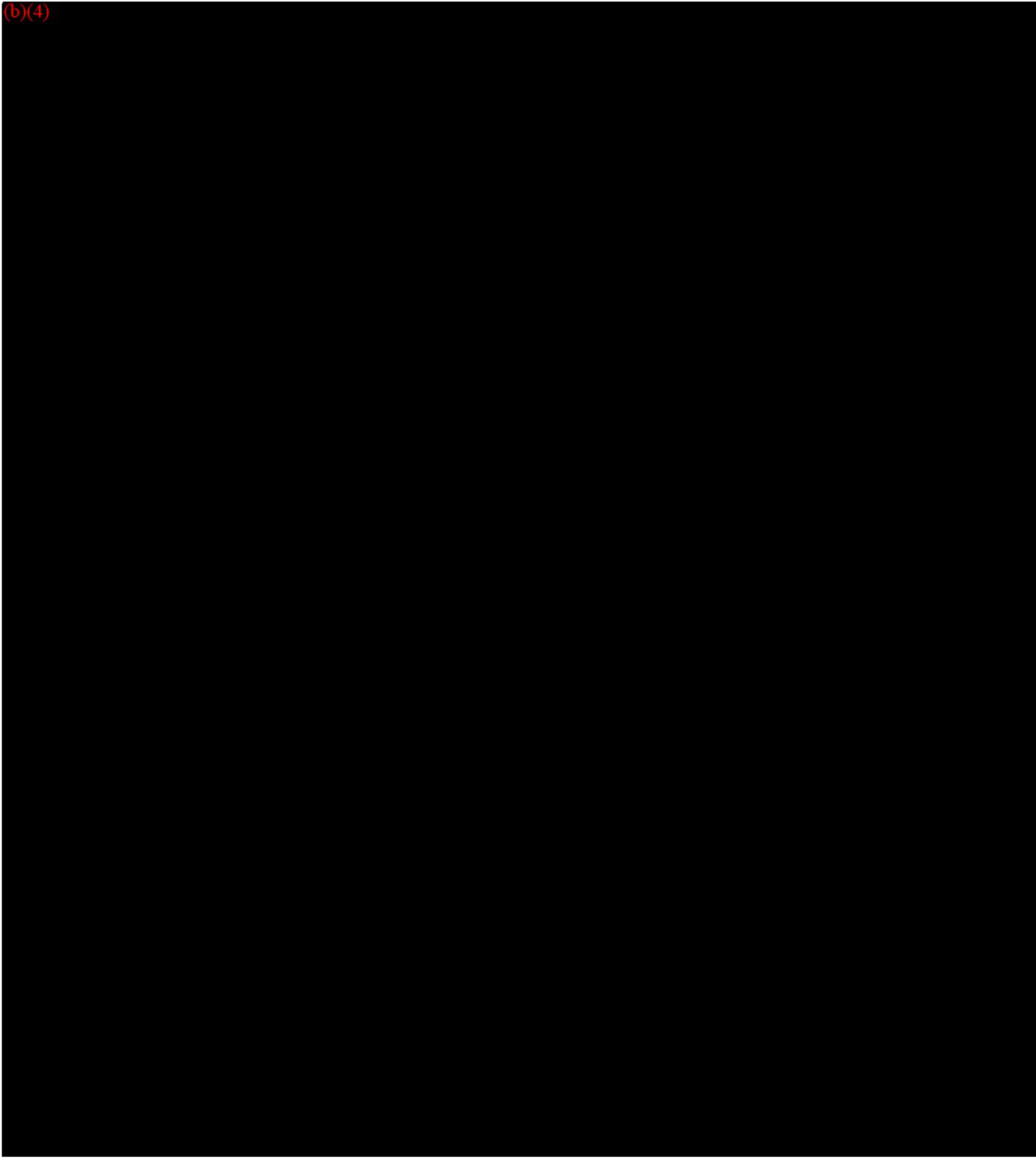
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ASHRAE 1134-RP

69

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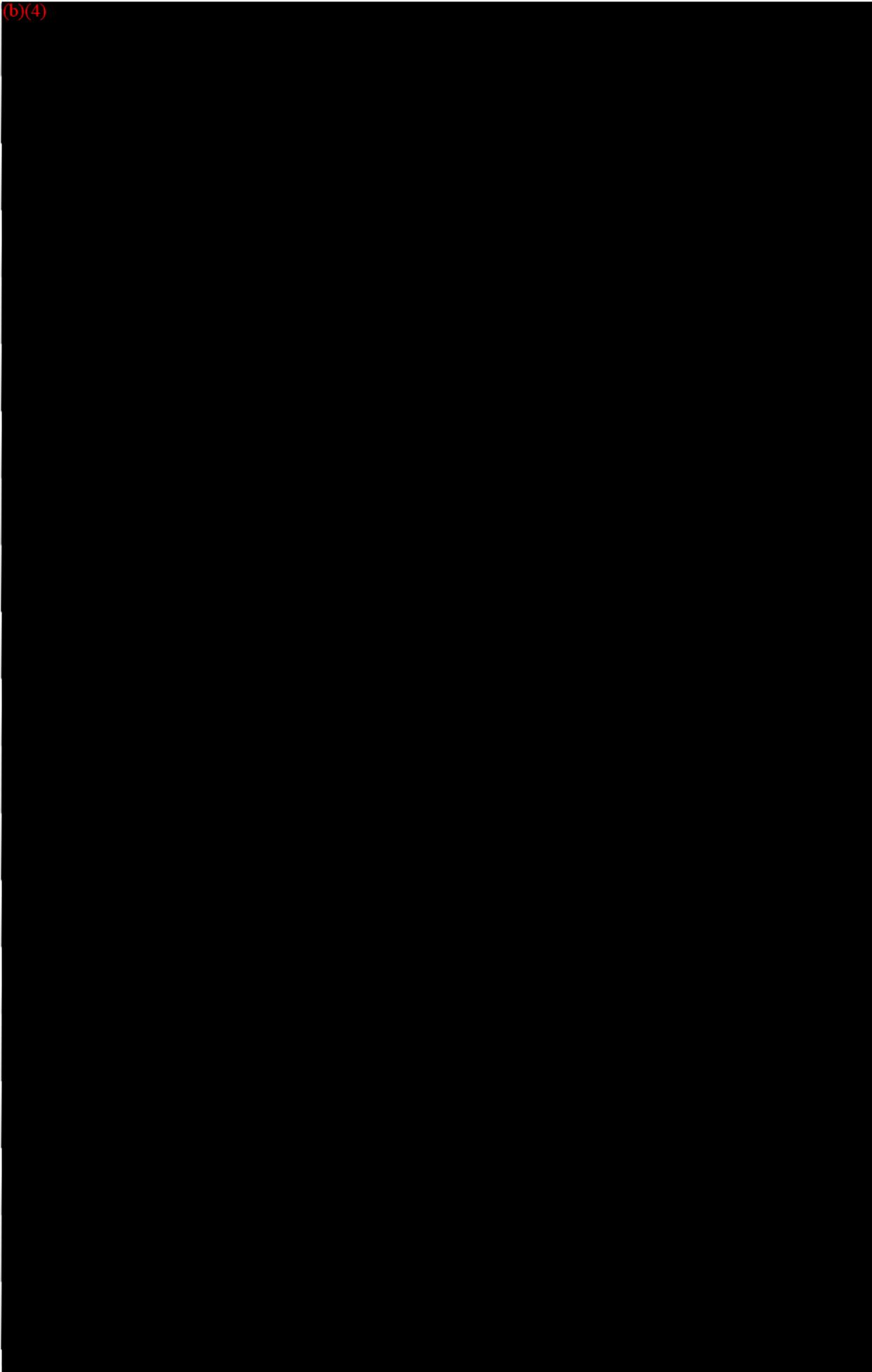


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119

ASHRAE 1134-RP

70

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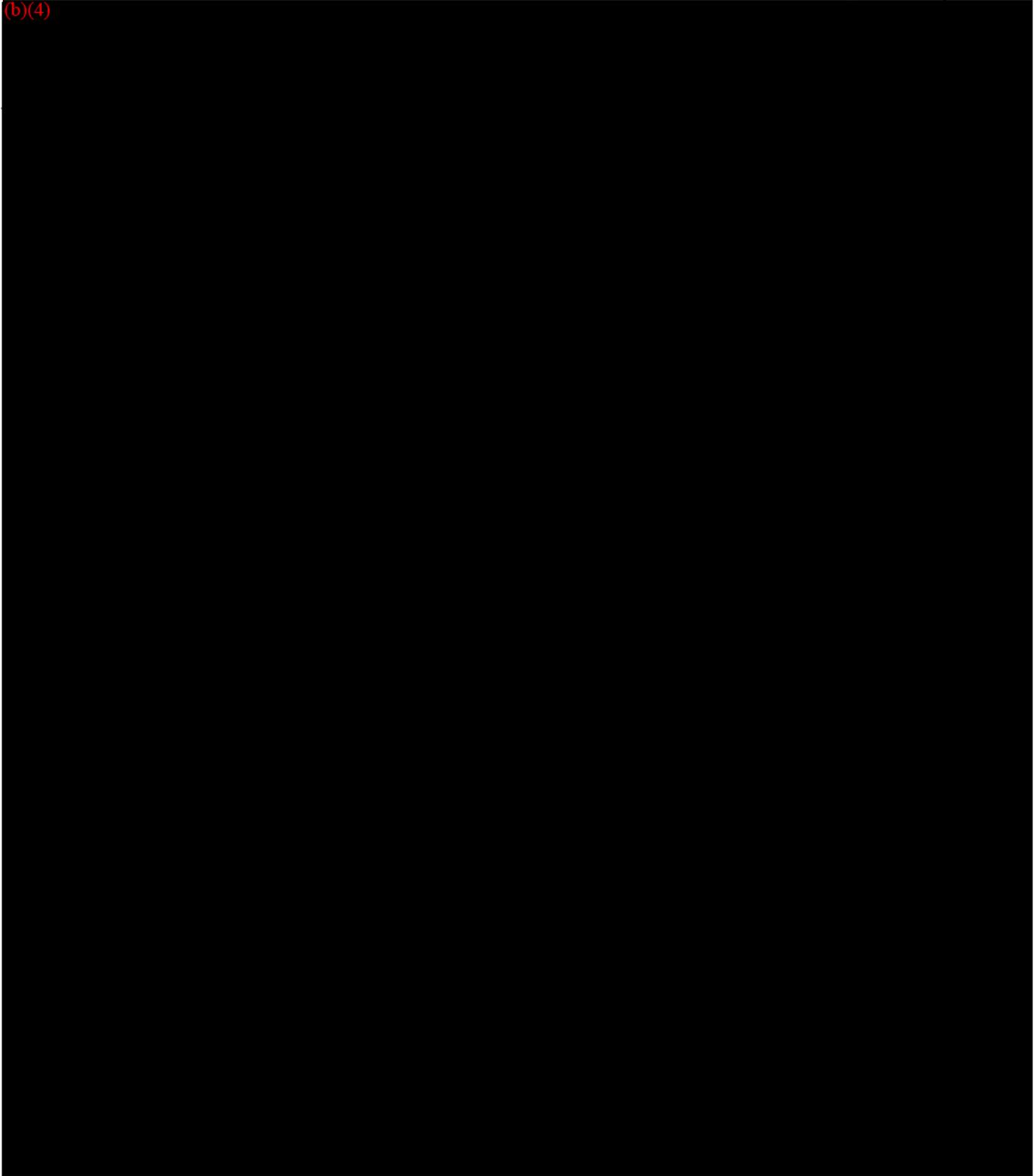


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71

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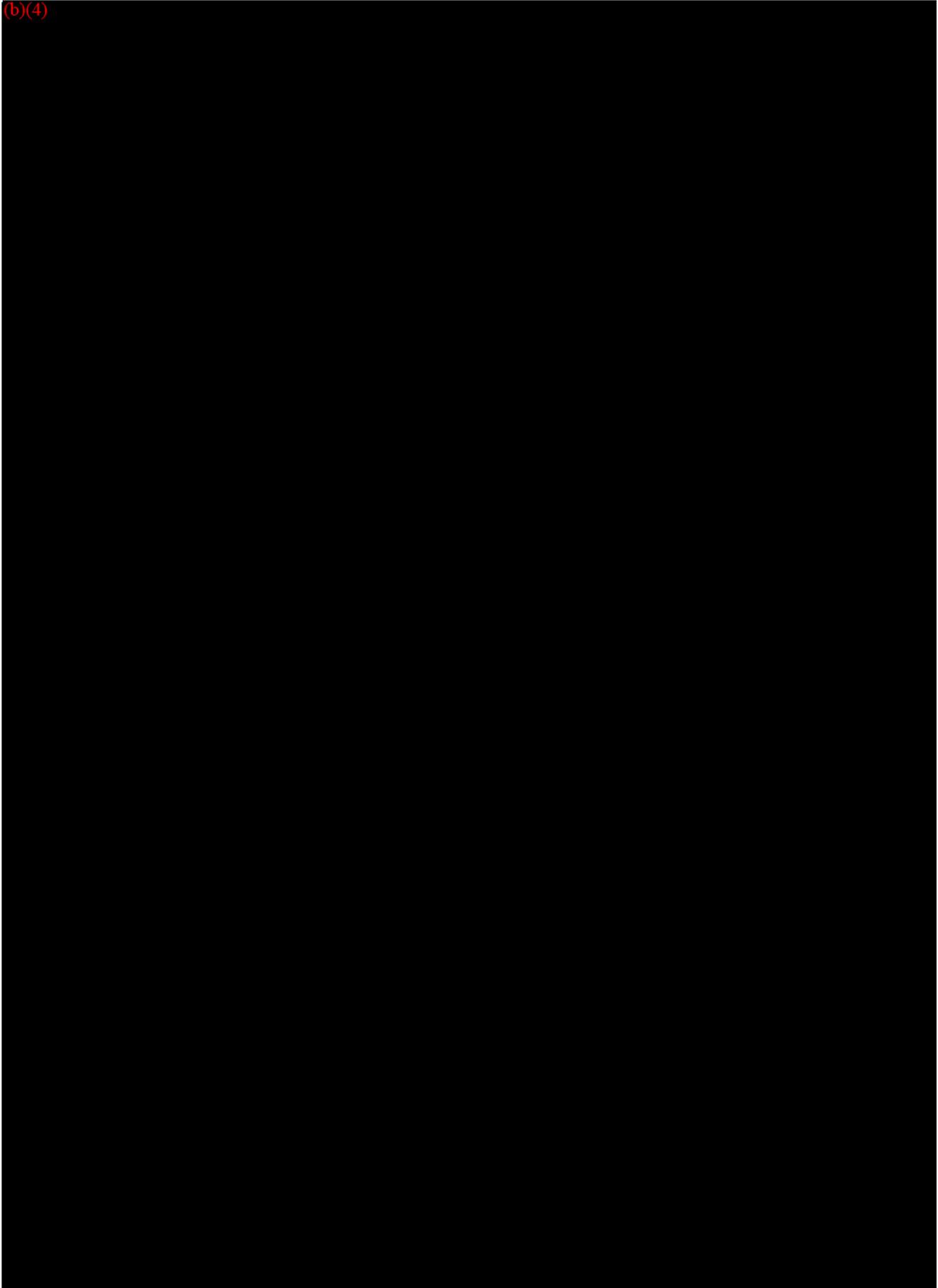


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ASHRAE 1134-RP

72

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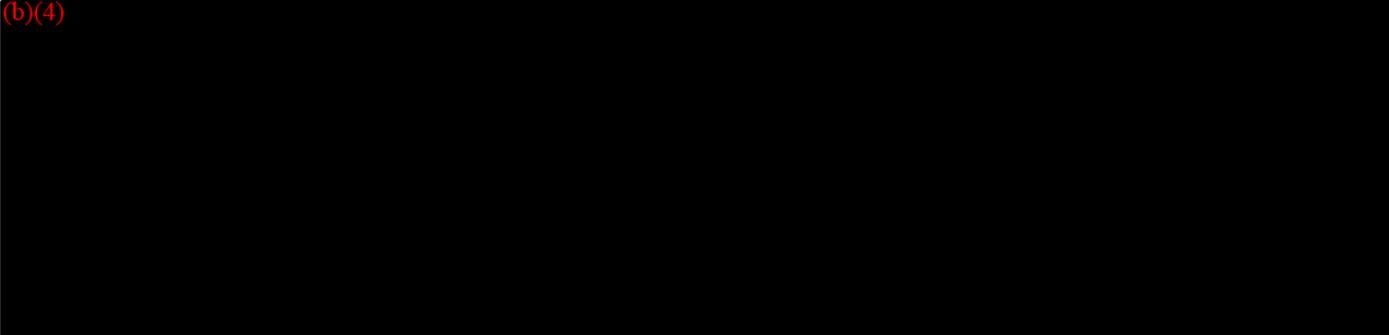


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ASHRAE 1134-RP

73

(b)(4)

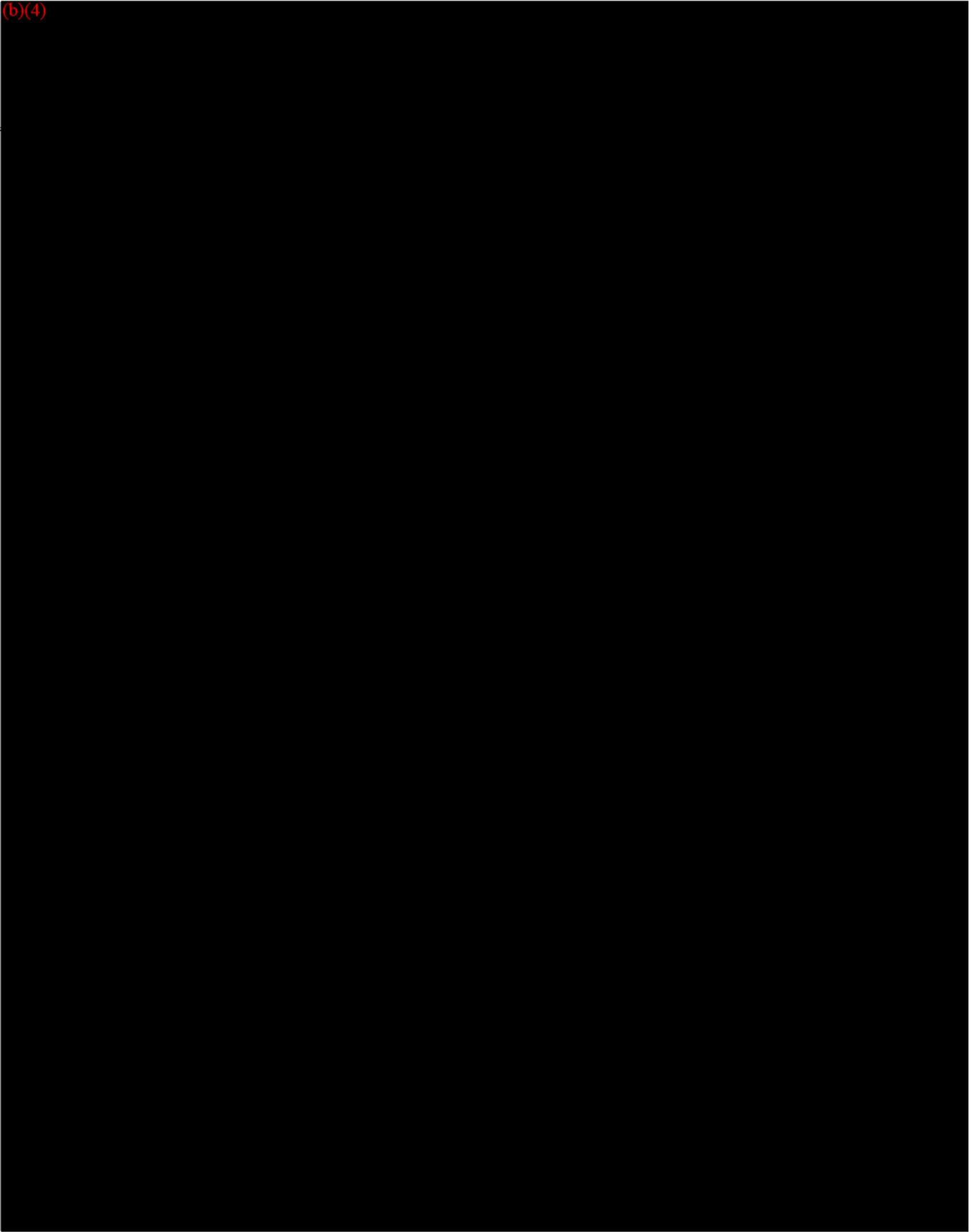


170
123

ASHRAE 1134-RP

74

(b)(4)

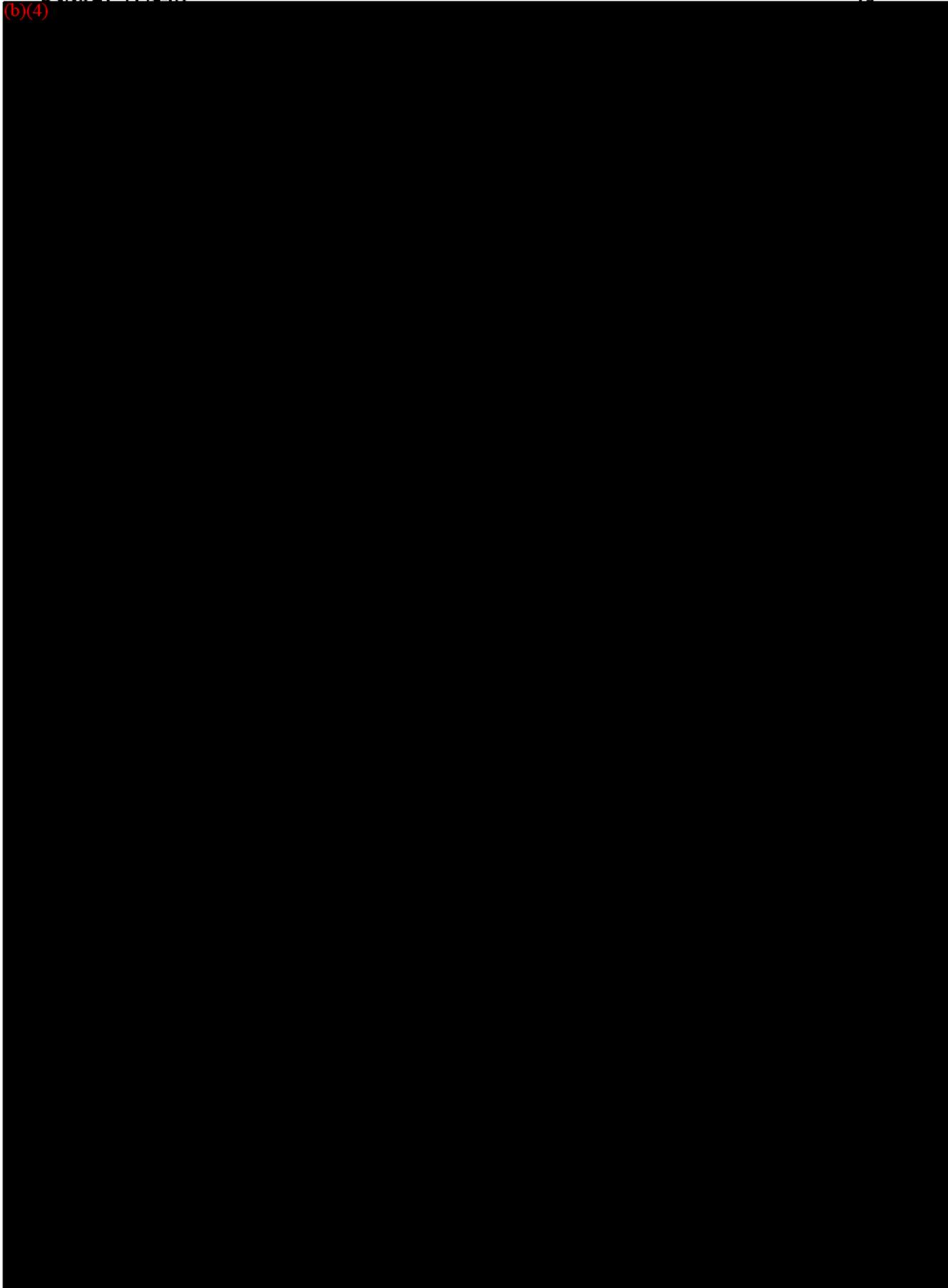


171

ASHRAE 1134-RP

75

(b)(4)

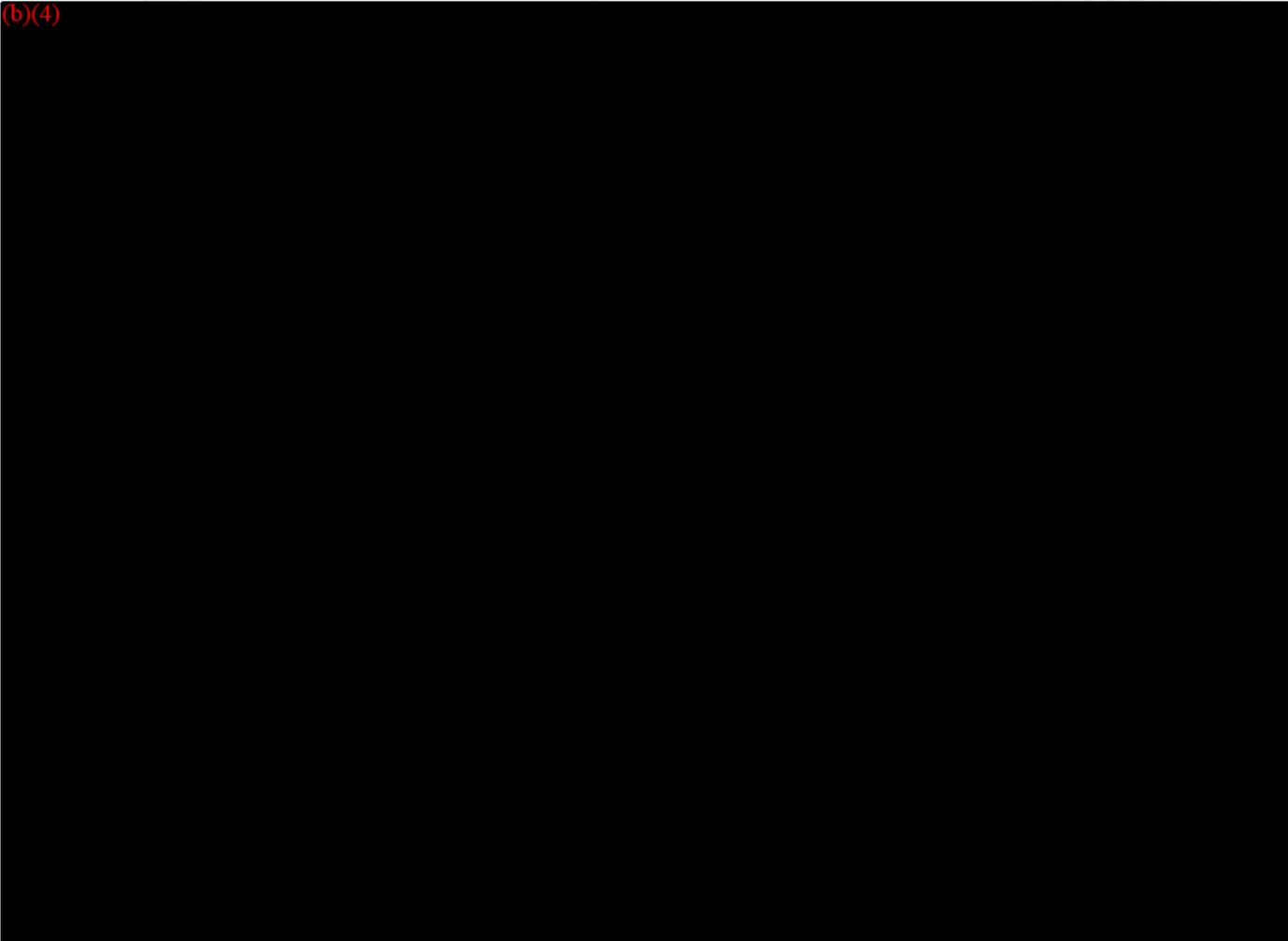


172
125

ASHRAE 1134-RP

76

(b)(4)

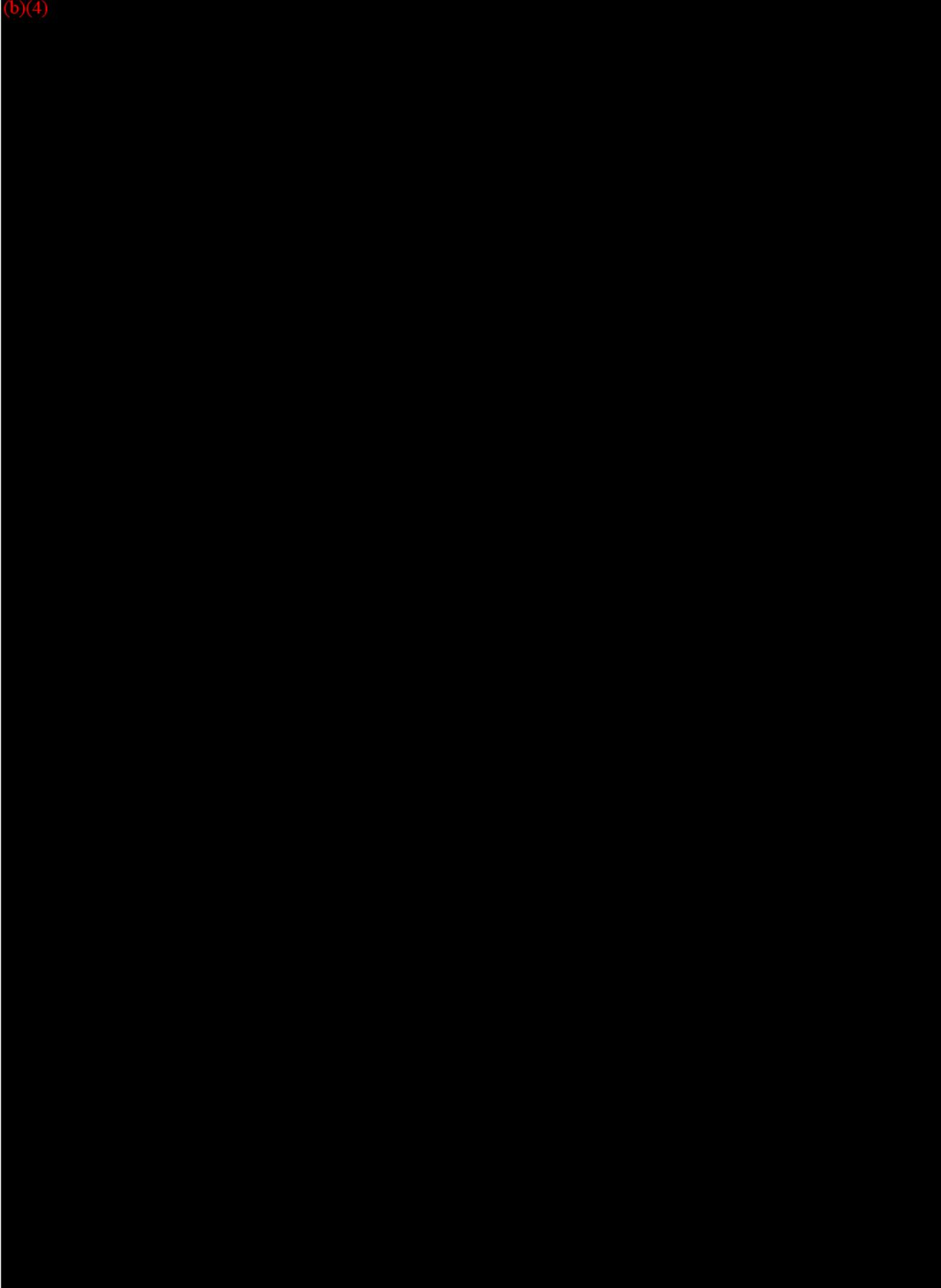


173

ASHRAE 1134-RP

77

(b)(4)



174
127

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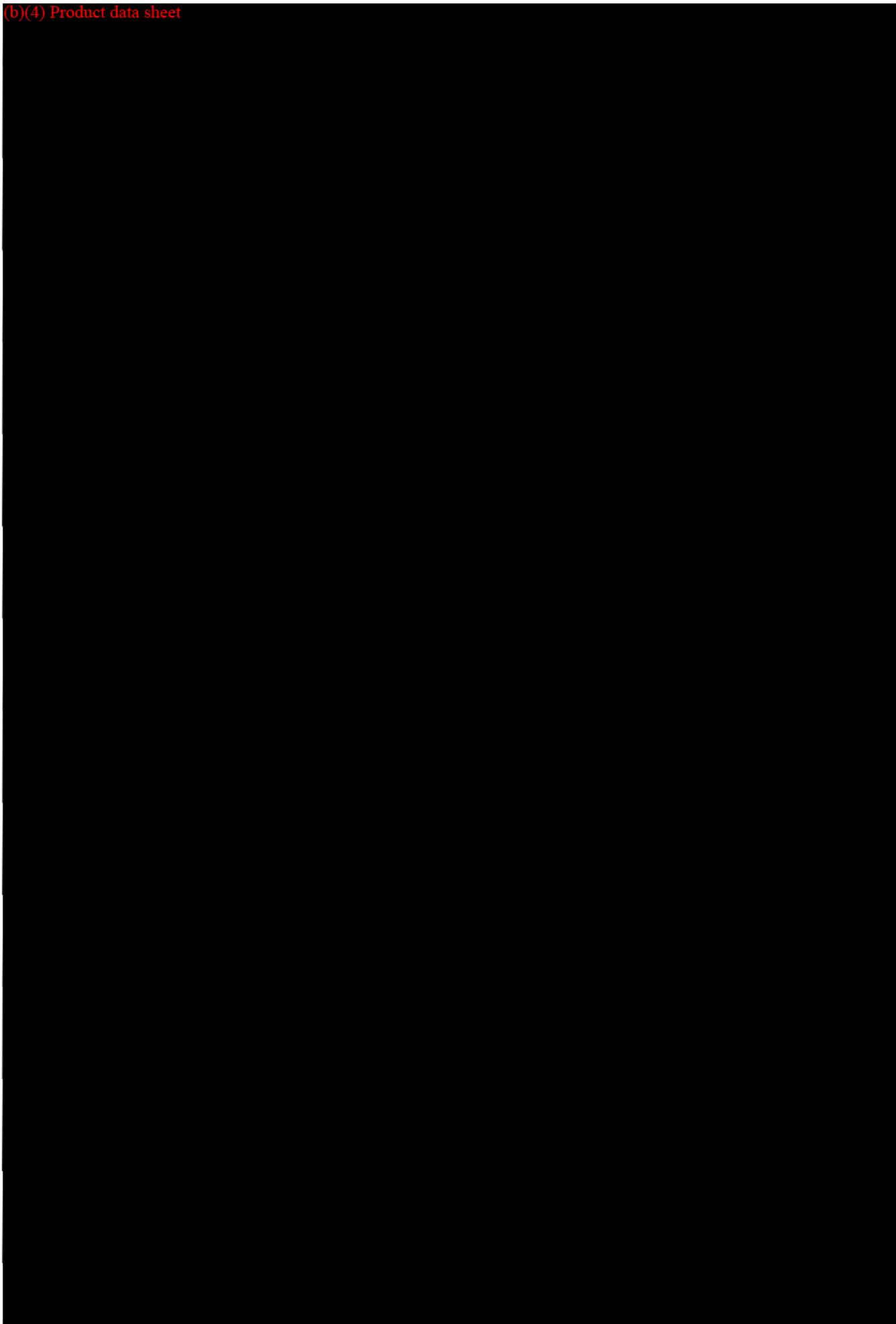
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MSDS – Material Safety Data Sheet – Page 1 of 3

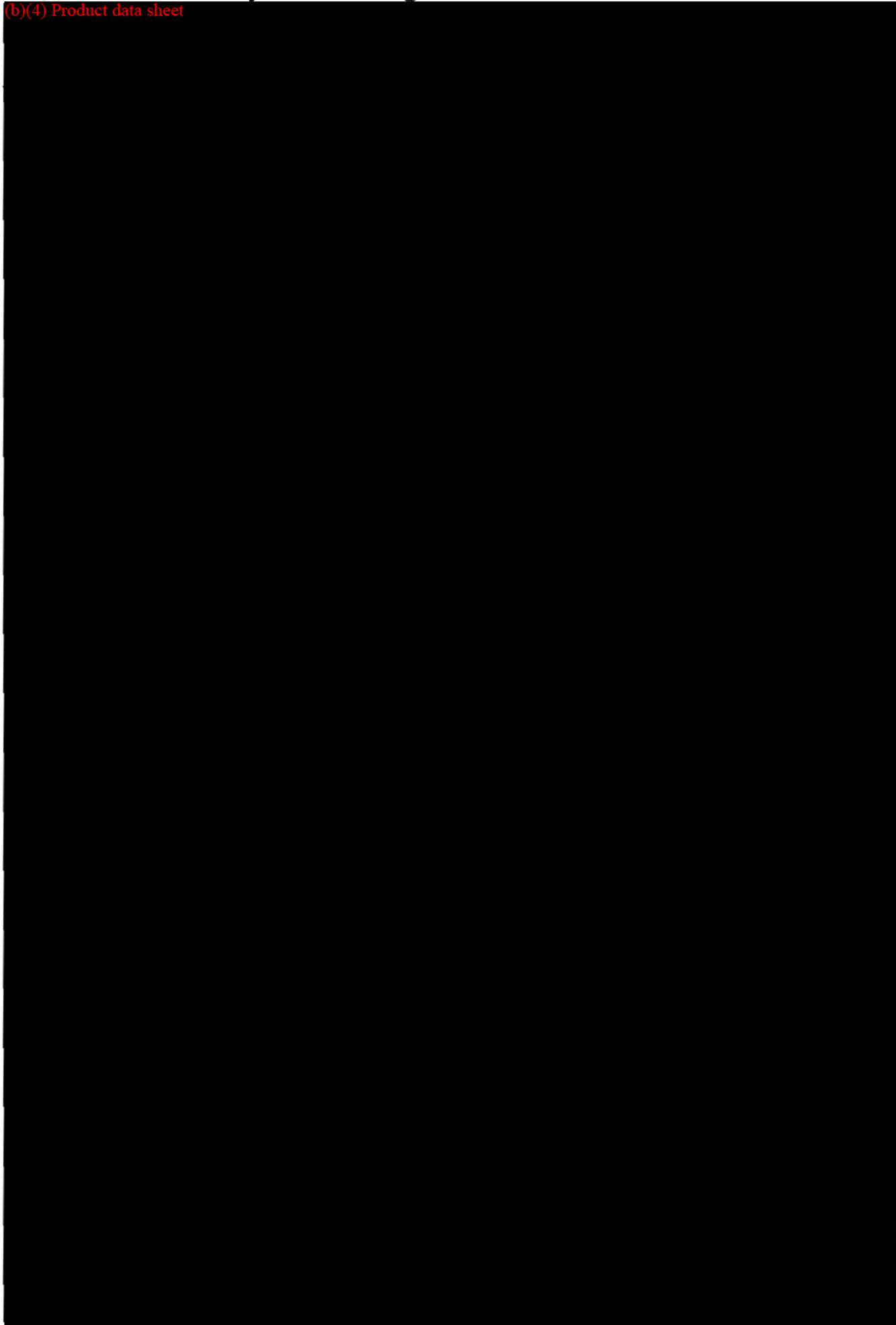
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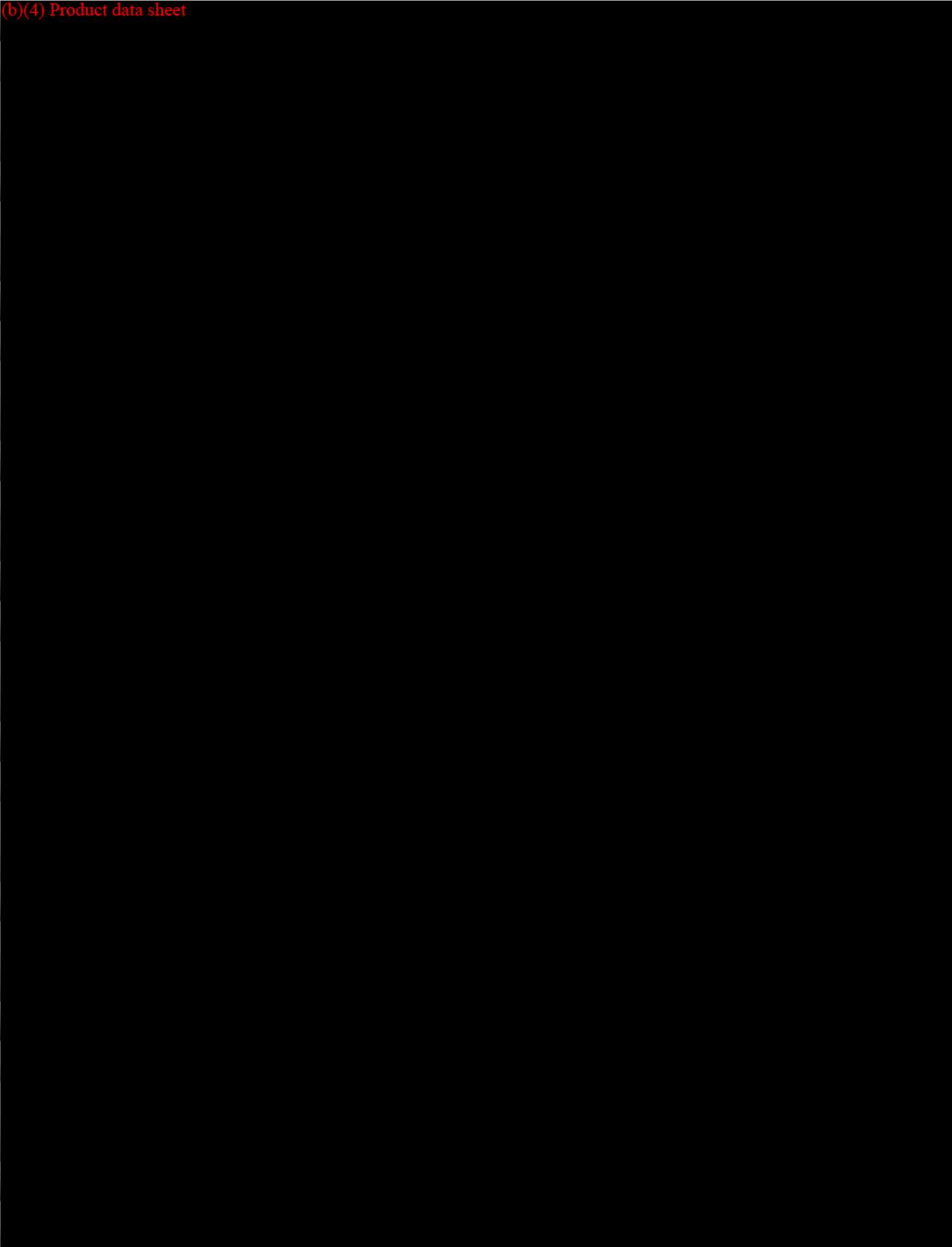
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August 1, 2002

Anne A. Busher and Kelly A. Smith
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(440) 234-0886
(440) 234-1725 fax

RE: **UPDATE of Performance Measures for AiroCide Device**
Response to Definitions of Decon Device Performance Measures for Buildings

Dear Ms. Busher and Ms. Smith,

As I mentioned in my letter to you dated May 3, 2002, please find attached an **update** on the *definitions device performance measures for buildings* for the **AiroCide product**, which is produced and marketed by **KES Science and Technology**. This update is being provided because additional performance measures (to those provided earlier) have been obtained from testing conducted in May and June of 2002. Therefore, please **find enclosed an updated (revision) Decon Definitions of AiroCide treatment device**. Text that is new to this revision is highlighted in red color.

Sincerely,

Decon Definitions of the AiroCide

May 7, 2002 August 6, 2002 (1/2 throughout)

(b)(4) Testing

DEFINITIONS OF DECON DEVICE PERFORMANCE MEASURES FOR BUILDINGS

BUILDINGS

For this effort, building decontamination refers to the ability to destroy or remove biological agents from internal surfaces and air contained within. Buildings will require special consideration during the performance of decontamination operations, as a variety of surfaces are contained within a building (e.g. painted surfaces, carpet, ceiling tile, fabrics, wood, glass, etc.), as well as the presence of ventilation systems and other complications. This presents a significant challenge to all decontamination technologies.

To effectively compare building decontamination technologies, a specific example building will be used. This example building has two floors totaling 40,000 square feet of floor surface area. The building contains an HVAC system. It is assumed that *Bacillus anthracis* spores are distributed throughout the building at varying concentrations. The building contents are a combination of porous and non-porous materials, and contain various other items, such as electronics, papers, and personal items. This model is designed to test the performance of various decontamination devices under these circumstances.

The technology considered can address structural items, HVAC, electronics, papers, and personal items in total or any one separately.

PREFACE – A Short Narrative on the Operational Character of the AiroCide:

The AiroCide device is designed to remove airborne particulates, microbiologicals (e.g., spores of *Bacilli*) and gaseous compounds via several treatment modalities operating concurrently. These modalities are described herein. In its present configuration, the AiroCide treatment device can be mounted to a ceiling, wall or other interior surface of a building. The AiroCide device contains an internally mounted fan. During operation, the fan will cause a local negative pressure differential between room air near the fan inlet and that downstream of the fan. In so doing, room air will be entrained into the AiroCide. The AiroCide is operated as a single-pass treatment device. The media within the AiroCide is designed to remove or immobilize the airborne biologicals entrained into the device. Once immobilized onto the surface of the media within the AiroCide, two treatment modalities operate concurrently to inactivate and oxidize the biologicals.

Decon Definitions of the AiroCide
May 3, 2002

(b)(4) Testing

1.0 BIOLOGICAL EFFICACY GOAL

Ability of the decontamination system to limit the effectiveness of biological agents during all environmental conditions, either by agent neutralization or removal. Assume normal conditions will consist of a variety of reasonably clean surfaces (plastic, fabric, painted, etc.) and moderate temperature and humidity.

- 1.1 **Effectiveness Measure.** Ability to destroy/remove spores to a specified level on all surfaces, components, or air. Examines the technology to determine the likely end-state of the decontamination effort.

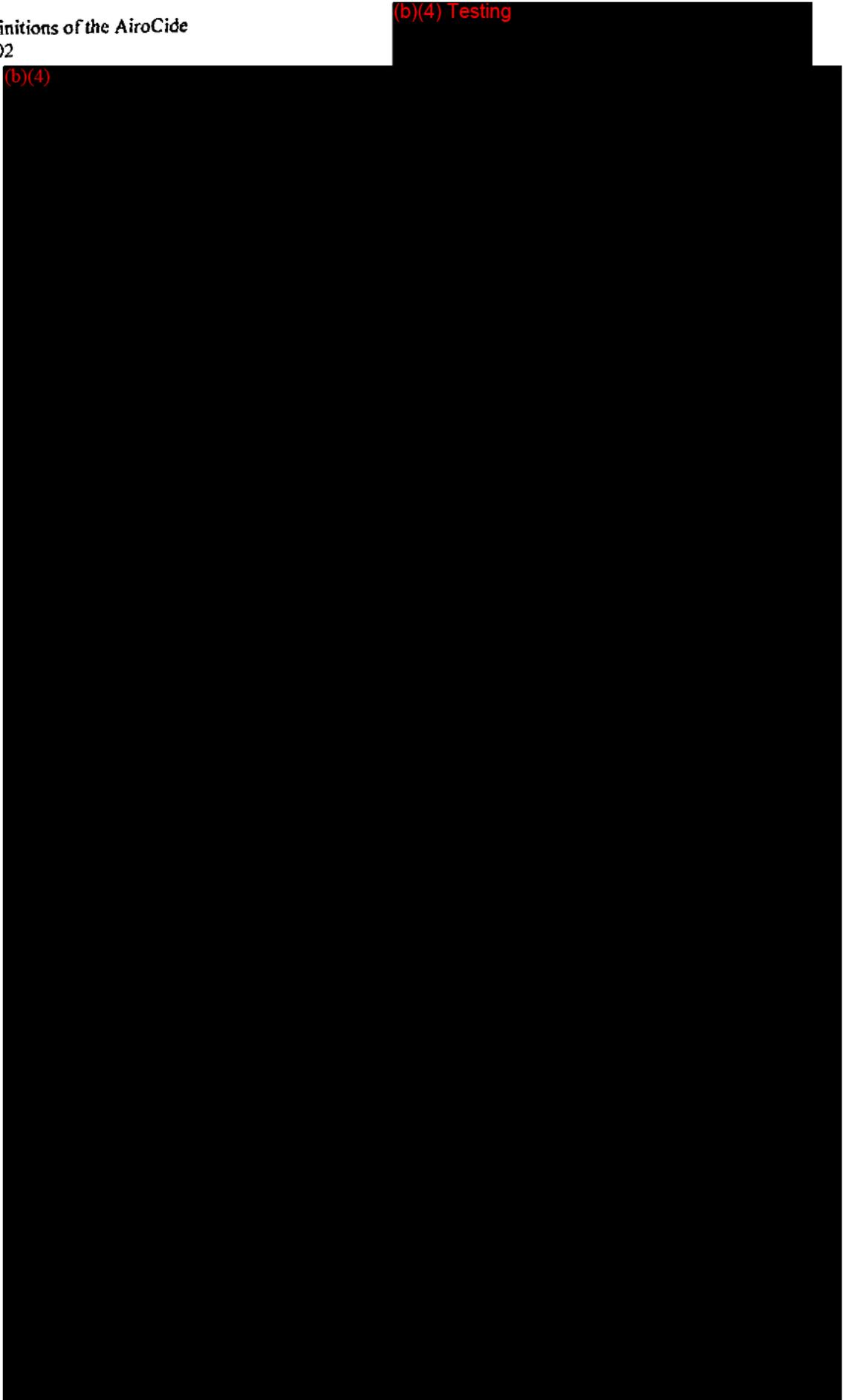
The AiroCide treatment device has been empirically examined for its removal efficiency based on performance testing of the full system. A report was prepared (December, 2001) describing the performance testing and is attached to this document as **Appendix A**. A summary of the testing is provided here:

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Decon Definitions of the AiroCide
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(b)(4) Testing

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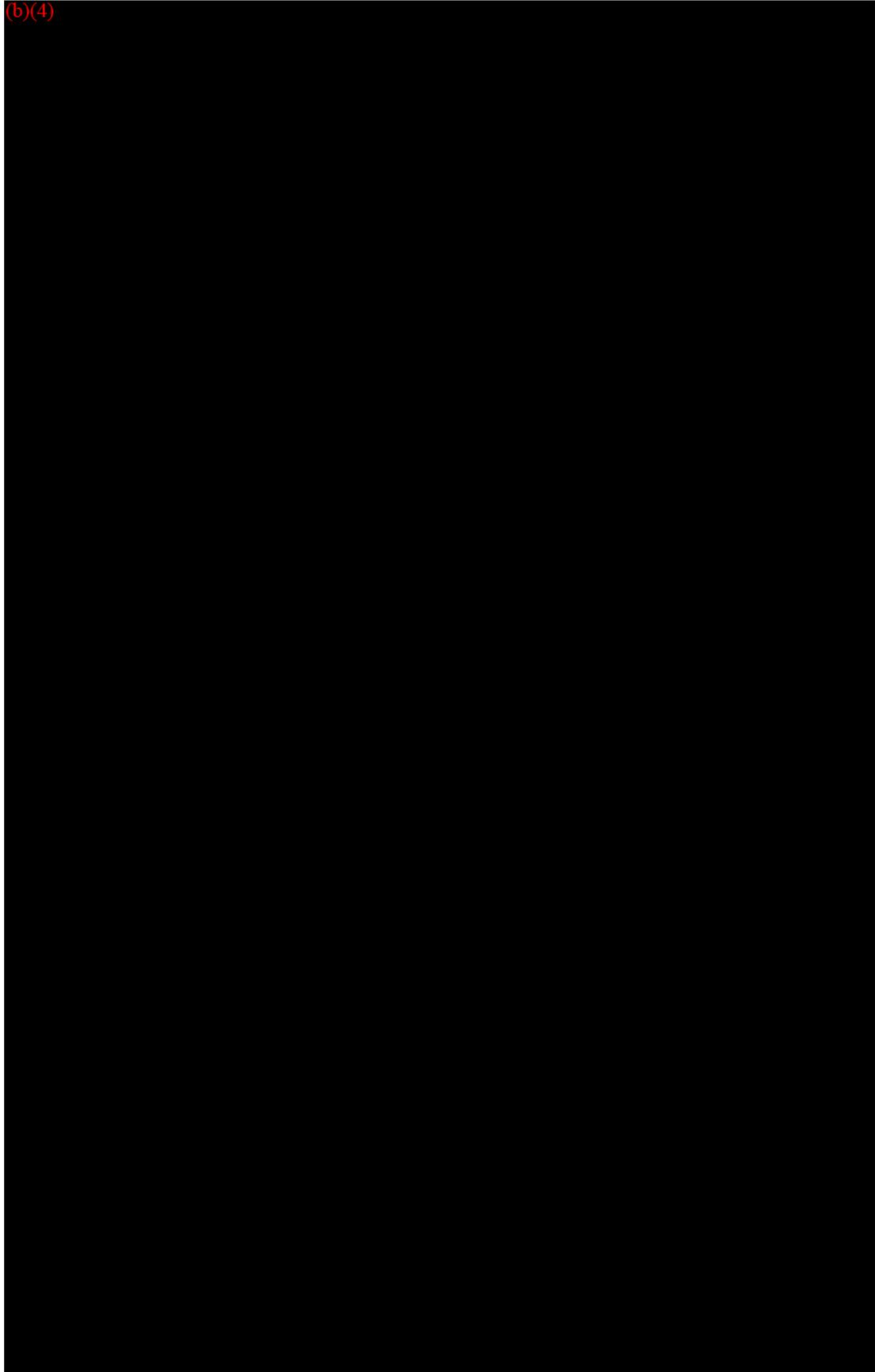


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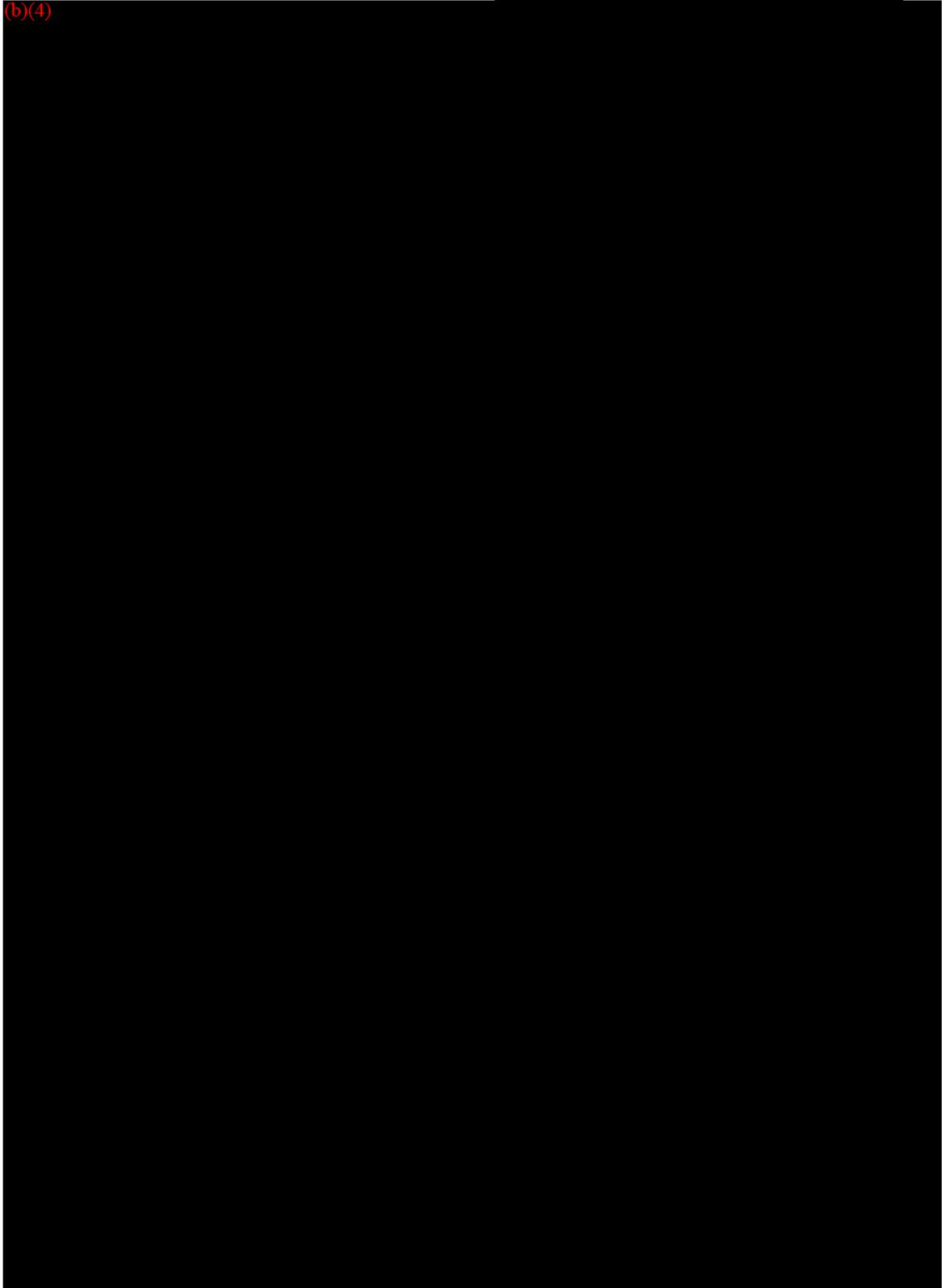


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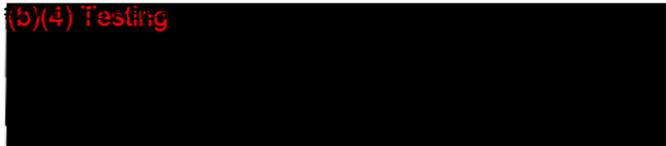
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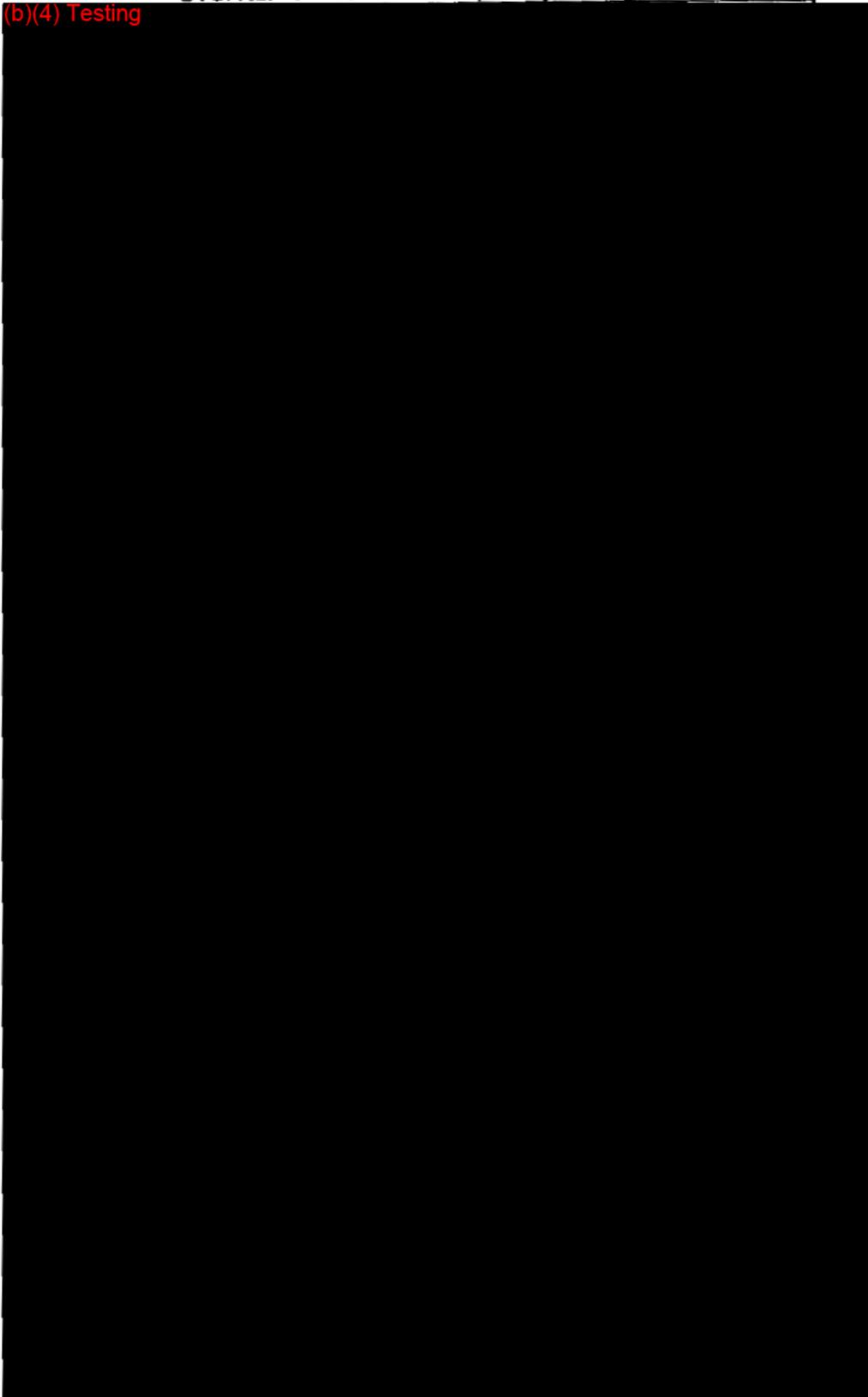
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UVGI Rate Constants for Respiratory Pathogens.



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(b)(4) Testing

The AiroCide employs 52 UVGI light sources in a tightly compacted arrangement, with the supported photocatalyst occupying the interstices between the light sources. Microorganisms contained in the air that is entrained into the AiroCide become immobilized onto the photocatalyst, where they are exposed to UVGI light indefinitely in the case of those organisms that remain permanently immobilized.

The second treatment technology is photocatalysis. The photocatalyst

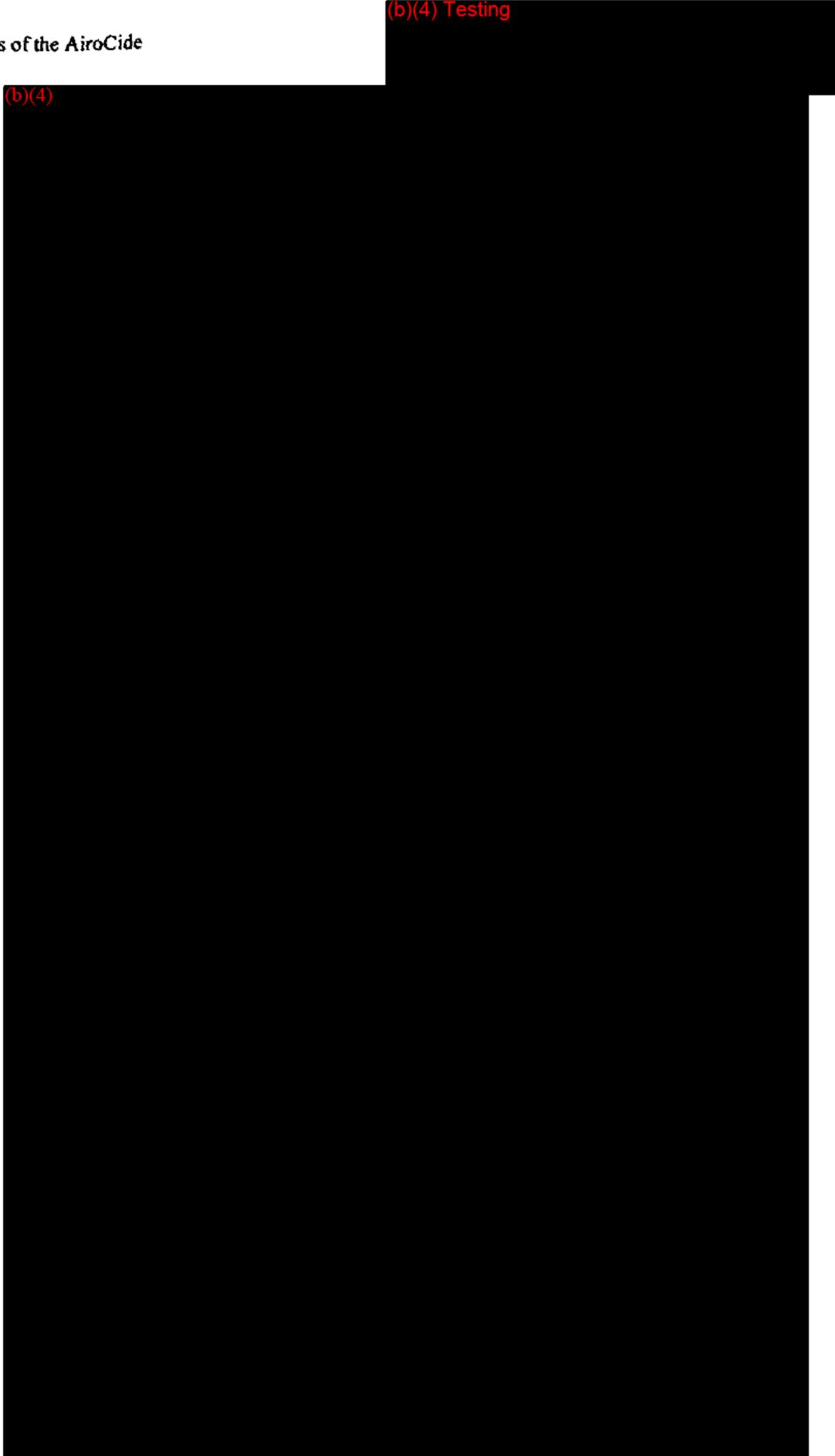
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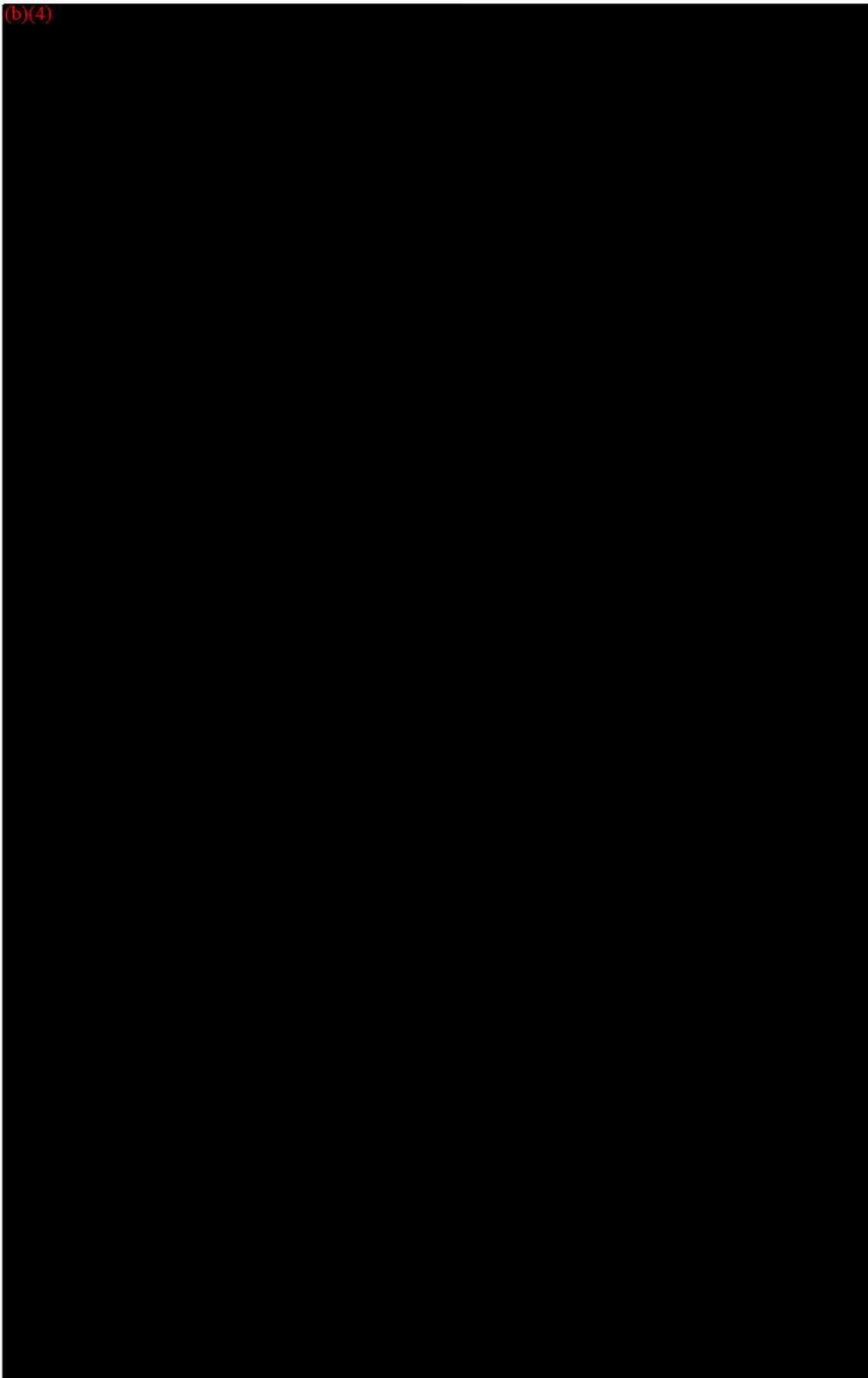
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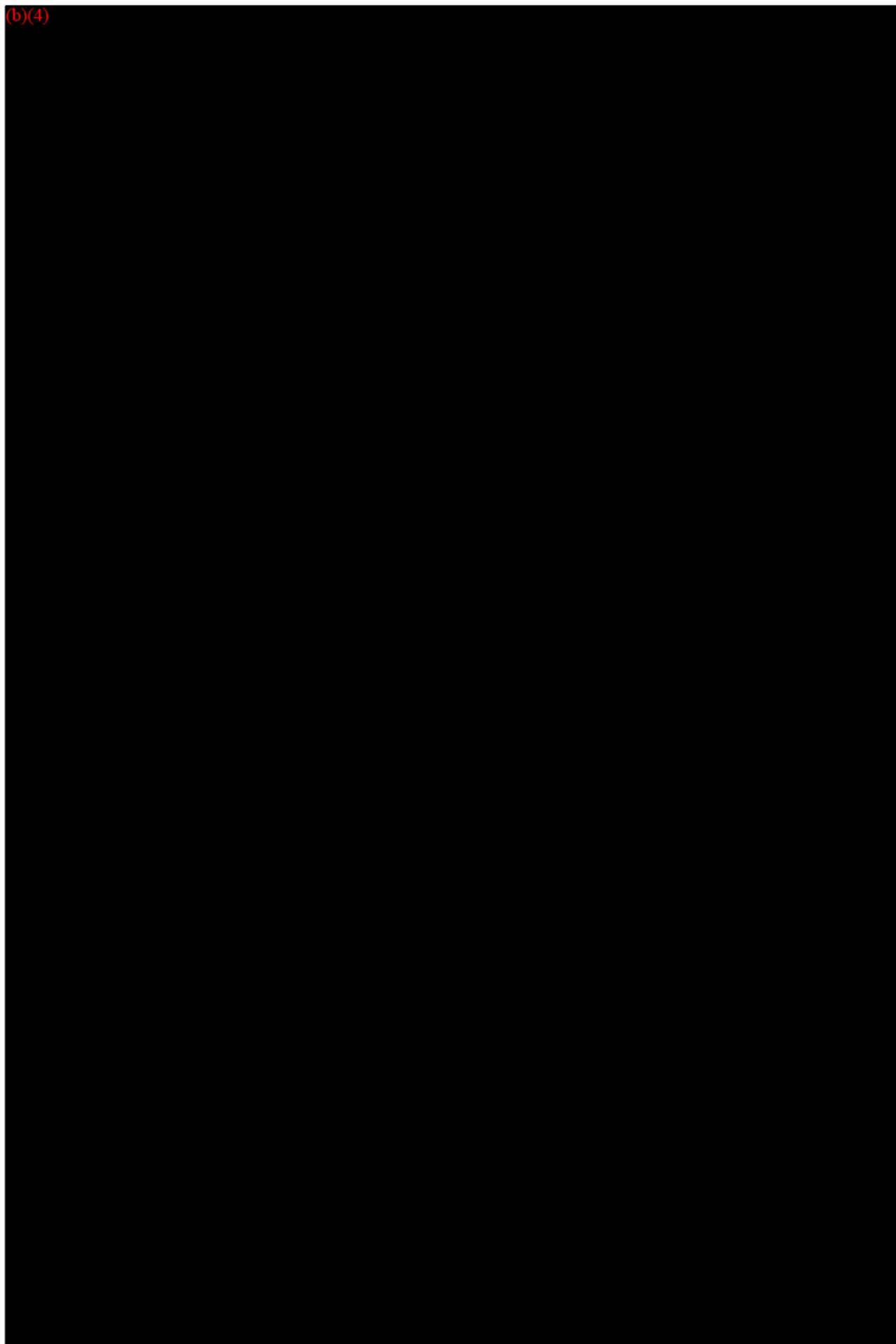
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- 32 C. Ash, J. A. E. Farrow, S. Wallbanks, and M. D. Collins, Phylogenetic heterogeneity of the genus *Bacillus* revealed by comparative analysis of small-subunit-ribosomal RNA sequences, *Lett. Appl. Microbiol.*, 13 (1991) 202-206.
- 33 Q. Wu, Effect of high-power microwave on indicator bacteria for sterilization, *IEEE Trans Biomed Engr*, 43 (1996) 752-754.

Decon Definitions of the AiroCide
May 3, 2002

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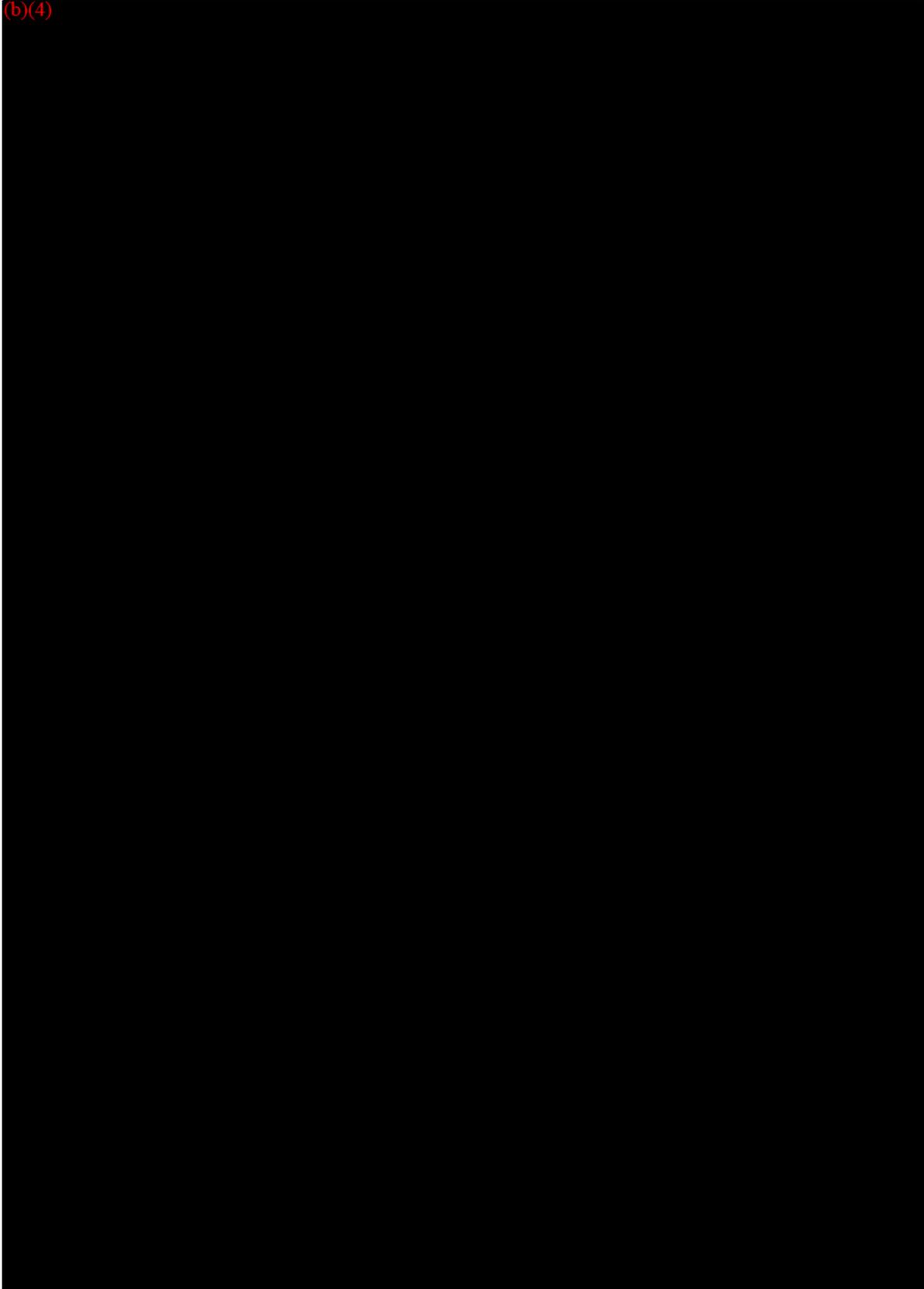


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(b)(4) Testing

Decon Definitions of the AiroCide
May 3, 2002

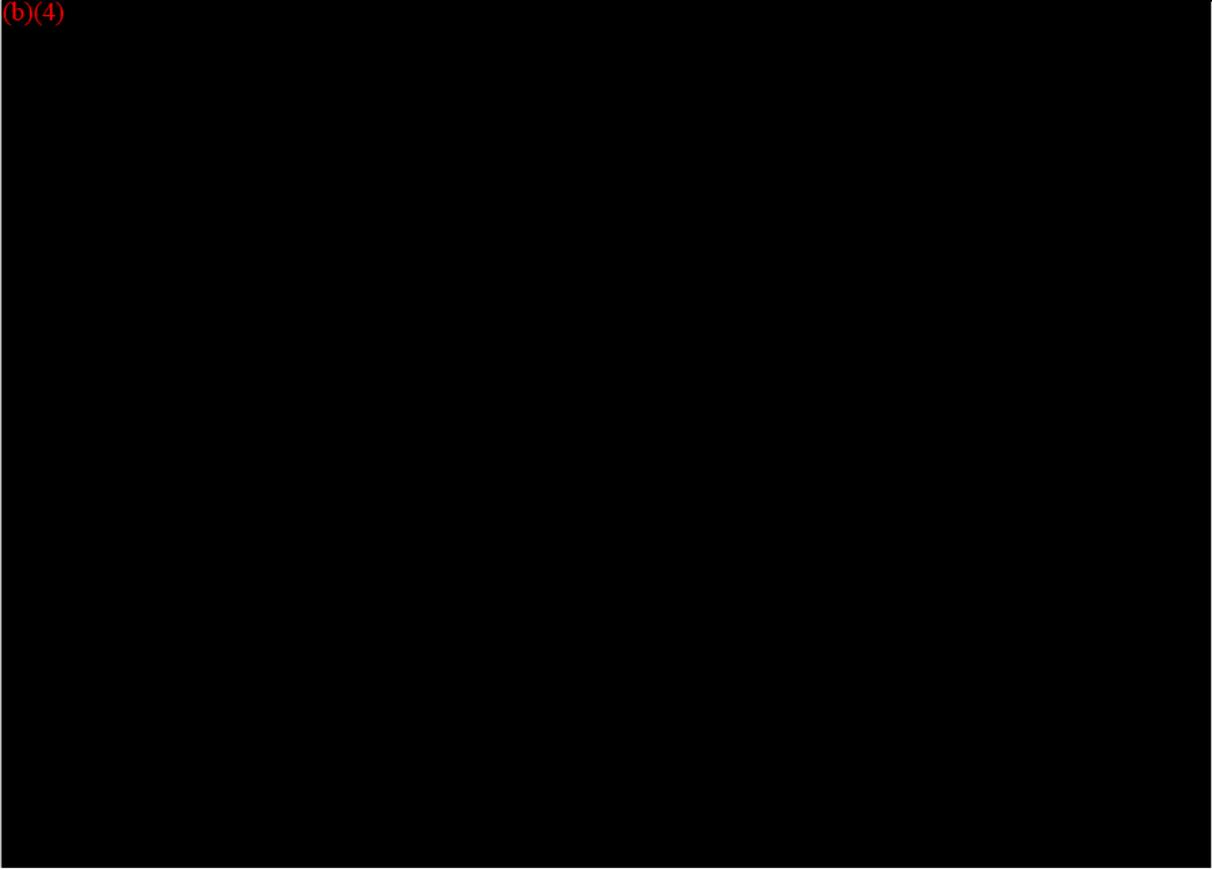
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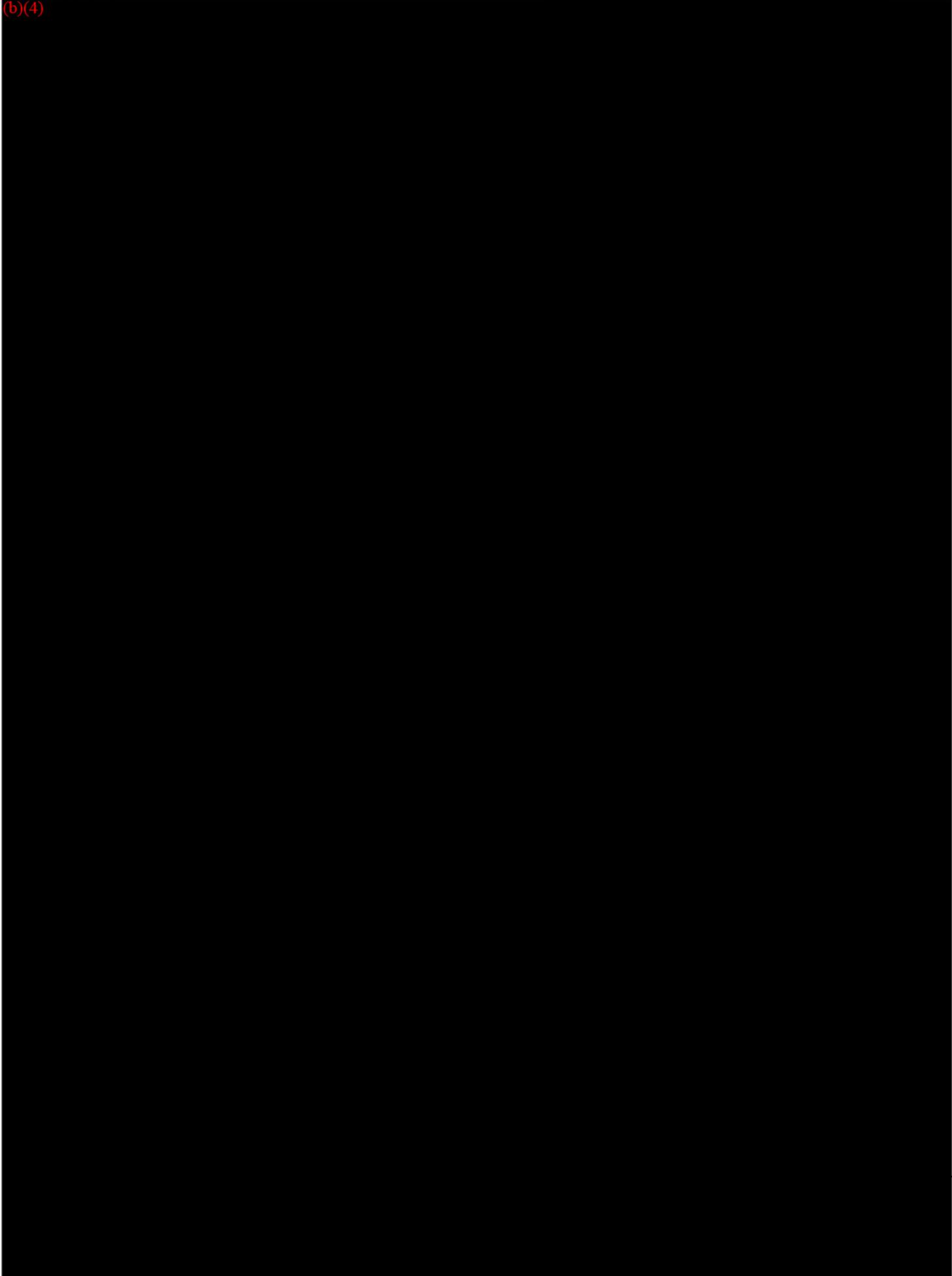
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May 3, 2002

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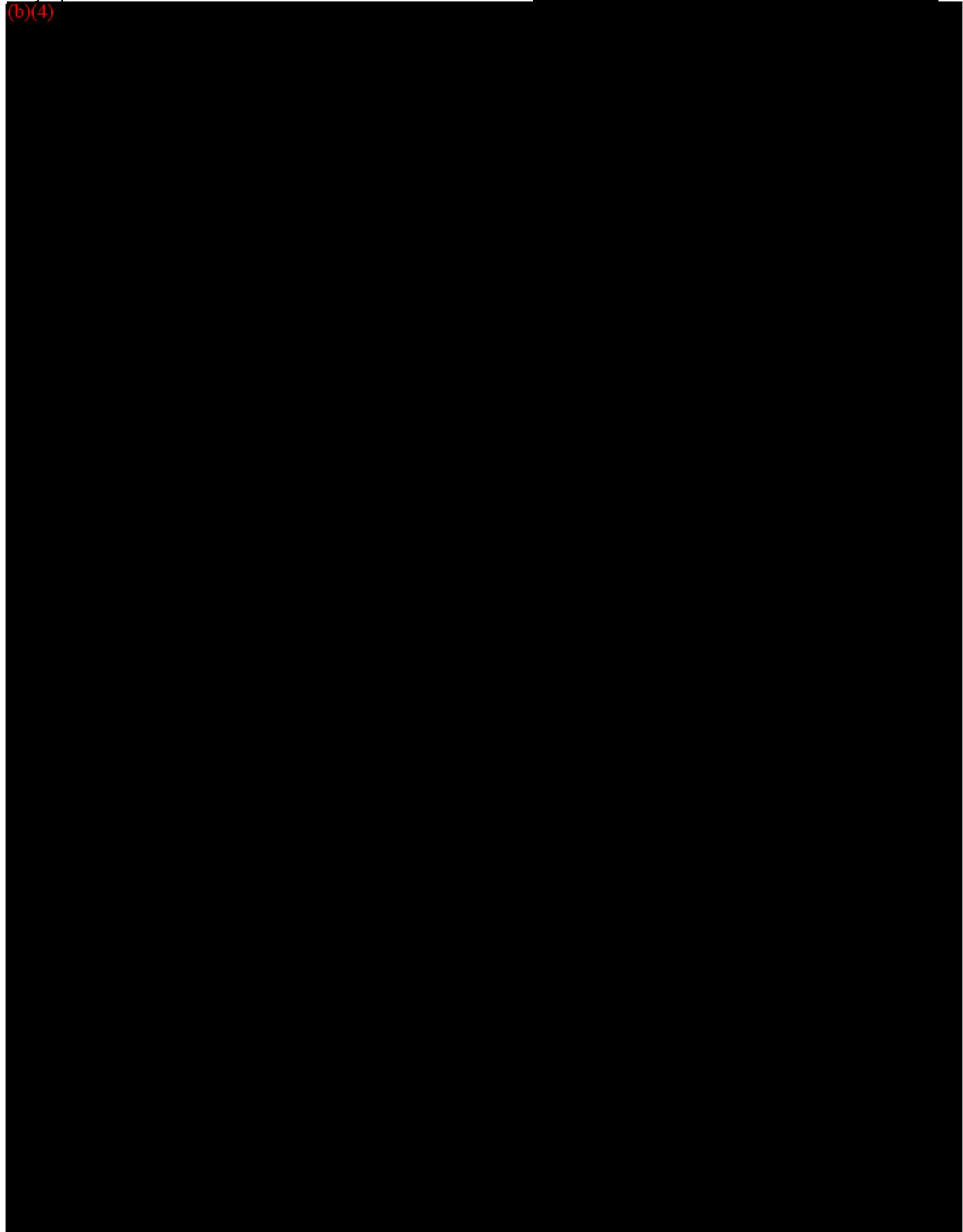


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Decon Definitions of the AiroCide

May 3, 2002

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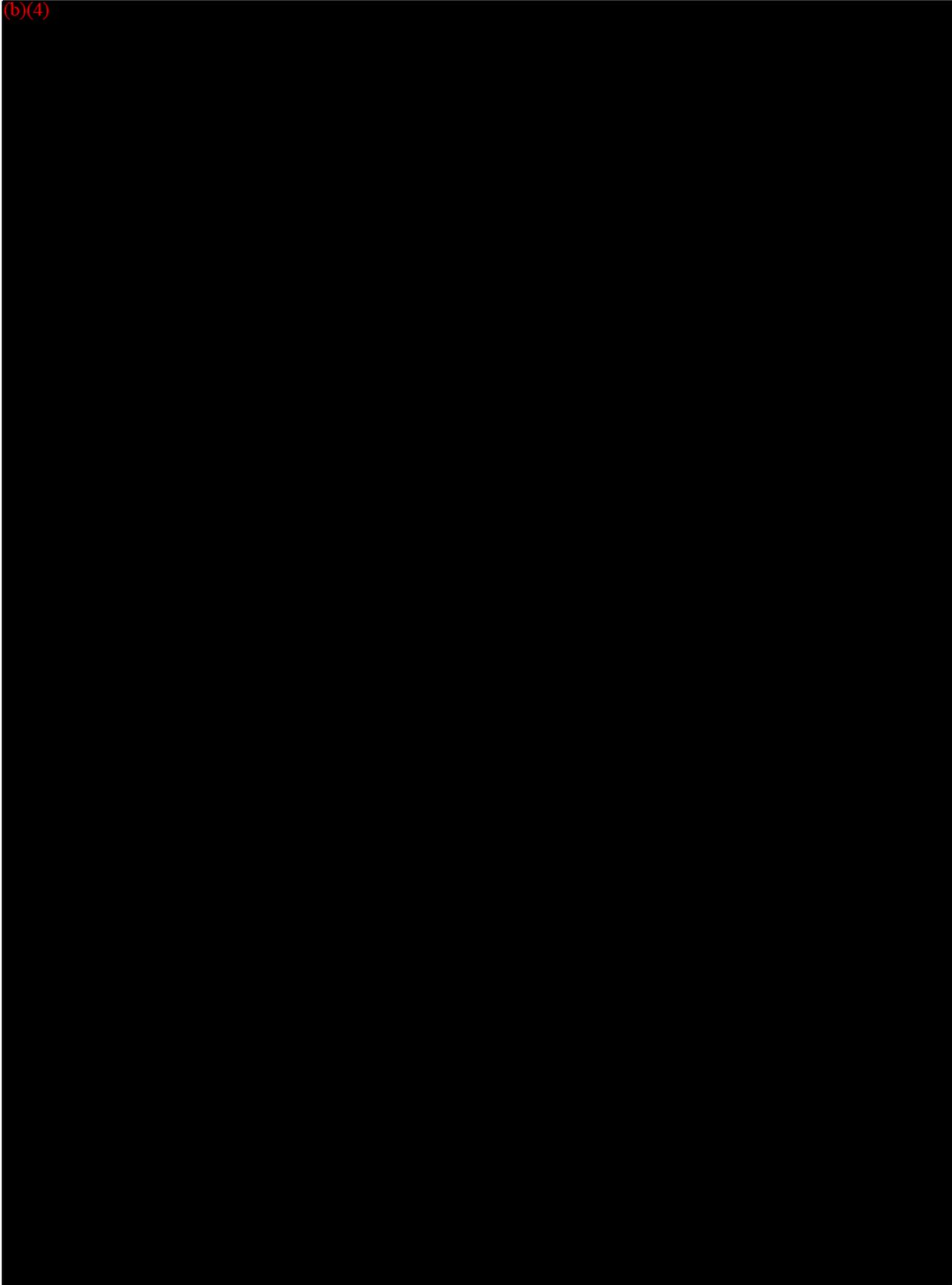


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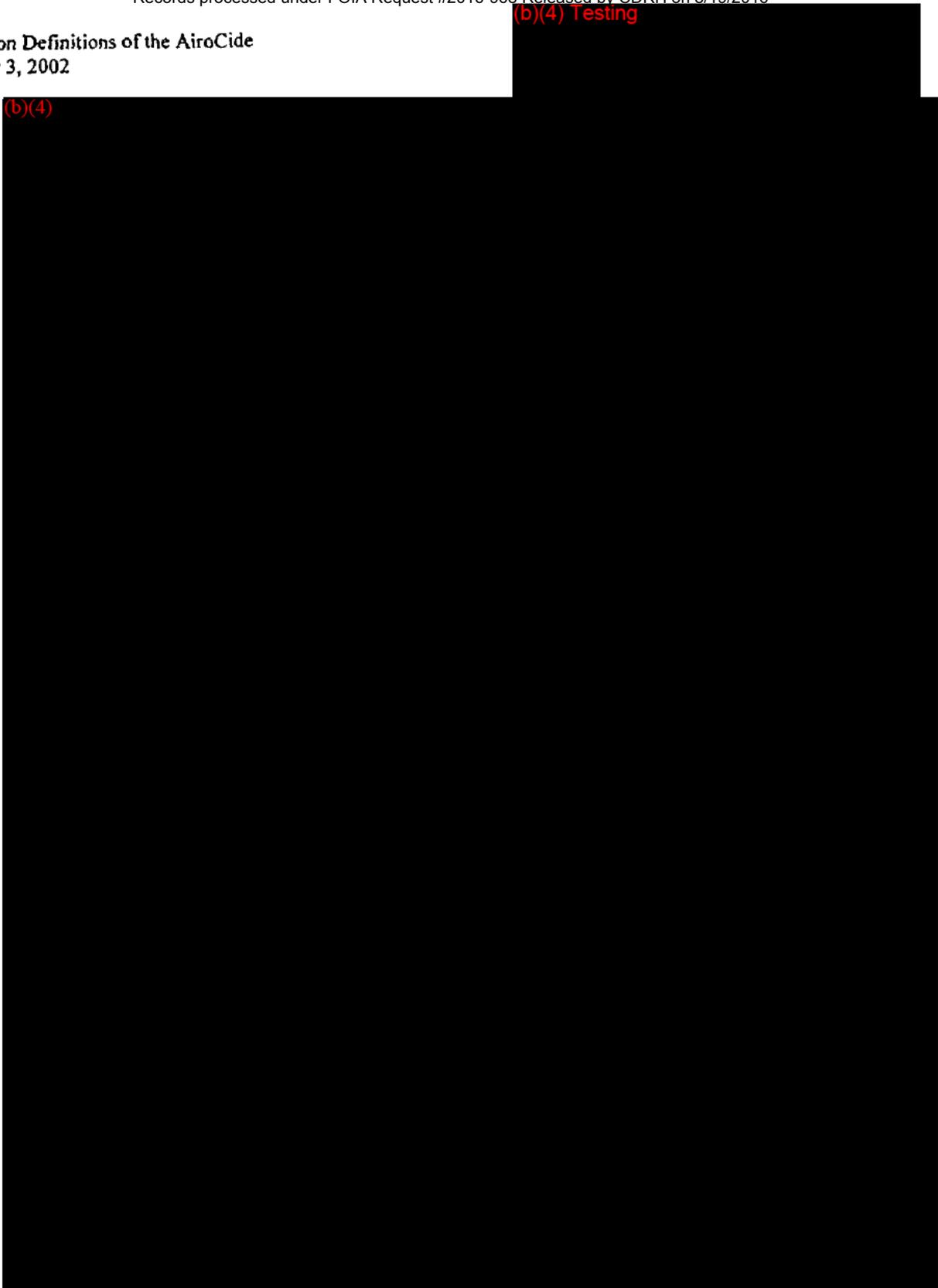


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Decon Definitions of the AiroCide
May 3, 2002

(b)(4) Testing

(b)(4)



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(b)(4) Testing

September 20, 2002

John Hayman
President
KES Science and Technology
3625 Kennesaw North Industrial Parkway
Kennesaw, GA 30144
(800) 627-4913

RE: Analysis of Effluent from AiroCide
(August 2002 Test Period)

Dear President Hayman,

Please find enclosed the results from two recently completed studies of the Bio-KES and the AiroCide:

Study #1 – Bio-KES Testing: A Bio-KES was tested with and without sleeves to determine the effect on performance. A complete discussion of these tests is found in **Enclosure #1**.

Study #2 – AiroCide Testing: Testing and subsequent analysis of the effluent from the AiroCide device (KES Science and Technology; Kennesaw, GA) (refer to **Enclosures 2 and 3**). The AiroCide is a technology for controlling airborne concentrations of microbiologicals. These tests were conducted in August of 2002, with analyses conducted in August and September. Below is a summary of the AiroCide effluent testing. **Several figures are found in the Appendix, which follow the tables.**

Executive Summary: The effluent from the AiroCide device was sampled and analyzed to determine gas species and concentrations. Ozone was found to be below detectable levels (Table 1) and the volatile organic compounds listed in Table 2 were found to be in the very low ppb (parts per billion range).

Sincerely,

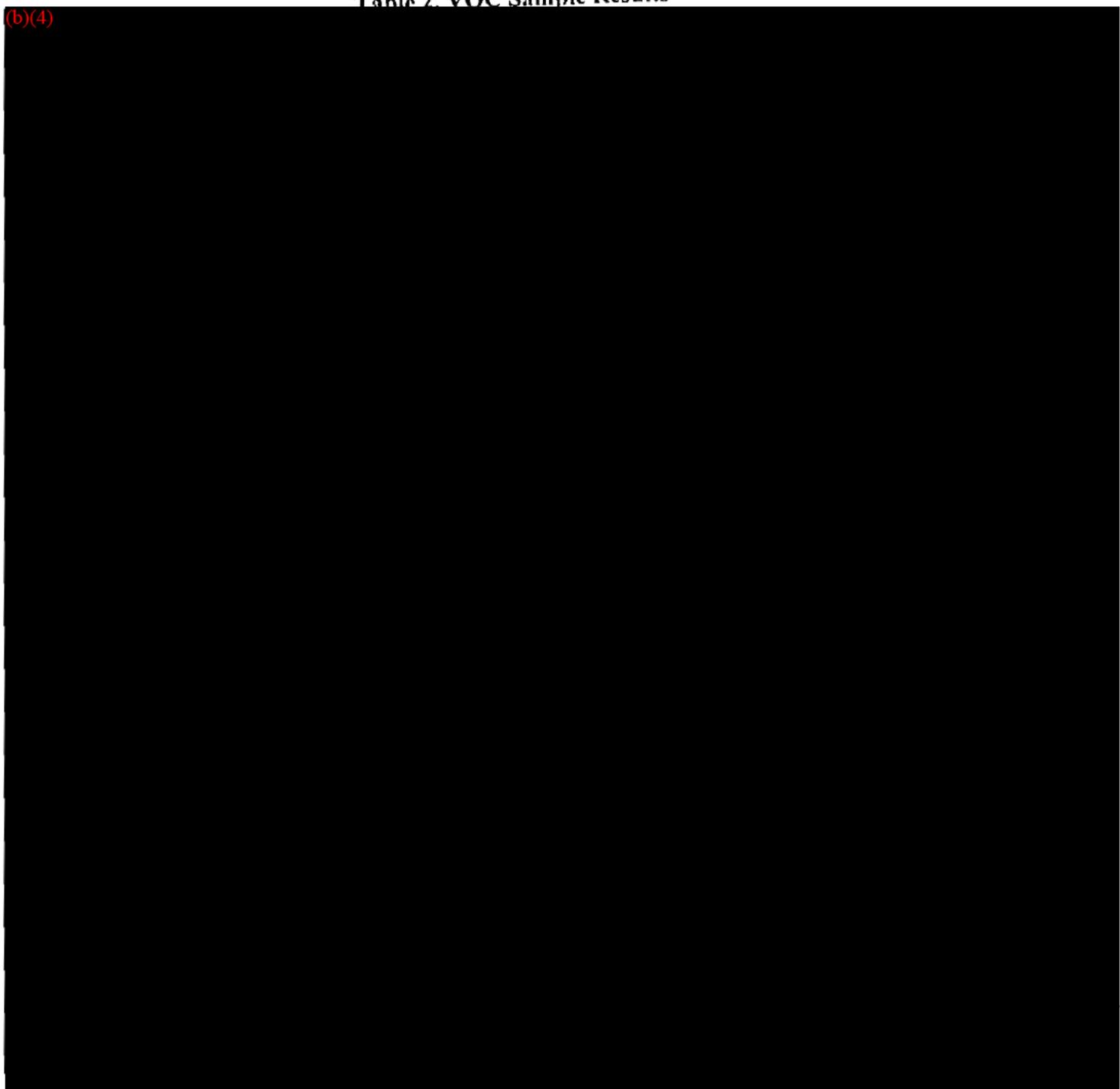
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Table 2. VOC Sample Results

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(b)(4) Testing

Appendix

(b)(4)

Figure 1. Experimental set-up to sample effluent of AiroCide device.

(b)(4)

Figure 2. Experimental set-up to sample effluent of AiroCide device; in particular, the data acquisition system is shown.

(b)(4) Testing



Figure 3. Experimental set-up to sample effluent of AiroClide device; in particular, the VOC sampling equipment is shown.

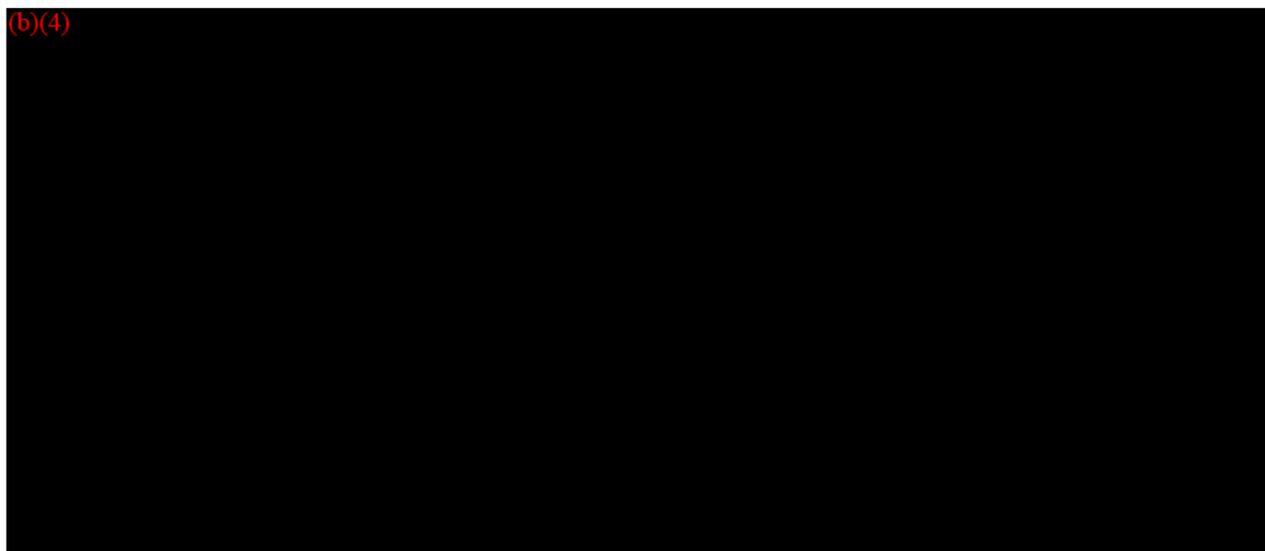


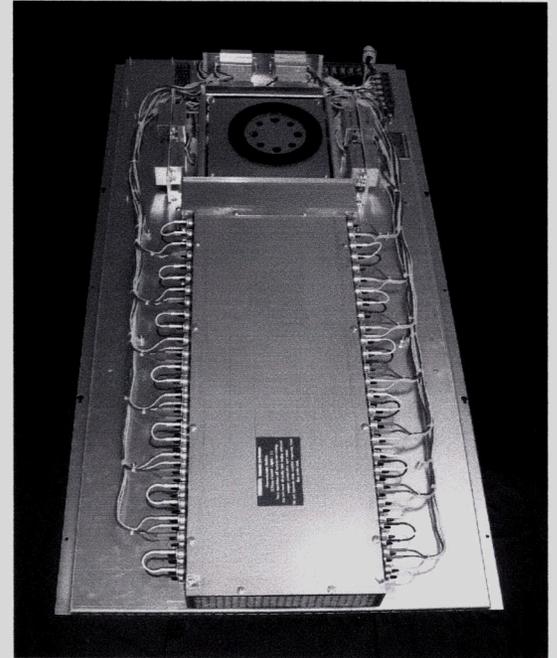
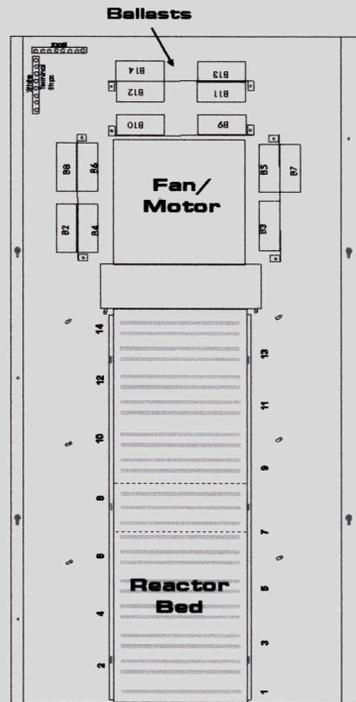
Figure 4. Experimental set-up to sample effluent of AiroClide device; in particular, the ozone sampler is shown.

AiroCide TiO₂

Airborne Pathogen Removal Device

Specifications

AiroCide TiO₂ is the most advanced and effective airborne pathogen reduction system available. AiroCide uses technology originally used by NASA to grow wheat in space. A non-depleting catalyst (Titanium Dioxide; TiO₂) inside the unit forms OH-radicals. These OH-radicals work with 52 Ultraviolet bulbs within the unit to kill airborne pathogens such as bacteria, viruses, dust mites, molds, spores, and fungi. Equipped with a 120 volt power supply, AiroCide is ready to plug in and start sanitizing.



(Always disconnect AiroCide from incoming power before removing its cover. Do not hardwire.)

Construction

Stainless Steel & Aluminum

Electrical

120 VAC
 40 watt, 120 VAC fan motor
 52 - 8 watt UVC light bulbs
 13 - 120 VAC bulb ballasts
 26' Power Cord - (20' From Unit to Power Control Box/ 6' From Power Control Box to Outlet)
 Maximum power consumption:
 456 watts (3.8 amps) @ 120 VAC

Controls

On/Off switch

Capacity

Processes 1,800 sq. ft. (w/ 8 ft. ceilings) in 24 hours

Maintenance

UV bulbs have an average life of one year, after which your system will run but not be effective. Contact KES or your AiroCide Distributor to schedule your yearly maintenance.

Dimensions	AiroCide TiO ₂	Shipping Carton
Length	46 1/2" (1.18 m)	53" (1.35 m)
Width	24 1/2" (.62 m)	30" (.76 m)
Height	3 1/2" (.089 m)	8" (.2 m)
Weight	59 lbs. (26.76 kg)	With AiroCide TiO ₂ : 71 lbs. (32.20 kg)



1-800-236-1846
www.kes-pro.com
 AiroCide_TiO2_Specifications.cdr

(b)(4) Testing



August 14, 2002

John Hayman
President
KES Science and Technology
3625 Kennesaw North Ind. Pkwy.
Kennesaw, GA 30144
(800) 627-4913

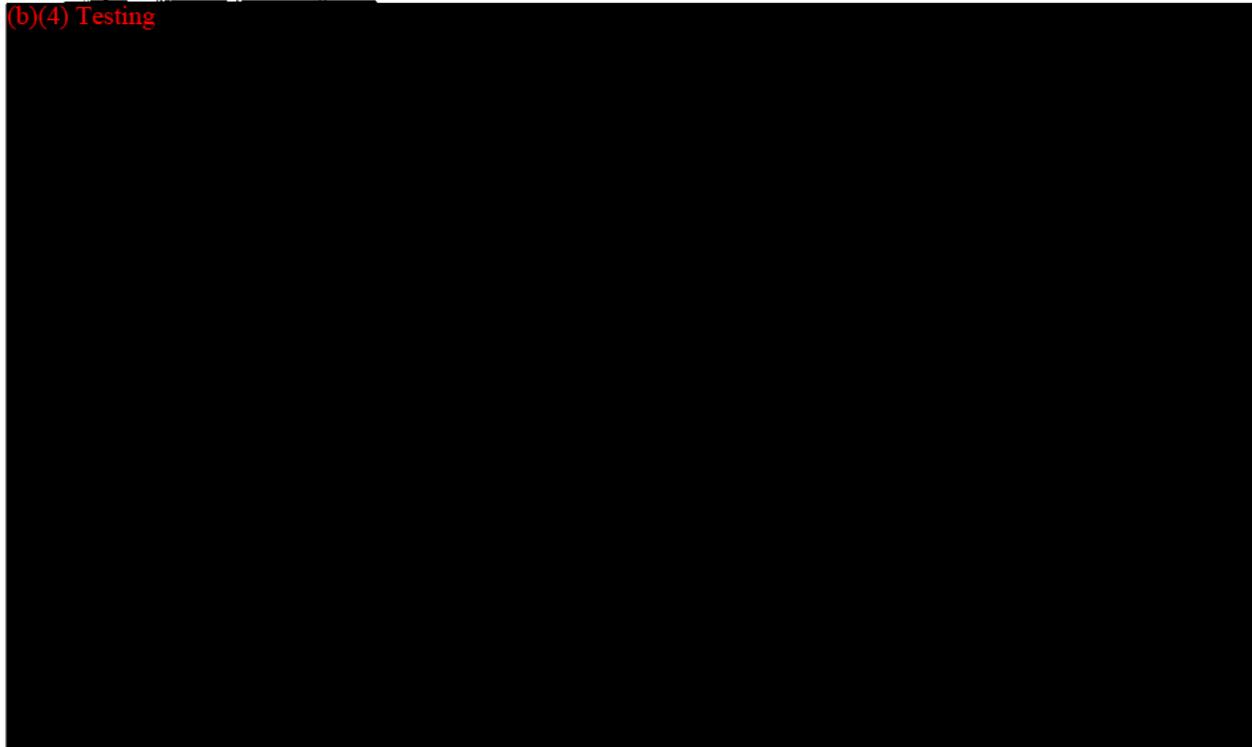
RE: Performance of AiroCide in Controlling Bacterial Spores
(June 2002 Test Period)

Dear President Hayman,

Please find below the results from testing the AiroCide device (KES Science and Technology, Kennesaw, GA) as a technology for controlling air-borne concentrations of bacterial spores. These tests were conducted in June of 2002. Several figures are found in the Appendix.

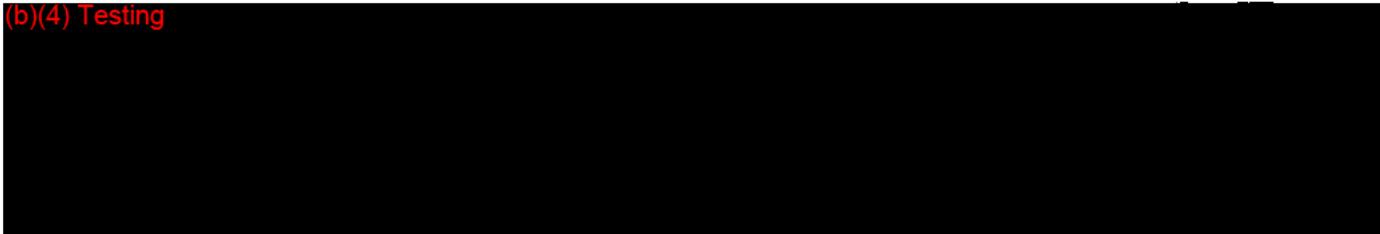
Experimental Methods

(b)(4) Testing

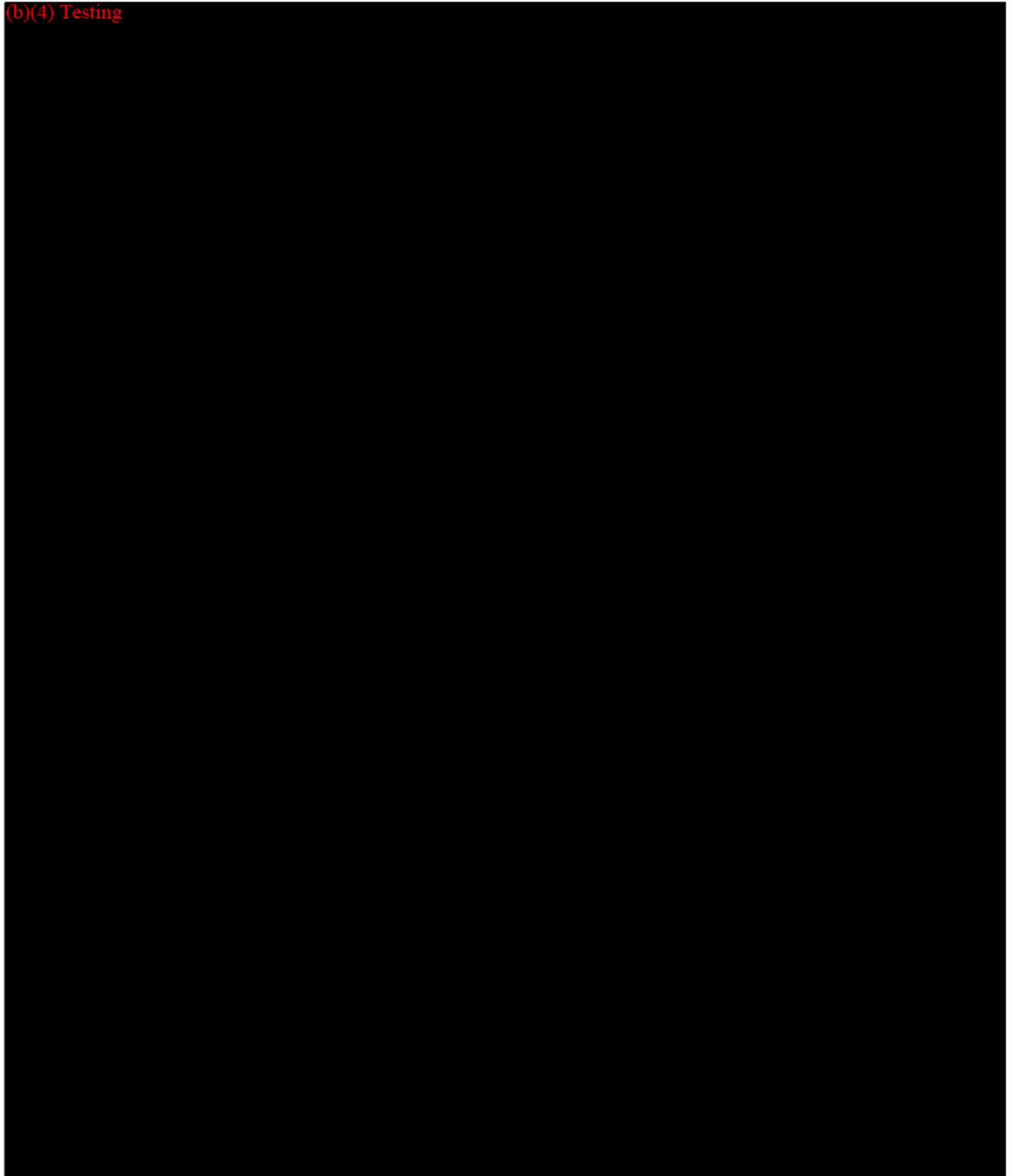


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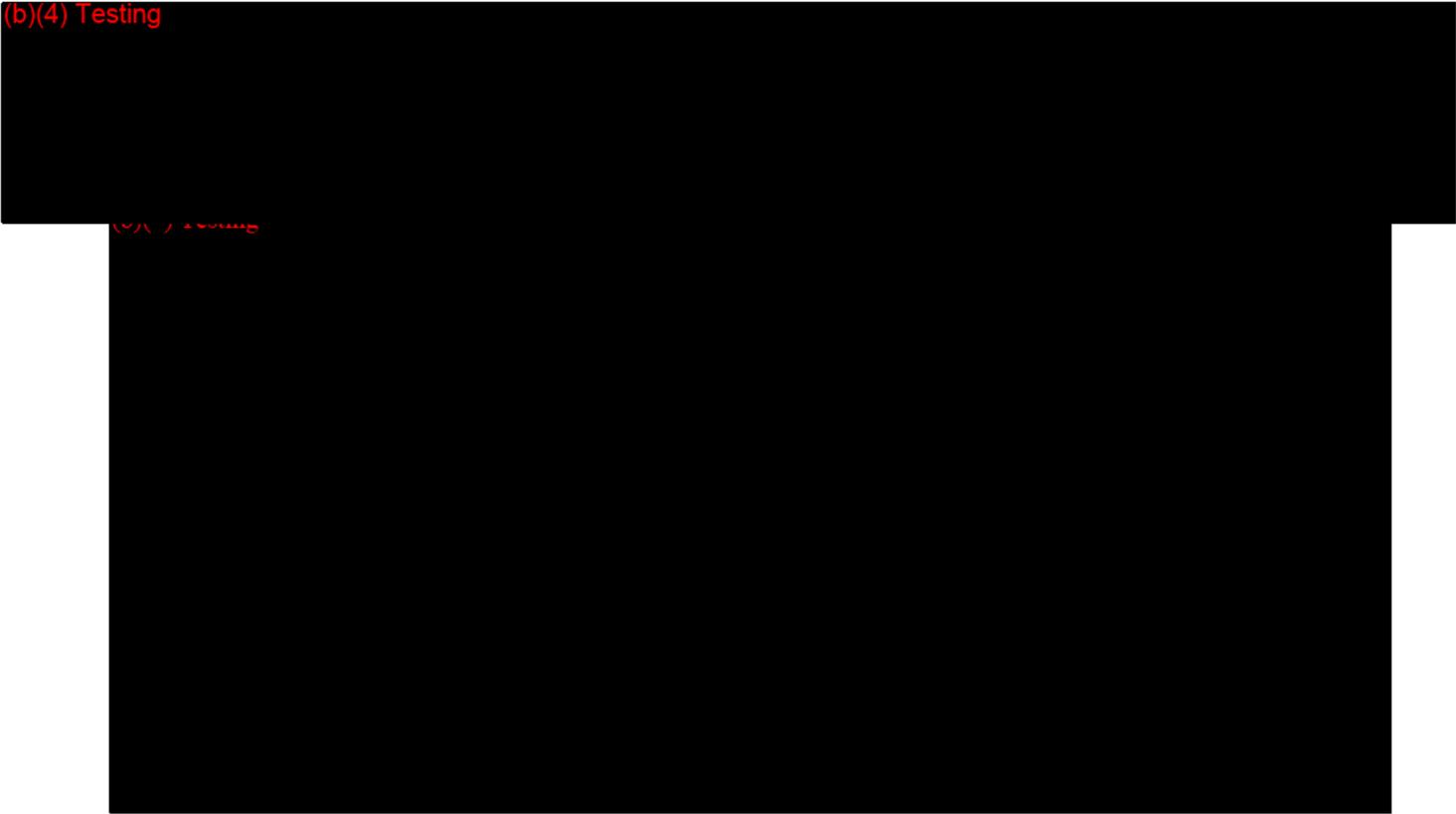
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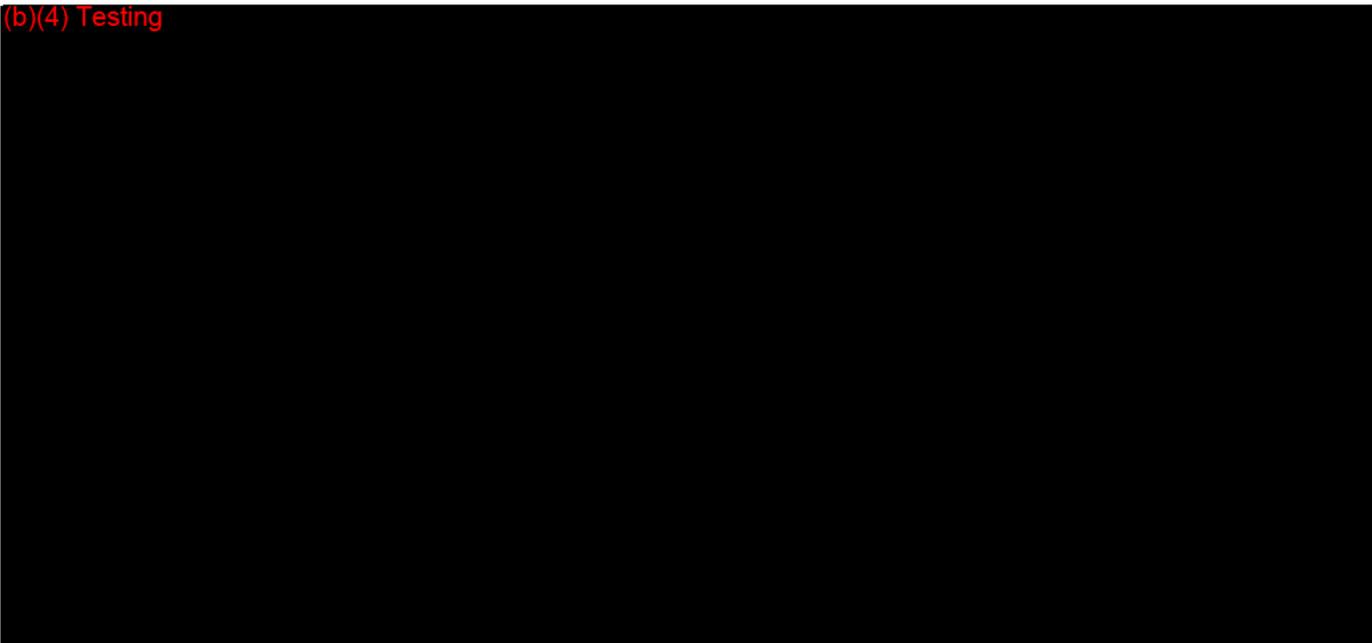
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(b)(4) Testing



Appendix

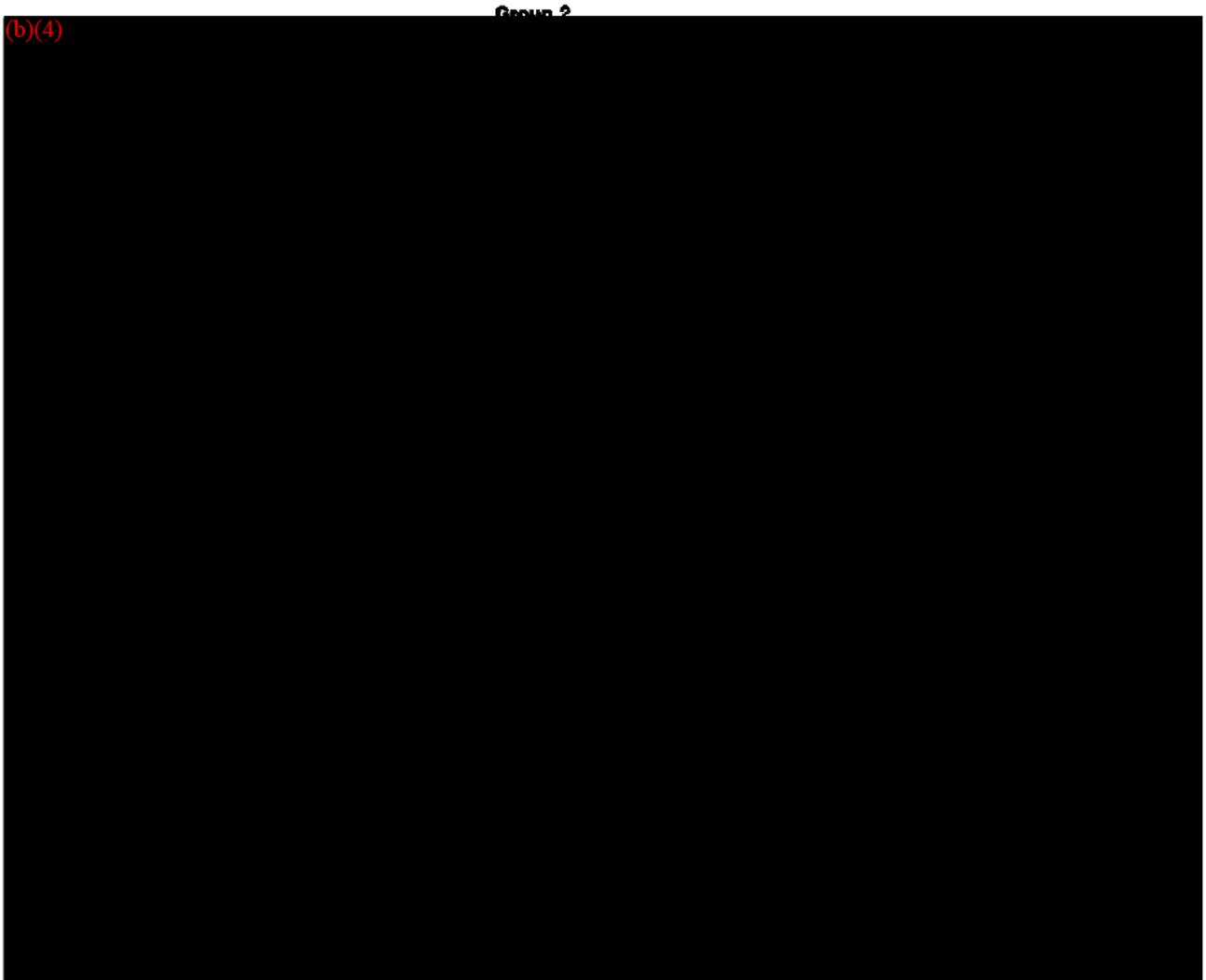
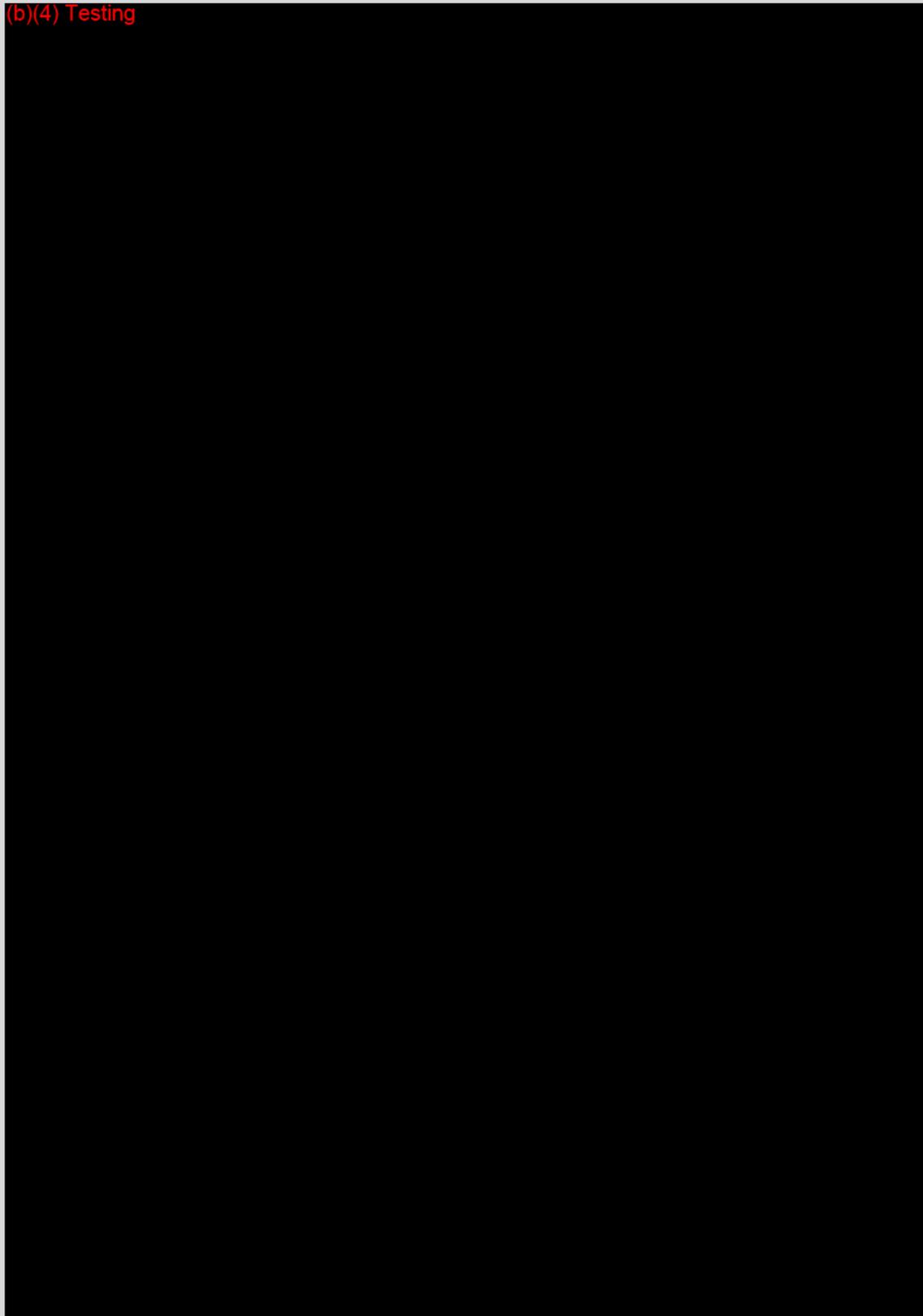


Figure 1 – Phylogenetic tree of genus *Bacillus*. Note group similarity between *B. anthracis* and *B. thuringiensis*.

(b)(4) Testing

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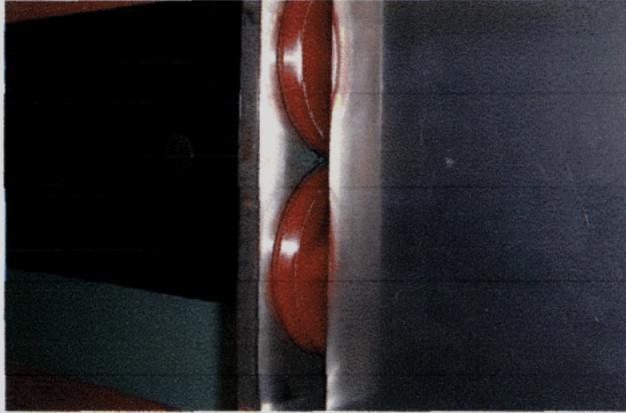
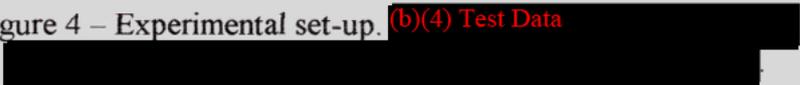


Figure 4 – Experimental set-up. (b)(4) Test Data



(b)(4)

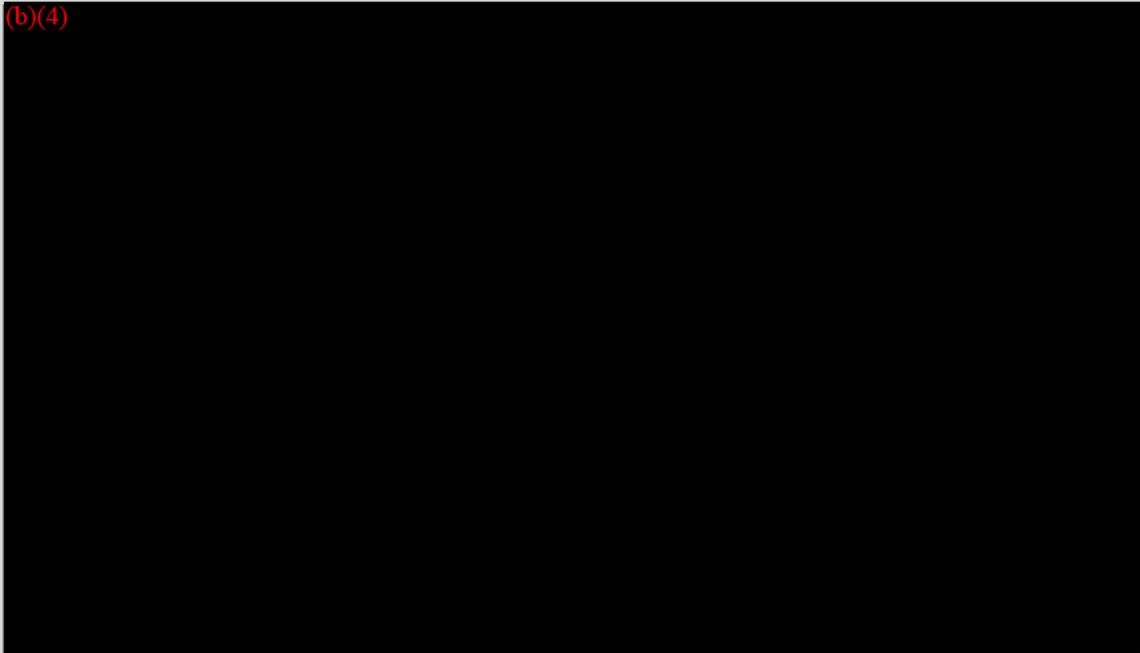
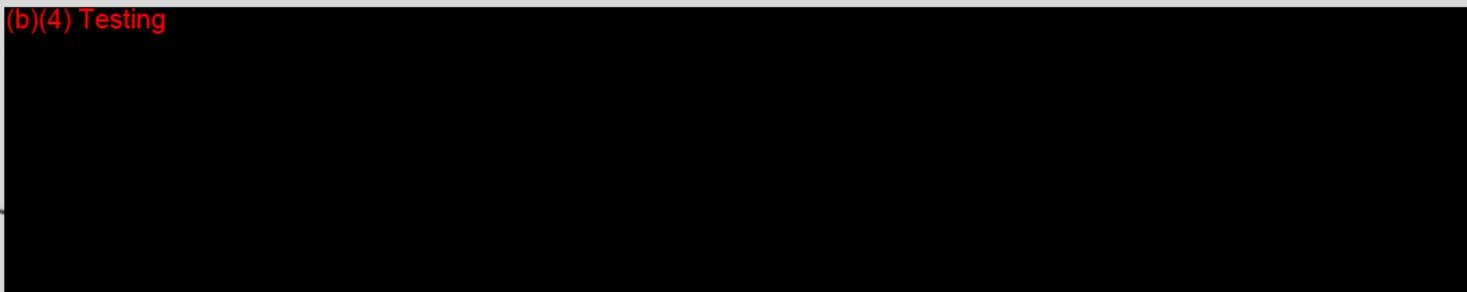


Figure 5 – AiroCide Operation: (b)(4)



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(b)(4) Testing

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(b)(4)

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Figure 6 – Summary of testing results overlaid on the AiroCide Zones 1, 2, and 3 had 465, 291, and 0 CFUs, respectively, during (b)(4) of operation.

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June 12, 2002

Attached is a Mold Inspection report which details the effectiveness of AiroCide TiO₂ in killing mold spores. Testing was done on May 27, 2002 at a condemned home in Austin, TX. The residence had previously been abandoned due to high mold counts inside. (b)(4) Testing

[Redacted]

The test procedure was as follows:

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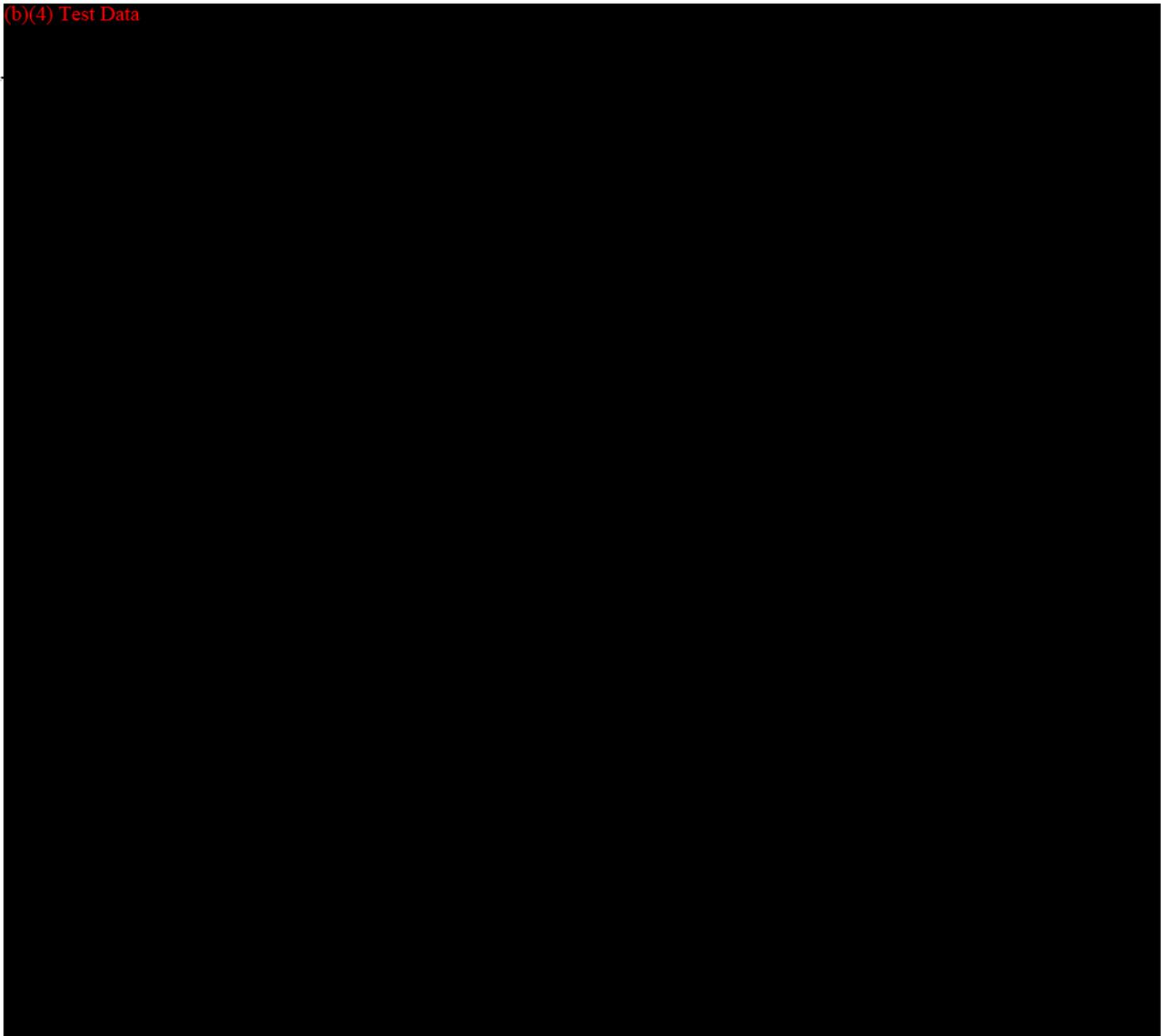
[Redacted]

Best regards,

A handwritten signature in black ink, appearing to read 'John J. Hayman, Jr.', written in a cursive style.

John J. Hayman, Jr.
President

(b)(4) Test Data



Michael A. Bakenkamp
Certified Mold Inspector
Certified Mold Contractor

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Thermal Prints Fading Away?

Protective Ultraviolet Light Dosage Requirements Updated

Anthrax
January 14, 2002

2002 JAN 14 - (**NewsRx.com & NewsRx.net**) -- Ultraviolet Devices, Inc., announced the initial results from its joint research with Pennsylvania State University (W.J. Kowalski, PhD) into the disinfection of *Bacillus anthracis* spores with ultraviolet (UVC) technology.

Following a directive from UVDI, researchers at Pennsylvania State University have identified what they believe to be the most appropriate rate constant for killing *B. anthracis* using ultraviolet germicidal irradiation (UVGI).

There have been three published studies relating to *B. anthracis* exposure to UVGI (Sharp 1939, Knudson 1986 and Dietz 1980), all having different levels of usefulness in identifying the UV dosage required.

With *B. anthracis* it is very important to differentiate between the vegetative and spore forms. Spore forms are most likely to be used for bioterrorism and are much more robust and difficult to disable with most disinfectants, including ultraviolet light.

After analyzing the results of these three published studies, as well as prior work completed at Pennsylvania State University relating to airborne pathogens, UVDI's previous position stating that it is necessary to provide high dosages of UV to kill *B. anthracis*, was confirmed.

Data for *B. anthracis* spores from a 1986 study by G.B. Knudson were analyzed and charted. From this the microorganism's sensitivity (rate constant) to ultraviolet light was calculated.

It was delineated that the dose required for 90% disinfection could be as high as 74,000 microwatt seconds/cm², or 220,000 microwatt seconds/cm² for 99.9% disinfection. To put this in perspective, this organism, in spore form, would require about 50 times the UV dose required to disinfect smallpox, tuberculosis, and *Leisionella*. It is even more robust than the *Aspergillus niger* spore that is considered one of the toughest airborne pathogens.

According to David Witham, UVDI, "This leads us to conclude that control of anthrax by UV alone is not practical." However, he went on to point out that "due to its relatively large size, about 1.2 microns in its most lethal single cell size, it can be effectively filtered. ...Once captured on a filter it can be readily disinfected with UV light."

Other pathogens, such as smallpox, can be readily handled by ultraviolet alone but

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may be more difficult to filter. Solutions with the proper UV dosage and filter efficiency can be tailored to most HVAC systems.

In partnership with Pennsylvania State University, UVDI has developed a proprietary software tool that supports the mathematical modeling of heating, ventilation and air conditioning (HVAC) systems utilizing a variety of UVGI and filtration strategies. This model incorporates numerous variables to predict kill-rates for airborne and surface pathogens and its accuracy as a modeling tool has been validated by a third party laboratory.

UVDI is now in a unique position in the market to model HVAC systems, predict kill rates, apply disinfection products driven by UV technology to achieve the kill rates desired, and to facilitate the third party testing of UV systems to validate performance supported by scientific evidence.

As previously announced, UVDI is disturbed with some of the recent claims by others stating UVC can easily kill the bacteria responsible for anthrax. By making this information available to consumers and competitors, it is UVDI's intent to allow consumers of UVGI systems to demand third party validation of all products and or promises of performance relating to their systems to kill or inactivate airborne and surface pathogens. This article was prepared by Health & Medicine Week editors from staff and other reports.

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Research Communications

Mineralization of Bacterial Cell Mass on a Photocatalytic Surface in Air

WILLIAM A. JACOBY,*
PIN CHING MANESS,
EDWARD J. WOLFRUM,
DANIEL M. BLAKE, AND
JOHN A. FENNELL

National Renewable Energy Laboratory,
Golden, Colorado 80401

Whole cells deposited on a titanium dioxide-coated surface have been oxidized in air to carbon dioxide via photocatalysis. This paper provides the first evidence that the organic matter in whole cells can be completely oxidized. Three experimental techniques were employed to monitor this reaction: scanning electron microscopy, ^{14}C radioisotope labeling, and batch reactor measurements. The scanning electron microscopy experiments illustrate the disappearance of *Escherichia coli* cell mass. The ^{14}C radioisotope labeling experiments establish that the carbon content of *E. coli* is oxidized to form carbon dioxide with substantial closure of the mass balance. The batch reactor experiments corroborate the mass balance and provide a preliminary indication of the rate of the oxidation reaction. These results provide evidence that a photocatalytic surface used for disinfection can also be self-cleaning in an air-solid system.

Introduction

Disinfection of air in a photocatalytic system has been reported (1), the photocatalytic deactivation of microorganisms has been demonstrated in the aqueous phase, and possible mechanisms have been postulated (2-4). Additional work is included in a recent review of photocatalytic chemistry (5). In an aqueous stream, the dead or damaged cells can be washed off the catalyst surface. However, in an air-phase system, the dead cells have the potential to accumulate and block the active surface. We report here the first evidence for the photocatalytic oxidation of whole cells to carbon dioxide. This is a key observation on the path to development of self-cleaning photocatalytic surfaces for air disinfection.

Bioaerosols are major contributors to indoor air pollution, and their impact on indoor air quality has been reviewed (6-8). More than 60 bacteria, viruses, and fungi are documented as infectious airborne pathogens. Diseases transmitted via bioaerosols include tuberculosis, Legionnaires, influenza, colds, mumps, measles, rubella, small pox, aspergillosis, pneumonia, meningitis, diphtheria, and scarlet fever. A larger number of bioaerosols are allergens and may

* Corresponding author's present address: Department of Chemical Engineering, W2016 Engineering Building East, University of Missouri-Columbia, Columbia, MO 65211. Phone: (573)882-5037; fax: (573)884-4940; e-mail: wjacoby@ecn.missouri.edu.

be responsible for a growing incidence of asthma and other respiratory illnesses.

Mineralization (e.g., complete oxidation) of low molecular weight organic molecules has been widely studied in gas and aqueous fluid-phase systems in which titanium dioxide is the photocatalyst. A survey of this chemistry and a discussion of the mechanisms that have been proposed are covered in a recent review (5). Oxidation is accomplished through the interaction between a photocatalyst and ultraviolet (UV) light. Titanium dioxide (TiO_2) is a semiconductor photocatalyst with a band gap energy of 3.2 eV. When this material is irradiated with photons with wavelengths of less than 385 nm, an electron is promoted from the valence band to the conduction band. The resulting electron-hole pair participates in chemical reactions that form hydroxyl radicals and superoxide ions. These highly reactive species oxidize organic compounds adsorbed on the catalyst surface. The technique has been explored as a means of removing volatile organic compounds (VOCs) from indoor air (9, 10).

The photocatalytic deactivation of bacterial cells using TiO_2 has been reported in both the aqueous and gas phases, but the fate of the cell mass has not been addressed in previous studies. For disinfection of air, it is necessary to remove or deactivate bioaerosols (7). A practical device for this purpose should accomplish three sequential steps: (1) bioaerosols are separated from air and immobilized on the catalyst surface; (2) bioaerosols are killed on the catalyst surface; and (3) bioaerosols oxidatively decompose. The focus of this paper is on step 3, oxidative decomposition of cell mass to carbon dioxide and water vapor. Oxidation of cell mass is a critical step for the continuous operation of a photocatalytic reactor as a self-sterilizing and self-cleaning filter for bioaerosols. Ultimately, the rate of cell mass oxidation must be matched to the rate of cell mass deposition if a practical device is to be designed. The first steps on this path are presented here.

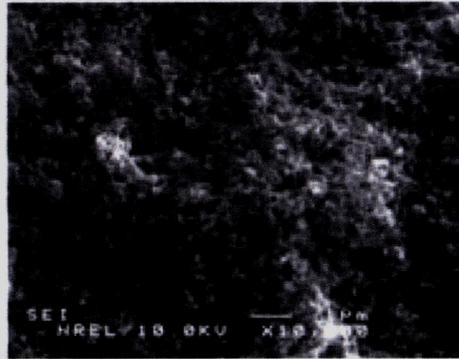
Cell mass oxidation was established using three experimental techniques: (a) scanning electron microscopy, (b) ^{14}C radioisotope labeling, and (c) batch reactor measurements of carbon dioxide evolution. The scanning electron microscopy experiments show the disappearance of *E. coli* cells deposited on the irradiated TiO_2 surface. The ^{14}C radioisotope labeling experiments show that the *E. coli* are the source of the observed carbon dioxide and provide substantial closure of the carbon mass balance. The batch reactor experiments corroborate the mass balance while providing an initial indication of the rate of the oxidation reaction.

Results and Discussion

Scanning Electron Microscopy Experiments. The disappearance of cell mass on an irradiated photocatalytic surface was shown by coating microscope slides with a thin film of TiO_2 (DeGussa P25). The slides were inoculated with a sterile water suspension of *E. coli* LE392 (grown in Luria broth) and dried in air. Inoculated slides were exposed to UV (~254 nm) or near-ultraviolet (nUV, ~356 nm) light for 75 h. A blank was kept in the dark. After sputter coating with gold, the slides were examined via SEM.

Figure 1 illustrates the results of this experiment. Figure 1a is a photomicrograph of a TiO_2 film cast on a glass slide. Figure 1b shows the appearance of *E. coli* on glass with no photocatalyst coating. The cylindrical shapes are the bacteria. Figure 1c is a catalyst-coated, bacteria-inoculated blank that received no irradiation. Figure 1d reveals that, without

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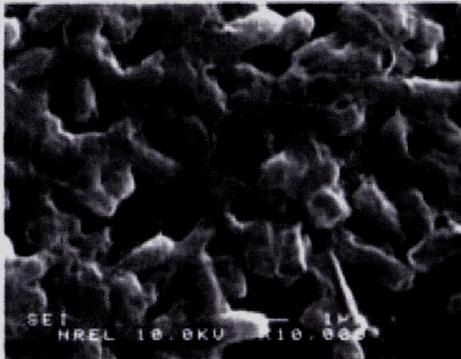
a) Titanium dioxide catalyst coated on a microscope slide.



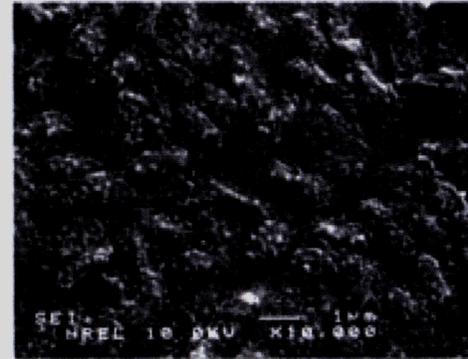
b) *E. coli* on a microscope slide, no catalyst, no exposure to light, cylindrical shapes are the bacteria.



c) *E. coli* on a microscope slide coated with catalyst, no exposure to light.



d) *E. coli* on a microscope slide, no catalyst, exposed to nUV light (356 nm) for 75 hours.



e) *E. coli* on a microscope slide, no catalyst, exposed to UV light (254 nm) for 75 hours.



f) *E. coli* on a microscope slide coated with catalyst, exposed to nUV light (356 nm) for 75 hours.



g) *E. coli* on a microscope slide coated with catalyst, exposed to UV light (254 nm) for 75 hours.

FIGURE 1. Scanning electron microscope images showing the disappearance of *E. coli* via heterogeneous photocatalysis.

catalyst, the nUV light has virtually no effect on the *E. coli* after 75 h of exposure. Exposure to UV radiation in the absence of catalyst for the same period effected some degree of decomposition, as shown in Figure 1e. In Figure 1, panels f and g, *E. coli* coated on irradiated films have decomposed almost completely after 75 h of exposure to nUV and UV radiation, respectively. These experiments were repeated four times using various TiO₂ coating techniques, and the results were consistent. In a fifth run, the films were cast onto quartz slides and the radiation was introduced from the reverse (uncoated and not inoculated) side of the slides. Similar results were again observed revealing that direct irradiation of the *E. coli* is not required to achieve decomposition of the microbes.

¹⁴C Experiments. A flow-through photocatalytic reactor assembly was used to oxidize ¹⁴C-labeled *E. coli* bacteria. The use of the radiolabeled bacteria provided the detection limits necessary to monitor the oxidation of cell mass and provide proof that the cell components are the source of the carbon dioxide. The ¹⁴C-labeled cells were prepared by culturing *E. coli* K12 in fructose minimal medium (11) supplemented with 5 μCi of [U-¹⁴C]fructose (New England Nuclear).

The photocatalytic reactor consisted of a fritted-glass disk (porosity E) with a total surface area of 12.6 cm² coated with 31.1 mg of TiO₂ catalyst (DeGussa P25). Approximately 0.33 mL of the ¹⁴C-labeled *E. coli* K12 suspension in water was pipetted directly onto the disk and dried under a stream of nitrogen gas. The total dry cell mass loaded onto the frit was 1.5 mg containing 24 411 disintegration per minute (dpm). The reactor was irradiated by a nUV lamp that provided a light intensity at the photocatalyst surface of 4.1 mW/cm². The ¹⁴CO₂ produced was carried by a constant stream of zero-grade air flowing at 11.5 mL/min and subsequently trapped into a two-stage bubbler, each stage containing 65 mL of 0.2 N KOH solution. After 97 h of reaction, an aliquot of the KOH solution was pipetted into a scintillation vial with 8 mL of Optifluor scintillation cocktail (Packard) and counted in a Beckman LS 6000 scintillation counter. A dark control experiment was performed with a frit inoculated with labeled cells but not exposed to light.

Fifty-one percent of the radioactivity from the added bacterial cell mass was recovered in the KOH fraction as ¹⁴CO₂, a product of complete cell mass mineralization. Approximately 33% of the radioactivity still remained on the glass frit. This may be due to some cells being deposited in regions of the porous structure of the frit that were not accessible to photons. A negligible amount of ¹⁴CO₂ was detected in the dark control experiment. Preliminary experiments have also demonstrated mineralization of *Rhodobacter sphaeroides* SCJ, a Gram-negative, photosynthetic bacterium.

Batch Reactor Experiments. The goal of the batch mineralization experiments was to photocatalytically oxidize bacteria in a closed volume so that evolved CO₂ could build up to measurable concentrations and the rate of the oxidation reaction could be approximated. The experiments were performed using 250-mL gas sampling tubes that were equipped with high-vacuum valves and a septum port (Kontes Glass Company, Catalog No. 653150-250). In a typical experiment, a 1.0-mL aliquot of a 0.05 g/mL suspension of TiO₂ (DeGussa P25) was added to the gas sampling tube through the septum port, followed by a 1.0-mL aliquot of a 0.3 mg/mL *E. coli* K12 suspension. In blank control experiments, an equivalent amount of deionized water was added in place of the TiO₂ or *E. coli* suspensions. The *E. coli*/TiO₂ slurry was then dried with house air and moderate heating. After drying, the slurry formed an irregular film on the side of the sampling tube.

The tubes were purged with an 80:20 nitrogen:oxygen gas mixture and irradiated with an array of six evenly spaced nUV lamps, which provided a light intensity at the surface of the sampling tubes of approximately 3.5 mW/cm². The array heated the sampling tubes slightly above room temperature. The dark control experiments were performed by wrapping the sampling tube with aluminum foil before placing it under the light table.

Periodic samples were taken according to the following procedure. The sampling tube was removed from illumination and allowed to cool to room temperature. Triplicate 0.5-mL samples were removed from the tube with a gastight syringe and analyzed by gas chromatography (GC) (Hewlett-Packard model 5890 with a 6 ft × 1/8 in., Porapak Q column). The sampling tube was then repurged with a CO₂-free nitrogen:oxygen gas mixture, and illumination was continued. The GC was calibrated daily using a 998 ppm CO₂ calibration standard (Scott Specialty Gases).

Figure 2 shows representative kinetic data, including the control experiments. The data in curves 1 and 2 are experimental cases, where sampling tubes containing the *E. coli* and TiO₂ were illuminated. Three control experiments were also performed (curves 3–5), where *E. coli*, light, and TiO₂ were sequentially excluded from the gas sampling tube.

The greater cumulative yield of CO₂ among the experimental cases relative to the control cases shows evolution of CO₂ due to photocatalytic oxidation of cell mass. The statistical significance of this conclusion is established by the fact that each data point in Figure 2 represents between 6 and 15 replicate samples. Curve 1 includes representative error bars corresponding to 99% confidence intervals.

Curve 2 is similar in shape to curve 1 but exhibits a lower CO₂ flux. This may be due the degree of contact between the suspended *E. coli* and irradiated TiO₂. To test this, 23 h into experiment 2 the *E. coli*/TiO₂ film was resuspended in 2 mL of deionized water, redistributed over the sampling tube surface, and dried as before. An increase in the rate of CO₂ evolution is observed at 23 h in curve 2. The CO₂ evolution in the control experiments (curves 3–5) is likely due to leakage of CO₂ from the ambient air, although for the light/TiO₂ control experiment (curve 3), oxidation of trace organic impurities on the catalyst would also produce CO₂.

The carbon fraction of bacterial mass recovered as CO₂ was calculated by subtracting the 80 h data point from curve 3 (0.03 mg, no *E. coli*) from the mass average of the 80 h data points in curves 1 and 2 (0.11 mg) and then dividing by the initial bacterial mass loading (0.30 mg) to give a value of 27%. The literature values for carbon content of a typical bacterium range from 47% to 53% (12, 13). If we assume 50% carbon content, the data in Figure 2 indicate 54% mineralization of the *E. coli* by photocatalytic oxidation. In this experiment, the amount of carbon remaining in the sampling tube could not be determined.

The literature contains references to cell killing via photocatalysis, but oxidation of cell mass has not been previously reported. Three different experimental approaches have demonstrated that a TiO₂ surface irradiated with nUV or UV illumination can oxidatively decompose a substantial portion of the bacterial cell mass in the presence of air. The carbon mass balances are not completely closed. The missing carbon could be due to cell material that is shaded from light and does not react or cell components that are refractory and do not react. The experiments reported here do not address the issue of the fate of mineral matter in the cells and the impact they might have on catalyst lifetime or activity. This inorganic matter could act to reduce the local photocatalytic activity at the site of the cell that is being decomposed.

Work is underway to further refine the carbon mass balances, to determine the fate of other elemental compo-

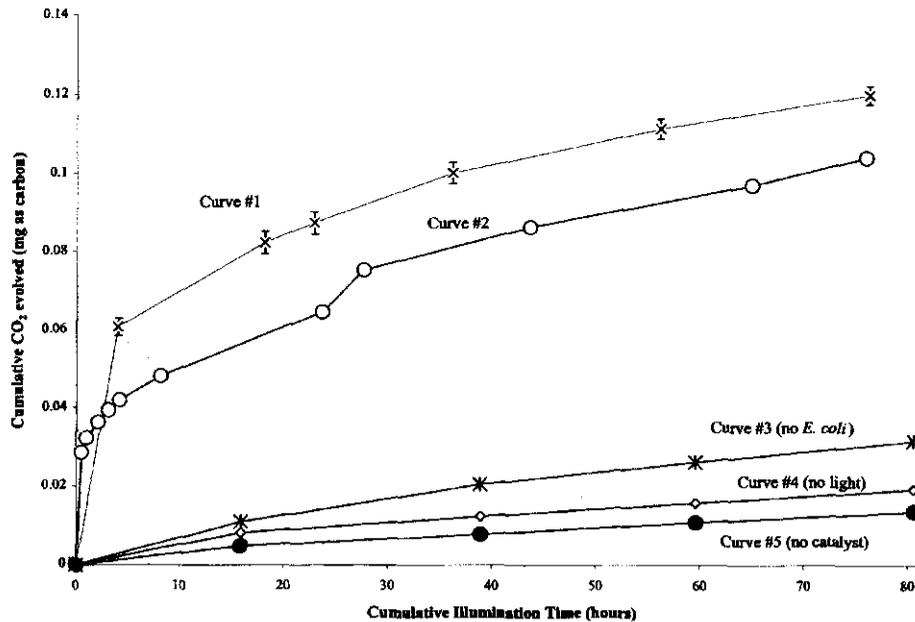


FIGURE 2. Cumulative CO₂ evolution as a function of irradiation time during the oxidation of cell mass via heterogeneous photocatalysis.

nents of mineralized cells, and to evaluate factors that control the rate and extent of cell mineralization. Variables to be investigated in this context include type of organism, light intensity, reactor design, and catalyst type and configuration.

Acknowledgments

This work was supported by the Department of Energy and the Center for Indoor Air Research.

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(b)(4) Testing

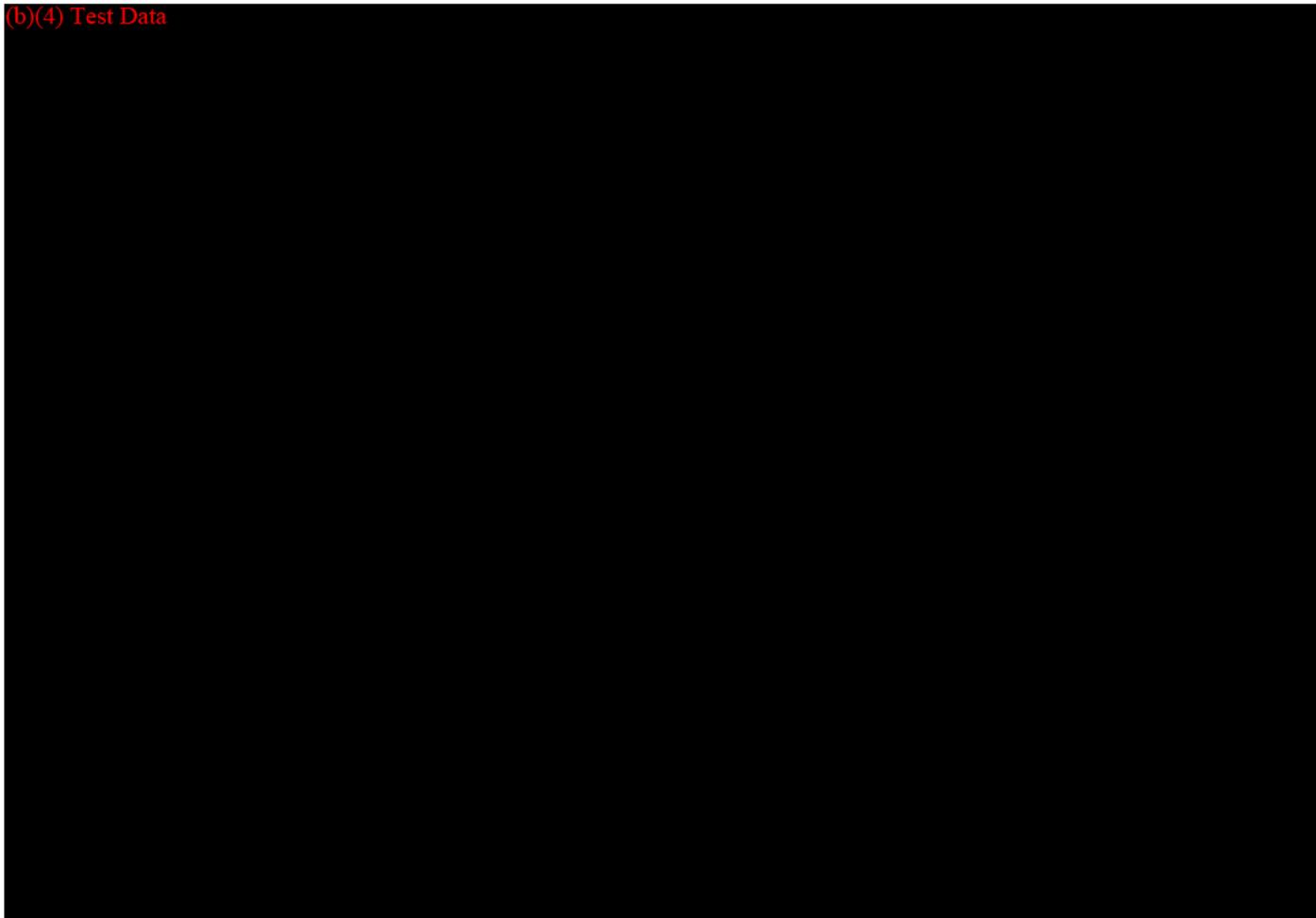


June 13, 2002

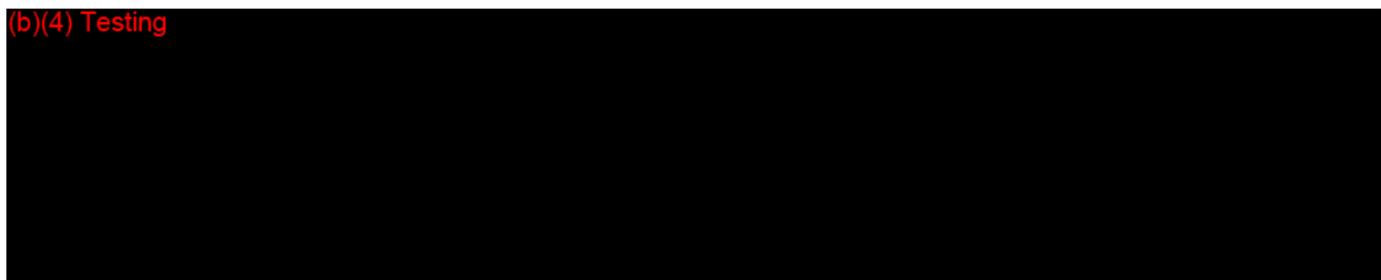
John Hayman
President
KES Science and Technology, Inc.
3625 Kennesaw North Industrial Parkway
Kennesaw, GA 30144

RE: Performance of UVGI and Photocatalytic Oxidation in Inactivating Bacterial Spores

(b)(4) Test Data



(b)(4) Testing



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National Renewable Energy Laboratory

Chemistry for Bioenergy Systems Division — Home

Overview and Mission | Analysis Tools | Capabilities | DOE Programs | Facilities | Information Resources | Our Staff | Working with Us

Research Highlights—Photocatalytic Chemistry for Environmental Applications

Photocatalytic chemistry for removing hazardous chemicals from water, soils, or air has been an active area of work at NREL since 1988. DOE and outside sponsors have supported this work. The photocatalytic group includes chemists, chemical engineers, mechanical engineers, and microbiologists. Researchers have

- Demonstrated solar processes for water and air purification, helped industry develop equipment for removing trichloro- and perchloroethylene from air stripper off-gas.
- Provided fundamental chemical and kinetic information on mechanisms of photocatalytic oxidation of many classes of organic compounds and the mechanism of cell killing.
- Added to the understanding of removing volatile organic compounds and bioaerosols from indoor air.
- Developed methods for designing and modeling solar and lamp reactor systems.

The group is available to assist companies interested in developments in the rapidly expanding applications of photocatalytic chemistry to indoor air purification, self-cleaning surfaces, disinfection, and environmental cleanup.

For more information about this program check out these publications. (The following documents are available as Adobe Acrobat PDFs. [Download Acrobat Reader](#)):

- Challenges and Potential Solutions for Reducing Climate Control Loads in Conventional and Hybrid Electric Vehicles ([PDF 174 KB](#))
- Bibliography of Work on the Photocatalytic Removal of Hazardous Compounds from Water and Air ([PDF 1.5 MB](#))
- Bibliography of Work on the Photocatalytic Removal of Hazardous Compounds from Water and Air (Update Number 1, to June 1995) ([PDF 2.7 MB](#))
- Bibliography of Work on the Photocatalytic Removal of Hazardous Compounds from Water and Air (Update Number 2, to October 1996) ([PDF 2 MB](#))
- Bibliography of Work on the Heterogeneous Photocatalytic Removal of Hazardous Compounds from Water and Air (Update Number 3, to January 1999) ([PDF 698 KB](#))
- Bibliography of Work on the Photocatalytic Removal of Hazardous Compounds from Water and Air (Update Number 4, to October 2001) ([PDF 2.4 MB](#))

The following are representative of the papers that have been published in this area:

- "Application of the Photocatalytic Chemistry of Titanium Dioxide to Disinfection and the Killing of Cancer Cells," *Separation and Purification Methods* 28:1-50, 1999.
- "Heterogeneous Photocatalysis for Control of Volatile Organic Compounds in Indoor Air," *J. Air & Waste Management Association* 46:891-895, 1996.
- "Bactericidal Mode of Titanium Dioxide Photocatalysis," *J. Photochem. Photobiol. A. Chem.* 130: 163-172, 1999.
- "Mineralization of Bacterial Cell Mass on a Photocatalytic Surface in Air," *Environ. Sci. Technol.* 32: 2650-2653, 1998.
- "Direct Mass Spectrometric Studies of the Destruction of Hazardous Wastes. 2. Gas-Phase Photocatalytic Oxidation of Trichloroethylene over TiO₂: Products and Mechanisms," *Environ. Sci. Technol.* 27:732-740, 1993.

Contact: Dan Blake, 303-384-7701

[Home](#) | [NREL Home](#) | [Webmaster](#)

Environment

Cleaning Indoor Air

*The **Industrialist** looks at indoor air pollution and reviews research into Photocatalytic Oxidation -- an effective way to improve indoor air quality.*

Over recent decades our exposure to indoor air pollutants has increased due to a variety of factors. These include the construction of more tightly sealed buildings, reduced ventilation rates to save energy, the use of synthetic building materials and furnishings, and the use of chemically formulated personal care products, pesticides and household cleaners.

Though the connection between respiratory problems (the most common effect of indoor air pollution) or other symptoms and conditions suffered as a result of poor indoor air quality (IAQ) is not clear, a US Environmental Protection Agency report commented that "such suggestions should be seriously considered and pursued".

Hong Kong's Environmental Protection Department (EPD) commissioned a study as early as 1995 to assess IAQ in office premises and selected public places including restaurants, cinemas and shopping malls. The study concluded that poor IAQ was commonly found in indoor environments. EPD estimated the annual economic losses in medical costs were HK\$0.16 billion and some HK\$12 billion in lost productivity costs.

Poor IAQ is particularly a problem in newer buildings with energy saving design features. "Many tend to have low levels of fresh air intake, which results in stale air continually circulating within the building, increasing the likelihood of air-borne viruses and the accumulation of other pollutants," says Dr Michael Leung, Research Assistant Professor of the University of Hong Kong's Department of Mechanical Engineering.

Photocatalytic oxidation

Against a background of mounting scientific evidence indicating that a range of health problems and complaints might be associated with poor IAQ, the search is on for ways to improve and mitigate the potentially harmful effects of poor quality air.

Prof Leung notes that there are various types of commercial products in the market to clean the air. These include high-efficiency particulate air (HEPA) filters, electrostatic precipitators, and ozone generators. "However, all have their weaknesses: micro-organisms trapped in a filter will continue to live and multiply; ozone is a potential lung irritant and exposure to elevated levels is a contributor to the exacerbation of lung diseases."

In view of the limitation of traditional products, Dr Leung decided to investigate further titanium dioxide ' a semiconductor photocatalyts that allows photocatalytic disinfection and detoxification.

When a photocatalyst (e.g. anatase TiO₂ powder) is illuminated by sunlight or placed near UV light, it initiates a series of chemical reactions involving water vapour and oxygen in the air. This photochemical process generates a very powerful oxidising agent ' hydroxyl radicals ' that effectively destroy microorganisms in the air, eliminate organic odours, and destruct volatile organic compounds into harmless basic compounds. Photocatalysts are effective in both indoor and outdoor environments.

In a field study, Dr Leung and his team evaluated the photocatalytic disinfection performance on indoor air in a hospital ward. A HEPA filter and photcatytic convertor together with a UV light were placed in a portable unit measuring about two-foot square.

The study first measured the total viable count of bacteria in the hospital ward under normal conditions, which recorded bacteria at 118 cfu per cubic metre. After which, the portable unit containing the photocatalytic converter and HEPA air purifier was placed in the ward for a period of 24 hours. Air measurements were then retaken that showed the bacterial count had reduced by 43 per cent to 67 cfu per cubic metre.

Dr Leung suspected that the elimination of larger bacteria in the ward could be attributed to the installed HEPA filter, while the inactivation of smaller bacteria could be attributed to UV light incident on the photocatalyst. He now set out to determine how much bacterial destruction could be attributed to each.

To ascertain this, he removed the photocatalyst and the UV light, only leaving the HEPA filter active for another 24 hour-period. The bacterial count increased to 93 cfu per cubic metre. "This means that the HEPA filter reduced the bacterial count by 21 per cent and the photocatalytic oxidation accounted for a 22 per cent destruction of bacterial colonies on the first experiment," he says.

Dr Leung carried out this test in an active hospital ward " people were entering and leaving, doors were being opened and shut, the air conditioning was on etc. " resulting in a large amount of ambient air entering the vicinity of the IAQ test. Tests have been carried out using similar systems in controlled laboratory environments that have reduced indoor air bacteria levels by 99 per cent.

The immediate disinfection effect of the photocatalytic converter was measured by taking bacterial counts of air samples collected at the inlet and outlet of a photocatalytic converter air purifier. The bacterial counts of the air samples reduced significantly by 52 per cent from 109 cfu per cubic metre at the inlet to 52 cfu per cubic metre after the air had been purified by both filtration and photocatalytic disinfection.

For comparison, the same test was performed with the photocatalytic converter disconnected. This showed filtration using only the HEPA filter reduced the bacterial count by just 5.4 per cent. Therefore, the immediate disinfection effect of the titanium dioxide filter led to the destruction of 46.6 per cent of airborne bacteria in one pass of air through the air purifier.

The results underscore the potential of photocatalytic disinfection to effectively reduce bacterial count in the air without any changes to the existing ventilation system. They also highlight that if air is allowed to flow freely between the treated zone and other areas, the

disinfection effect is much lower.

The equipment that Dr Leung used retails at HK\$12 thousand. "Relatively expensive," he says, "However, as with all new technology, as demand increases it should become more affordable."

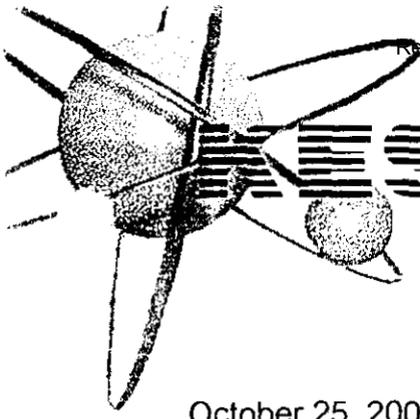
Most recently Dr Leung conducted IAQ tests with a photocatalytic converter unit connected within a central air conditioning system, with positive results. In the future, he plans to focus his research on ways of using natural sunlight opposed to energy consuming artificial UV light with photocatalysts. "We could then reduce the operational and maintenance cost of the system."

Dr Leung notes that there are numerous outside companies offering IAQ measuring services; the EPD has a list of recommended service providers. Those that want to learn more about the acceptable levels of IAQ can refer to a 1999 report by the Indoor Air Quality Management Group of Hong Kong, which established 3-levels of IAQ objectives for occupants spending 8 hours in indoor environments.

"In each level, the exposure limits are specified for carbon dioxide, carbon monoxide, nitrogen dioxide, ozone, formaldehyde, individual organic compounds, total VOC, airborne bacteria, respirable suspended particulates, and radon," concludes Dr Leung.

If you would like more information on the work of Dr Leung, you may contact him at email: mkhleung@hkucc.hku.hk.





Science &
Technology, Inc.

October 25, 2002

Preliminary results from the Colony Forming Unit (CFU) testing in an operating room (located at the Hamot Medical Center in Erie, PA) indicate a 56.54% reduction in CFU's when the KES AiroCide units were operating vs. when they were not. Preliminary results will be statistically analyzed for accuracy. Further testing and analysis will be conducted.

Best regards,

A handwritten signature in black ink, appearing to read "John J. Hayman, Jr.", with a long, sweeping horizontal line extending to the right.

John J. Hayman, Jr.
President
JJH:ds

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(b)(4) Test Data





November 7, 2002

PREMARKET NOTIFICATION
Truthful and Accurate Statement

I certify that, in my capacity as President of KES Science & Technology, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



John J. Hayman, Jr.
President

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KC23830
516(K) Statement

November 7, 2002

PREMARKET NOTIFICATION STATEMENT

I certify that, in my capacity as President of KES Science & Technology, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential information, as defined in 21 CFR 20.61.

A handwritten signature in black ink, appearing to read 'John J. Hayman, Jr.', is written over the printed name.

John J. Hayman, Jr.
President

Common Organic Gases (Volatile Organic Compounds - VOCs)

- ethane
- ethene
- acetylene
- iso-butene
- propene
- propane
- Isobutane
- acetaldehyde
- n-butane
- methanol
- ethanol
- isopentane
- acetone
- n-pentane
- 2-methyl-2-butene
- benzene
- 2-methylhexane
- 2,2,4-trimethylpentane
- toluene
- 2,3,5-trimethylhexane
- m- & p-xylene
- 2-methyloctane
- styrene + heptanal
- o-xylene
- 2,6-dimethyloctane
- m-ethyltoluene
- 1,3,5-trimethylbenzene
- o-ethyltoluene
- 1,2,4-trimethylbenzene
- 1,2,3-trimethylbenzene
- C10 aromatic

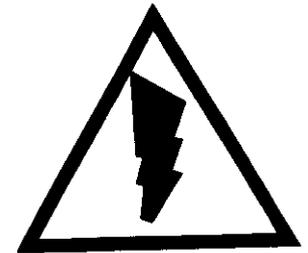
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AiroCide TiO₂



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Shut Off Power
Before Opening
Or Servicing



KES Science & Technology, Inc.

AiroCide

Model# TiO2 Hertz 60 Volts 115

Serial# AC0018 Amps 4 Phase 1

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900-627-4913 www.kesmist.com



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ELECTRIC
FANS

CONFORMS TO UL STD 507



SLSOL.COM No. 5019e-K

Warning: Use ONLY a 120 VAC
power supply with at least
10 AMPS of power.



303

AUTHORIZATION TO MARK

This authorizes the manufacturer to apply the ETL mark to certified products; also to the multiple listee model numbers as listed on the correlation page of the Listing Report where applicable; when made in accordance with the accompanying descriptions and drawings under the conditions set forth in the Certification Agreement herein:

Applicant: KES Science and Technology
3625 Kennesaw North Industrial Park
Kennesaw, GA 30144

Contact: Mr. Richard Zoellick
Phone: 770-427-6500 Fax: 770-425-0837

Manufacturer: Same as applicant

Reference Report: 3020865A

Product Covered: Bio-KES 348, AiroCide TiO2, AiroCide TiO2 II.

Description: Cord-connected Ethylene Gas & Airborne Pathogen Removal System

Standard(s): Electric Fans; UL 507, 9th Edition, 1999

This procedure, with all revisions, etc., is the property of Intertek Testing Services and is intended solely for the guidance of the listee and the representative of Intertek Testing Services, and is not transferable.

Issued by: Intertek Testing Services NA Inc., 24 Gorton Avenue, Cortland, NY 13045-2014 USA



Authorized by: William T. Starr
William T. Starr *mt*
Certification Manager

Date: 5-23-02 *fs*

Control Number: 3023400

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AiroCide TiO₂

Airborne Pathogen Removal System

Owner's Manual & Installation Instructions

Congratulations! By purchasing AiroCide TiO₂, the most advanced and effective airborne pathogen reduction system available, you've positioned yourself as a leader in your industry. AiroCide uses technology originally used by NASA to grow wheat in space for the first time ever. A non-depleting catalyst (Titanium Dioxide; TiO₂) inside the unit forms OH- radicals. These OH-radicals work with 52 Ultraviolet bulbs within the unit to kill airborne pathogens such as bacteria, viruses, dust mites, molds, spores and fungi.

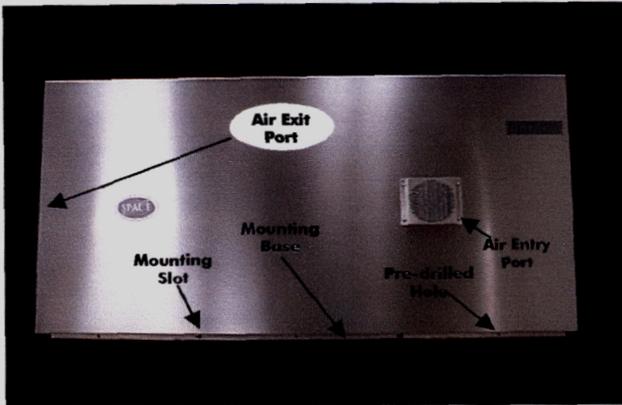


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www.kes-pro.com

AiroCide_TiO2_Installation_Manual.cdr

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AiroCide TiO₂



CAUTION: Never remove AiroCide cover while it is plugged in. (UV bulbs buried within the unit are harmful to human eyes)

About AiroCide TiO₂

AiroCide TiO₂ uses truly breakthrough technology to clean the air of airborne pathogens. It works by drawing in air through its Air Entry Port and then forcing it through its Reactor Bed where a photo-catalytic reaction occurs.

Tiny, hollow borosilicate glass tubes (Rasching rings) which have been coated with titanium dioxide (TiO₂) are packed tightly into the reactor bed. TiO₂ is a photo-catalyst stimulated by ultraviolet energy at 340 nm to 350 nm, which AiroCide produces with 52 ultraviolet bulbs. The germicidal bulbs, together with the titanium dioxide's formation of hydroxyl radicals (OH⁻), will kill 98% of airborne pathogens, i.e., bacteria, virus, dust mites, molds, spores, and fungi.

To Install

Note: Due to the size of the AiroCide TiO₂ unit (60 lbs./27 kg) and the nature of its installation, it will require heavy-duty bolts (included) and two people to mount.

- 1) Take the unit carefully out of its shipping box.
- 2) AiroCide is designed to mount to a ceiling using 10 mounting screws. However, if space or the ceiling's building material will not accommodate the unit, it may be mounted to a wall with the Air Exit Port (see photo above) pointing toward the ceiling.

3) Determine where the AiroCide unit will be mounted. It should be located centrally in the room so that the air vents are not blocked by walls, light fixtures or any other objects. The air exit port must be at least 36" away from any obstructions.

4) Place the unit on the ceiling and attach to ceiling with the four 3/8" panhead screws (included) through the four large mounting slots on the unit's base. The screws should go through the large hole in the mounting slots.



5) Further secure the unit to the wall or ceiling by threading the smaller panhead screws (included) through the 6 smaller pre-drilled holes in unit's mounting base (3 on each side).



Caution: Be sure that the AiroCide unit is securely attached to its surface, paying special attention when mounting to ceilings. Because of its weight (60 lbs.) coming detached from a wall or ceiling will damage the unit and could cause bodily harm.

6) Use the enclosed power supply box screws (Part A) to mount the Power Supply Box to the wall in a convenient, easy to reach location.



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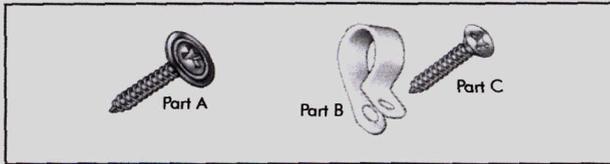
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AiroCide TiO₂

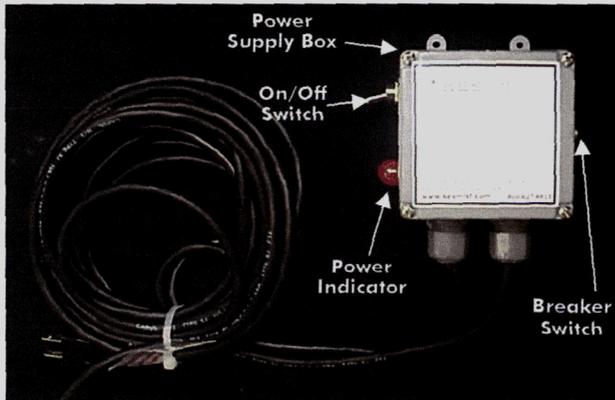
KES supplies 20' of 18/3 attached wire and a 6' 18/3 power supply cord.

7) Use the enclosed cable clamps (Part B) and cable clamp screws (Part C) to secure power supply cords to ceiling and/or wall.



System start-up

- 1) Adjust the on/off switch on the Power Supply Box to the "on" position.
- 2) As the AiroCide unit turns on, the red power indicator light should come on and a very light hum can be heard from the fan in the unit. (Do not remove the AiroCide cover when the unit is plugged in.)



Limited Warranty

KES Science & Technology, Inc. offers a one year from date of invoice limited warranty on the material and workmanship of all metal and plastic components of AiroCide. This limited warranty does not cover any of the electrical components of the AiroCide System. This warranty does not cover loss of or damage to any parts of this system not installed in accordance with the furnished installation and maintenance instructions. At its option, KES will repair or replace any components which upon inspection KES finds to be defective. KES will only repair or replace components if the components have been installed in accordance with the furnished instructions and that there has been no misuse or negligence. This limited warranty does not cover any repair/maintenance labor or shipping costs for repaired or replaced parts.



Specifications

Function

The flow rate through the unit is 8 CFM +/- 1 (0.227 m³/min) or 480 CFH (13.6 m³/h).

Application

Mail handling areas, conference rooms, offices, kitchens, common areas

Construction

Stainless Steel & Aluminum

Electrical

- 120 VAC
- 50 watt, 120 VAC fan motor
- 52 - 8 watt UV
- 13 - 120 VAC bulb ballasts
- 26' Power Cord - (20' From Unit to Power Control Box/ 6' From Power Control Box to Outlet)
- Power consumption: 432 watts (3.6 amps) @ 120 VAC

Controls

On/Off switch

Maintenance

UV bulbs have an average life of one year, after which your system will run but not be effective. Contact KES or your AiroCide Distributor to schedule your yearly maintenance.

Dimensions

	Bio-KES	Shipping Carton
Length	46 1/2" (1.18 m)	53" (1.35 m)
Width	24 1/2" (.62 m)	30" (.76 m)
Height	3 1/2" (.089 m)	8" (.2 m)
Weight	59 lbs. (26.76 kg)	Loaded: 71 lbs. (32.20 kg)

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AiroCide TiO₂

Date of Purchase

Date of Installation

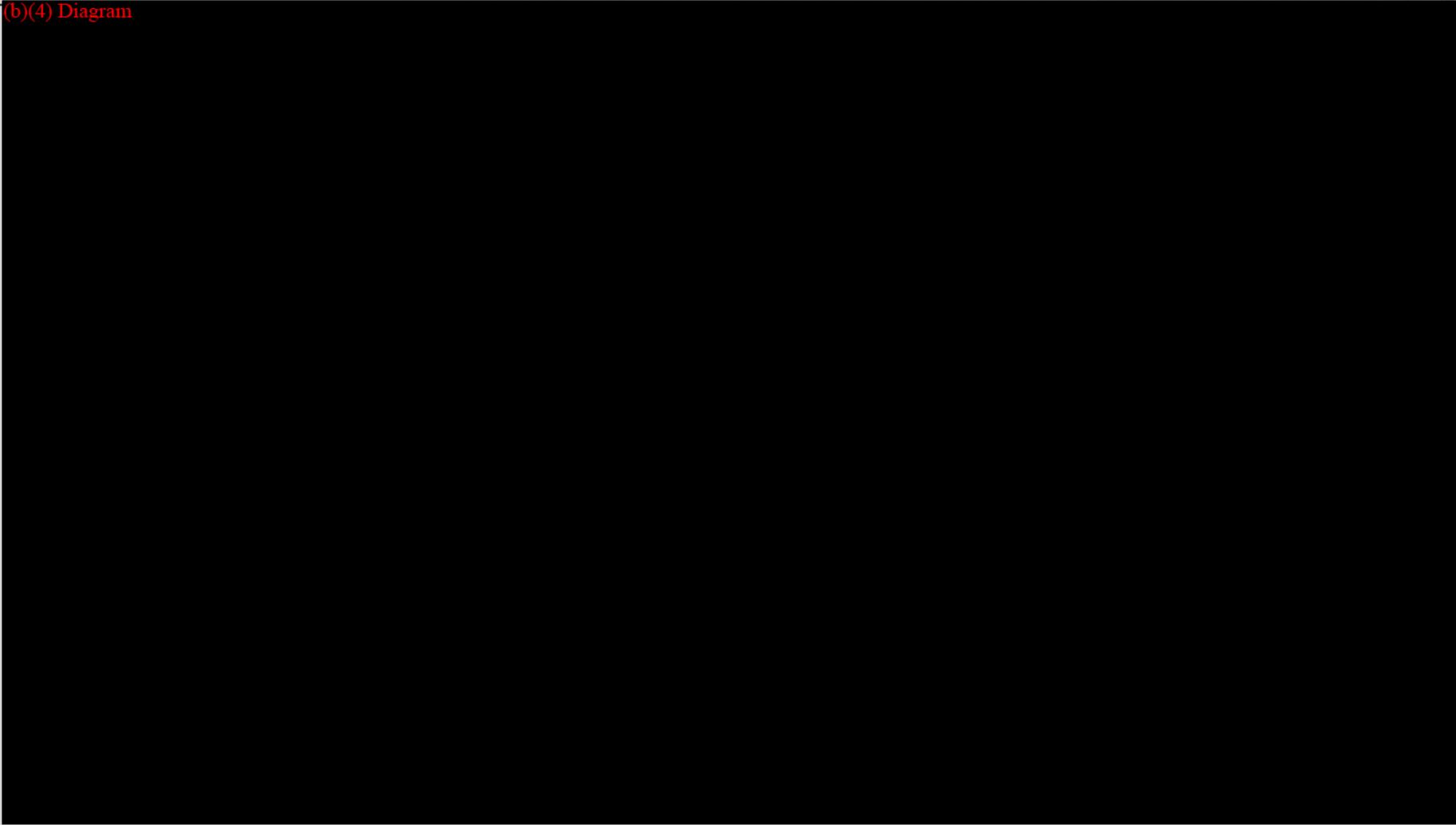
Dates of Service

308
259a

AiroCide TiO₂

Records processed under FOIA Request #2016-968 Released by CDRH on 8/19/2016

(b)(4) Diagram

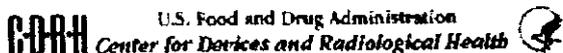


260
309



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3625 Kennesaw North Industrial Pkwy.; Kennesaw, GA 30144 USA
(800) 236-1846 FAX (770) 425-0837 Local (770) 427-6500
www.kes-pro.com
AiroCide_TiO2_Diagram.cdr 12/04/01



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Prototype - for testing only

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[Code of Federal Regulations]
 [Title 21, Volume 8]
 [Revised as of April 1, 2002]
 From the U.S. Government Printing Office via GPO Access
 [CITE: 21CFR880.6500]

[Page 398]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 880--GENERAL HOSPITAL AND PERSONAL USE DEVICES--Table of Contents

Subpart G--General Hospital and Personal Use Miscellaneous Devices

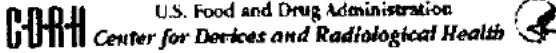
Sec. 880.6500 Medical ultraviolet air purifier.

(a) Identification. A medical ultraviolet air purifier is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation.

(b) Classification. Class II (performance standards).

Database Updated April 1, 2002

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Product Classification Database

Device PURIFIER, AIR, ULTRAVIOLET, MEDICAL
Medical Specialty General Hospital
Product Code FRA
Device Class 2
510(k) Exempt? No
Regulation Number 880.6500
Third Party Review Eligible for Accredited Persons Expansion Pilot Program
Accredited Persons and Third Party Program Information

Accredited Persons

- CALIFORNIA DEPARTMENT OF HEALTH SERVICES
- CITECH
- ENTELE, INC.
- INTERTEK TESTING SERVICES
- N.V. KEMA
- TUV AMERICA, INC.
- TUV RHEINLAND OF NORTH AMERICA, INC.
- UNDERWRITERS LABORATORIES, INC.

Database Updated 10/6/2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

113103

Memorandum

From: Reviewer(s) - Name(s) Feli A. Marshall

Subject: 510(k) Number K023830

To: The Record - It is my recommendation that the subject 510(k) Notification:

Refused to accept.

Requires additional information (other than refuse to accept).

Is substantially equivalent to marketed devices.

NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

YES

NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?

YES

NO

Is this device subject to the Tracking Regulation?

YES

NO

Was clinical data necessary to support the review of this 510(k)?

YES

NO

Is this a prescription device?

YES

NO

Was this 510(k) reviewed by a Third Party?

YES

NO

Special 510(k)?

YES

NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers

YES

NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source

YES

NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SIEs):

No Confidentiality

Confidentiality for 90 days

Continued Confidentiality exceeding 90 day

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

FRA / 80 / II 880.6500

Review: Quinn S. Lim
(Branch Chief)

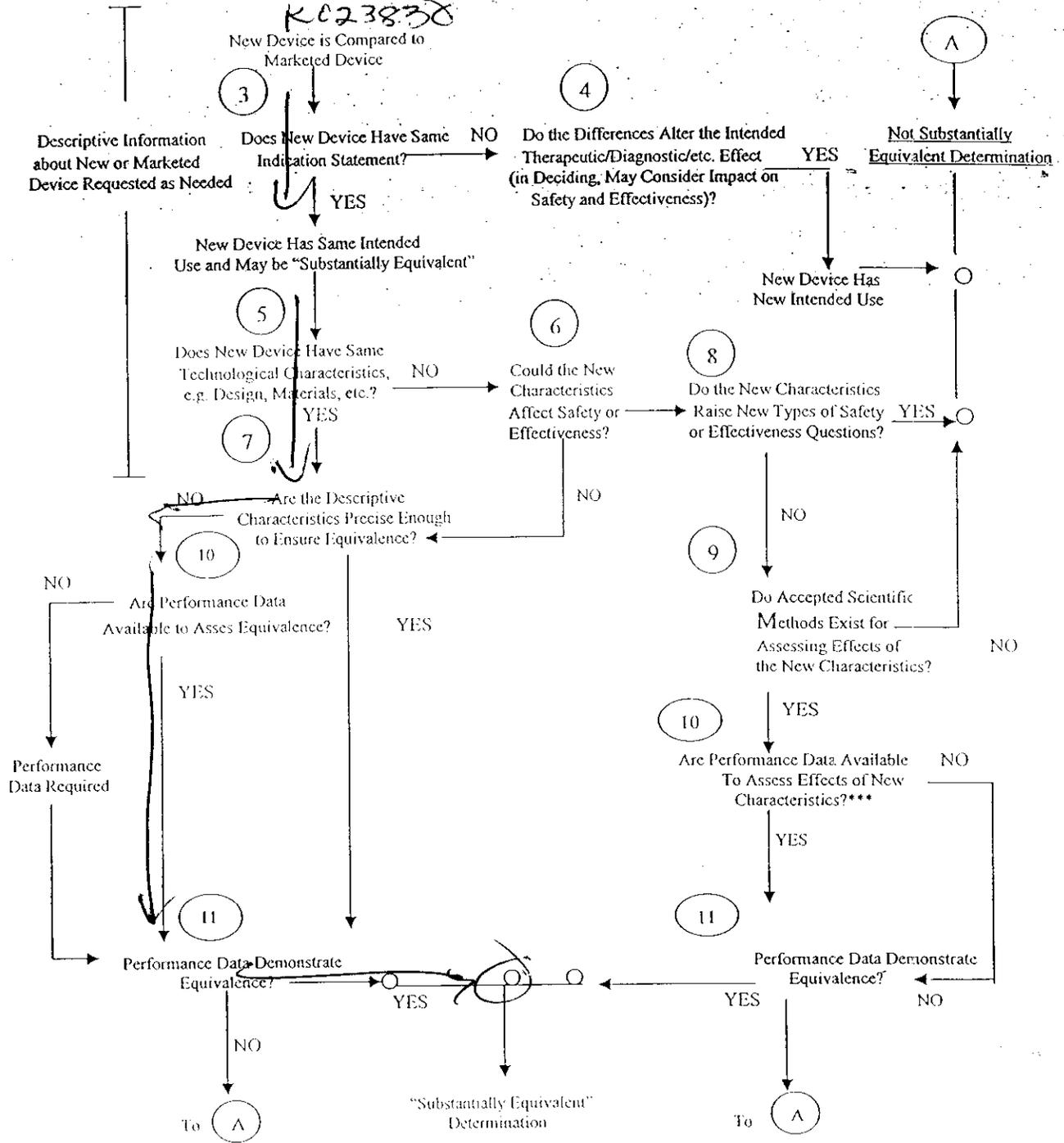
Jacob
(Branch Code)

1-31-03
(Date)

Final Review: Susan Purver
(Division Director)

2/2/03
(Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 023830

Reviewer: Feli Q. Marshall

Division/Branch: ~~Avroide TIO₂~~ DAVID/INCB

Device Name: Avroide TIO₂

Product To Which Compared (510(K) Number If Known): K9008546, K980745, Second Wind RX Air 3000

	YES	NO	
1. Is Product A Device	<input checked="" type="checkbox"/>		If NO = Stop
2. Is Device Subject To 510(k)?	<input checked="" type="checkbox"/>		If NO = Stop
3. Same Indication Statement?	<input checked="" type="checkbox"/>		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	<input checked="" type="checkbox"/>		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		<input checked="" type="checkbox"/>	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	<input checked="" type="checkbox"/>		If NO = Request Data
11. Data Demonstrate Equivalence?	<input checked="" type="checkbox"/>		Final Decision: <u>SE</u>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

6

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

K023830

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		

Fayyaz

Date: January 30, 2003
From: Feli A. Marshall, Nurse Consultant, INCB, DAGID (HFZ-480)
Subject: K023830 AiroCide TiO₂
ProCode: FRA/80/11
Firm: KES Science and Technology
Contact: John Hayman Jr.
Phone: 770-427-6500
Fax: 770-425-0837

MEMO TO THE RECORD

KES Science and Technology has submitted a premarket notification for an ultraviolet air purifier with a trade name AiroCide TiO₂.

INDICATION OF USE

The firm states that the potential application of the device includes removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas such as: treatment rooms, hospital wards, intensive care, holding areas, jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming room, funeral homes, and postal facilities.

DEVICE DESCRIPTION

The AiroCide TiO₂ unit is a 48" x 24" x 4" aluminum box, ETL-listed, which plugs into a standard 110 outlet (456 watt max power consumption). The AiroCide has 522 UVGI 8 watt bulbs and approximately 5 pounds of TiO₂ coated (b)(4) rings. The AiroCide also contains an internally mounted fan. The fan will cause a local negative pressure differential between room air near the fan inlet and downstream of the fan. The AiroCide operates as a single pass treatment device. The media inside the AiroCide is designed to remove or immobilized the airborne pathogens (bacteria, virus, dust mites, etc) entrained into the device and then would be acted upon by the two treatment modalities that operate concurrently to inactivate and oxidize the trapped bacteria and others in the device. Each unit processes approximately 15,000 cubic feet in 245 hours and mounts on the wall or ceiling. The only maintenance required is replacing the UVGI bulbs once per year.

In its present configuration, the firm states that the AiroCide can be mounted to a ceiling, wall, or other interior surface of a building. The firm states that the device conforms to UL Std. 507 and is also (b)(4) listed.

The firm states that the unit pulls in air from the room and passes it through a reactor bed which contains UVGI (ultra violet germicidal irradiation) plus Titanium dioxide (TiO₂), which is a semiconductor photocatalyst. The catalyst is irradiated with photons of less than (b)(4) (the UVGI light), which causes the band gap energy to exceed and an electron is promoted from the valence band to the conduction band. This process generates Hydroxy radicals.

Hydroxyl radical and super-oxide ions are highly reactive species that also kill and decomposes volatile organic compounds (VOCs) adsorbed on the catalyst surface. They will also kill and decompose adsorbed bioaerosols. The process is referred to as heterogeneous photocatalysis or, more specifically, photocatalytic oxidation (PCO). The firm claims that in their test, the carbon atoms in the pathogens were radioisotopes tagged. The hydroxyl radicals mineralized the organisms (reduced the organics to non-organic form such as H₂O and CO₂). The CO₂ was found to contain the tagged Carbon (this also demonstrates that the catalyst is self cleaning).

The firm claims that Airocide has been proven to kill 99.99998% of bacillus Thuringiensis spores in one pass through its reactor. The firm further state that AiroCide will easily kill weaker or similar spores as well as the vegetative state of most all bacteria found in the proposed areas listed on the intended use.

It appears that AiroCide utilizes two well established scientific mechanisms to kill bacteria, fungi, virus, spores, and to break down volatile organic compounds. The first of the killing mechanism is the 245 nm UVGI. Fifty two, 245 nm UVGI 8-watt lamps produce this light. These lamps produce billions of UVGI photons. The second killing mechanism is the photocatalytic reaction with TiO₂. This reaction occurs when photocatalytic reaction produces millions of hydroxyl radicals, which kill and or mineralize bacteria.

The specifications and illustration of how the air passed through the device are provided in the document.

PREDICATE

The firm claims substantially equivalent to the Second Wind UV Air Purifier, and RX Air 3000, both of which were also reviewed by this reviewer. Because of the presence of TiO₂, this reviewer consulted with Dr. Howard Cyr from the Office of Science and Technology. Dr. Cyr was also present when the firm had a telephone conference with this reviewer pre 510(k) submission of this device.

TESTING

Please see the two pages summary of the submission marked "A" and "B" by this reviewer which consist of the history, Overview, and Application.

Testings; Test 1 (December 1, 2001) Tested against Bacillus Thuringiensis.

Test 2 (June 13, 2002) UVGI and Photocatalytic Oxidation in inactivating bacterial spores.

Test 3 (August 14, 2002) AiroCide TiO₂ device with redesigned catalyst-full reactor bed tested for control of bacterial spores.

Mold Spore Test (June 12, 2002) Mold test at a condemned home in Austin Texas.

All testing and results were reviewed by Dr. Howard Cyr, of the Office of Science and Technology, (OST) [review attached.] Results of the testing were found acceptable and appear to support the claims the firm made in this submission. Testing data are provided in the Test Data Section of the submission. This reviewer did not have additional questions on the test data as presented on the document and discussed on the telephone with Dr. Cyr. Therefore, this reviewer concurs with the review and recommendation provided by Dr. Cyr.

LABELING

The draft product label provided by the firm is acceptable. The promotional and instruction provided also appear to be acceptable.

ADMINISTRATIVE REQUIREMENTS

The firm provided acceptable Indication of Use statement, Truthful and Accurate Statement and a 510(k) premarket notification statement.

RECOMMENDATION

Based on the information provided by the firm, we can recommend that the UV air purifier AiroCide TiO₂ is substantially equivalent to the other legally marketed UV Air purifier.


Feli A. Marshall RN, MSN



AiroCide TiO₂ - KES Science & Technology, Inc.

AiroCide TiO₂ is a brand new, unique air scrubbing device. It uses a patented combination of ultraviolet light and titanium dioxide photo catalysis to both irradiate and mineralize microorganisms.

The device may be used in a wide variety of settings, including: infection control in medical facilities; curbing the cross-contamination of tuberculosis, the common cold and other contagious respiratory ailments; mold reduction; reducing the presence of harmful VOC's like formaldehyde; and safeguarding against airborne anthrax and other bio-agents

History

The technology utilized in the AiroCide system was jointly developed in 1997-98 by the University of Wisconsin Madison and the Wisconsin Center for Space Automation and Robotics (WCSAR), a NASA Commercial Space Center. Commercial rights to the technology were obtained by KES in 1998.

KES first used the technology in its Bio-KES 348 to enhance the storage of fruits and vegetables. Bio-KES removes ethylene gas and airborne pathogens from the air. In September, 2001, KES made minor modifications to the Bio-KES to produce a device which was even more effective at killing airborne pathogens.

Overview

One AiroCide unit is approx. 47"(l) x 25" (w) x 4" (d) and weighs about 60 lbs. The device runs on 120 VAC and easily mounts to ceilings or walls. Mobile applications can also apply, mounting the device to a table or cart.

AiroCide will process the air in a 1,800 sq. ft. area with 8 ft. ceilings in 24 hours. Multiple units can be applied for more air turns in that period of time.

The UVGI germicidal lightbulbs within AiroCide's reactor bed completely oxidize the organic matter caught on the titanium dioxide-coated glass rings inside it. This mineralization produces harmless carbon dioxide and water.

Application

AiroCide TiO₂ is designed to stop cross-contamination of airborne pathogens in enclosed areas. By mounting the appropriate number of units in a given area, living beings are protected from a variety of airborne dangers.

AiroCide is not designed for use inside of HVAC systems. While ultraviolet light is promoted by some for disinfection of air within HVAC systems, the high velocity of air flowing through vents is counter-productive considering the amount of contact time needed to sterilize air.

Testing

Test #1 (December 1, 2001)

Dean T. Tompkins, PhD, Professional Engineer, University of Wisconsin Madison
Terry A. Kurzynski, MS, Advanced Microbiologist, University of Wisconsin Madison

The AiroCide TiO₂ device containing several dozen UVC lamps, a catalyst bed and a heating block set at 100°F was tested for control of bacterial spores.

B
N

The device was challenged using a commercial preparation of *Bacillus thuringiensis*. [NOTE: In lieu of testing the virulent *Bacillus anthracis* (the anthrax spore), tests were conducted with a non-virulent form of bacillus *B. thuringiensis* which is a spore-forming bacillus that is very similar to *B. anthracis*.]

Duplicate experiments using an initial inoculum of 1,386 nebulized spores indicate that 101 and 250 survived the experiment, resulting in a % removal from the feed stream of air of **93% and 82%**.

Test #2 (June 13, 2002)

Dean T. Tompkins, PhD, Professional Engineer, University of Wisconsin Madison

Terry A. Kurzynski, MS, Advanced Microbiologist, University of Wisconsin Madison

A slide study was conducted to test the performance of UVGI and Photocatalytic Oxidation in inactivating bacterial spores.

Microscope slides were coated with a proprietary titania-based photocatalyst and then later inoculated with spores of *Bacillus subtilis*, a surrogate of spores of *Bacillus anthracis*.

Interpolation between the resulting data reveals that 6.35×10^5 CFUs would survive a 30-sec exposure, which represents **99.9937% kill or 4.61 logarithms (logs) of inactivation (of kill)**.

This level of inactivation overwhelmingly meets the definition of 'sanitization' as established by the **Environmental Protection Agency (EPA)** and the Association of Official Analytical Chemists, which requires that a **non-food contact surface** have a contamination reduction of **99.9%, which is equivalent to 3 logs of kill**.

Test #3 - Latest Results (August 14, 2002)

Dean T. Tompkins, PhD, Professional Engineer, University of Wisconsin Madison

Terry A. Kurzynski, MS, Advanced Microbiologist, University of Wisconsin Madison

The AiroCide TiO₂ device with a redesigned, catalyst-full reactor bed was tested for control of bacterial spores.

The device was challenged using a commercial preparation of *Bacillus thurengiensis*. [NOTE: In lieu of testing the virulent *Bacillus anthracis* (the anthrax spore), tests were conducted with a non-virulent form of bacillus *B. thurengiensis* which is a spore-forming bacillus that is very similar to *B. anthracis*.]

71,750 spores were introduced into the AiroCide. The fan was found to contain 10,400 CFUs, or 14.49% of the original inoculum. The ante-chamber was found to contain 485 CFUs, or 0.676% of the original inoculum. Therefore, a total of 60,865 spores entered the reactor zone. Of this inoculum, only 5 CFUs exited the device and were collected on the surface of the seven sets of blood agar plates over the 70-min sampling period. The result was a **99.99998% kill rate or 6.2 log kill** in one pass.

Mold Spore Test - (June 12, 2002)

Certified Mold Inspector Michael A. Bokenkamp of Houston, Texas

May 27, 2002 test at a condemned home in Austin, TX - abandoned due to high mold counts inside. Initial air samples contained **27 colonies of mold spores: Alternaria sp. (3 colonies), Penicillium sp. (22 colonies), Sepedonium sp. (1 colony), and Nigrosporium sp. (1 colony)**. AiroCide was used to turn (process) the air in this bathroom **one** time.

After **one (1) turn the room's air air samples contained only 4 colonies of mold spores. These were Penicillium sp. (3 colonies), and Mucor sp. (1 colony)**.

Michael A. Bokenkamp, Certified Mold Inspector, stated that before the introduction of the AiroCide unit, the bathroom would have been **UNSAFE** for human occupants. The inspector said that after one air turn, the room was **SAFE** for human occupants. The drop from 27 colonies to 4 colonies with **one (1) turn of the air** represents an **85% reduction** of the mold spores at this test site.

Airocide TiO2 - Medical ultraviolet air purifier

K023830

KES Science and Technology, Inc.
3625 Kennesaw N. Industrial Pky.
Kennesaw, GA 30144
John Hayman, Jr, President

I've gone over the entire 510(k) for Airocide TiO2 and I was really impressed. The company did an outstanding job of describing the device, the science behind the device, and did 4 different tests for efficacy. The device not only inactivates the most difficult form of bacillus, it can also eliminate contaminants by oxidizing them to carbon dioxide and water.

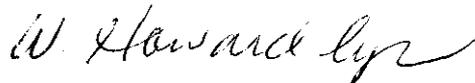
Mr. Hayman's cover letter makes reference to all required documentation. The intended use is to eliminate airborne pathogens and organic compounds. There are no claims for treatment of any diseases. Independent laboratory tests were conducted by Dr. Dean Thompson of the University of Wisconsin and details of those experiments showing that this device eliminates 99.99982% of airborne *Bacillus thuringiensis* on one passage through the device (page 185). Removal of mold spores was less successful, but still there was an 85% removal on one passage (pages 190-191). They also showed that no significant levels of ozone or other volatile organic compounds (VOC) were produced (Tables 1 and 2, page 170).

The truth and accurate statement is included on pages 207 and 208. The supporting documentation is covered on pages 209-254. Labels are on page 255, with an ETL accreditation label on page 256.

The predicate device is K980745, the Second Wind Air Purifier, that uses the same technology of UV lamps and a catalyst of titanium dioxide. I remember that device well, as I was the reviewer for it, also.

All required documentation is present. It is ready to be declared substantially equivalent with no additional information needed. I don't think I've ever seen such an expertly compiled 510(k). It should be the model for all others to follow.

SE
Recommendation



W. Howard Cyr, Ph.D.
Acting Branch Chief
Radiation Biology Branch
Division of Life Sciences
Office of Science and Technology
Center for Devices and Radiological Health

Records processed under FOIA Request #2016-968 Released by CDRH on 8/19/2016

*** TX REPORT ***

TRANSMISSION OK

TX/RX NO	2608	
CONNECTION TEL		917704250837
SUBADDRESS		
CONNECTION ID		
ST. TIME	01/31 01:59	
USAGE T	00'55	
PGS.	2	
RESULT	OK	

DHHS/PHS/FDA/CDRH
DIVISION OF ANESTHESIOLOGY,
GENERAL HOSPITAL, INFECTION CONTROL
AND DENTAL DEVICES
9200 CORPORATE BOULEVARD
ROCKVILLE, MARYLAND 20850 HFZ-480



DATE: 1/31/03

FROM: ms. Feli Marshall RN, MSN

TO: Mr John Hayman 770-425-0837

SUBJECT: K023830

ADDITIONAL COMMENTS:

I'm sorry I was not more specific. This is the page
I'm referring to in your report. Please review + send 15

DHHS/PHS/FDA/CDRH
DIVISION OF ANESTHESIOLOGY,
GENERAL HOSPITAL, INFECTION CONTROL
AND DENTAL DEVICES
9200 CORPORATE BOULEVARD
ROCKVILLE, MARYLAND 20850 HFZ-480



DATE: 1/31/03

FROM: ms. Feli Marshall RN, MSN

TO: mr John Hayman 770-425-0837

SUBJECT: K023830

ADDITIONAL COMMENTS:

I'm sorry I was not more specific. This is the page
I'm requesting you ^{to review}. Please review + send
back by fax Thank you,

NO. OF PAGES: 2 *Feli Marshall*

PHONE NO: 301-443-8879 FAX NO: 301-480-3002

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KES Science & Technology, Inc.

3020 Kennesaw North Industrial Pkwy. Kennesaw, GA 30144 USA
PHONE (800) 627-4913 FAX (770) 425-0837 www.kesmist.com

January 31, 2003

Food and Drug Administration
Center for Devices and Radiological Health
(HFZ-308)
Office of Compliance
Information Processing and Office Automation Branch
9200 Corporate Boulevard
Rockville, MD 20850-4015

501(k) Notification

Dear Sir/Madam,

AiroCide TiO₂ INTENDED USE: Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc.

Please call or email me with any questions you may have.

Best regards,

John J. Hayman, Jr.

KES Science & Technology, Inc
Chairman
KES Science & Technology, Inc.

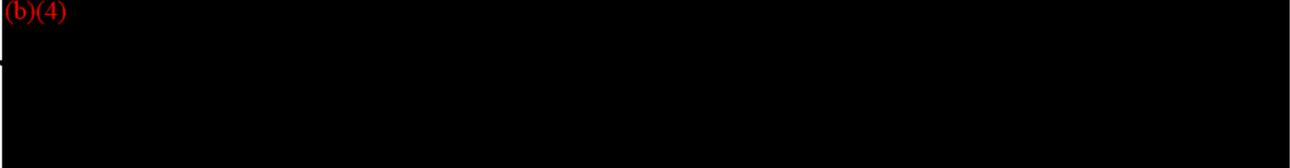
Phone: 770-427-6500
Email: chairman@kesmist.com

510(k) Number (if known): K023830

Device Name: AIROCIDE TiO₂

Indications For Use:

AiroCide TiO₂ INTENDED USE: Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc. ~~We~~

(b)(4)


(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)



FACSIMILE

3625 Kennesaw N. Industrial Pkwy. Kennesaw, GA 30144 • PHONE (800) 627-4913 • FAX (770) 425-0837 • www.kesmist.com

Company: FDA
Attn: Ms. Feli Marshall

Date: January 31, 2003
From: John J. Hayman, Jr.
Page: 1 of 5

Ref: Your tel call January 31, 2003
Fax #: (301) 480-3002

Dear Ms. Marshall,

As you requested please find attached our 501 (k) Notification letter revised per your instructions.

Best regards,

John J. Hayman, Jr.



Science & Technology, Inc.

3620 Kennesson North Industrial Pkwy. Kennesson, GA 30144 USA
PHONE (800) 627-4913 FAX (770) 425-0837 www.kesmsi.com

Food and Drug Administration
Center for Devices and Radiological Health
(HFZ-308)
Office of Compliance
Information Processing and Office Automation Branch
9200 Corporate Boulevard
Rockville, MD 20850-4015

501(k) Notification

Dear Sir/Madam,

We understand that if we (KES Science & Technology, Inc.) are to make claims that our Air purifying system ("AiroCide TiO₂" - for photo catalytic removal of airborne pathogens) is suitable for many applications, including helping to protect people in medical settings, then we are required to complete the 510k process. We believe the AiroCide System will list as follows:

Device	Purifier. Air, Ultraviolet, Medical
Product Code	FRA
Device Class	2
510(k) exempt	NO
Regulation Number	880.6500

AiroCide TiO₂ INTENDED USE: Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc.

AiroCide CURRENT FIELD TESTING: In addition previously completed laboratory testing, we will be testing an AiroCide unit at the Fulton County, Georgia, Department of Health, in their sputum collection room. We have units currently in place in Erie, PA at the Hamot Medical Center in one of their operating rooms (to see if there is a reduction of CFU's during procedures). We have tested AiroCide in a mold-condemned residence, with positive results (see attached.) We have a registration number from EPA.

HOW THE AiroCide UNIT WORKS:

- A) UVGI photons
- B) Hydroxyl radicals

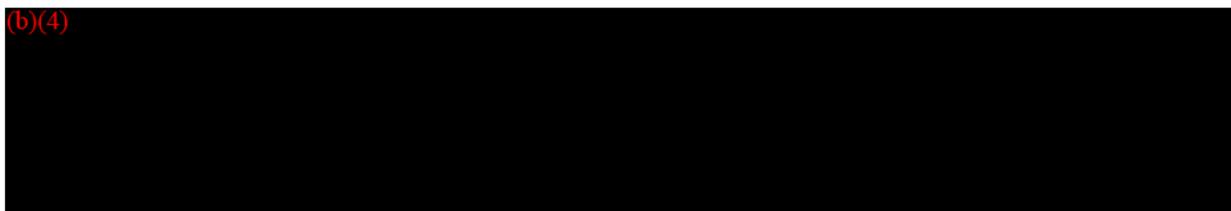
The unit pulls in air from the room and passes it through a reactor bed, which contains UVGI (Ultra Violet Germicidal Irradiation) plus Titanium Dioxide (TiO₂), which is a semiconductor photocatalyst. When the catalyst is irradiated with photons of less than 385 nm (the UVC light), the band gap energy is exceeded and an electron is promoted from the valence band to the conduction band. This process generates Hydroxyl radicals. Hydroxyl radicals and super-oxide ions are highly reactive species that oxidize volatile organic compounds (VOCs) adsorbed on the catalyst surface. They will also kill and decompose adsorbed bioaerosols. The process is referred to as heterogeneous photocatalysis or, more specifically, photocatalytic oxidation (PCO). In our test, the carbon atoms in the pathogens were radioisotope tagged. The Hydroxyl radicals mineralized the organisms (reduced the organics to non organic forms such as H₂O and CO₂). The CO₂ was found to contain the tagged Carbon (this also demonstrates that the catalyst is self cleaning)

Organisms That AiroCide Removes, Kills and/or Mineralizes:

AiroCide has been proven to kill 99.99998 % of *Bacillus Thuringiensis* spores in one pass through its reactor. (*Bacillus Thuringiensis* is the most similar spore-forming bacterium to *Bacillus Anthracis* on the phylogenic tree.) It scientifically follows that AiroCide will easily kill weaker or similar spores as well as the vegetative states of most all bacteria found in the areas of proposed application of AiroCide (as noted above in the section of this document "AiroCide INTENDED USE:")

To substantiate our above statement we note the following: According to Pennsylvania State University (W.J. Kowalski, PhD), highly regarded in the US as an expert in bio-terrorism "... To put this in perspective, this organism, in spore form, would require about 50 times the UV dose required to disinfect smallpox, tuberculosis, and *Legionella*. ..."

AiroCide System Description:



We believe there are many uses for our system as it currently is engineered (for reducing airborne pathogens). We have been working with the researchers at the University of Wisconsin and with NASA (it is their technology) to quantify other potential prophylactic applications for our system

SUBJECT: AiroCide TiO₂

Synopsis: AiroCide TiO₂ utilizes two well-established scientific mechanisms to kill bacteria, mold, fungi, virus, spores, and to break down volatile organic compounds (VOCs). The first killing mechanism is 245 nm UVGI light. Fifty-two, 245 nm UVGI 8-watt lamps produce this light.

These lamps produce billions of UVGI photons. The second killing mechanism is a photocatalytic reaction with TiO₂. This reaction occurs when photocatalytic TiO₂ coated rings are placed around and excited by the UVGI lamps. This photocatalytic reaction produces millions of hydroxyl radicals, which kill and/or mineralize bacteria, etc. These two scientific mechanisms have been proven to be effective pathogen killers by the University of Wisconsin and other University laboratories. In University of Wisconsin testing these two mechanisms demonstrated a 99.99998 % effective kill rate of *B. thuringiensis* spores (the very robust brother of *B. anthrax* spores). AiroCide TiO₂ reduces the concentration of bacteria, mold, fungi, spores, etc. in the air. A mold test was conducted in an abandoned trailer in Austin, Texas on May 27, 2002 by Michael A. Bokenkamp Certified Mold Inspector. The test results indicate an 85% reduction in mold spores with only one air turn with an AiroCide TiO₂ Unit.

Please find attached the following:

#1 FDA 2891 and a 2892 application for a new device dated October 29, 2002.

#2 A cover letter to the Tetra Tech EMI group that is evaluating systems for the EPA of Dr. Dean Thompkins, PhD, PE University of Wisconsin Environmental Chemistry & Technology Program dated May 3, 2002.

#3 A cover letter to the Tetra Tech EMI group that is evaluating systems for the EPA of Dr. Dean Thompkins, PhD, PE University of Wisconsin Environmental Chemistry & Technology Program dated August 1, 2002.

#4 A cover letter with supporting laboratory test results to John J. Hayman, Jr. - President KES Science & Technology, Inc. from Dr. Dean Thompkins, PhD, PE University of Wisconsin Environmental Chemistry & Technology Program dated September 20, 2002 reporting the laboratory testing of AiroCide using gas chromatography/mass spectrometry (GC/MS) by the University of Wisconsin Occupational Health Laboratory indication that the AiroCide system does NOT generate any ozone (O₃) gas nor any other harmful bi-products.

#5 AiroCide's ETL listing of certified products.

#6 An AiroCide Device Description and Specification sheet.

#7 A letter and test results directed to John J. Hayman, Jr. - President KES Science & Technology, Inc. from Dr. Dean Thompkins, PhD, PE University of Wisconsin Environmental Chemistry & Technology Program and Terry Kurzynski, MS Advanced Microbiologist University of Wisconsin dated August 14, 2002 reporting the laboratory testing of AiroCide reflecting 60,865 spores entered the reactor and ONLY 5 CFU's were cultured. A 99.999982% kill rate.

#8 A summary memo written by John J. Hayman, Jr. - President KES Science & Technology, Inc. regarding the attached mold test results conducted in an abandoned trailer in Austin, Texas on May 27, 2002 by Michael A. Bokenkamp Certified Mold Inspector. This test shows an 85% reduction in mold spores with only one air turn with an AiroCide.

#9 Pennsylvania State University Professor Dr. W. J. Kowalski PhD statements regarding that "To put this in perspective, this organism, in spore form," B. anthrax "would require about 50 times more UV dose required to disinfect smallpox, tuberculosis and Legionella." Dated Anthrax January 14, 2002 NewsRx.com & NewsRx.net. From http://www.obgyn.net/newsrx/general_health-Anthrax-20020114-2.asp

#10 Publication from the National Renewable Energy Laboratory Mineralization of Bacteria Cell Mass on a Photocatalytic Surface in Air from Vol 32 NO. 17 1998 / Environmental Science & Technology showing that E. coli was mineralized by TiO₂ to CO₂ and H₂O.

#11 Overview of Photocatalysis Chemistry

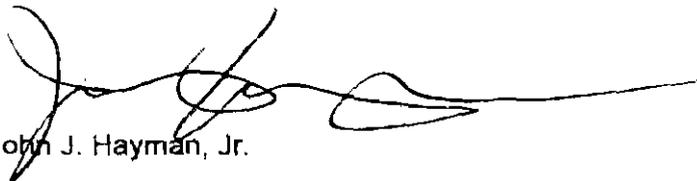
#12 National Renewable Energy Laboratory - Chemistry for Bioenergy Systems Outlines what science researchers have demonstrated regarding photocatalytic reactions. From http://www.nrel.gov/chemistry_bioenergy/chemistry.html

#13 Summary Internet document of Dr. Michael Leung's testing in a hospital operating room "...For comparison, the same test was performed with the photocatalytic converter disconnected. This showed filtration using only the HEPA filter reduced the bacterial count by just 5.4 per cent. Therefore, the immediate disinfection effect of the titanium dioxide filter led to the destruction of 46.6 per cent of airborne bacteria in one pass of air through the air purifier. ..." From <http://www.fhki.org.hk/hki09.htm>

#14 Summary of test data of an AiroCide TiO₂ conducted at the Hamot Medical Center Erie, PA on September 24, 2002 before the AiroCide TiO₂ was turned on and October 15, 2002 when the AiroCide TiO₂ was operating.

Please call or email me with any questions you may have.

Best regards,



John J. Hayman, Jr.

KES Science & Technology, Inc
Chairman
KES Science & Technology, Inc.

Phone: 770-427-6500

Email: chairman@kesmist.com

www.kes-pro.com PDF files about the testing and operation of the Airocide are available at this site.

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: Ke23830

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual.	✓	
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		

is posted with the study folder on the H drive. For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	} n/a	
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No
 Reviewer: Raymond
 Concurrence by Review Branch: _____

Date:

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>