DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 16, 2012

(b) (4), (b) (6)

510k Number: K121593

Product: 3M ATTEST (TM) SUPER RADID REA

Extended Until: 01/11/2013

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room WO66-G609
Silver Spring, MD 20993-0002

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

(b) (4), (b) (6)

March 15, 2013

Regulatory Affairs Manager

(b) (4)

ST. PAUL MN 55144-1000

Re: K121593
Trade/Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack
3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: March 1, 2013
Received: March 4, 2013

(b) (4), (b) (6)

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K121593

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Clarence W. Murray Iii III Digitally signed by Clarence W. Murray Iii III DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300197254, cn=Clarence W. Murray Iii III Date: 2013.03.14 18:55:05 -04'00'
Branch Chief Sign-Off	Elizabeth F Claverie 2013.03.15 10:50:26 -04'00'
Division Sign-Off	Tejashri S Purohitsheth -S 2013.03.15 15:32:42 -04'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

510(k) Number: K121593

Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack
3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack

Indications for Use:

Use the 3M Attest™ Super Rapid Readout Steam Challenge Pack 1496V and the 3M Attest™ Super Rapid 5 Steam-Plus Steam Challenge Pack 41482V in conjunction with the 3M Attest™ Auto-reader 490 to qualify or monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles of 270°F (132°C) at 4 minutes and 275°F (135°C) at 3 minutes.

The 3M Attest™ Super Rapid Readout Biological Indicator 1492V contained in the challenge pack provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.03.14 18:12:58 -04'00'

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

510(k) Number: K121593

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 14, 2012

3M COMPANY
(b) (4)
ST. PAUL, MINNESOTA 55144-1000
ATTN (b) (4), (b) (6)

510k Number: K121593
Product: 3M ATTEST (TM) SUPER RADID REA
On Hold As of 12/13/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified 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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request. In this instance, pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

68

Mcdonald, Lisa *

From: Microsoft Outlook
To: (b) (4), (b) (6)
Sent: Friday, December 14, 2012 10:43 AM
Subject: Relayed: K121593 Hold Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

(b) (4), (b) (6)

Subject: K121593 Hold Letter

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 15, 2012

3M COMPANY
(b) (4), (b) (6)
ATTN: (b) (4), (b) (6)

510k Number: K121593
Product: 3M ATTEST (TM) SUPER RADID REA
On Hold As of 11/14/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

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In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request. In this instance, pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Chin, Yeuly *

m: Microsoft Outlook
(b) (4), (b) (6)
Sent: Thursday, November 15, 2012 7:53 PM
Subject: Relayed: K121593 Hold Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

(b) (4), (b) (6)

Subject: K121593 Hold Letter

284

Payne, Melissa T*

From: (b) (4), (b) (6)
Sent: Thursday, August 16, 2012 10:12 AM
To: Payne, Melissa T*
Subject: K121593 FDA Extension Letter

Return Receipt

Your document: K121593 FDA Extension Letter
was received by: (b) (4), (b) (6)
at: 08/16/2012 09:12:00 AM

334

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 16, 2012

3M COMPANY
(b) (4), (b) (6)
ST. PA [redacted]
ATTN: (b) (4), (b) (6)

510k Number: K121593

Product: 3M ATTEST (TM) SUPER RADID REA

Extended Until: 01/11/2013

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

K122

FDA CDRH DMC

AUG 15 2012

3M

August 14, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Dr. Clarence Murray III, Scientific Reviewer
Ms. Marjorie Shulman, Consumer Safety Officer

Subject: **Request for Extension of Time – 180 Days**
K121593, 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack

Dear Dr. Murray and Ms. Shulman,

3M Health Care is requesting a 180 day extension of time for our 510(k) submission K121593 for 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack.

(b) (4)

Please confirm that this request has been granted by sending an acknowledgment to the address provided. Thank you very much for your assistance.

Sincerely,

(b) (4), (b) (6)

(b) (4), (b) (6)

Regulatory Affairs, 3M Health Care

(b) (4)

St. Paul, MN 55144

(b) (4), (b) (6)

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3M

August 14, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Dr. Clarence Murray III, Scientific Reviewer
Ms. Marjorie Shulman, Consumer Safety Officer

Subject: **Request for Extension of Time – 180 Days**
K121593, 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack

Dear Dr. Murray and Ms. Shulman,

3M Health Care is requesting a 180 day extension of time for our 510(k) submission K121593 for 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack.

(b) (4)

Please confirm that this request has been granted by sending an acknowledgment to the address provided. Thank you very much for your assistance.

Sincerely,

(b) (4), (b) (6)

Regulatory Affairs, 3M Health Care

(b) (4)

(b) (4), (b) (6)

337

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 19, 2012

(b) (4), (b) (6)

ATTN (b) (4), (b) (6)

510k Number: K121593
Product: 3M ATTEST (TM) SUPER RADID REA
On Hold As of 7/17/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified 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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

339

Mcdonald, Lisa *

From: Microsoft Outlook
To: (b) (4), (b) (6)
Sent: 8:28 AM
Subject: Relayed: K121593 Hold Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

(b) (4), (b) (6)

Subject: K121593 Hold Letter

Sent by Microsoft Exchange Server 2007

340

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 31, 2012

(b) (4)
ST. PAUL, MINNESOTA 55133-3275
ATT(b) (4), (b) (6)

510k Number: K121593

Received: 5/31/2012

Product: 3M ATTEST (TM) SUPER RADID REA

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

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Grayson, Giovanna *

From: Microsoft Outlook
To: (b) (4), (b) (6)
Sent: [illegible] 2:17 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

(b) (4), (b) (5)

Subject: ack letter

Sent by Microsoft Exchange Server 2007

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Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Thursday, May 31, 2012 2:17 PM
To: (b) (4), (b) (6)
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 31, 2012

(b) (4), (b) (6)

(b) (4)

ATTN: (b) (4), (b) (6)

510k Number: K121593
Received: 5/31/2012
Product: 3M ATTEST (TM) SUPER RADID REA

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 – 2012. The legislation – the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301) 796-5640.

Sincerely,

510(k) Staff

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K121593
1 to 1 Page 15

1.0 510(k) Notice of Intent

3M

FDA CDRH DMC
MAY 31 2012
Received

May 15, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Premarket Notification for 3M Attest™ Super Rapid Readout Biological Indicator Challenge Packs for Steam 1496V and 41482V

Dear Sir or Madam:

In compliance with the Federal Food, Drug and Cosmetic Act (as amended) and as required in 21 CFR § 807, Subpart E, 3M Health Care submits this subject Premarket Notification for your review. In accordance with 21 CFR §807.90(c), this document is submitted in duplicate, with a paper copy and an electronic copy that is an exact duplicate of the paper copy.

The purpose of the submission is to notify the Agency of the intent of 3M to manufacture and market the Attest™ Super Rapid Biological Indicator Challenge Packs 1496V and 41482V.

Product Code:	FRC
Classification:	Class II, 21 CFR 880.2800(a)
Tradenames:	3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack

The table below summarizes the products covered in the current submission, the Intended Use and the predicate device.

Product Name	Intended Use	Predicate
Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack	To monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles	3M Attest™ Steam-Plus Pack (b) (4) (b) (4) cleared under K925496, (b) (4)

3M considers the intent to market these devices as confidential commercial information. Therefore, 3M considers the information provided under this submission to be a trade secret and confidential commercial information under 21 CFR §20.61 and requests that the Food and Drug Administration not disclose this information either in response to a Freedom of Information Request or by any other means.

An electronic payment of $4,049.00 was made to FDA on April 25, 2012 in support of this submission, and 3M's Medical Device User Fee Payment Identification Number for this submission is MD6061508-956733. Should you have any questions regarding this submission, please contact me at the phone number provided.

Sincerely,

(b) (4), (b) (6)

3M Health Care Regulatory Affairs

(b) (4)

St. Paul, MN 55144-1000

(b) (4), (b) (6)

Traditional 510k Premarket Notification for 3M Attest™ 1496V and 41482V Super Rapid Biological Indicator Challenge Packs for Steam

Submitted by
3M Health Care
(b) (4)

Submission Date: May 30, 2012

Contact (b) (4), (b) (6)
Phone:
Fax:
Email:

Table of Contents

(b) (4)

(b) (4)

(b) (4)

List of Figures

(b) (4)

1.0 510(k) Notice of Intent

May 15, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Premarket Notification for 3M Attest™ Super Rapid Readout Biological Indicator Challenge Packs for Steam 1496V and 41482V

Dear Sir or Madam:

In compliance with the Federal Food, Drug and Cosmetic Act (as amended) and as required in 21 CFR § 807, Subpart E, 3M Health Care submits this subject Premarket Notification for your review. In accordance with 21 CFR §807.90(c), this document is submitted in duplicate, with a paper copy and an electronic copy that is an exact duplicate of the paper copy.

The purpose of the submission is to notify the Agency of the intent of 3M to manufacture and market the Attest™ Super Rapid Biological Indicator Challenge Packs 1496V and 41482V.

Product Code:	FRC
Classification:	Class II, 21 CFR 880.2800(a)
Tradenames:	3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack

The table below summarizes the products covered in the current submission, the Intended Use and the predicate device.

Product Name	Intended Use	Predicate
Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack	To monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles	3M Attest™ Steam-Plus Pack (b) (4) (b) (4) cleared under K925496, (b) (4)

3M considers the intent to market these devices as confidential commercial information. Therefore, 3M considers the information provided under this submission to be a trade secret and confidential commercial information under 21 CFR §20.61 and requests that the Food and Drug Administration not disclose this information either in response to a Freedom of Information Request or by any other means.

An electronic payment of $4,049.00 was made to FDA on April 25, 2012 in support of this submission, and 3M's Medical Device User Fee Payment Identification Number for this submission is MD6061508-956733. Should you have any questions regarding this submission, please contact me at the phone number provided.

Sincerely,

(b) (4), (b) (5)

(b) (4), (b) (6)

3M Health Care Regulatory Affairs
(b) (4)
St. Paul, MN 55144-1000

2.0 Device User Fee Cover Sheet

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
(b) (4) US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****7775	(b) (4), (b) (6) ...e Area code) ...nclude Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

(b) (4) AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

25-Apr-2012

"Close Window" Print Cover sheet

3.0 CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission: 05/04/2012

(b) (4)

FDA Submission Document Number *(if known)*:

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: 3M Company (b) (4), (b) (6)

Establishment Registration Number *(if known)*:

Division Name *(if applicable)*: 3M Health Care (b) (4), (b) (6)

Phone Number *(including area code)*:

Street Address: (b) (4), (b) (6)

FAX Number *(including area code)*:

City	State / Province	ZIP/Postal Code	Country
St. Paul	MN	55144	USA

Contact Name: (b) (4), (b) (6)

Contact Title: Regulatory Affairs Manager

Contact E-mail Address: (b) (4), (b) (6)

SECTION C — APPLICATION CORRESPONDENT (if different than above)

Company / Institution Name:

Division Name *(if applicable)*:

Phone Number *(including area code)*:

Street Address:

FAX Number *(including area code)*:

City	State / Province	ZIP Code	Country

Contact Name:

Contact Title:

Contact E-mail Address:

FORM FDA 3514 (3/08)

Page 1 of 5 Pages

PSC Graphics (301) 443-1090 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ 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:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FRC	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

(b) (4)

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Biological Indicator

	Trade or Proprietary or Model Name for This Device		Model Number
1	3M Attest(TM) Super Rapid Readout Steam Challenge Pack	1	1496V
2	3M Attest(TM) Super Rapid 5 Steam-Plus Challenge Pack	2	41482V
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 - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FRC	21 CFR 880.2800	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Biological Sterilization Process Indicator

Indications *(from labeling)*

Use the 3M Attest™ Super Rapid Readout Steam Challenge Pack 1496V and 3M Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V in conjunction with the 3M Attest™ 490 Auto-reader to qualify and monitor 270°F (132°C) and 275°F (135°C) dynamic-air-removal (pre-vacuum) steam sterilization cycles.
The 3M Attest™ Super Rapid Readout Biological Indicator 1492V contained in the challenge pack provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

FORM FDA 3514 (3/08) Page 3 of 5 Pages

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	

(b) (4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

FORM FDA 3514 (3/08) Add Continuation Page Page 4 of 5 Pages

SECTION I **UTILIZATION OF STANDARDS**

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	11138:1	ANSI/AAMI/ISO	Sterilization of health care products – Biological indicators - Part 1: General Requirements	2006/(R)2010	04/22/2010
2	11138:3	ANSI/AAMI/ISO	Sterilization of health care products – Biological indicators - Part 3: Biological indicators for moist heat sterilization processes	2006/(R)2010	04/22/2010
3	11140:1	ANSI/AAMI/ISO	Sterilization of health care products – Chemical indicators - Part 3: General Requirements	2005	07/15/2005
4	18472:2006	ANSI/AAMI/ISO	Sterilization of health care products - Biological and chemical indicators: Test equipment	2006	10/01/2006
5	ST79	ANSI/AAMI	Comprehensive guide to steam sterilization & sterility assurance in health care facilities	2010, A1:2010 and A2:2011	09/19/2011
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 3514 (3/08) Page 5 of 5 Pages

4.0 Indications for Use Statement

510(k) Number (if known): To be assigned

Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack
3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack

Indications For Use:

Use the 3M Attest™ Super Rapid Readout Steam Challenge Pack 1496V and the 3M Attest™ Super Rapid 5 Steam-Plus Steam Challenge Pack 41482V in conjunction with the 3M Attest™ Auto-reader 490 to qualify or monitor 270°F (132°C) and 275°F (135°C) dynamic-air-removal (pre-vacuum) steam sterilization cycles.

The 3M Attest™ Super Rapid Readout Biological Indicator 1492V contained in the challenge pack provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

Prescription Use _____	AND/OR	Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

5.0 Premarket Notification (510(k)) Summary

3M

Sponsor Information:

3M Health Care
(b) (4)
St. Paul, MN 55144-1000

Contact Person: (b) (4), (b) (6)
Regulatory Affairs
Phone Number: (651) 575-8052
FAX Number: (651) 737-5320

Date of Summary: May 15, 2012

Device Name and Classification:

Common or Usual Name: Sterilization Biological Indicator

Proprietary Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack
3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack

Classification Name: Indicator, Biological Sterilization Process (21 CFR § 880.2800(a))

Predicate Devices:

3M Attest™ Steam-Plus Pack (b) (4)
cleared under K92549(b) (4)
3M Attest™ 1492V Super Rapid Readout Biological Indicator for Steam (K121484)
3M Attest™ 490 Auto-reader (K121484)

Description of Device:

The 3M Attest™ 1496V Super Rapid Readout Steam and 41482V Super Rapid 5 Steam-Plus Challenge Packs are specifically designed to qualify or routinely challenge 270°F (132°C) and 275°F (135°C) dynamic-air-removal (prevacuum) steam sterilization cycles in healthcare facilities.

The 1496V and 41482V Challenge Packs consist of multiple layers of medical index cards, some of which are die-cut to contain monitoring products. The pack is overwrapped and secured with a label. The Challenge Packs have the same design as the predicate device. Each 1496V test pack contains an Attest™ 1492V Super Rapid Biological Indicator (1492V SRBI) while the 41482V Super Rapid 5 Steam-Plus Challenge Pack contains a 1492V SRBI and a SteriGage™ steam chemical integrator. The 1492V SRBI is specifically designed for a rapid fluorescent result when used in conjunction with the 3M Attest™ 490 Auto-reader. A fluorescence change indicates a steam sterilization process failure. Attest™ 1492V SRBI controls are provided with the Challenge Packs. The SteriGage™ integrator offers an immediate Accept/Reject reading that allows for implant load early release in emergency situations as defined in AAMI ST-79. Each Challenge Pack has a chemical process indicator on the outside of the device that changes from yellow to brown or darker when exposed to steam.

Indications for Use:

Use the 3M Attest™ Super Rapid Readout Steam Challenge Pack 1496V and the 3M Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V in conjunction with the 3M Attest™ Auto-reader 490 to qualify or monitor 270°F (132°C) and 275°F (135°C) dynamic-air-removal (pre-vacuum) steam sterilization cycles.

The 3M Attest™ Super Rapid Readout Biological Indicator 1492V contained in the challenge pack provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Testing was conducted on the indicators and the challenge packs following the FDA guidance and standards below:

- FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions;* October 4, 2007
- FDA's *Premarket Notification [510(k)] Submissions for Chemical Indicators:*

Guidance for Industry and FDA Staff, December 19, 2003

- ANSI/AAMI/ISO 11138-1:2006/(R)2010 *Sterilization of health care products – Biological indicators – Part 1: General requirements*
- ANSI/AAMI/ISO 11138-3: 2006/(R)2010 *Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes*
- ANSI/AAMI/ISO 11140-1:2005/(R)2010 *Sterilization of health care products – Chemical indicators, Part 1: General requirements*
- ANSI/AAMI/ISO 18472:2006 *Sterilization of health care products – Biological and chemical indicators: Test equipment*
- United States Pharmacopeia, Chapter <1035> *Biological Indicators for Sterilization* and Chapter <55> *Biological Indicators – Resistance Performance Tests*.
- ANSI/AAMI ST-79: 2010, A1:2010 and A2:2011, *Comprehensive guide to steam sterilization & sterility assurance in health care facilities*

Multiple lots of 3M Attest™ Super Rapid Challenge Packs were prepared containing multiple lots of 1492V Super Rapid BIs and Steri-Gage™ chemical integrators. The indicators were evaluated for performance when incorporated into the challenge packs and used with the 3M Attest™ 490 Auto-reader. A Summary of the Nonclinical Testing is shown below.

Summary of Nonclinical Testing

(b) (4)

The results of these evaluations showed that the 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs present a challenge to the sterilization process equivalent to the biological indicator AAMI towel pack recommended by ANSI/AAMI ST-79 *Comprehensive guide to steam sterilization & sterility assurance in health care facilities*.

Conclusion

The 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs and the 3M Attest™ 490 Auto-reader meet all applicable voluntary performance standards and are substantially equivalent to the predicate device in terms of their intended use, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

6.0 Truthful and Accuracy Statement

Pursuant to 21 CFR §807.87(k), I certify that, in my capacity as Regulatory Affairs Manager for 3M Health Care, I believe to the best of my knowledge, that all data and information submitted in this Premarket Notification are truthful and accurate and that no material fact has been omitted.

(b) (4), (b) (6)

(b) (4), (b) (6)

Pr

29 May 2012

Date

7.0 Class III Summary and Certification

Not applicable. The subject medical device is not a Class III device.

8.0 Financial Certification or Disclosure Statement

Not applicable. This submission does not contain information from clinical studies.

9.0 Declarations of Conformity and Standards Data Report for 510(k)

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11138-1:2006(R) 2010 STERILIZATION OF HEALTH CARE PRODUCTS – BIOLOGICAL INDICATORS - PART 1

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-296	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Premarket Notification [510(k)] Submissions for Biological Indicators, Oct. 4, 2007

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 11138-1:2006(R) 2010 STERILIZATION OF HEALTH CARE PRODUCTS – BIOLOGICAL INDICATORS - PART 1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex C	D-value determination by survivor curve method	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
Resistance characteristics assessed by: 1. D-value determination by fraction negative and 2. Verification of Survival/Kill

DESCRIPTION
See Appendix A of this submission for summary of testing

JUSTIFICATION
Standard only requires 2 methods for resistance characterization. D-value and Survival/Kill window were the methods chosen

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Paperwork Reduction Act Statement

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
AAMI/ANSI/ISO 11138-3:2006/(R)2010 Sterilization of health care products - Biological indicators - Part 3

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# _____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Biological Indicator (BI) Premarket Notification 510(k) Submissions; Oct. 4, 2007

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 11138-1:2006(R) 2010 STERILIZATION OF HEALTH CARE PRODUCTS – BIOLOGICAL INDICATORS - PART 3

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Section 9	Population and resistance	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
D-value is determined at 270F and 275F, no z-value is determined

DESCRIPTION
See Appendix A of this submission for summary of testing

JUSTIFICATION
The product will only be used for 270F and 275F cycles. No z-value is needed as D-values are already determined at those temperatures.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11140-1:2005 STERILIZATION OF HEALTH CARE PRODUCTS – CHEMICAL INDICATORS, PART 1: GENERAL REQUIREMENTS

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-195	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Premarket Notification [510(k)] Submissions for Chemical Indicators, Dec. 19, 2003

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 11140-1:2005 STERILIZATION OF HEALTH CARE PRODUCTS – CHEMICAL INDICATORS, PART 1: GENERAL REQUIREMENTS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆
None

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 18472:2006 Sterilization of health care products: Biological and chemical indicators - Test equipment

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3]	# 14-222	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Biological Indicator (BI) Premarket Notification 510(k) Submissions; Oct. 4, 2007

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 18472:2006 Sterilization of health care products: Biological and chemical indicators - Test equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

United States Pharmacopeia 34: 2011, Biological Indicator for Steam Sterilization - Self Contained

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-320	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
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Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
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Title of guidance: Premarket Notification [510(k)] Submissions for Biological Indicators, Oct. 4, 2007

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (9/07) Page 1 PSC Graphics: (301) 443- 1090 EF

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
UNITED STATES PHARMACOPEIA 34: 2011, BIOLOGICAL INDICATOR FOR STEAM STERILIZATION - SELF CONTAINED

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Chapter <1035>	Biological Indicators for Sterilization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
D-value is determined at 270F and 275F instead of 250F

DESCRIPTION
See Appendix A of this submission for a summary of testing

JUSTIFICATION
The product will be used for 270F and 275F cycles instead of 250F cycles

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Chapter <55>	Biological Indicators - Resistance Performance Tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
Population (Total Viable Spore Count) determination is performed on a non-heat shocked sample

DESCRIPTION
See Appendix A of this submission for a summary of testing

JUSTIFICATION
Product is used without prior heat shock and therefore the non-heat shocked population is more relevant

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI / ANSI ST79:2010 & A1:2010, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-312	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Premarket Notification [510(k)] Submissions for Biological Indicators, Oct. 4, 2007

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI / ANSI ST79:2010 & A1:2010, COMPREHENSIVE GUIDE TO STEAM STERILIZATION AND STERILITY ASSURANCE IN HEALTH CARE FACILITIES

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex K	Development and qualification of the 16 towel PCD	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖ See Section 12, Performance Testing		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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10.0 Executive Summary

10.1 The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

The following trade name is applicable to this device:

3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack
3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack

The common or usual names for this type of product:

Sterilization Biological Indicator

The classification name for this device:

Indicator, Biological Sterilization Process (21 CFR §880.2800(a))

10.2 The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

This 510(k) Premarket Notification is submitted by:

3M Health Care
3M Center
(b) (4)
St. Paul, MN 55144-1000
(b) (4)

(b) (4)

10.3 Performance Standards - Action taken by 3M to comply with the requirements of the act under section 514 for performance standards.

There are no mandatory performance standards under section 514 of the Act to which this device is subject. Voluntary performance standards to which the Challenge Packs comply include:

- AAMI ST79: 2010, A1:2010 and A2:2011, *Comprehensive guide to steam sterilization & sterility assurance in health care facilities*
- FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions;* Oct. 4, 2007.

Voluntary performance standards to which the 1492V Biological Indicator contained within the Challenge Packs comply include:

- FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions;* Oct. 4, 2007
- ANSI/AAMI/ISO 11138-1:2006/(R)2010 *Sterilization of health care products – Biological indicators – Part 1: General Requirements*
- ANSI/AAMI/ISO 11138-3: 2006/(R) 2010 *Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes*
- ANSI/AAMI/ISO 18472:2006 *Sterilization of Health Care Product- Biological and Chemical Indicators: Test Equipment*
- United States Pharmacopeia, Chapter <1035> Biological Indicators for Sterilization and Chapter <55> Biological Indicators – Resistance Performance Tests.

Voluntary performance standards to which the SteriGage™ chemical integrator contained within the 41482V Challenge Packs comply include:

- ANSI/AAMI/ISO 11140-1:2005/(R)2010 *Sterilization of health care products – Chemical indicators, Part 1: General Requirements*
- FDA's *Premarket Notification [510(k)] Submissions for Chemical Indicators: Guidance for Industry and FDA Staff*, December 19, 2003.

10.4 Concise Description of Device

The 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs are designed to routinely challenge dynamic-air-removal (prevacuum) steam sterilization processes in healthcare facilities. The Challenge Packs have the same Intended Use as the predicate device 3M Attest™ Steam-Plus Pack, (b) (4) (b) (4) 925496), and are similar in design.

The Challenge Packs consist of multiple layers of medical index cards, some of which are die-cut to contain monitoring products. The pack is overwrapped and secured with a label. Each pack has a process indicator on the outside of the pack that changes from yellow to brown or darker when exposed to steam. This disposable pack has been designed to present a challenge to the steam sterilization process that is equivalent to or more resistant than the towel pack biological indicator challenge device recommended by the Association for the Advancement of Medical Instrumentation (AAMI).

Each Attest™ 1496V Challenge Pack contains an Attest™ 1492V Super Rapid Readout Biological Indicator and a record keeping sheet. Each Attest™ 41482V Challenge Pack contains an Attest™ 1492V Super Rapid Readout Biological Indicator, a SteriGage™ chemical integrator, and a record keeping sheet. Attest™ 1492V biological indicator controls are provided with both challenge packs.

Biological Indicator Design and Attest ™ Super Rapid Readout Technology

The Attest™ 1492V Super Rapid Readout Biological Indicator (1492V Super Rapid BI or 1492V SRBI) contained within the 1496V and 41482V Challenge Packs utilizes the Attest™ Super Rapid Readout Technology (b) (4) (b) (4) The 1492V is a new model of the Super Rapid Biological Indicator currently under review for dynamic-air-removal (prevacuum) steam sterilization cycles (K121484).

(b) (4)

(b) (4)

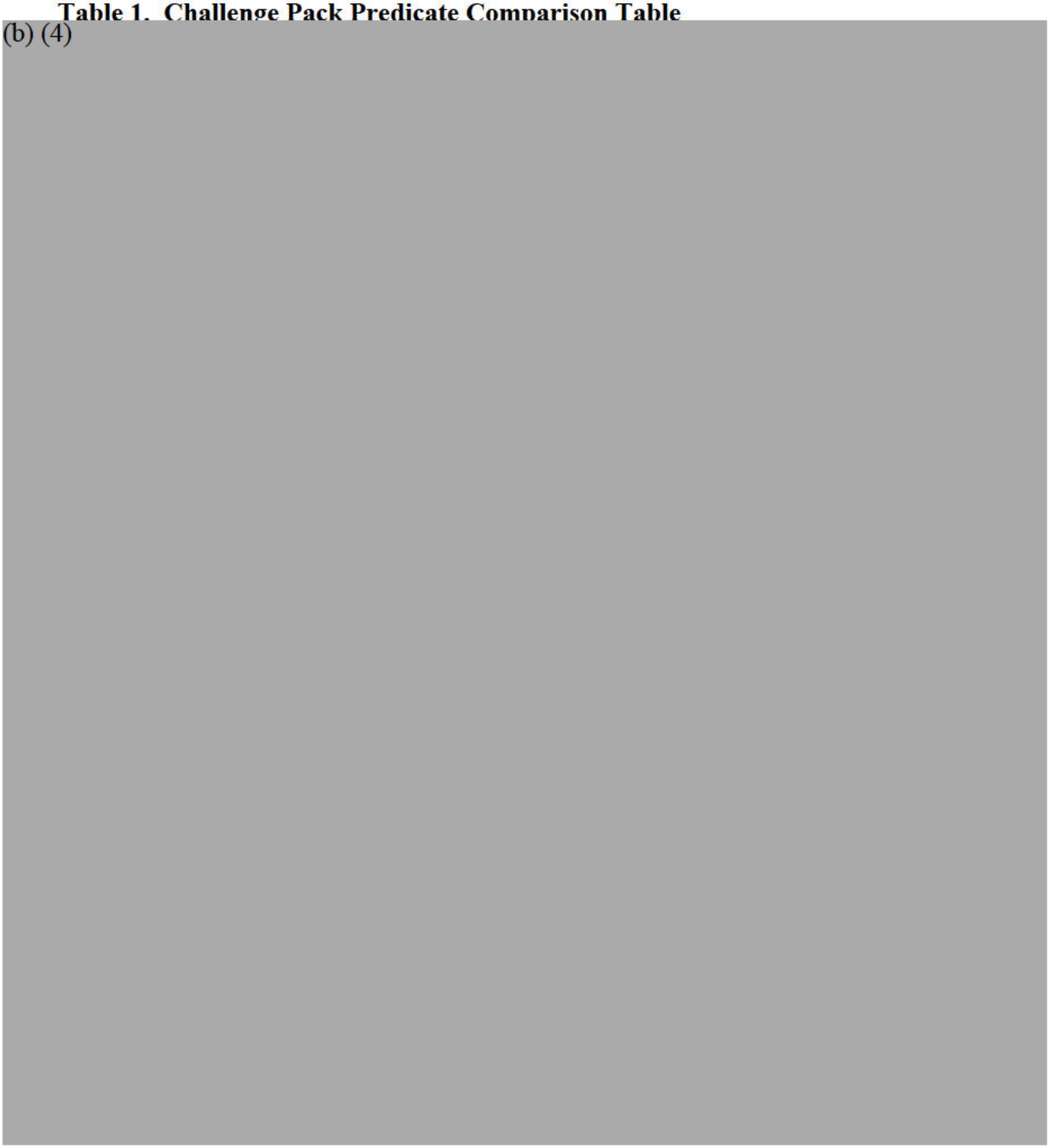
(b) (4)

Design

SteriGage™ chemical integrators contain a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked ACCEPT and REJECT; the extent of migration depends on steam, time, and temperature. SteriGage™ has been cleared under K101249.

Table 1. Challenge Pack Predicate Comparison Table

(b) (4)



The Attest™ 1496V Super Rapid Readout Steam and 41482V Super Rapid 5 Steam-Plus Challenge Packs are substantially equivalent to the predicate test pack device 3M Attest™ Steam-Plus Pack (b) (4) cleared under K925496, in terms of intended use and technological characteristics.

The differences between the Attest™ Super Rapid Challenge Packs and the predicate device are:

1. The substitution of the biological indicator with the 1492V Super Rapid Readout Biological Indicator.
2. Alignment of the Indications for Use with the steam sterilization cycles claimed by the 1492V Super Rapid Readout Biological Indicator.

The performance testing summaries provided demonstrate the products meet the requirements of their intended use for the indications claimed. There are no new questions of safety or effectiveness.

10.5 Concise Summary of Performance Testing

Three lots of the 3M Attest™ 1496V and 41482V Challenge Packs were manufactured and tested to the applicable requirements of FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions,* October 4, 2007. The resistance of the pack was compared to the Towel Pack biological process challenge device as described in ANSI/AAMI ST-79: 2010, A1:2010 and A2:2011, *Comprehensive guide to steam sterilization & sterility assurance in health care facilities.*

(b) (4)

11.0 Device Description and Drawings

The 1496V and 41482V Challenge Packs are similar in design to the predicate 3M Attest™ Steam-Plus Pack cleared under K925496. Both contain a laminated sheet, die cut paper sheets, and index cards that form the bulk of the challenge pack. (b) (4)

(b) (4)

Table 2 shows the composition of the Super Rapid Challenge Packs as compared to the predicate device Attest™ Steam-Plus Pack cleared under K925496.

(b) (4)

Diagrams showing the composition of the 3M Attest™ 1496V and 41482V Challenge Packs are provided on the following page. (b) (4)

(b) (4)

(b) (4)

(b) (4)

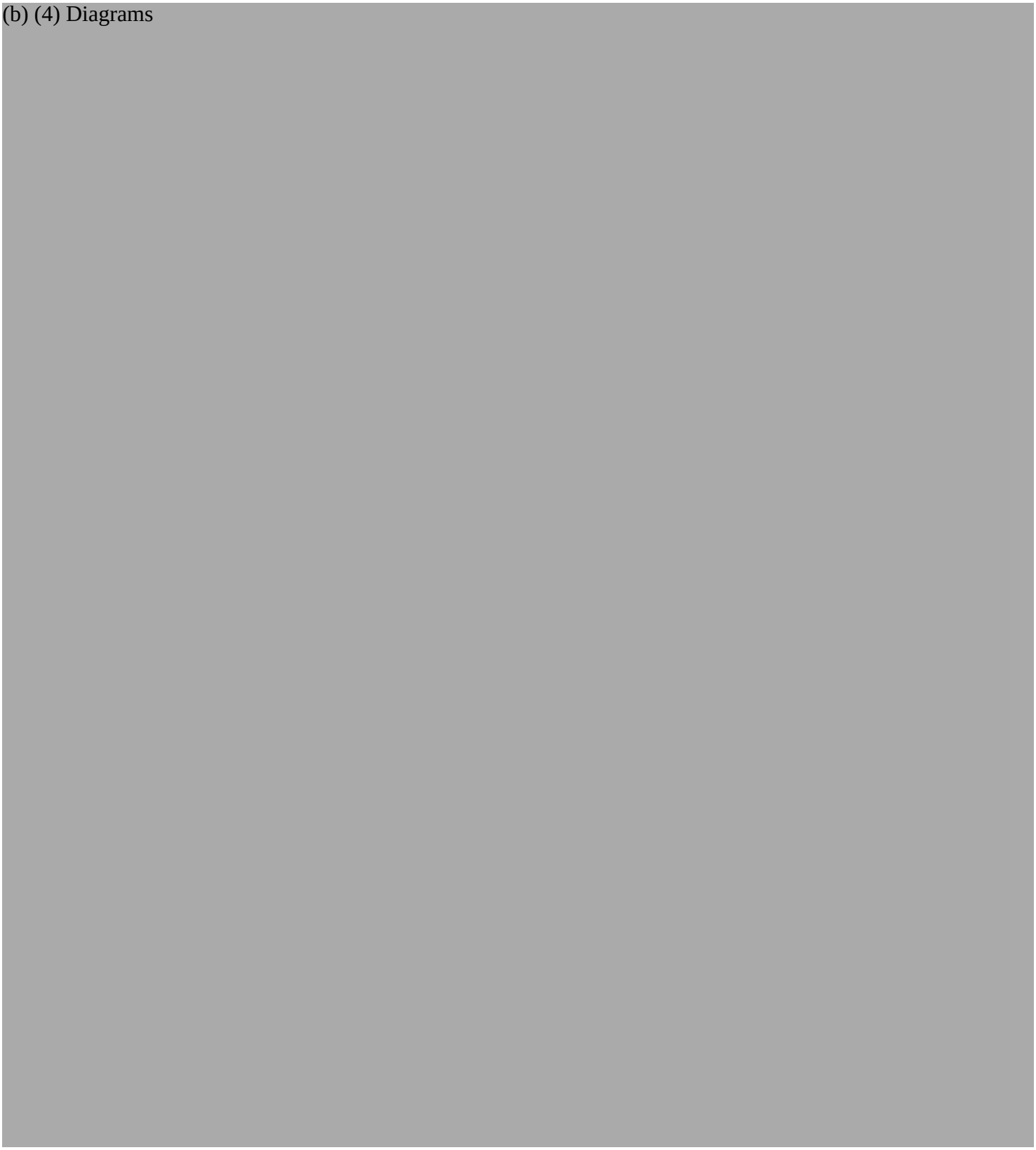
(b) (4) process indicator dot on the Challenge Pack label (1496V and 41482V) turn from yellow to brown or darker when processed in 270°F and 275°F prevacuum cycles. The process indicator is used by the customer to verify that the Challenge Pack was exposed to steam. It does not verify that the cycle was complete or that sterilization conditions were met.

The process indicator ink chemistry is shown below (b) (4)

(b) (4)

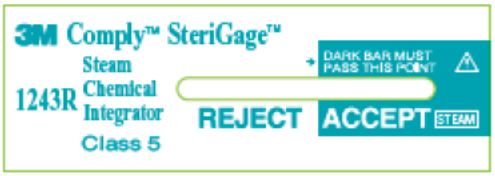
(b) (4)

(b) (4) Diagrams

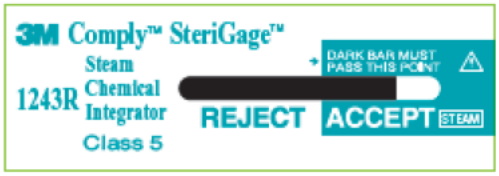


Design of the SteriGage™ Chemical Integrator (in 41482V only)

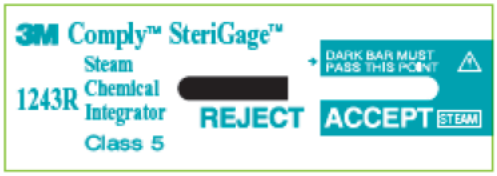
3M SteriGage™ Steam Chemical Integrators are single-use chemical indicators consisting of a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. Upon exposure to steam, the chemical pellet melts and migrates as a dark color along the paper wick as a moving front. The migration is visible through a window marked ACCEPT or REJECT; the extent of migration depends on steam, time, and temperature.



Unexposed



After a passing cycle



After a failing cycle

Design of the Attest™ 1492V Super Rapid BI (SRBI)

The 1492V Super Rapid BI (SRBI) has been submitted as a separate 510(k), K121484. The basic design is similar to many current self-contained biological indicators in the marketplace. The 1492V SRBI contains a spore carrier coated with (b) (4) (b) (4) of the SRBI serve to secure the spore carrier and growth media ampoule within the tube. The sterilant enters the BI through entry ports on the cap. During activation, the cap is depressed fully onto the sleeve which crushes the growth media ampoule, allowing the liquid growth media to flow down to the spores. After activation, the cap (b) (4) closes the sterilant entry ports and contains the liquid growth media within the SRBI. (b) (4) (b) (4)

The chemical process indicator on the cap contains a steam-sensitive ink printed onto a paper substrate (b) (4) (b) (4) ne Process Indicator on top of the cap and undergoes a color change from

pink to light brown upon exposure to steam, allowing the user to identify processed from unprocessed biological indicators.

(b) (4)

12.0 Performance Testing

12.1 Materials

1496V and 41482V Challenge Packs

Three lots of the 1496V Challenge Packs were manufactured using 3 lots of 1492V Super Rapid Biological Indicators (SRBIs). Three lots of 41482V Challenge Packs were manufactured with 3 lots of 1492V SRBIs and 3 lots of SteriGage™ chemical integrators. **Table 3** details the specific SRBI and SteriGage™ lots used in each 1496V and 41482V Challenge Pack lot.

Indicators Used in each 1496V and 41482V Challenge Pack Lots

(b) (4)

AAMI Towel Packs

AAMI Towel Packs were constructed per ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 with towels of approximately 16 inches by 26 inches folded lengthwise into thirds and then folded widthwise in the middle. Towels were placed one on top of another, with folds opposite each other, to form a stack that was approximately 9 inches wide X 9 inches long X 6 inches high (the pack was taped in a manner that resulted in the approximately 6 inch height)

(b) (4)

(b) (4)

12.2 Equipment

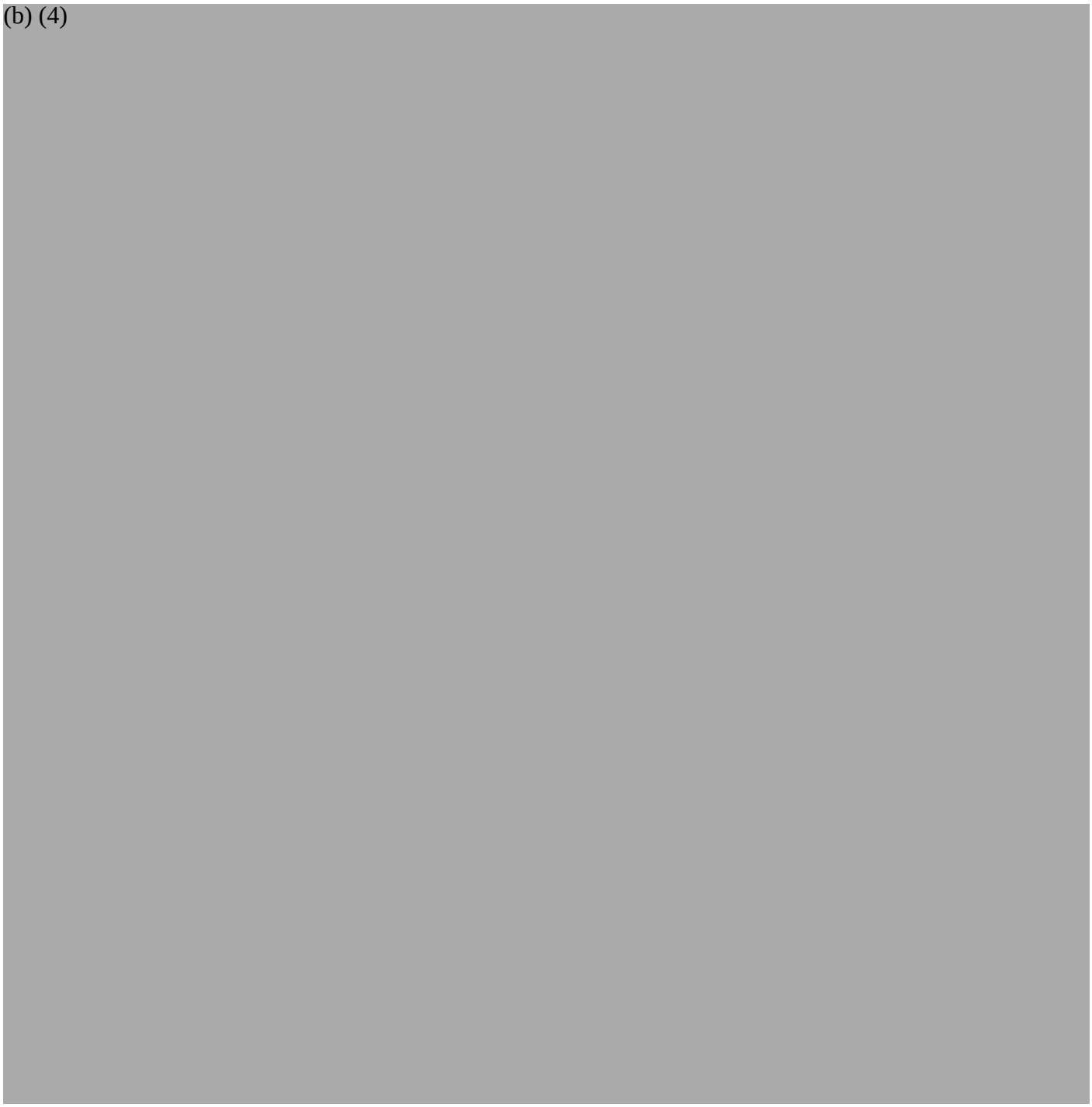
(b) (4)

(b) (4)

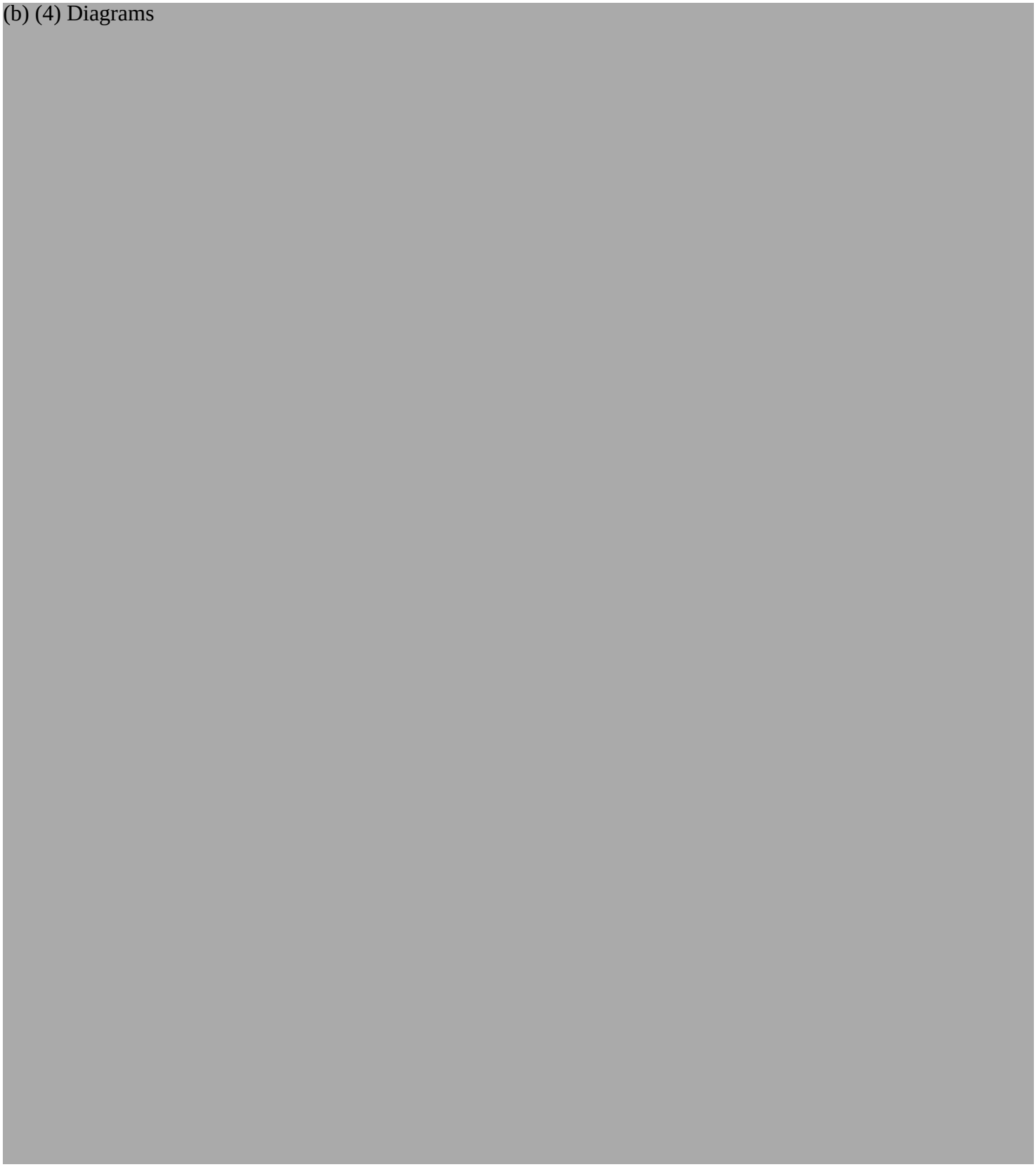
12.3 Performance Testing Protocols and Results

(b) (4)

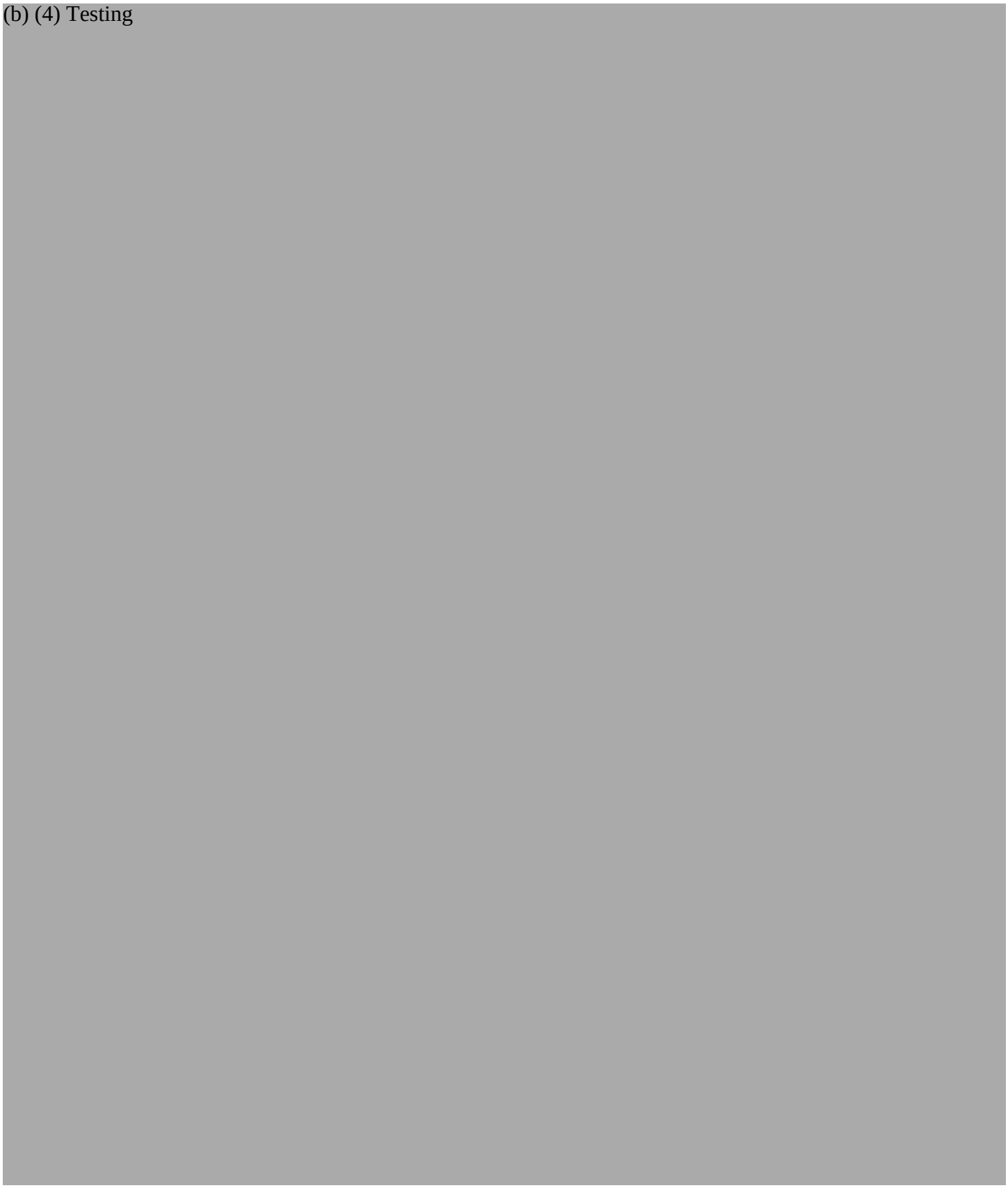
(b) (4)



(b) (4) Diagrams

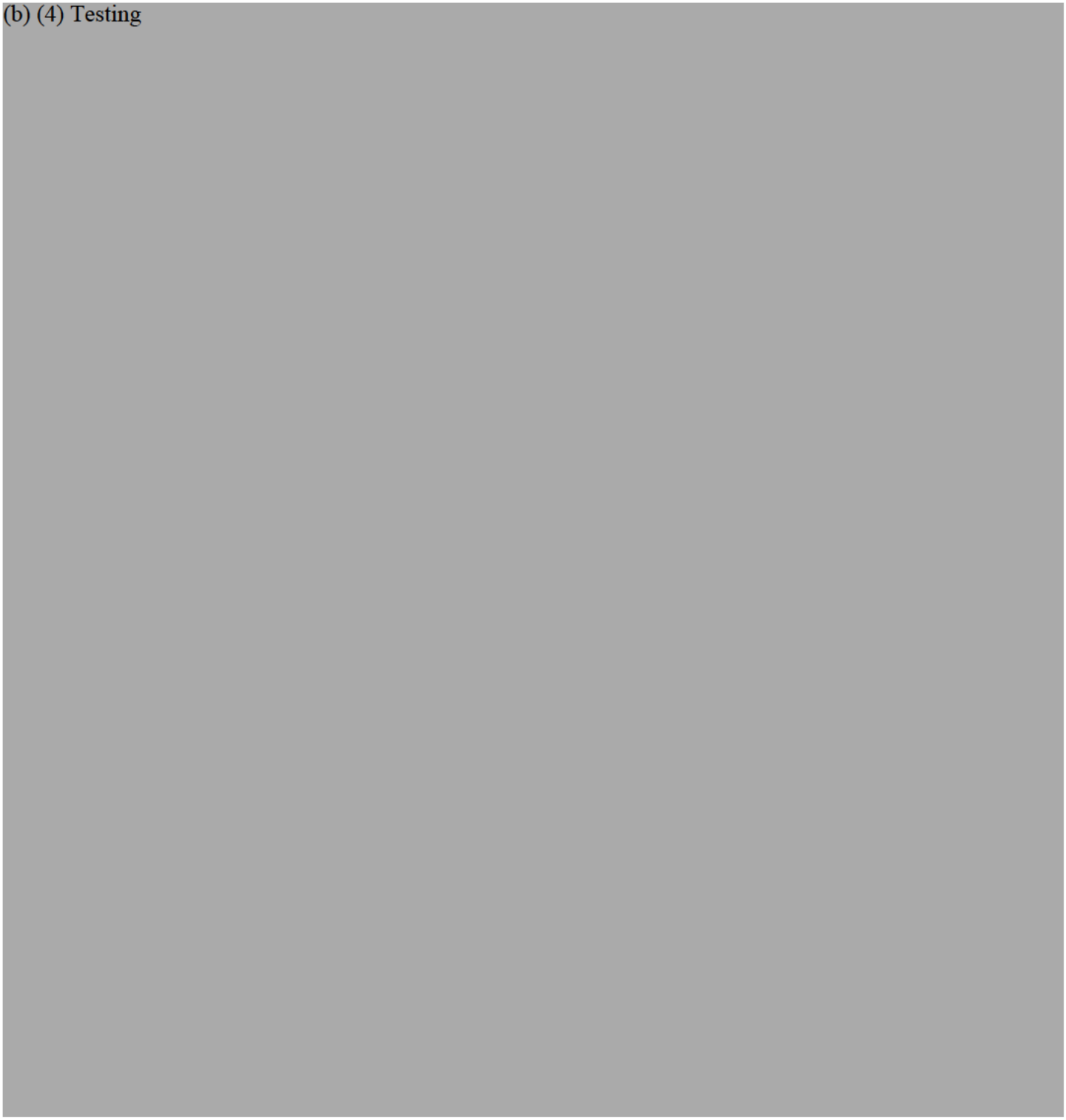


(b) (4) Testing



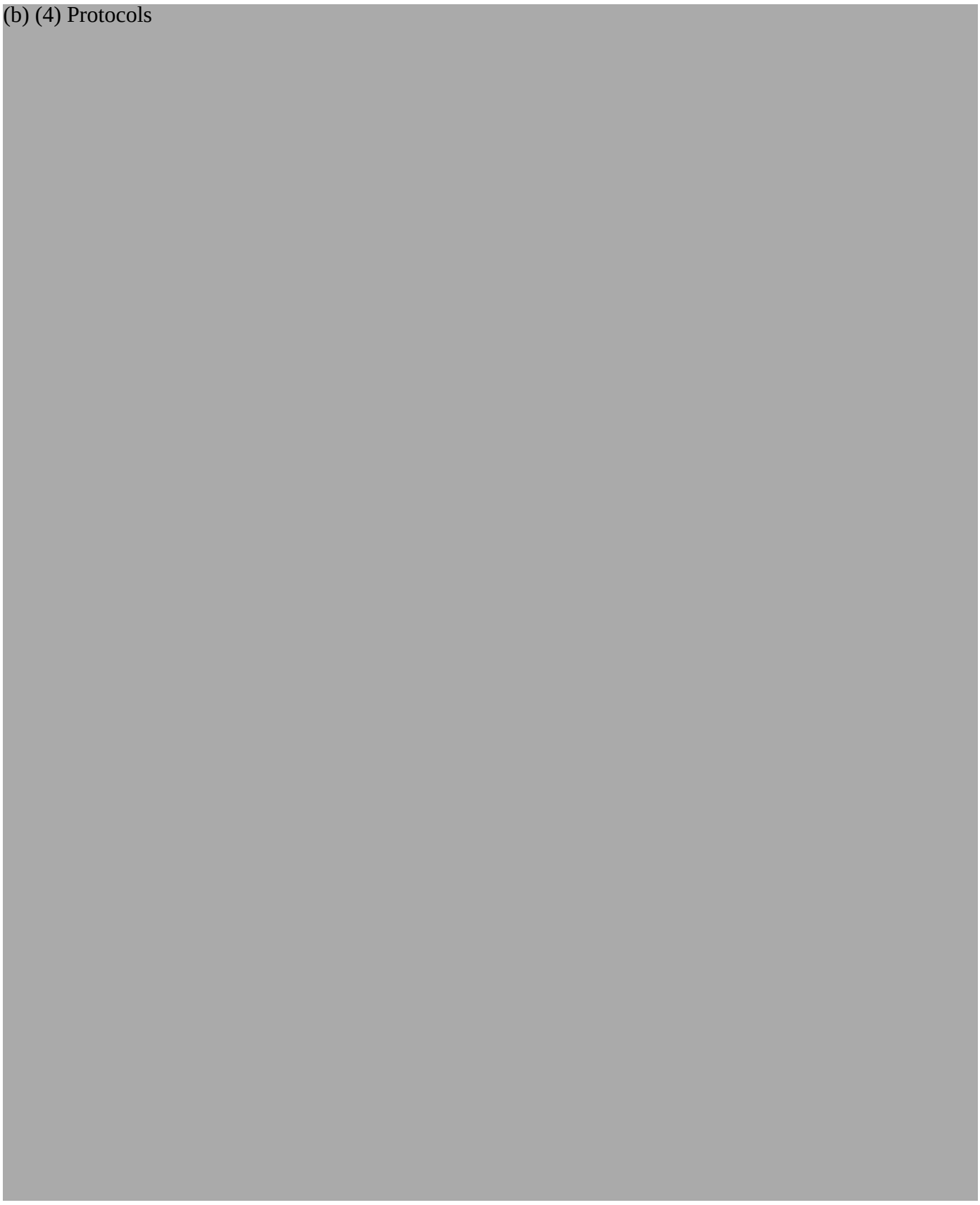
All process indicators on the Challenge Pack labels were yellow prior to exposure and brown or darker after exposure. All process indicators on the BI caps are pink prior to exposure and light brown or darker after exposure.

(b) (4) Testing

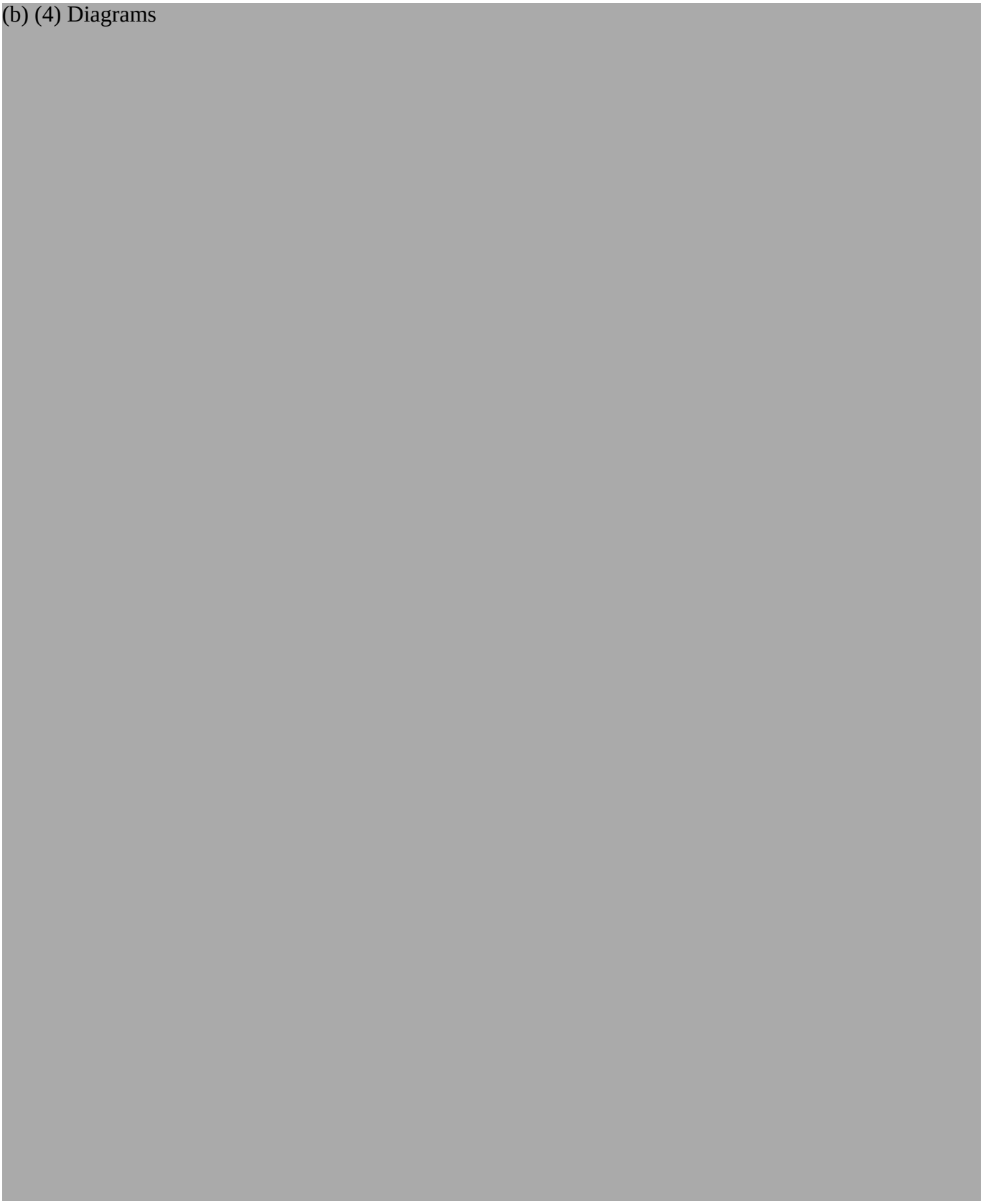


(b) (4) Testing

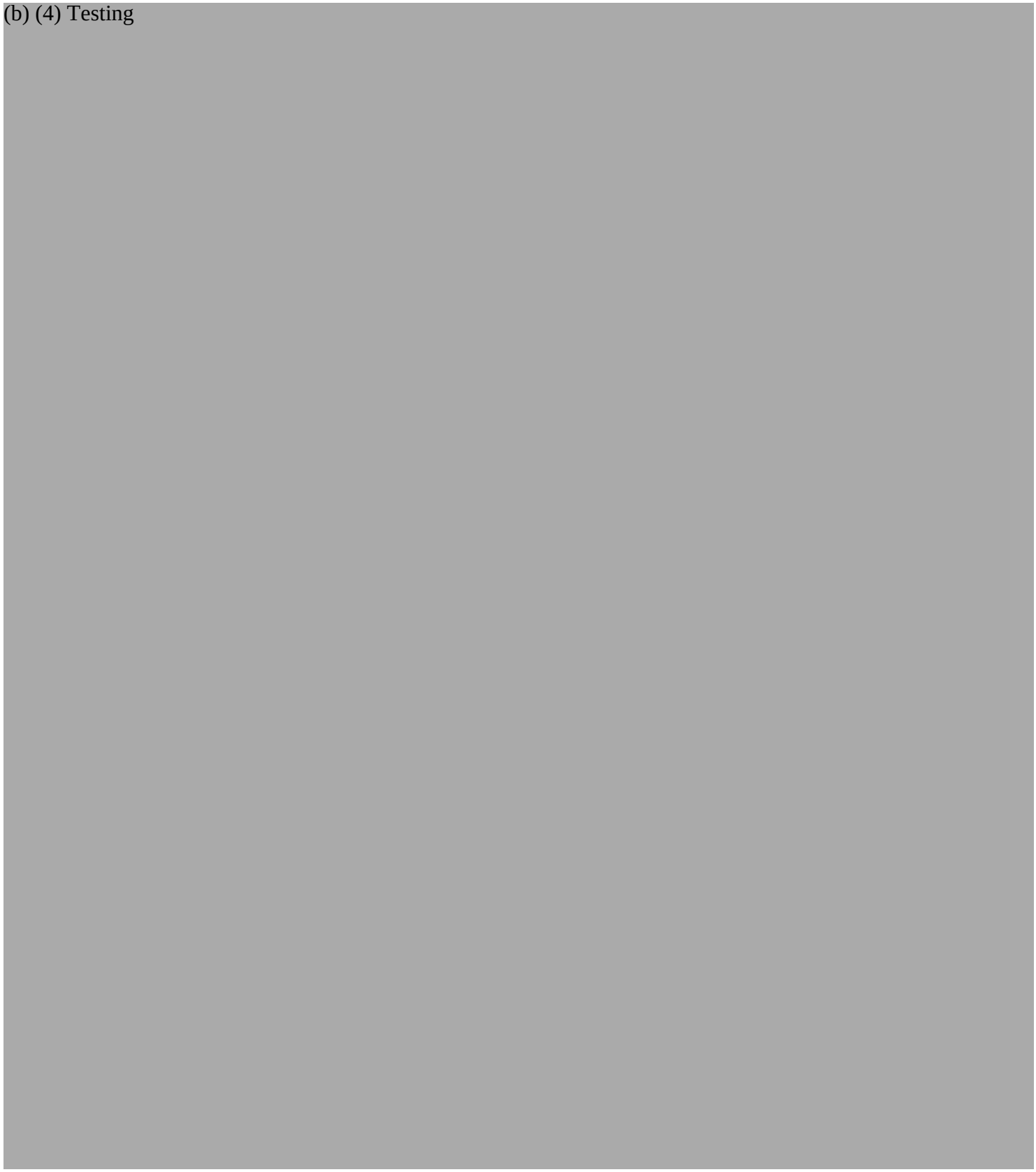
(b) (4) Protocols



(b) (4) Diagrams

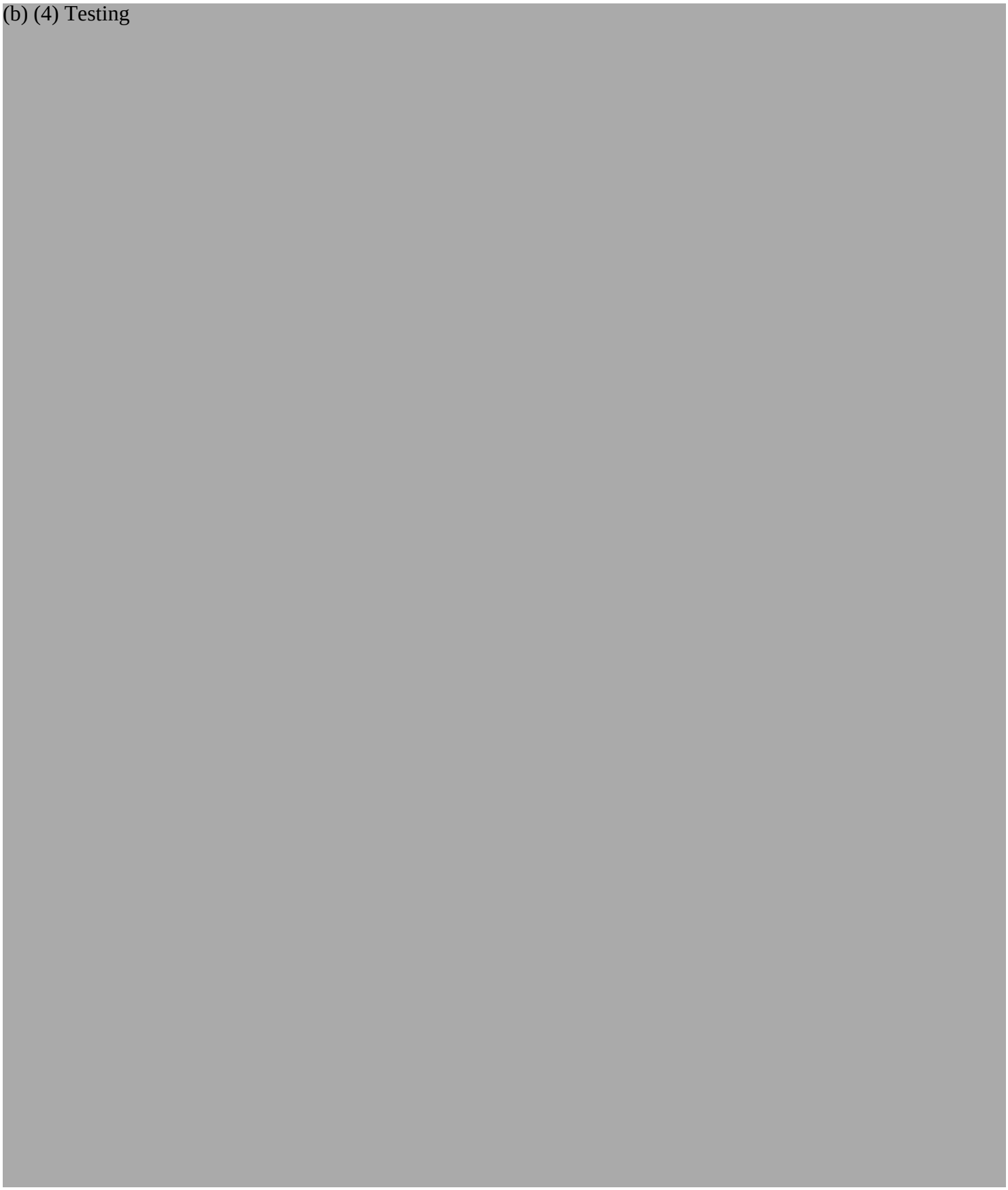


(b) (4) Testing



(b) (4) Testing

(b) (4) Testing



13.0 Proposed Labeling

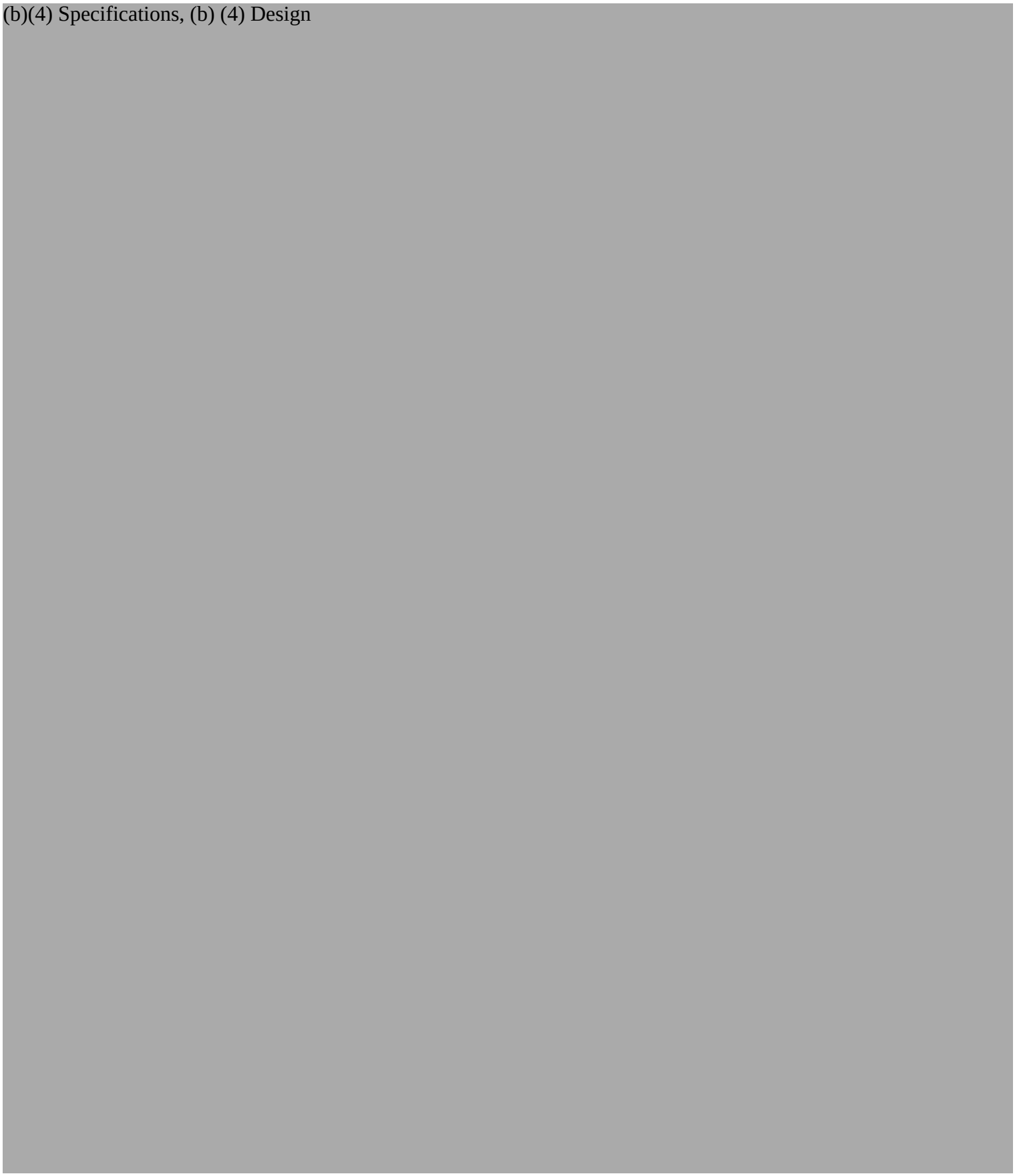
13.1 Labeling for Attest™ 1496V Super Rapid Readout Steam Challenge Pack

13.1.1 Instructions for Use for Attest™ 1496V Super Rapid Readout Steam Challenge Pack

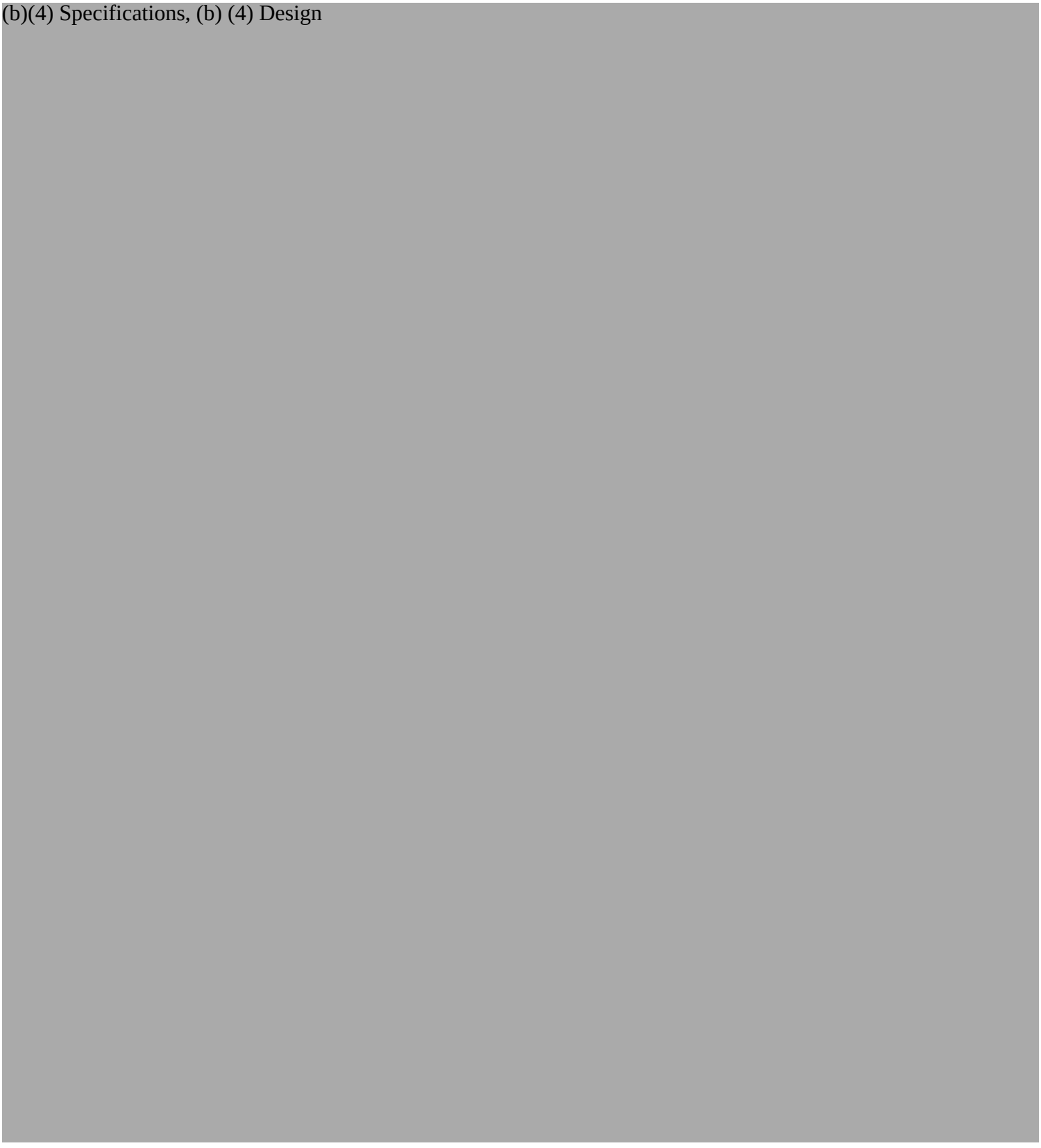
3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V

(b)(4) Specifications, (b) (4) Design

(b)(4) Specifications, (b) (4) Design



(b)(4) Specifications, (b) (4) Design



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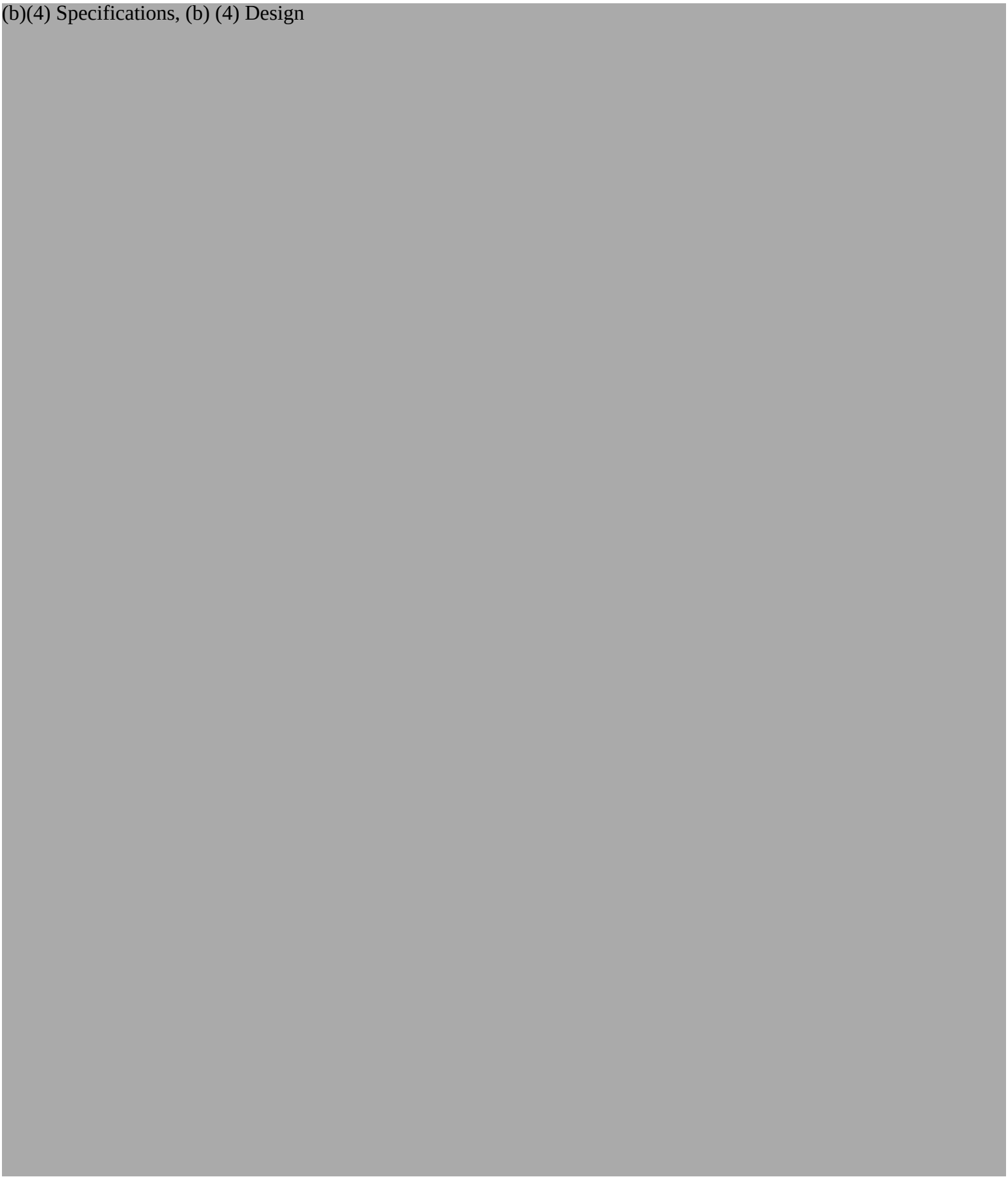
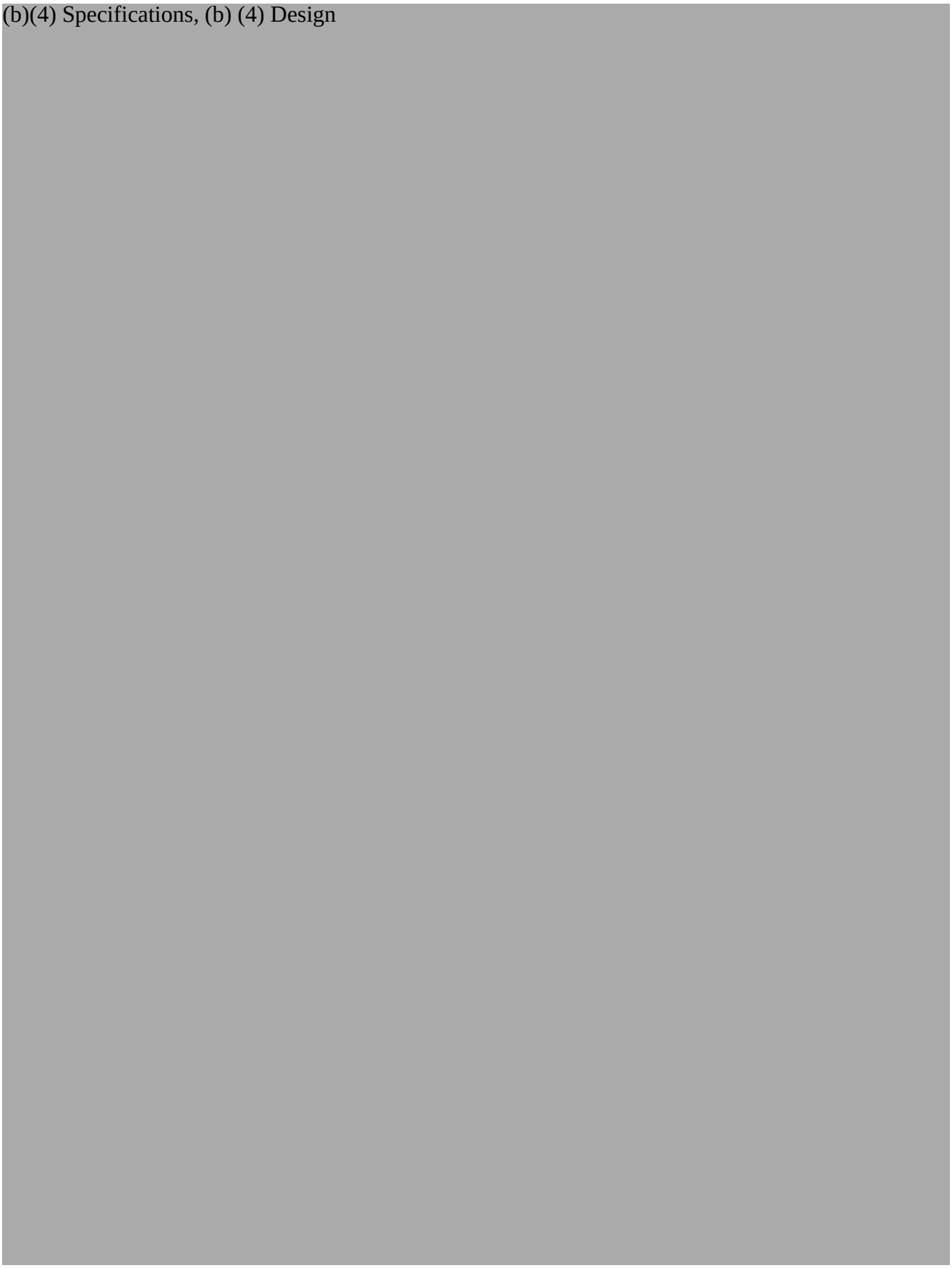
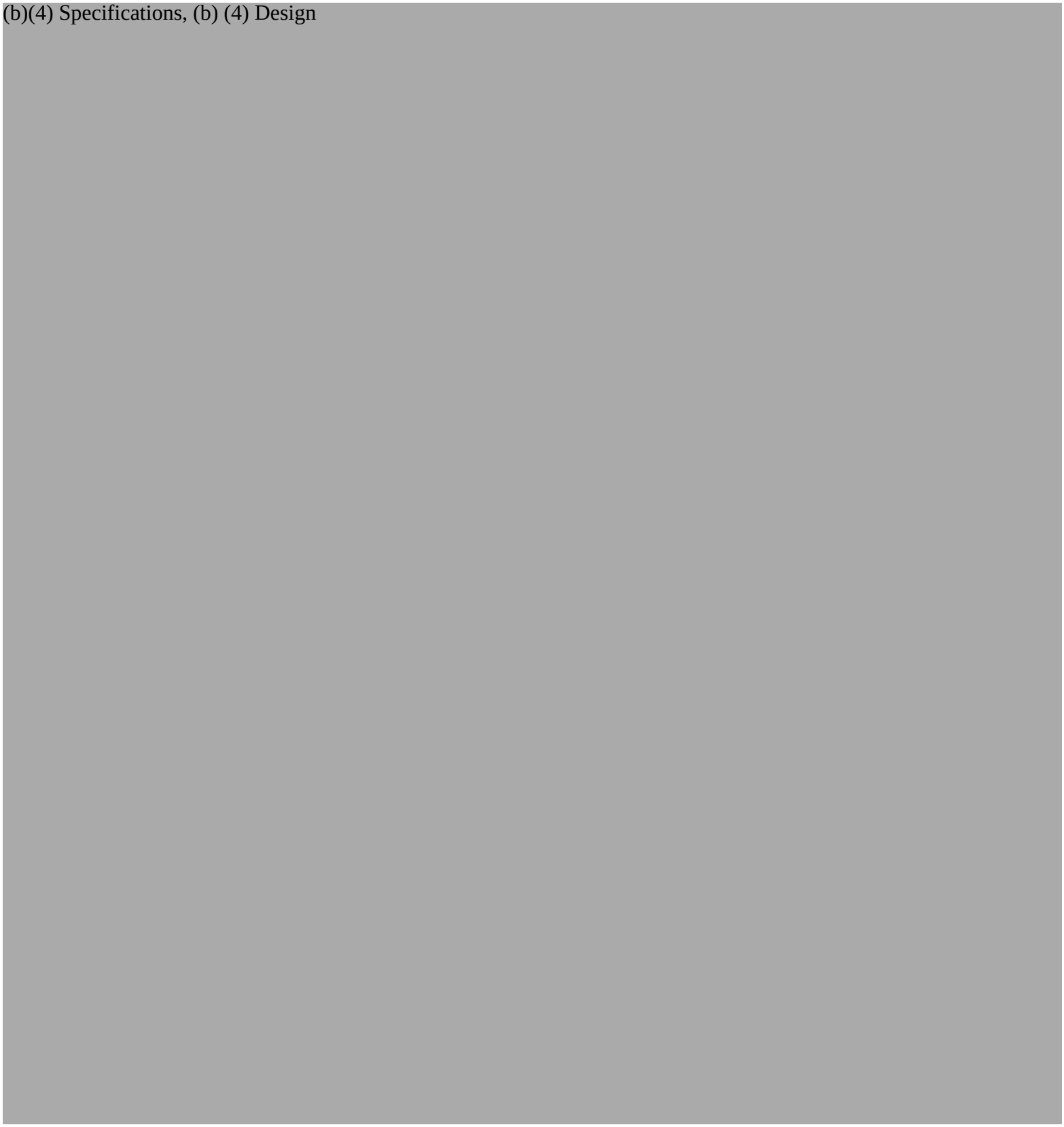


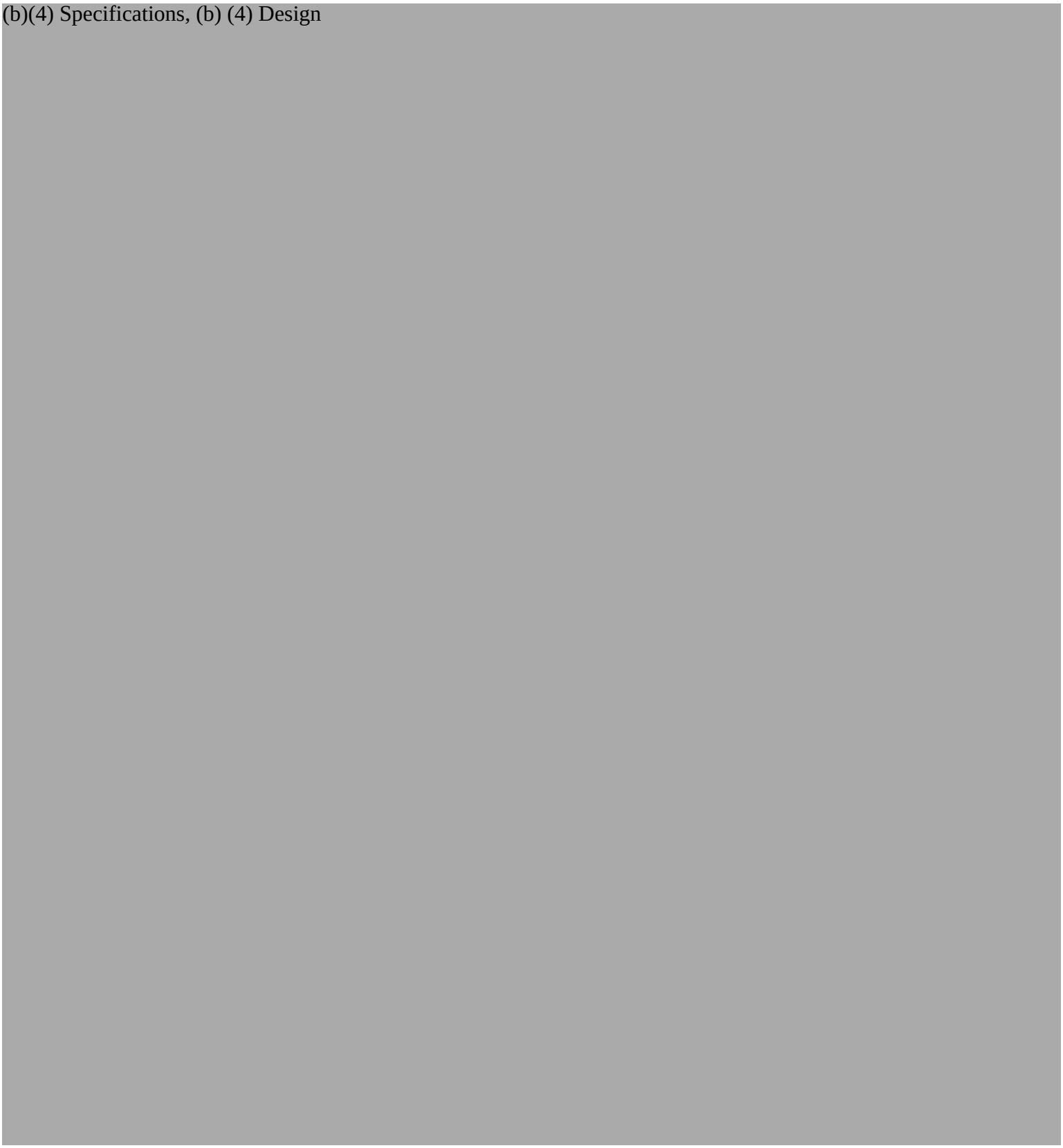
(b)(4) Specifications, (b) (4) Design



(b)(4) Specifications, (b) (4) Design



(b)(4) Specifications, (b) (4) Design



13.1.2 Label on Attest™ 1496V Super Rapid Readout Steam Challenge Pack

Below is a representation of the finished product (not to scale), showing the label on each 1496V Challenge Pack (b) (4)

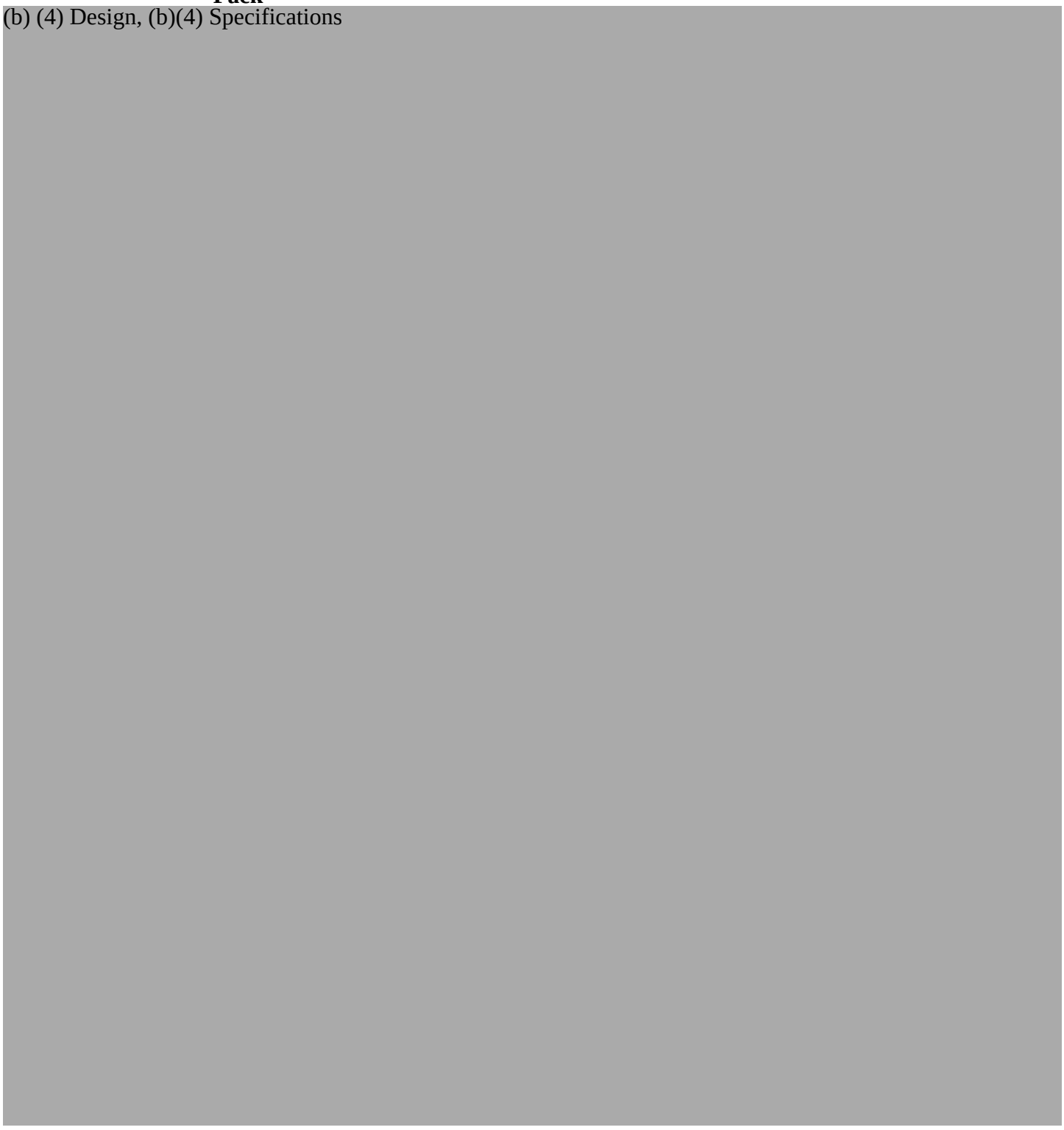
(b) (4)

(b) (4)

13.2 Labeling for Attest™ 41482V Rapid 5 Steam-Plus Challenge Pack

13.2.1 Instructions for Use for Attest™ 41482V Rapid 5 Steam-Plus Challenge Pack

(b) (4) Design, (b)(4) Specifications



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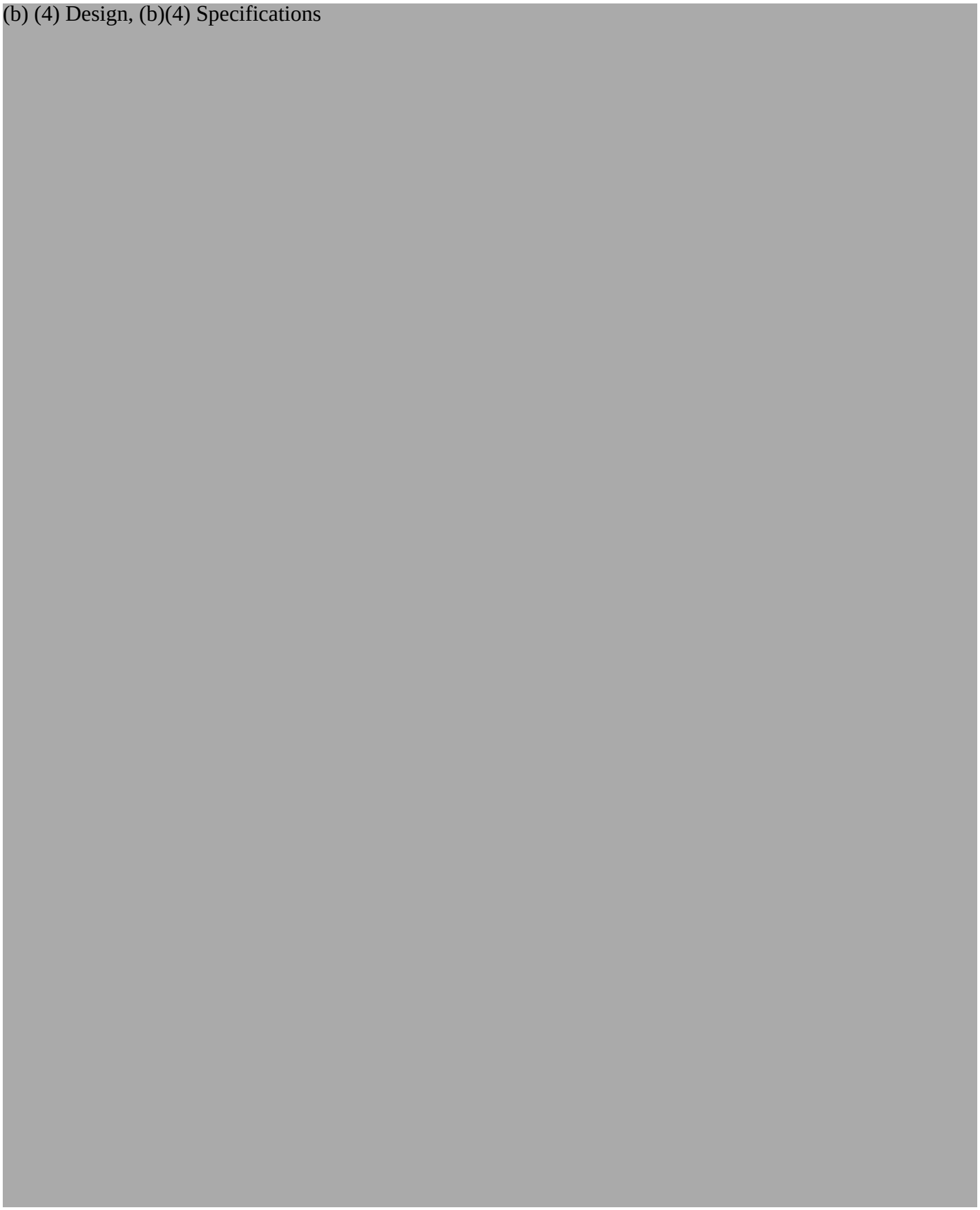

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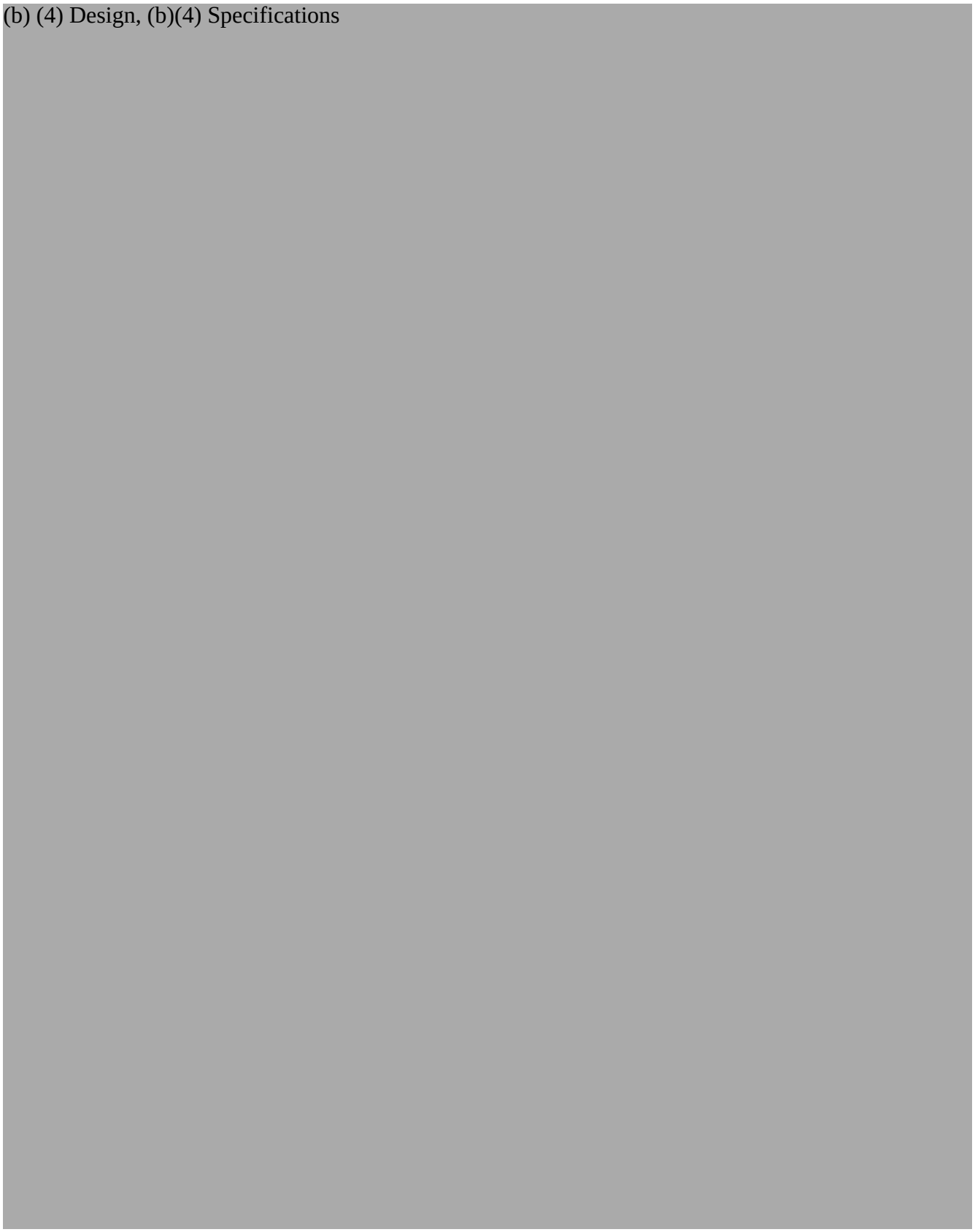

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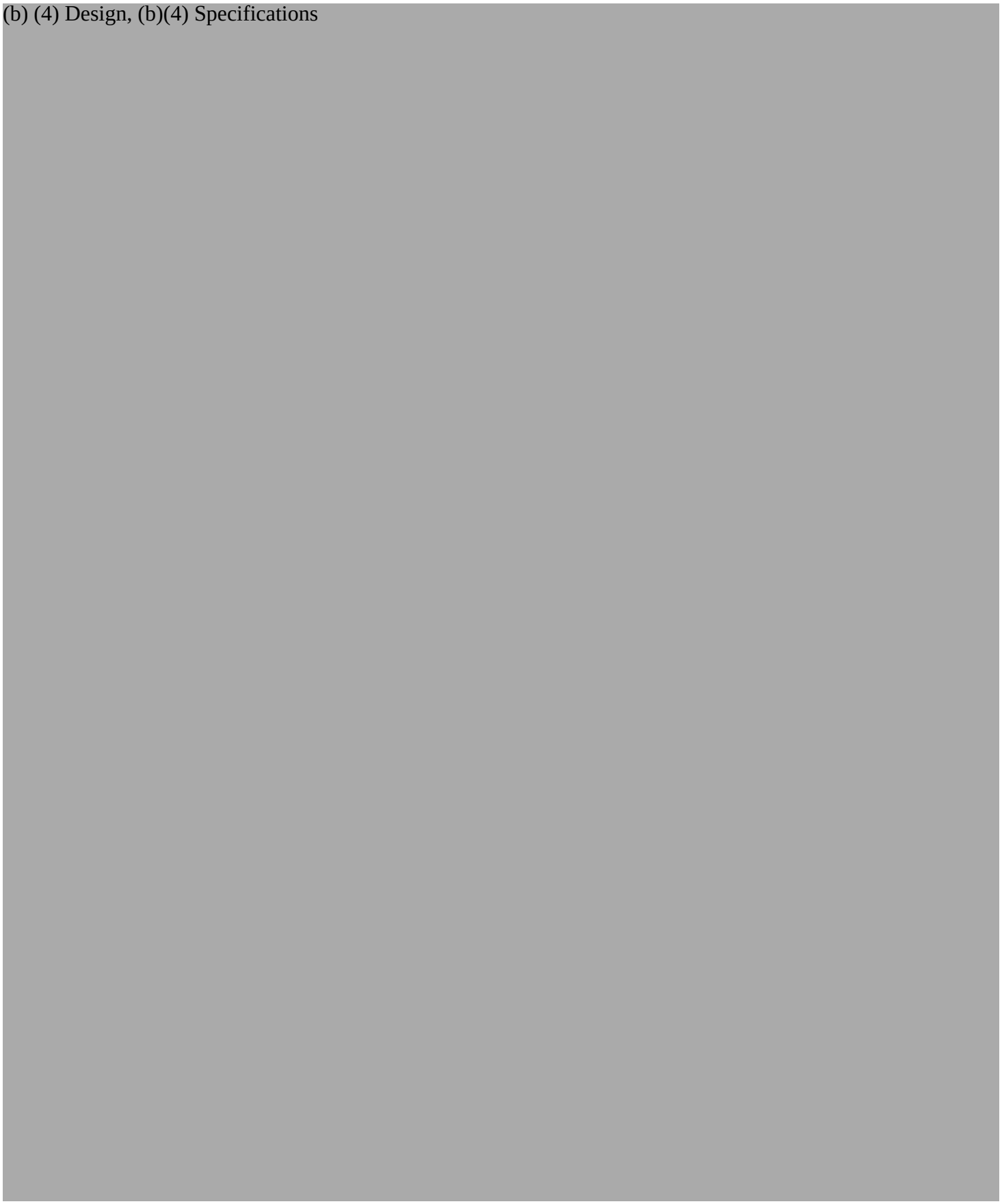
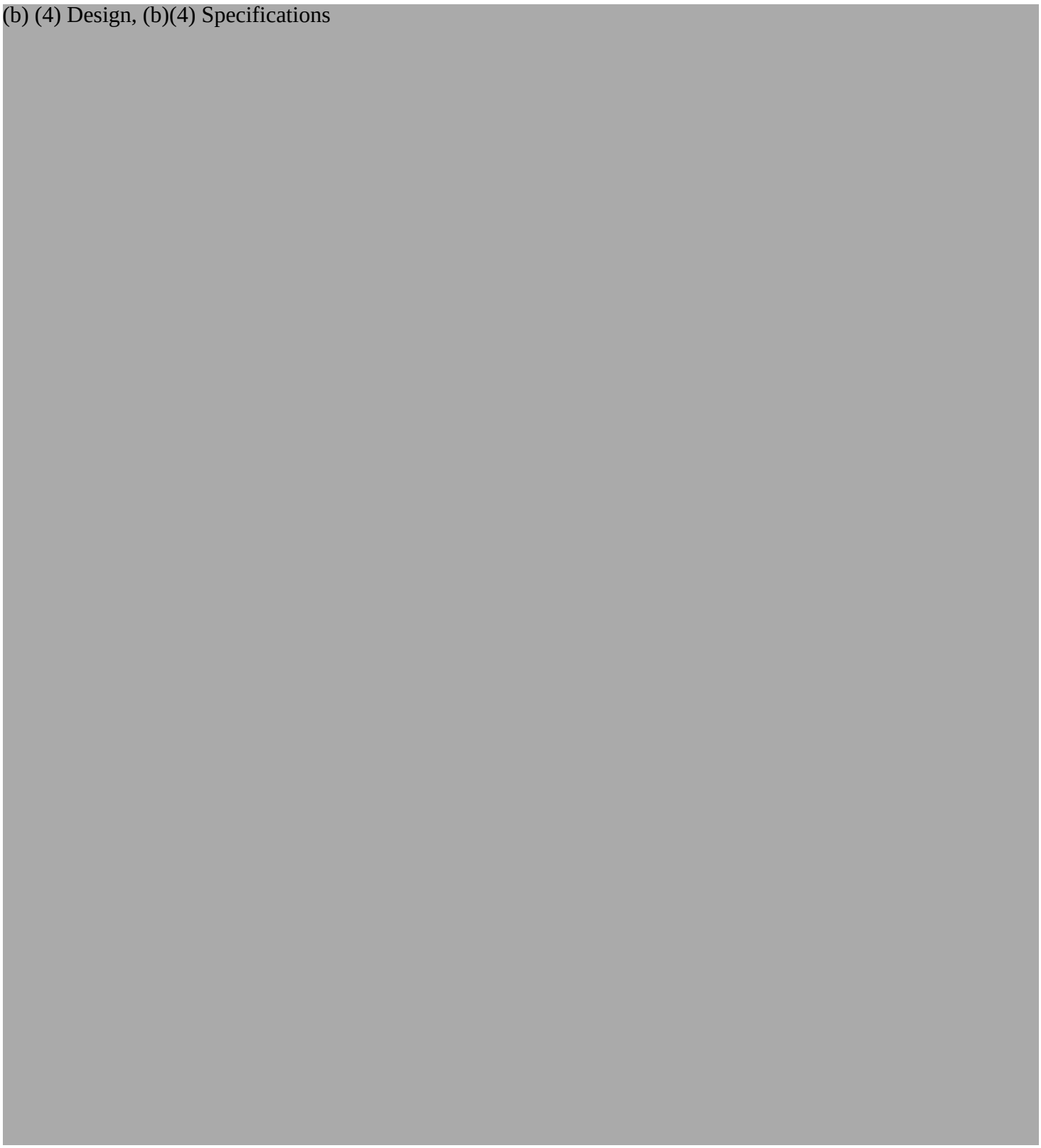
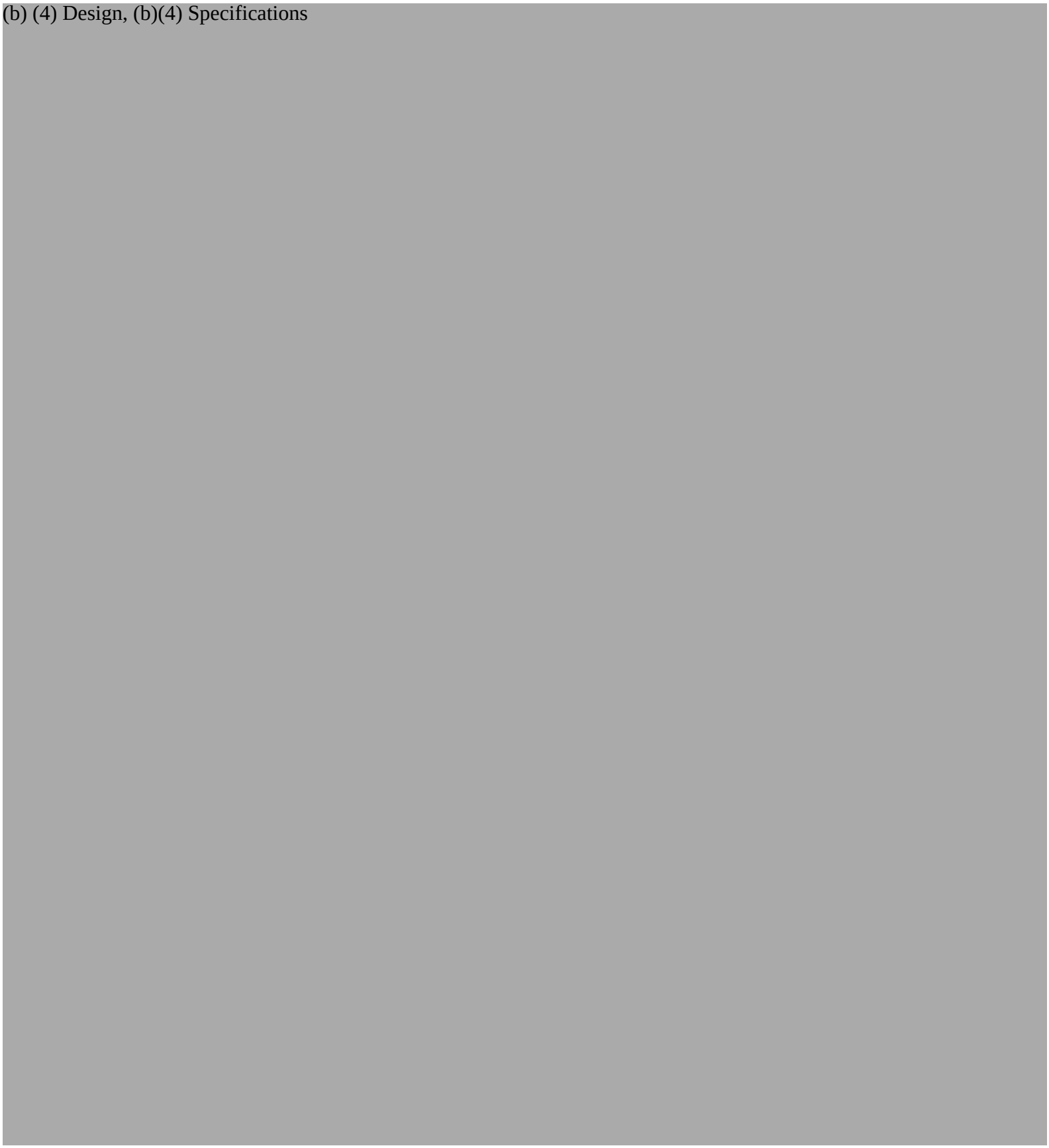


(b) (4) Design, (b)(4) Specifications



(b) (4) Design, (b)(4) Specifications



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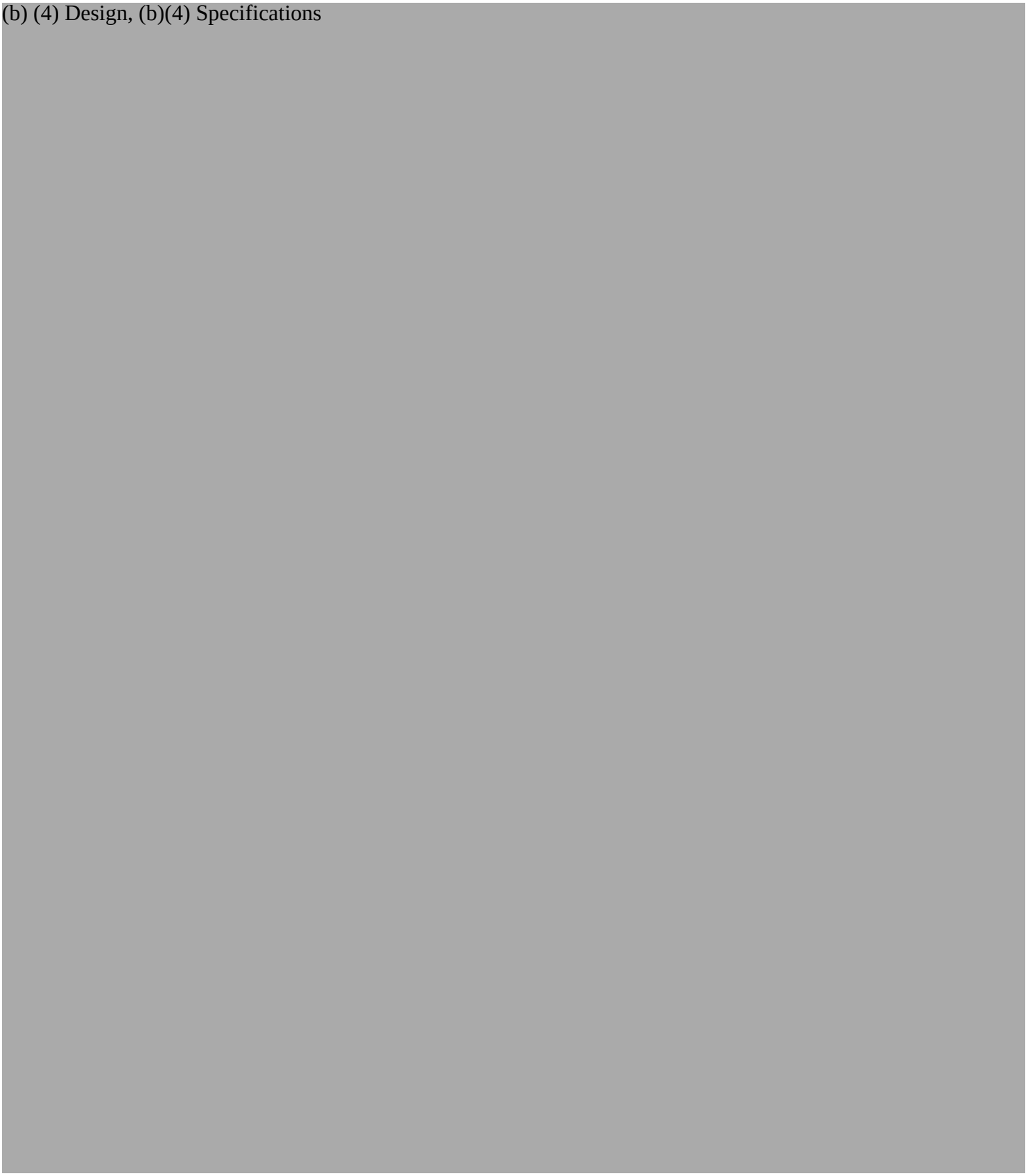


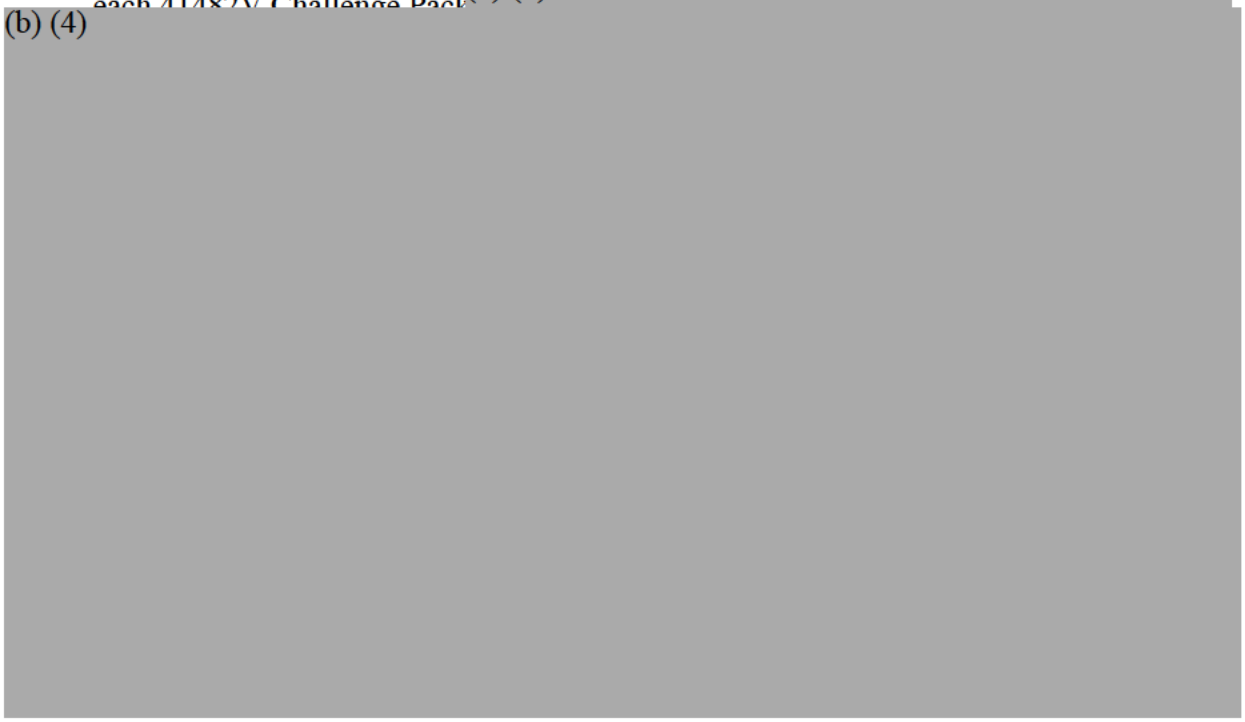
(b) (4)

13.2.2 Label on Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack

Below is a representation of the finished product (not to scale), showing the label on each 41482V Challenge Pack.

(b) (4)

(b) (4)



13.3 Template for Certificate of Analysis of Attest™ 1492V Super Rapid Readout Biological Indicator

Below is the certificate of analysis for the 1492V BI that will be included in each lot of 1496V and 41482V Challenge Pack.

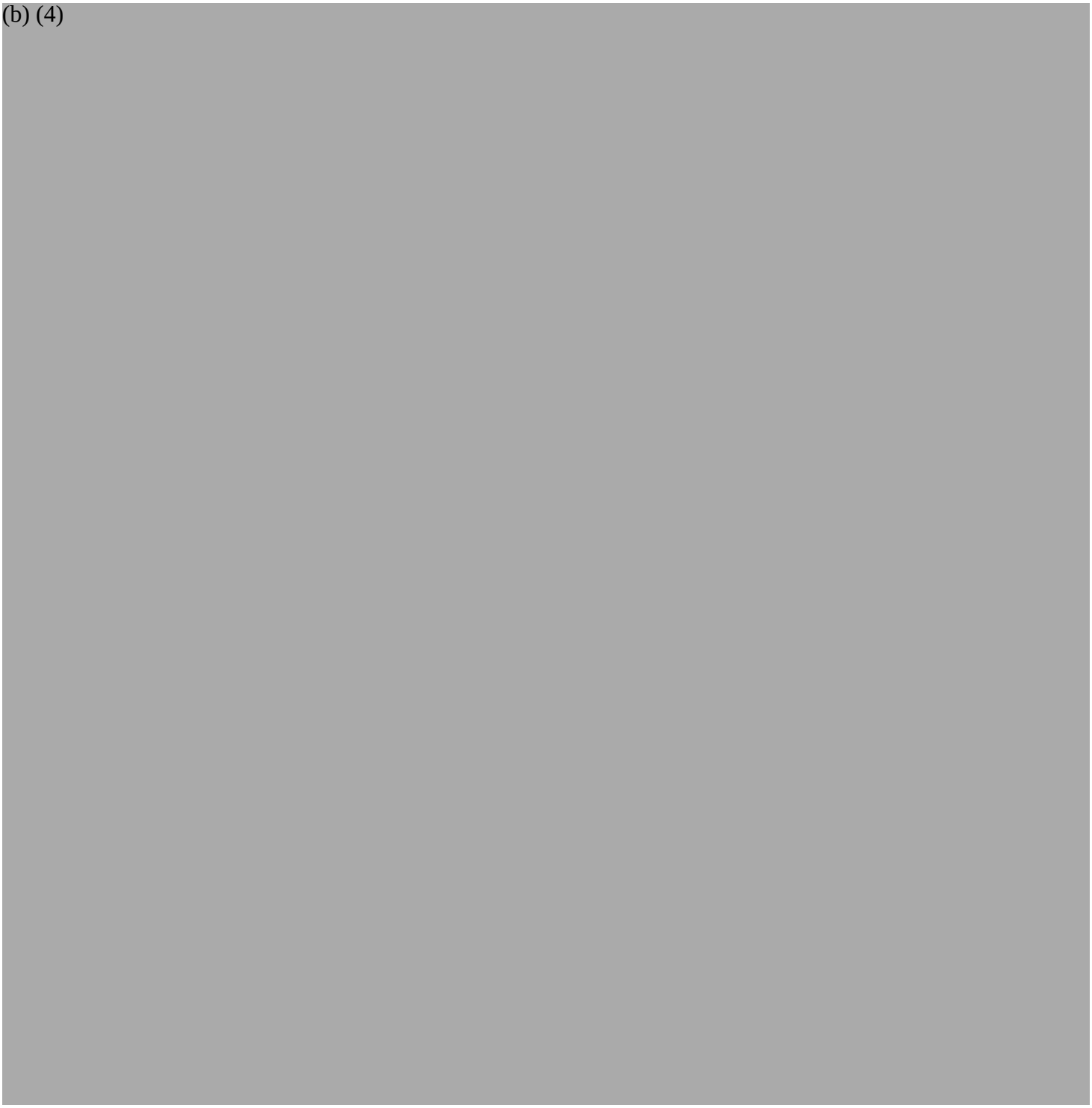
(b) (4)

(b) (4)

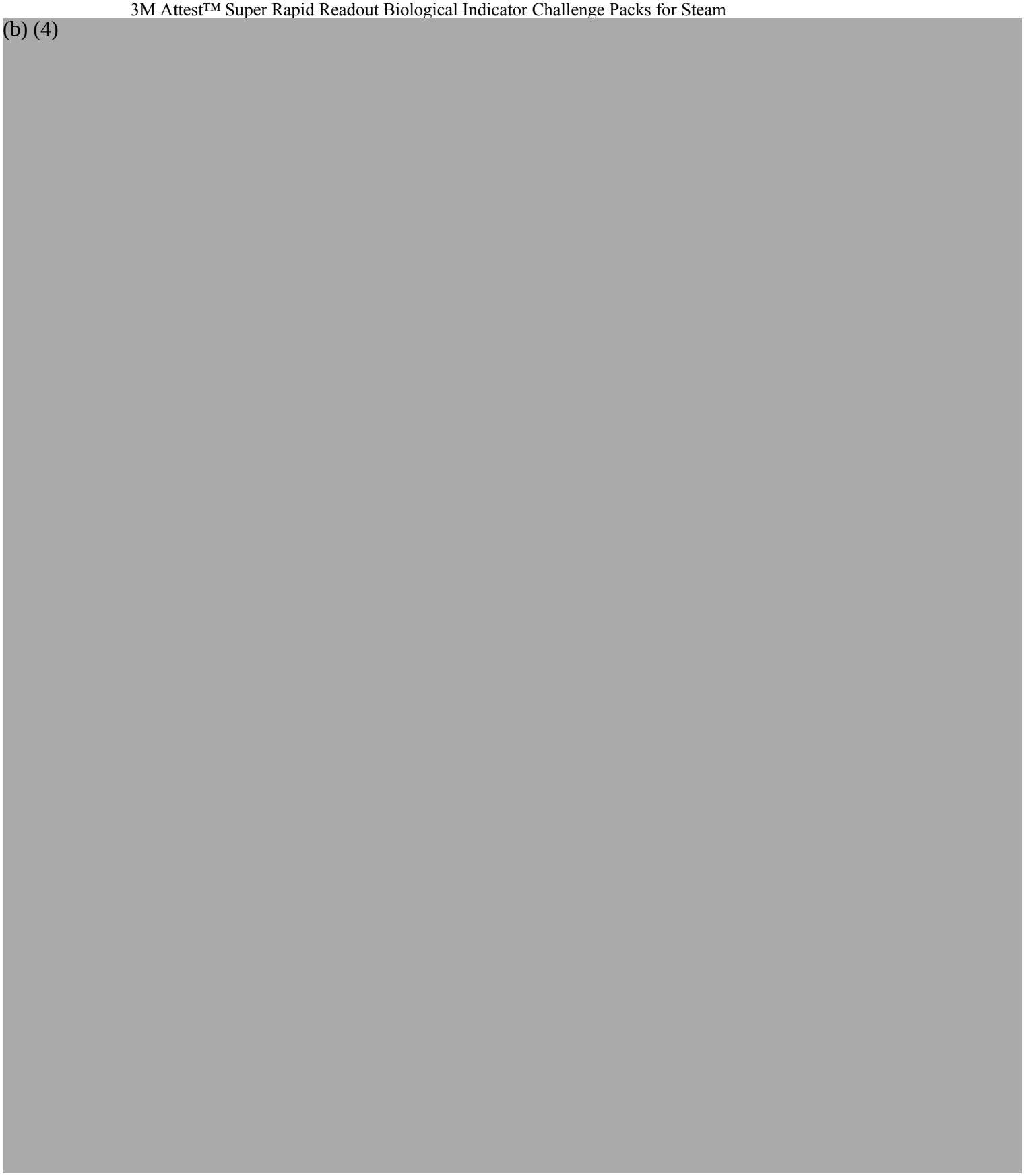
13.4 Labeling for the Predicate Device

13.4.1 Predicate Instructions for Use

(b) (4)



(b) (4)



(b) (4)

(b) (4)

(b) (4)

(b) (4) Biocompatibility

(b) (4) Biocompatibility

16.0 Substantial Equivalence Discussion

16.1 Intended Use and Indications for Use

The 3M Attest™ 1496V and 41482V Super Rapid Challenge Pack (b) (4) the Attest™ Steam-Plus Pac (b) (4) cleared under K925496. Bo biological indicator process challenge devices that are intended to be used in healthcare facilities to accompany products being sterilized and to monitor adequacy of sterilization process. This is accomplished through the biological challenge of bacterial spores. Subsequent growth or failure of the spores upon incubation of the biological indicator indicates the adequacy of the sterilization process.

The Attest™ Super Rapid Challenge Packs have been further optimized from the design of the predicate device to provide a challenge to 135°C/275°F prevacuum cycles, as reflected in the new Indications for Use for the Super Rapid Challenge Packs. The differences in Indications for Use do not alter the fundamental Intended Use of these products as load monitors. The verification data presented within this submission substantiates this new claim and do not raise new questions of safety and effectiveness.

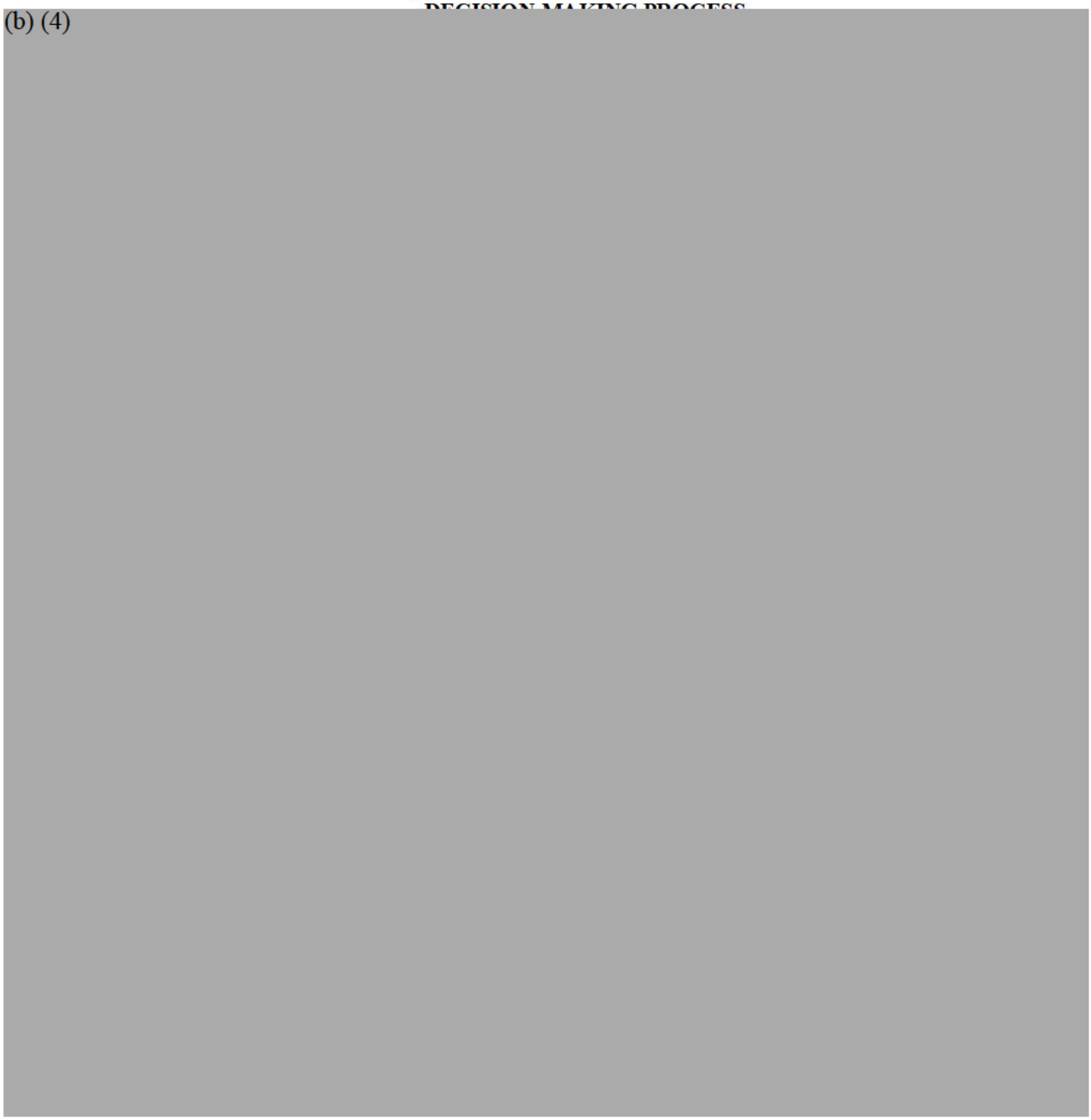
16.2 Performance Characteristics

(b) (4)

(b) (4)

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

(b) (4)



* 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 maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature

Appendix A: Performance Characteristics of the Attest™ 1492V Super Rapid Readout Biological Indicator

As both the Attest™ 1496V and 41482V Challenge Packs contain a biological indicator, the Challenge Packs fall under FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions*, October 4, 2007. The Attest™ 1492V Super Rapid Readout Biological Indicator contained within the Challenge Packs meet the requirements under this guidance. The biological indicator also meets performance standards ANSI/AAMI/ISO 11138-1:2006/(R)2010, ANSI/AAMI/ISO 11138-3:2006/(R)2010, and USP 34.

A 510(k) premarket notification has been submitted to the FDA for Attest™ 1492V Super Rapid Readout Biological Indicator (K121484). A summary of the performance characteristics of the Attest™ 1492V Super Rapid Readout Biological Indicators that has been provided as part of the 1492V submission is provided on the following page.

(b) (4) Testing

* * * COMMUNICATION RESULT REPORT (MAR. 18. 2013 9:30AM) * * *

FAX HEADER 1:
FAX HEADER 2:

ISMITTED/STORED : MAR. 18. 2013 9:26AM
RESULT PAGE
(b) (4)

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 15, 2013

(b) (4), (b) (6)
Regulatory Affairs Manager
3M Company
(b) (4)

Re: K121593
Trade/Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack
3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: March 1, 2013
Received: March 4, 2013

Dear (b) (4), (b) (6)

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name _____Clarence W. Murray, III_____

Subject: 510(k) Number _____K121593_____

To: The Record

Please list CTS decision code _SE_____

o Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

o Hold (Additional Information or Telephone Hold).

X Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

o	NO	NSE for lack of predicate
o	NI	NSE for new intended use
o	NQ	NSE for new technology that raises new questions of safety and effectiveness
o	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
o	NP	NSE for lack of performance data
o	NS	NSE no response
o	NL	NSE for lack of performance data AND no response
o	NM	NSE pre-amendment device call for PMAs (515i)
o	NC	NSE post-amendment device requires PMAs
o	NH	NSE for new molecular entity requires PMA
o	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)			X
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			X
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			X

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number: 21 CFR 880.2800(a) Class: II **Product Code: FRC**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Digital Signature Concurrence Table	
Reviewer Sign-Off	Clarence W. Murray Iii III Digitally signed by Clarence W. Murray Iii III DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300197254, cn=Clarence W. Murray Iii III Date: 2013.03.14 18:57:28 -04'00'
Branch Chief Sign-Off	Elizabeth F. Claverie 2013.03.15 10:25:36 -04'00'
Division Sign-Off	Tejashri S. Purohitsheth -S 2013.03.15 15:34:47 -04'00'

7

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K121593/S003

Date: March 12, 2013
To: The Record
From: Clarence W. Murray, III

Office: ODE
Division: DAGRID/INCB

510(k) Holder: 3M Health Care
Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack
Cont(b) (4), (b) (6)
Phor
Fax:
Emai

I. Purpose and Submission Summary:

3M Health Care would like to introduce 3M Attest™ 1496V and 41482V Super Rapid Biological Indicator Challenge Packs for Steam into interstate commerce. The subject device is a biological indicator (Class II, 21 CFR § 880.2800(a), product code - FRC). The subject device is intended to monitor dynamic – air – removal (pre-vacuum) steam sterilization cycles. This submission was placed on telephone hold on July 17, 2012.

The submission was placed on telephone hold on November 14, 2012. The firm provided additional information to FDA on December 6, 2012 and the submission was returned to telephone hold on December 13, 2012.

It is recommended that this submission be considered for SE.

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

The 510(k) summary for this submission is found on pages 10 - 13

(b) (4)

9

(b) (4)

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

Device Summary:

The 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs are designed to routinely challenge dynamic-air-removal (pre-vacuum) steam sterilization processes in healthcare facilities. The challenge packs have the same Intended Use as the predicate 3M AttestTM Steam-Plus Pack (b) (4) (b) (4) K925496) and are similar in design.

The challenge packs consist of multiple layers of medical index cards, some of which are die-cut to contain monitoring products. The pack is overwrapped and secured with a label. Each pack has a process indicator on the outside of the pack that changes from yellow to brown or darker when exposed to steam. This disposable pack has been designed to present a challenge to the steam sterilization process that is equivalent to or more resistant than the towel pack biological indicator challenge device recommended by the AAMI.

Each Attest™ 1496V challenge Pack contains an Attest™ 1492V Super Rapid Readout Biological Indicator and a record keeping sheet. Each Attest™ 41482V Challenge Pack contains an Attest™ 1492V Super Rapid Readout Biological Indicator, a SteriGage™ chemical integrator, and a record keeping sheet. Attest™ 1492V biological indicator controls are provided with both challenge packs.

Biological Indicator Designed and AttestTM Super Rapid Readout Technology:

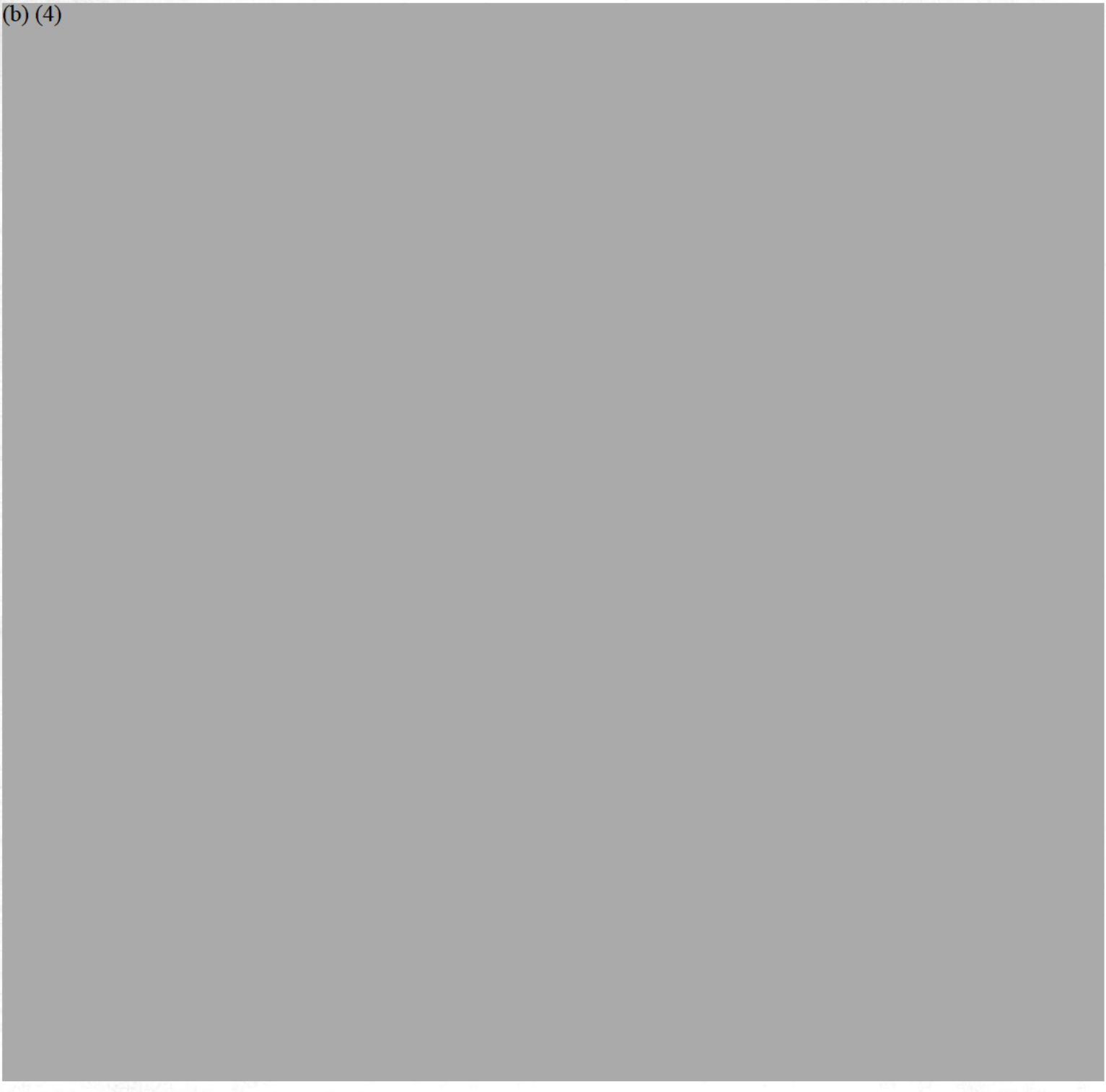
The AttestTM 1492V Super Rapid Readout Biological Indicator (1492V Super Rapid BI or 1492V SRBI) contained within the 1496V and 41482V challenge packs utilizes the AttestTM Super Rapid Readout Technology.(b) (4)

(b) (4)

The 1492V is a new model of the Super Rapid biological Indicator currently under review for dynamic-air-removal (pre-vacuum) steam sterilization cycles (K121484).

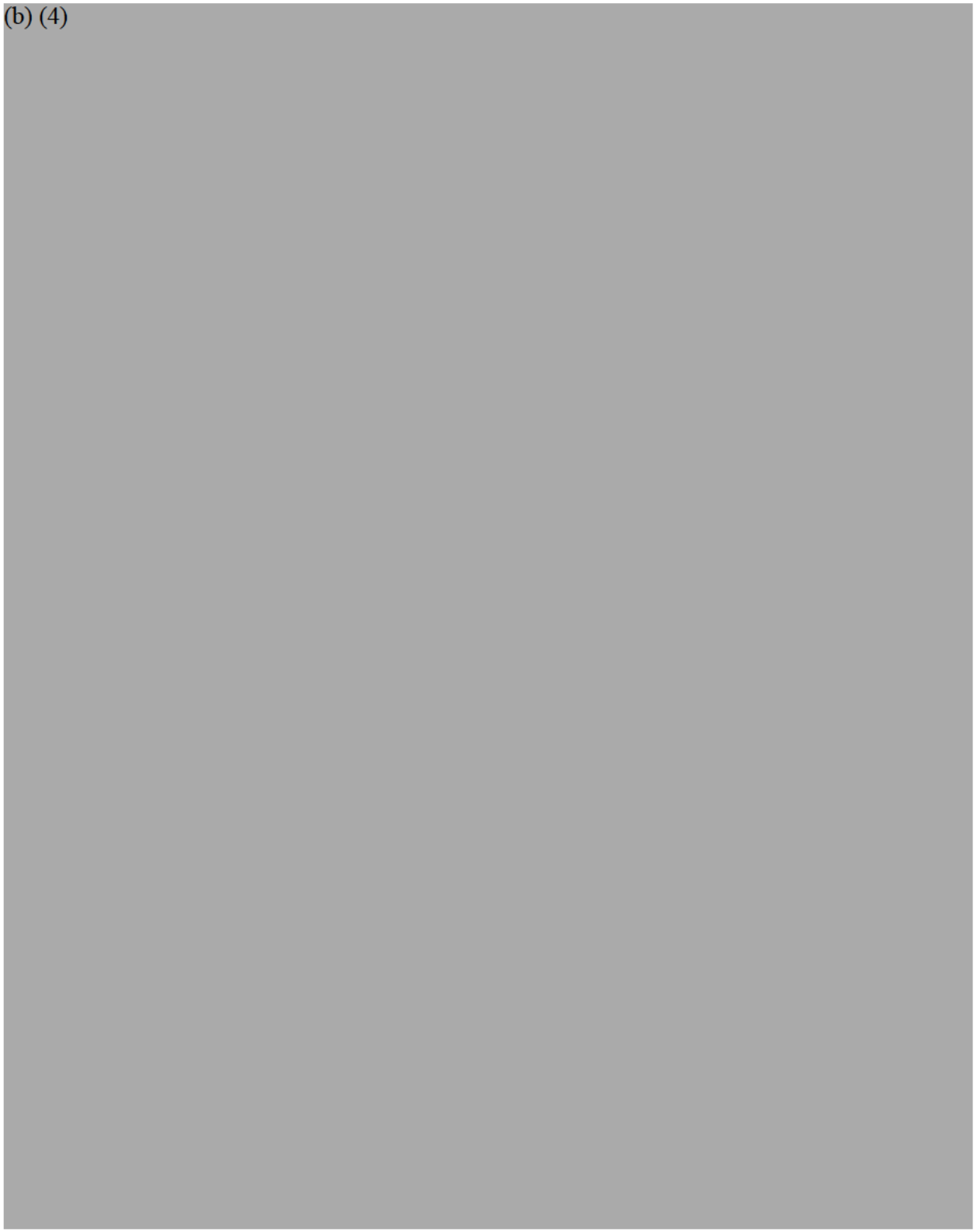
Mechanism:

(b) (4)

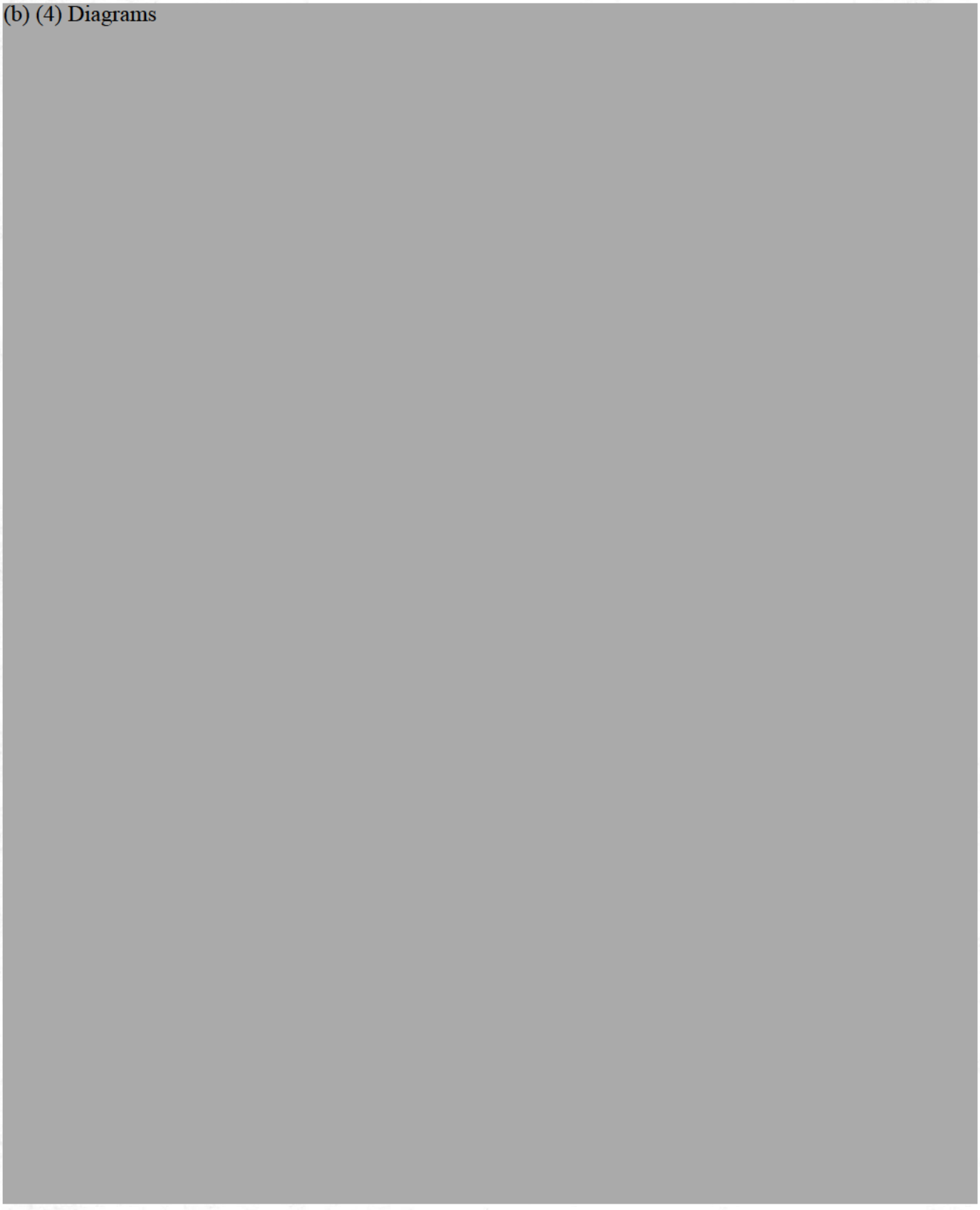


(b) (4)

(b) (4)

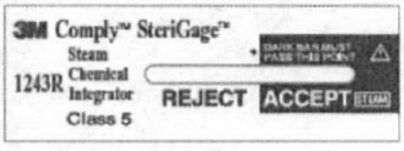


(b) (4) Diagrams

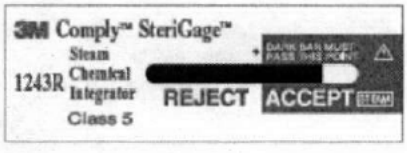


Design of the SteriGage™ Chemical Integrator (in 41482V only)

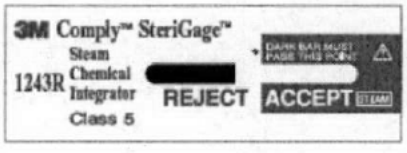
3M SteriGage™ Steam Chemical Integrators are single-use chemical indicators consisting of a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. Upon exposure to steam, the chemical pellet melts and migrates as a dark color along the paper wick as a moving front. The migration is visible through a window marked ACCEPT or REJECT; the extent of migration depends on steam, time, and temperature.



Unexposed



After a passing cycle

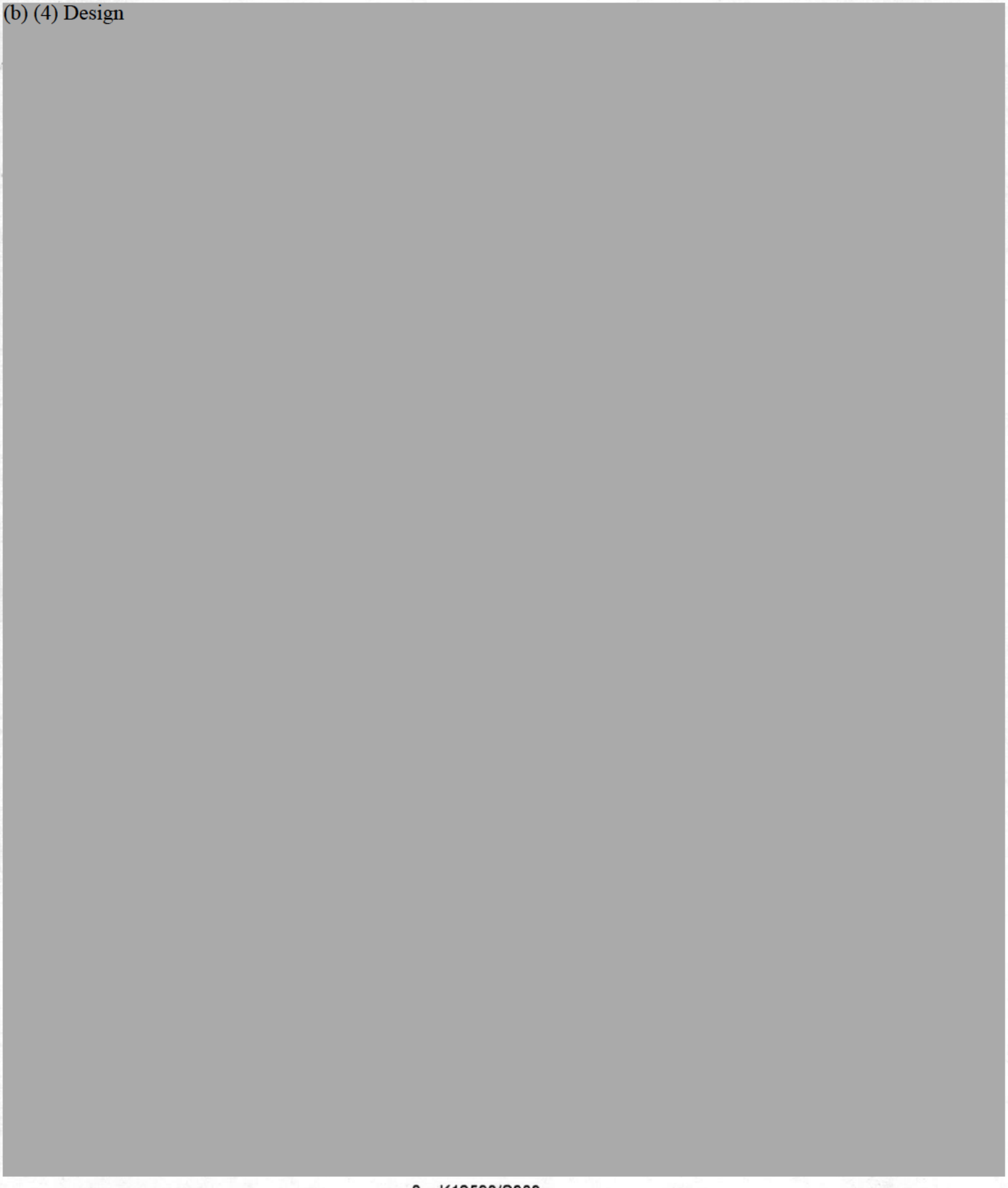


After a failing cycle

(b) (4) Design

15

(b) (4) Design



(b) (4)

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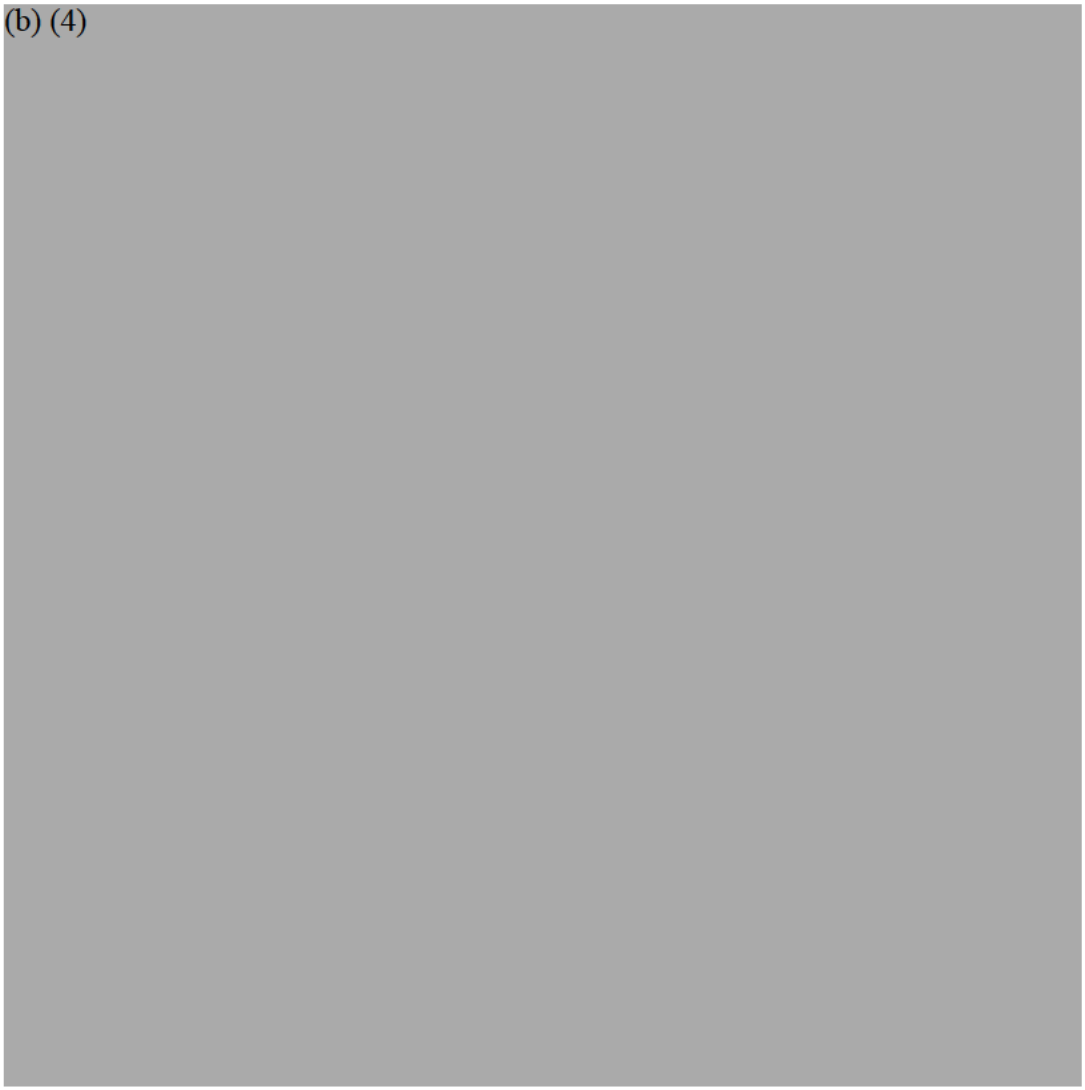
V. **Predicate Device Comparison**

(b) (4)



The Attest™ 1496V Super Rapid Readout Steam and 41482V Super Rapid 5 Steam-Plus Challenge
(b) (4) test pack device 3M Attest™ Steam-Plus Pack,
cleared under K925496, in terms of intended use and
technological characteristics.

The differences between the Attest™ Super Rapid Challenge Packs and the predicate device are:

1. The substitution of the biological indicator with the 1492V Super Rapid Readout Biological Indicator.
2. Alignment of the Indications for Use with the steam sterilization cycles claimed by the 1492V Super Rapid Readout Biological Indicator.

The performance testing summaries provided demonstrate the products meet the requirements of their intended use for the indications claimed. There are no new questions of safety or effectiveness.

(b) (4)

(b) (4)

[redacted]

VI. Labeling

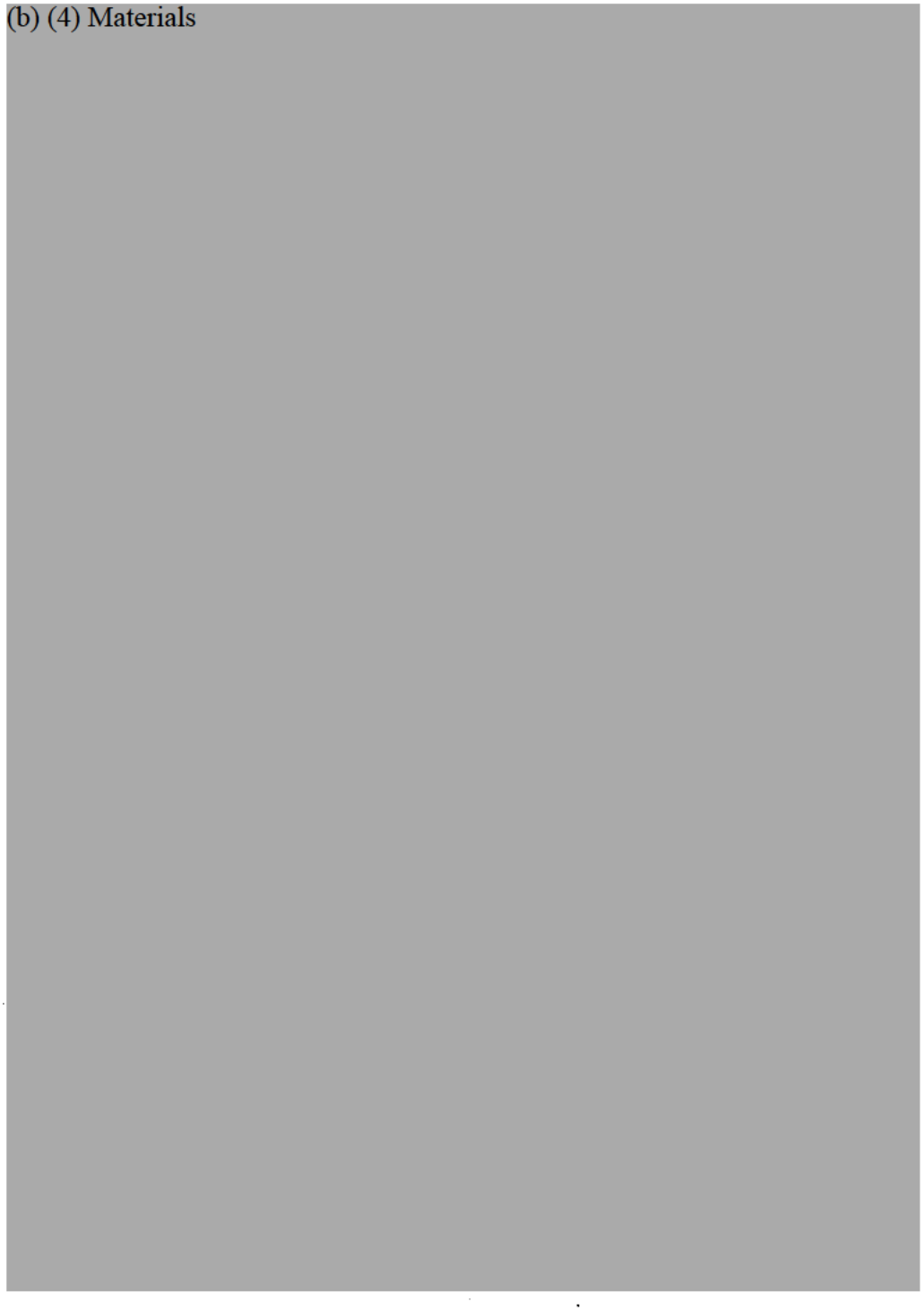
Labeling for AttestTM 1496V Super Rapid Readout Steam Challenge Pack

(b) (4) Materials

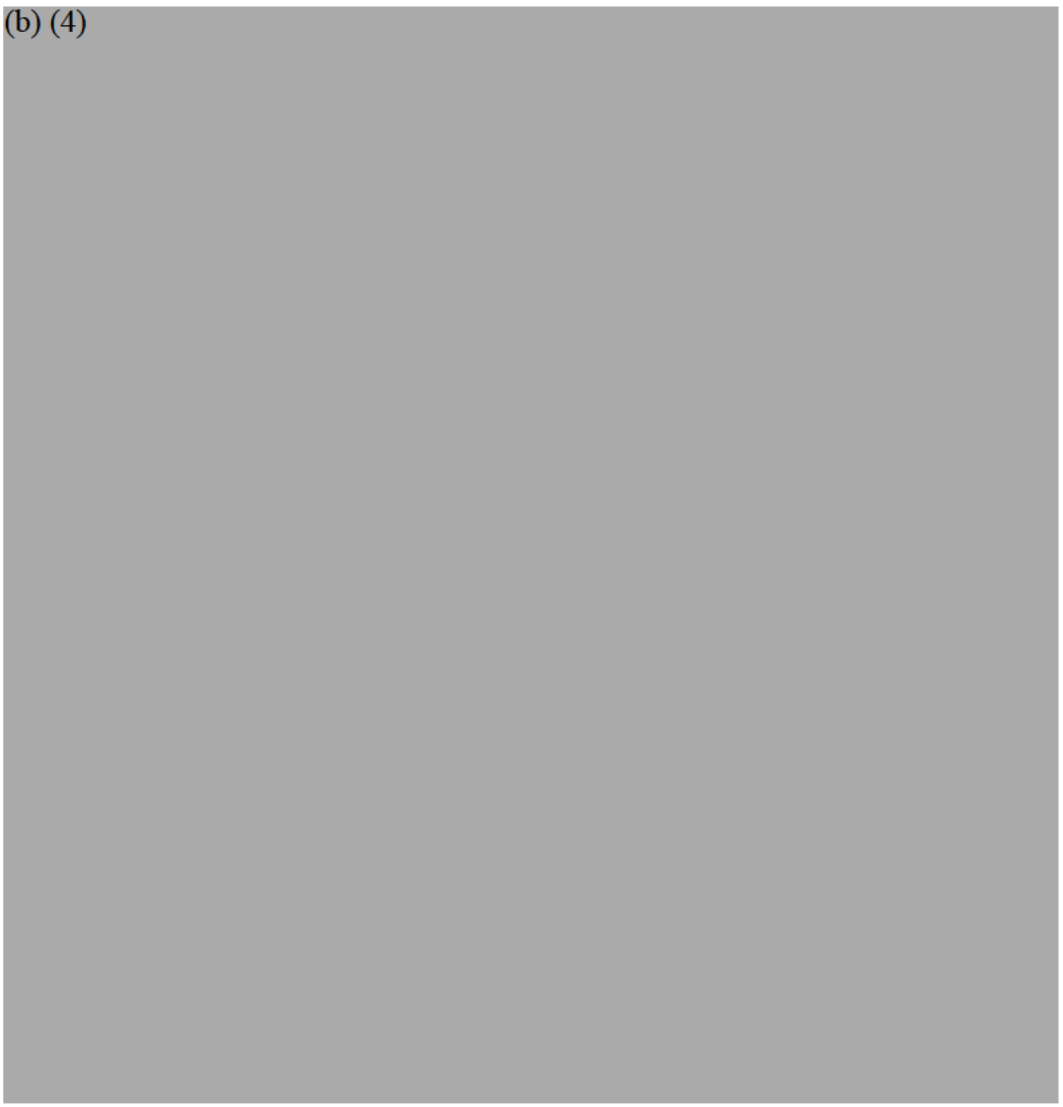
(b) (4) Materials

[redacted]

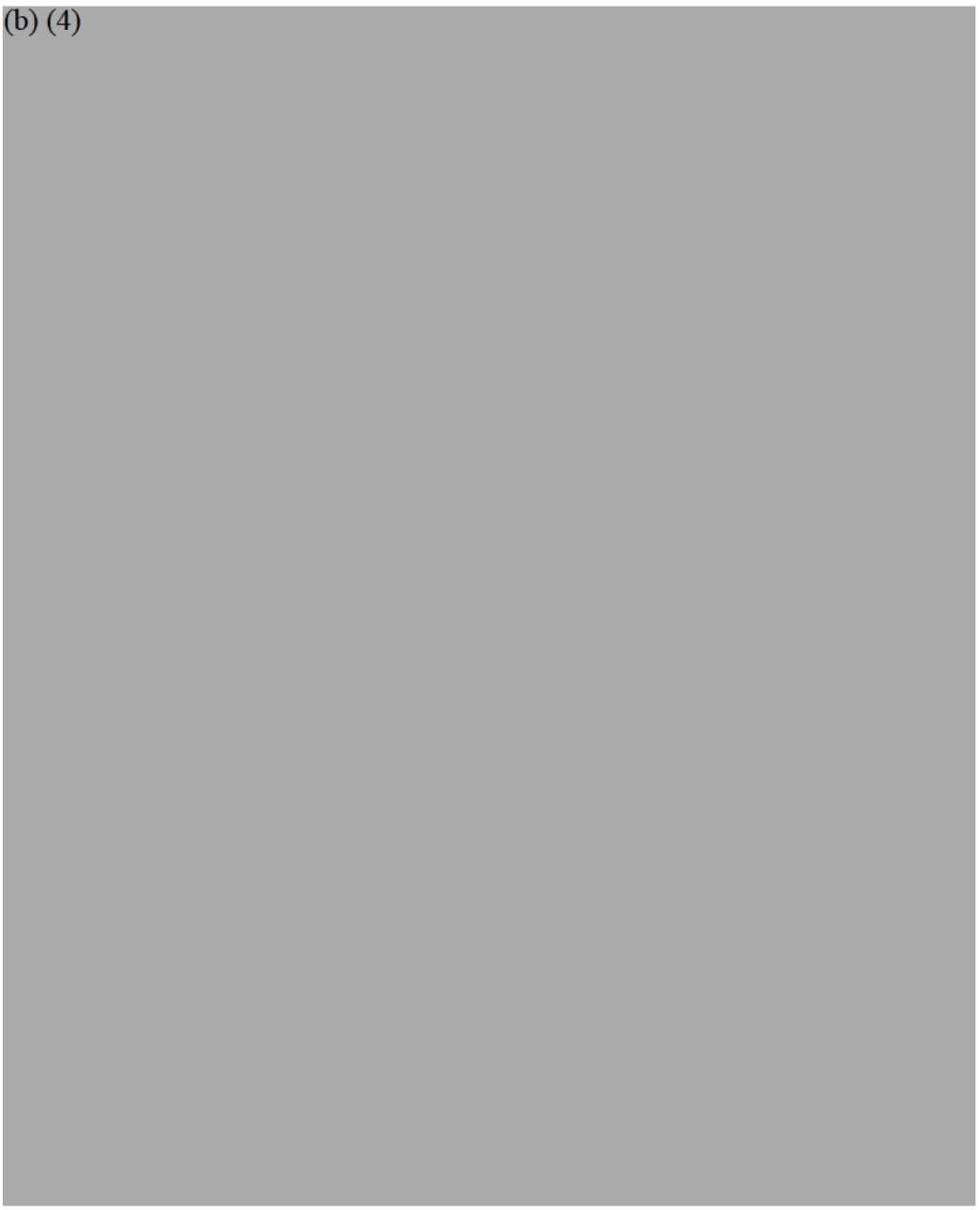
(b) (4) Materials



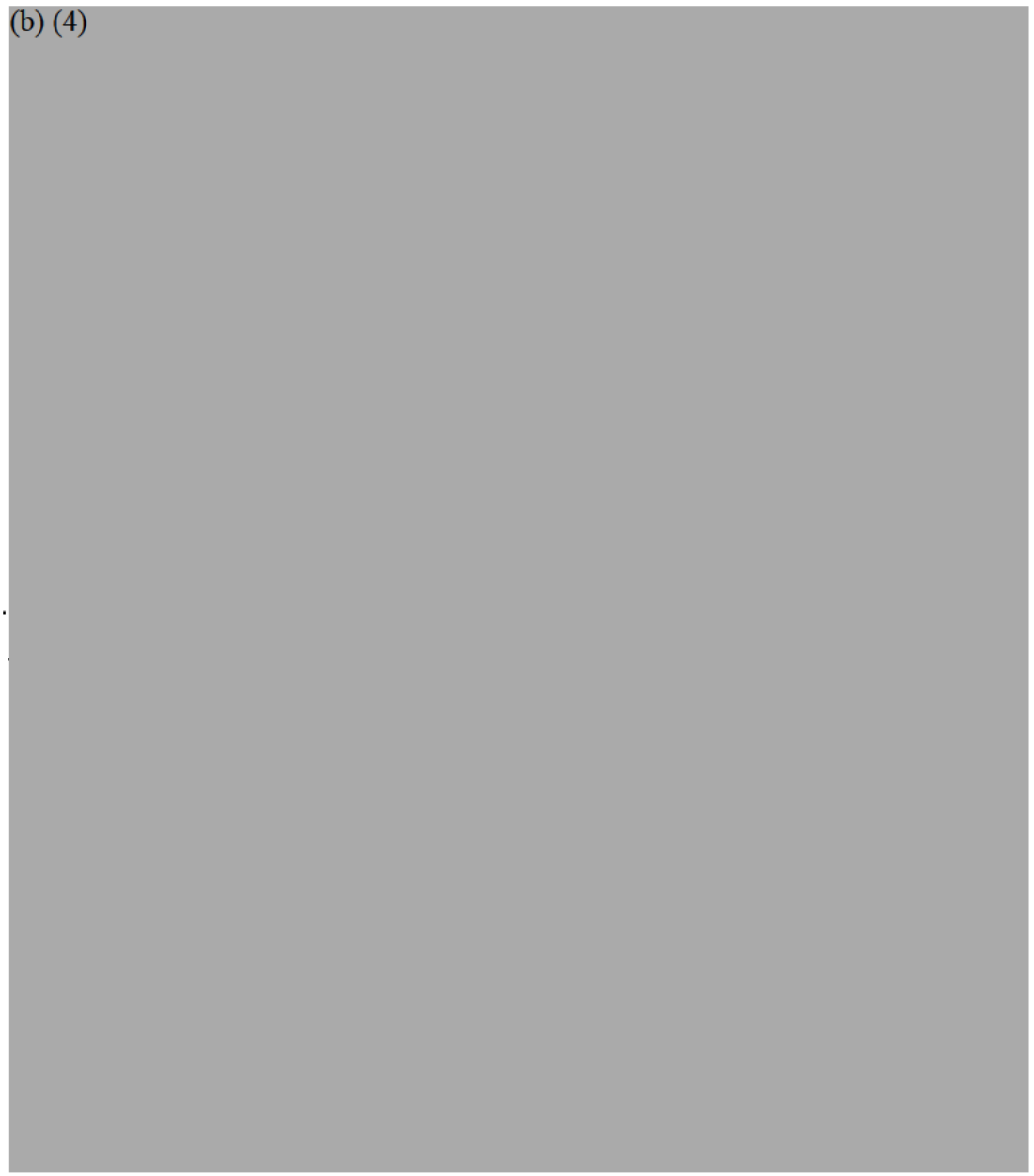
(b) (4)



(b) (4)



(b) (4)



(b) (4)

13.1.2 Label on Attest™ 1496V Super Rapid Readout Steam Challenge Pack

Below is a representation of the finished product (not to scale), showing the label on

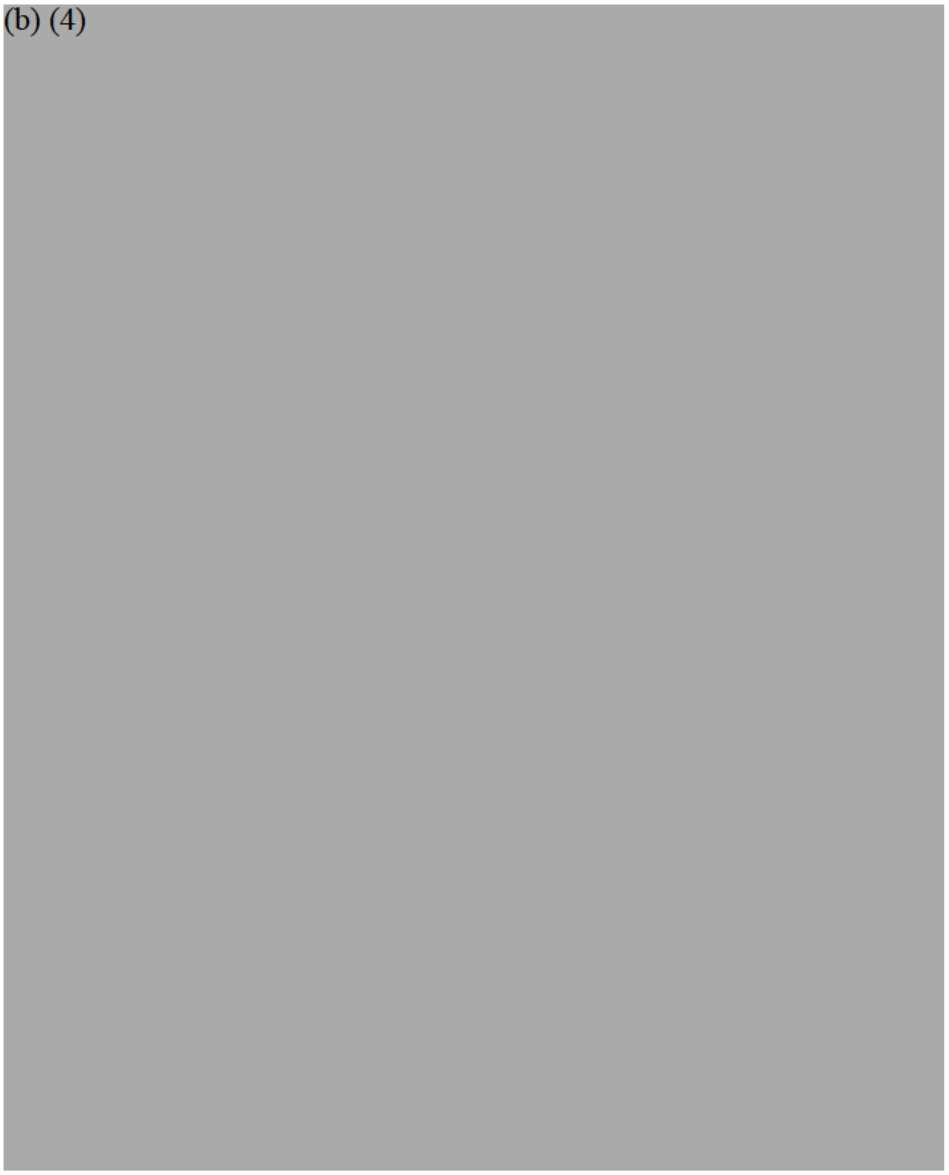
(b) (4)

(b) (4)

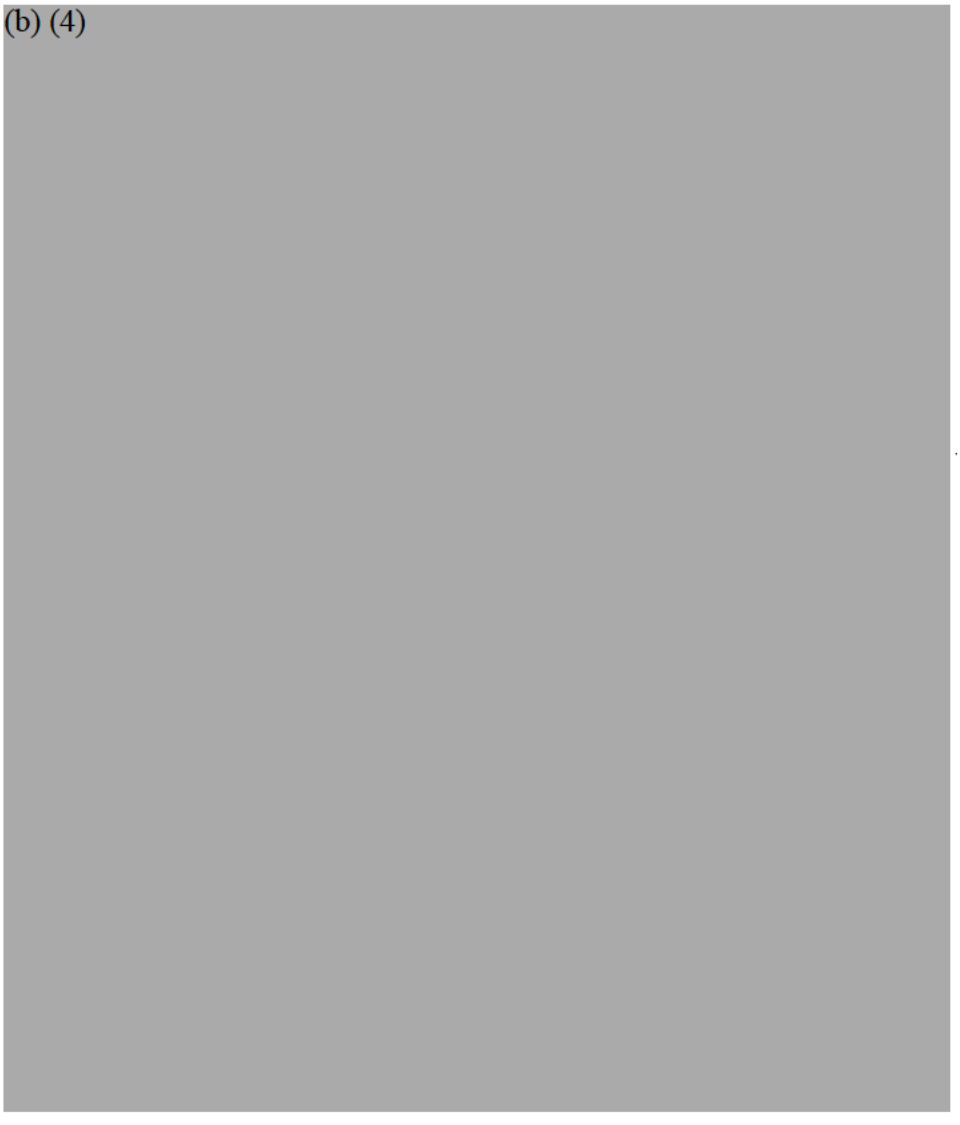
Labeling for Attest™ 41482V Rapid 5 Steam-Plus Challenge Pack

(b) (4)

(b) (4)



(b) (4)



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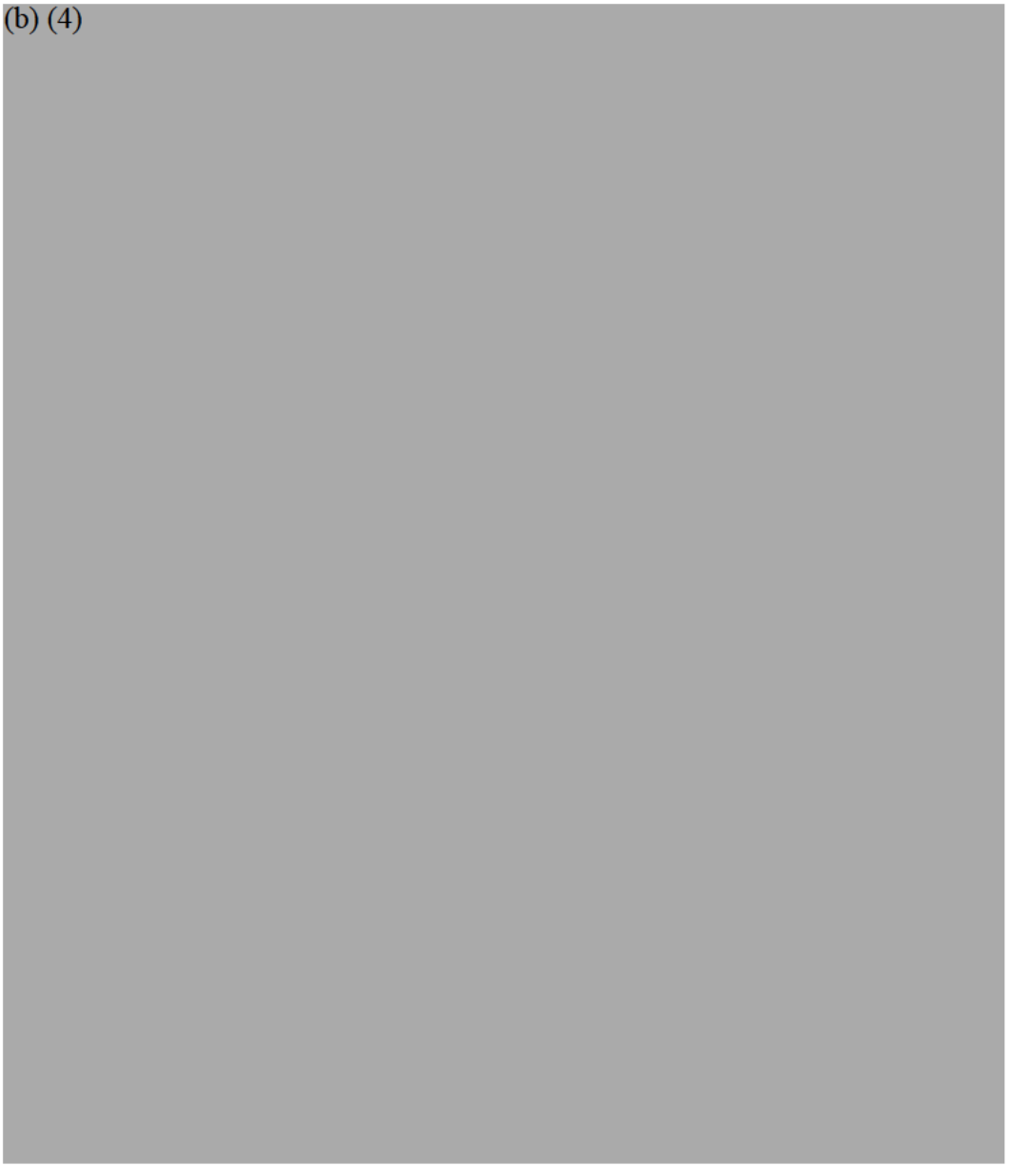

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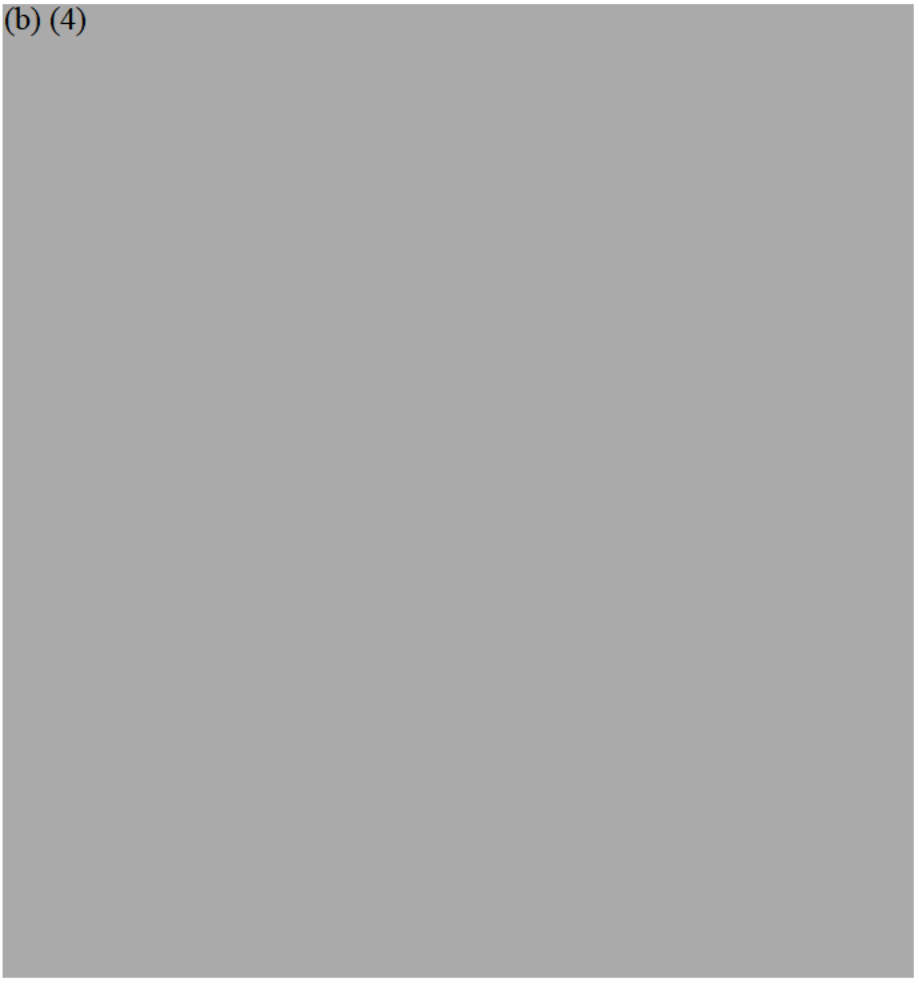

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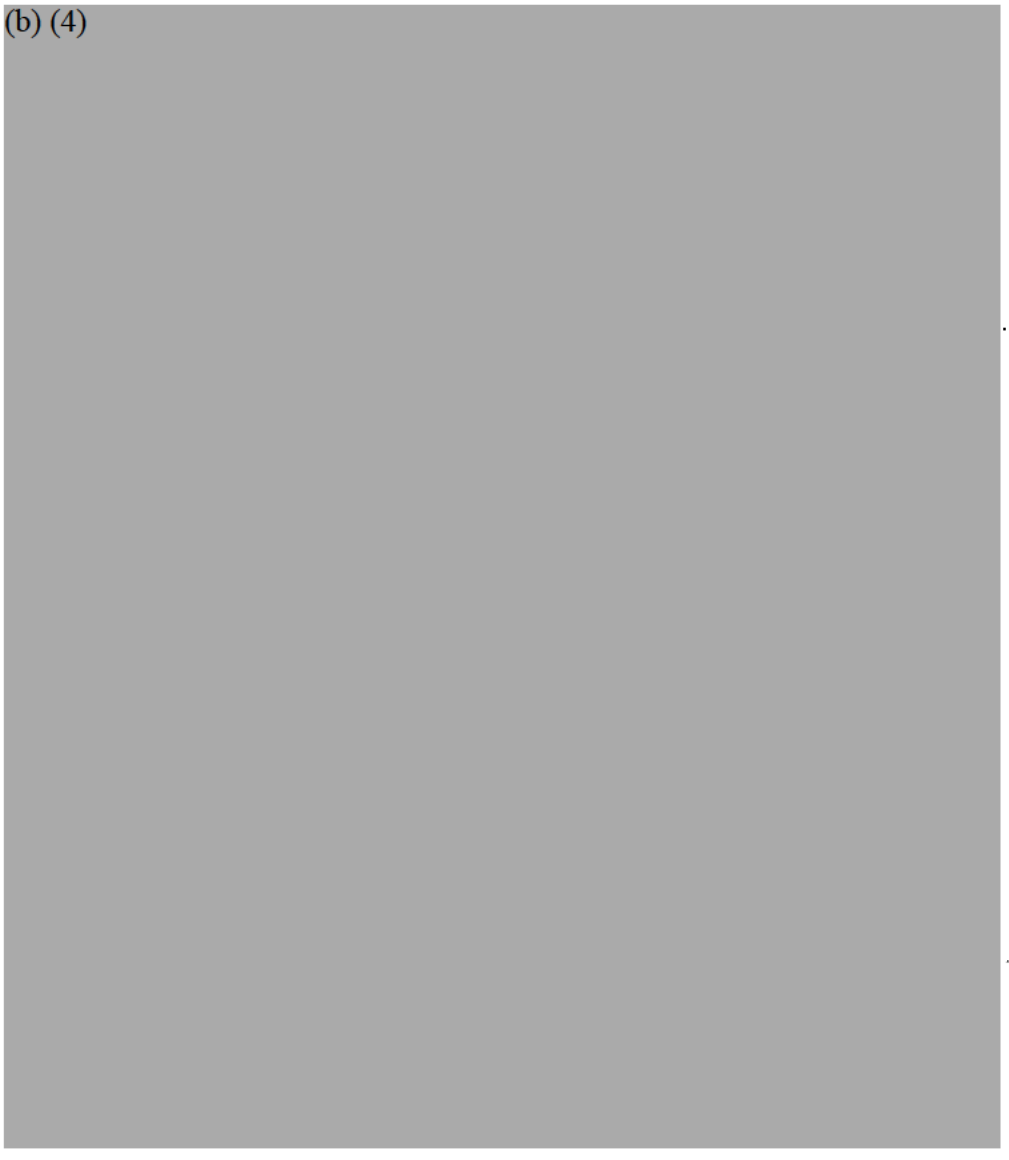


(b) (4)

13.2.2 **Label on Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack**

Below is a representation of the finished product (not to scale), showing the label on each 41482V Challenge Pack(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

VII. Sterilization/Shelf Life/Reuse

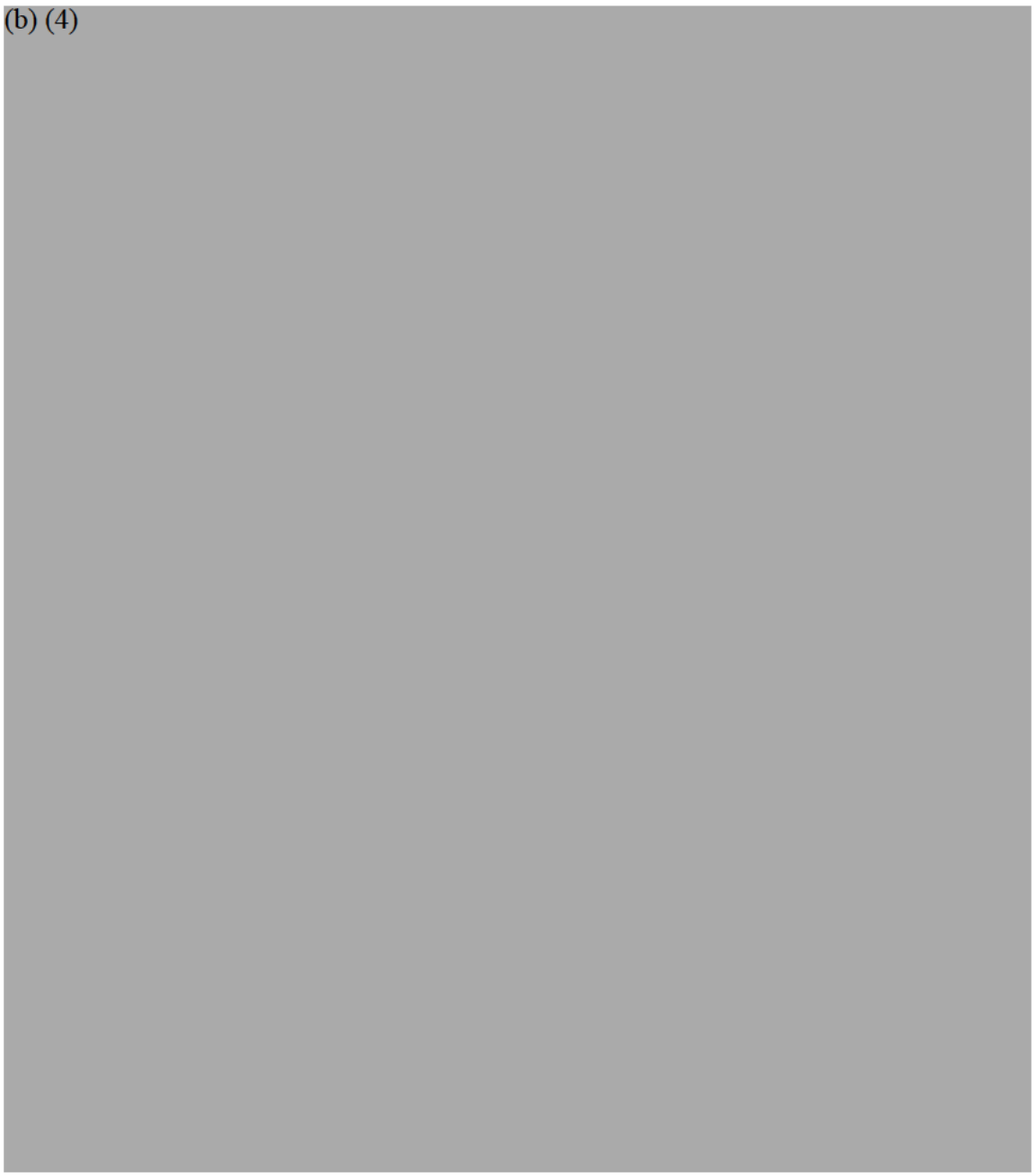
(b) (4)

(b) (4)

(b) (4)

VIII. **Biocompatibility**

(b) (4)



(b) (4)

[redacted]

IX. Software

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		

38

Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

The firm's October 24, 2012 S001 response to FDA:

The firm provided the clearance letter for the1492V Attest™ Super Rapid Biological Indicator which will be used in this subject device.

Reviewer Comments: Questions regarding software has been addressed in the clearance of the biological indicator: 1492V Attest™ Super Rapid Biological Indicator. **This is acceptable.** ***The deficiency is resolved.***

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

N/A

XI. Performance Testing – Bench

(b) (4)

[redacted]

(b) (4) Testing

[redacted]

(b) (4) Testing

(b) (4) Testing

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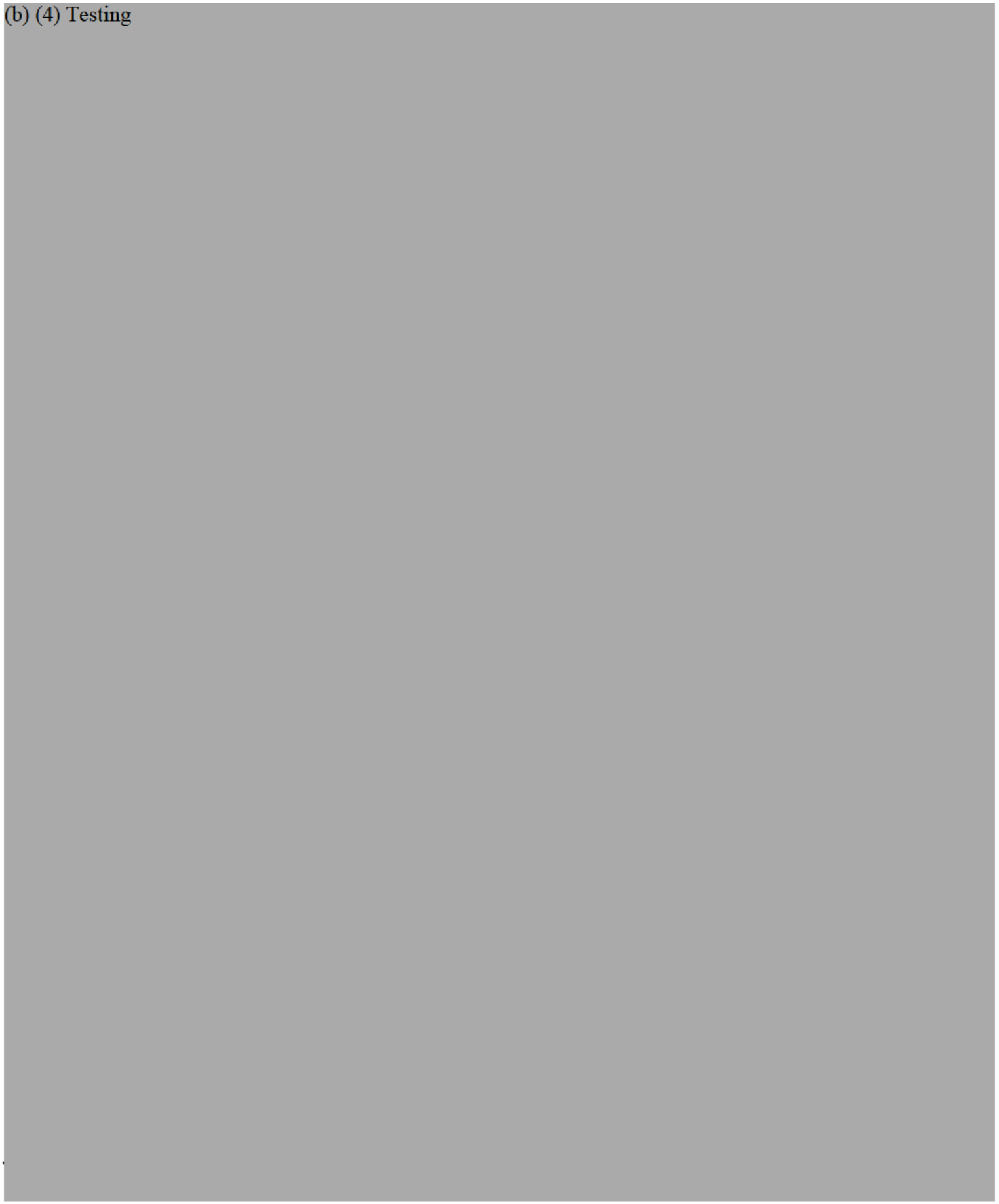
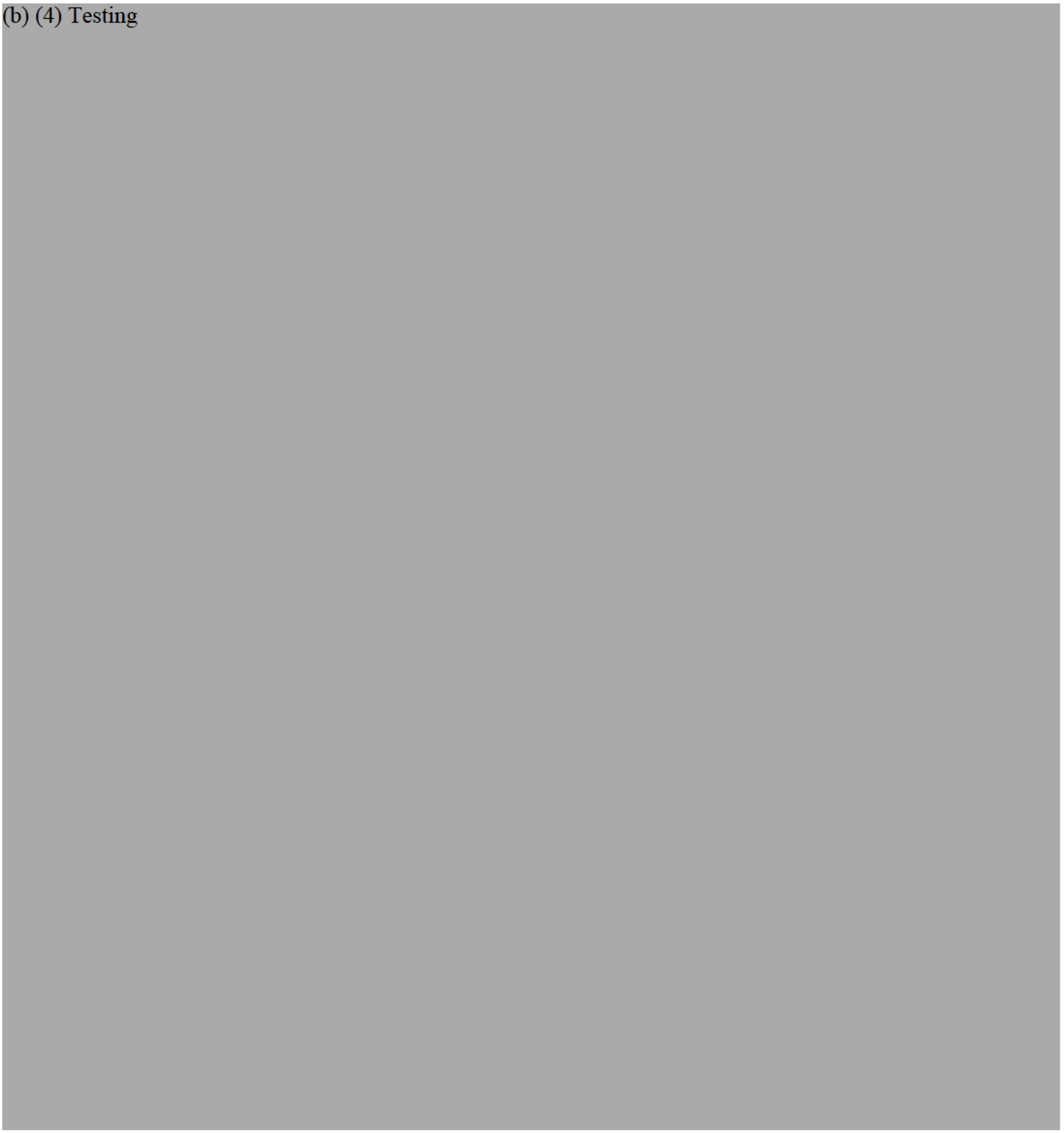
(b) (4) Testing



(b) (4) Testing



(b) (4) Testing

XIV. Substantial Equivalence Discussion

(b) (4)

1. Same Indication Statement?	**YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	**YES** = Stop **NSE**
3. Same Technological Characteristics?	**YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	**YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	**NO** = Go To 8 **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?	**YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	**NO** = Stop **NSE**
8. Performance Data Available?	**NO** = Request Data
9. Data Demonstrate Equivalence?	inal Decision: SE

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough: (b) (4)

(b) (4)

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b) (4)

XV. Deficiencies

(b) (4)

(b) (4)

[redacted]

Deficiencies from S001 Review:

Administrative

510(k) Summary

1. Please provide the product code in this summary.

The firm's December 6, 2012 S002 response to FDA:

3M included the product code in the 510(k) summary.

Reviewer Comments: The response is acceptable. ***The deficiency is resolved.***

(b) (4)

[redacted]

3. Please include a discussion of the similarities and differences between the subject devices and the predicate device.

The firm's December 6, 2012 S002 response to FDA:

3m included a table and discussion of the similarities and differences between the subject device and the predicate device.

Reviewer Comments: The response is acceptable. ***The deficiency is resolved.***

Indications for Use

(b) (4)

[redacted]

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Predicate Device Comparison

(b) (4)

Labeling

In regards to the labeling for your 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V:

(b) (4)

In regards to labeling for your 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V:

(b) (4)

10. Please remove the language regarding the Class 5 integrating indicator because the Agency does not recognize this class of integrating indicators.

The firm's December 6, 2012 S002 response to FDA:

3M stated that this particular language was cleared through the SteriGage 510(k), K101249. The firm also provided the 510(k) Summary for K101249 was included in their response.

Reviewer Comments: The response is acceptable. ***The deficiency is resolved.***

(b) (4)

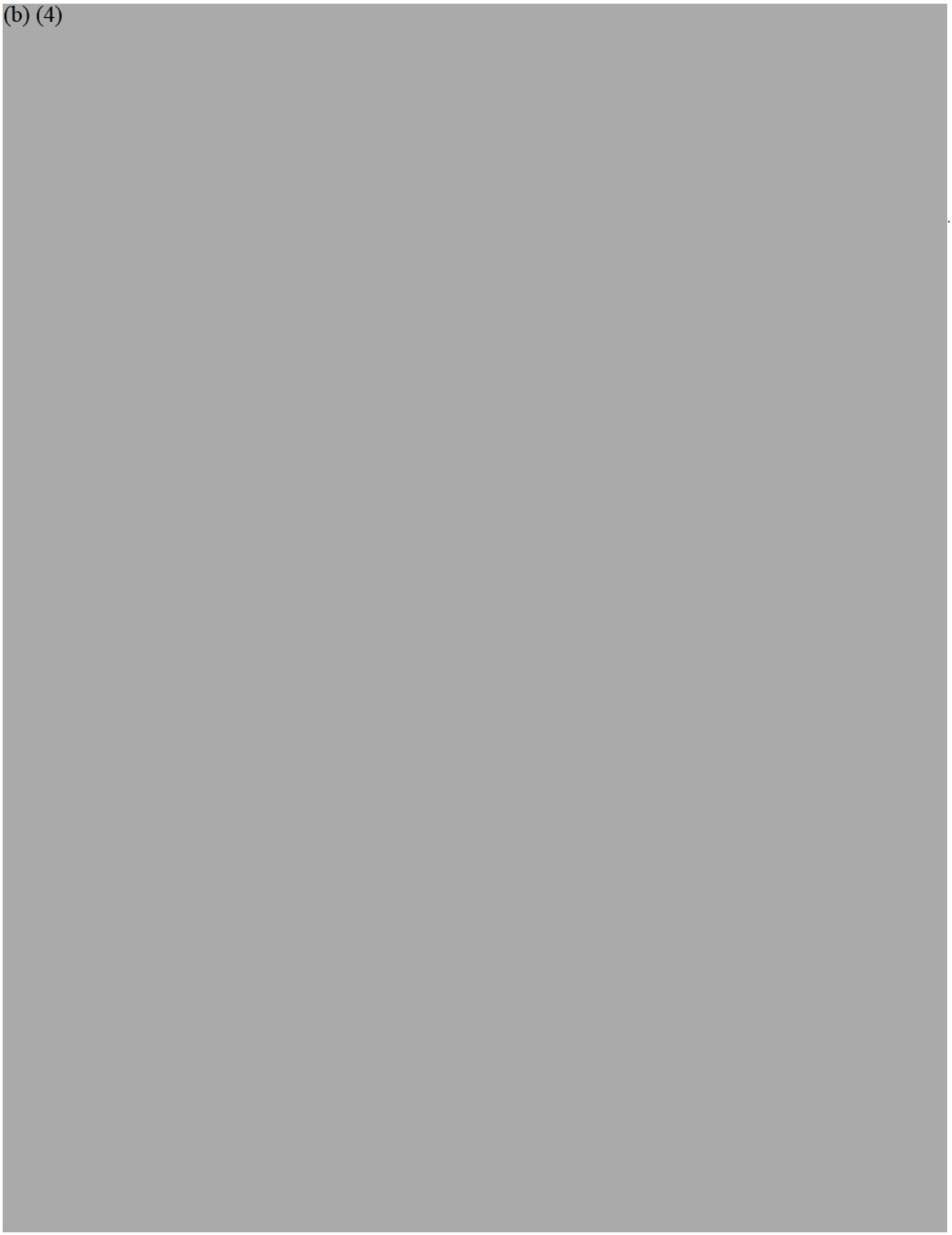
Sterilization/Shelf Life/Reuse

(b) (4)

Performance Testing

(b) (4)

(b) (4)



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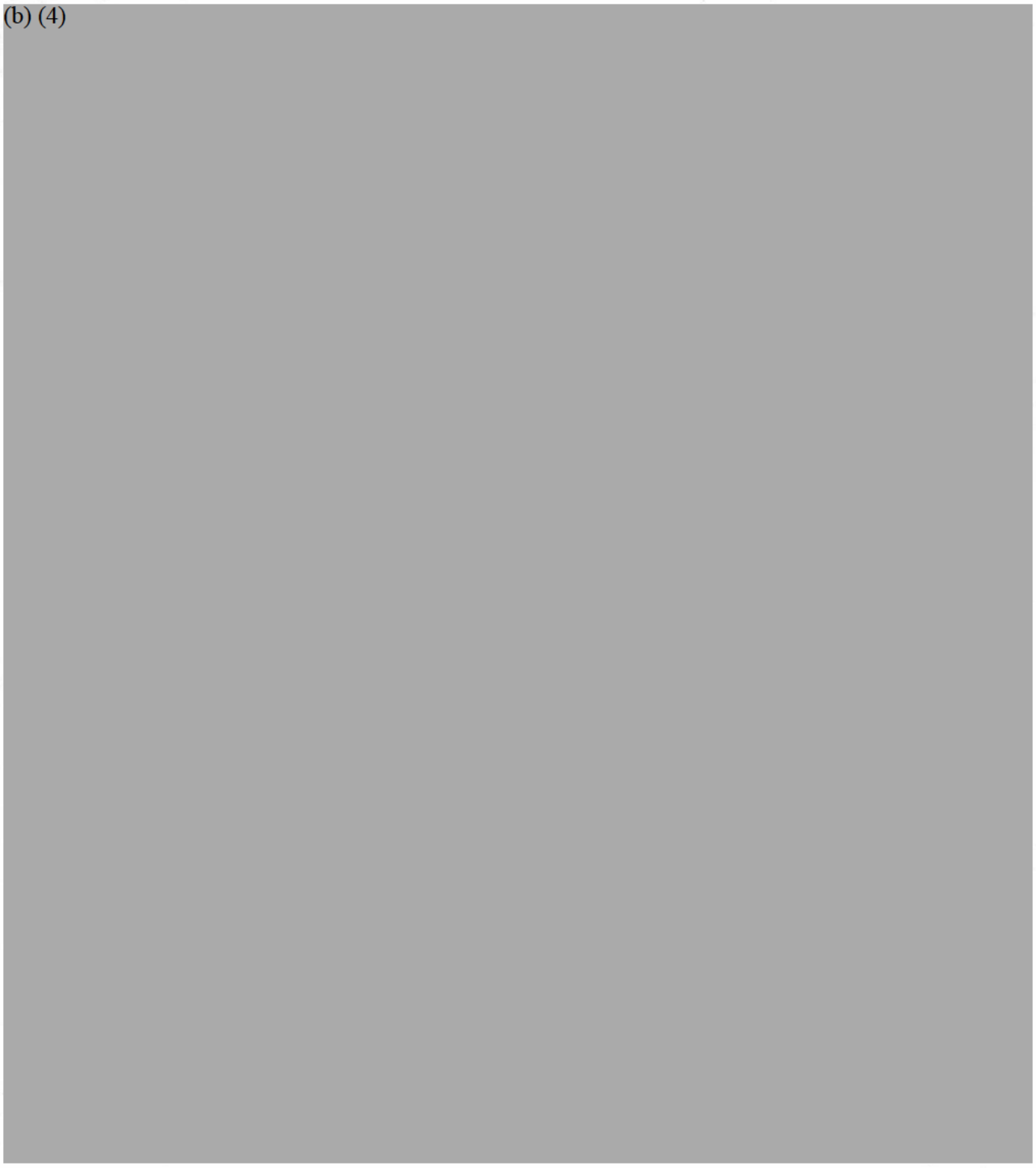
General Comments:

(b) (4)

(b) (4)



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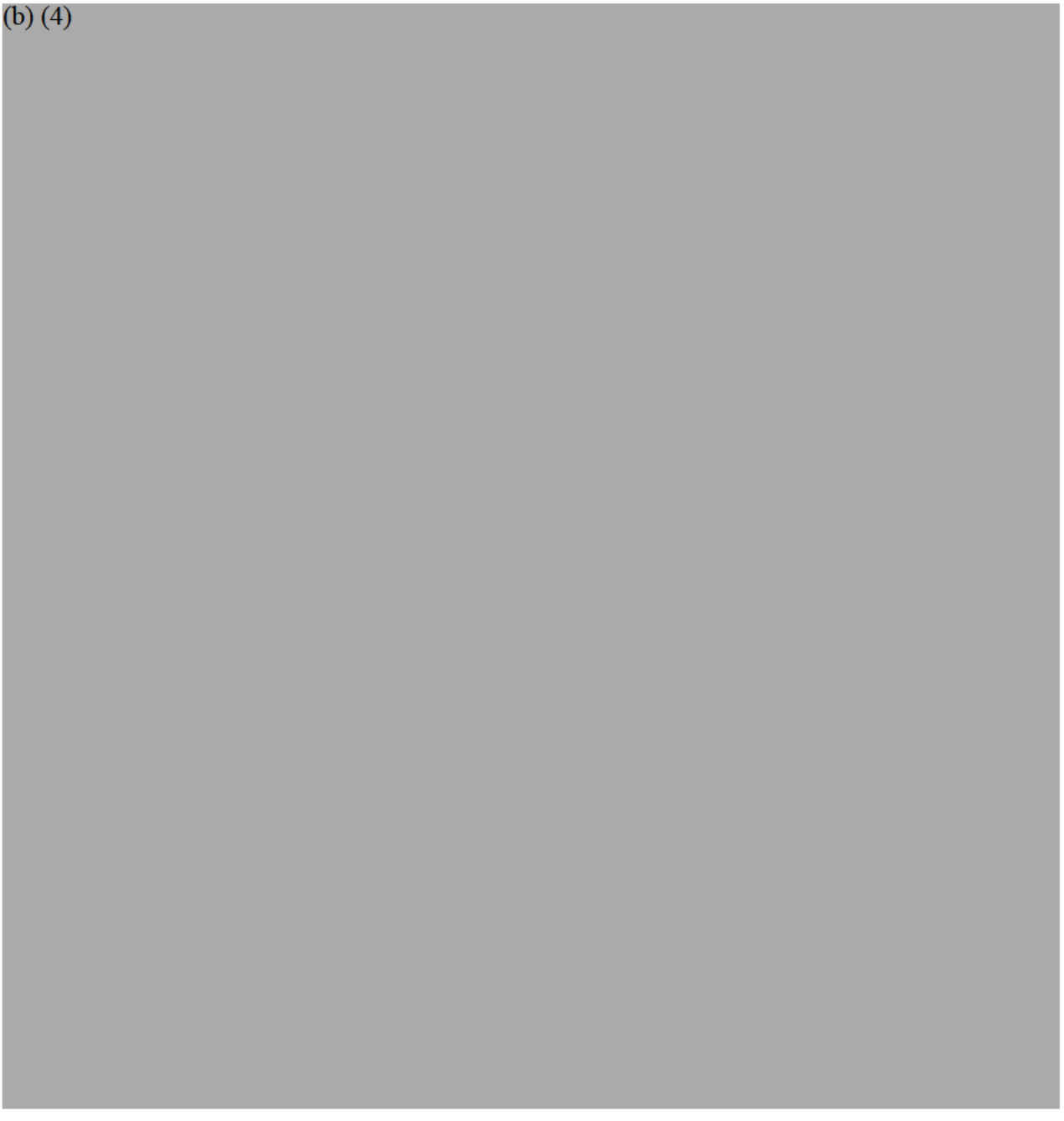

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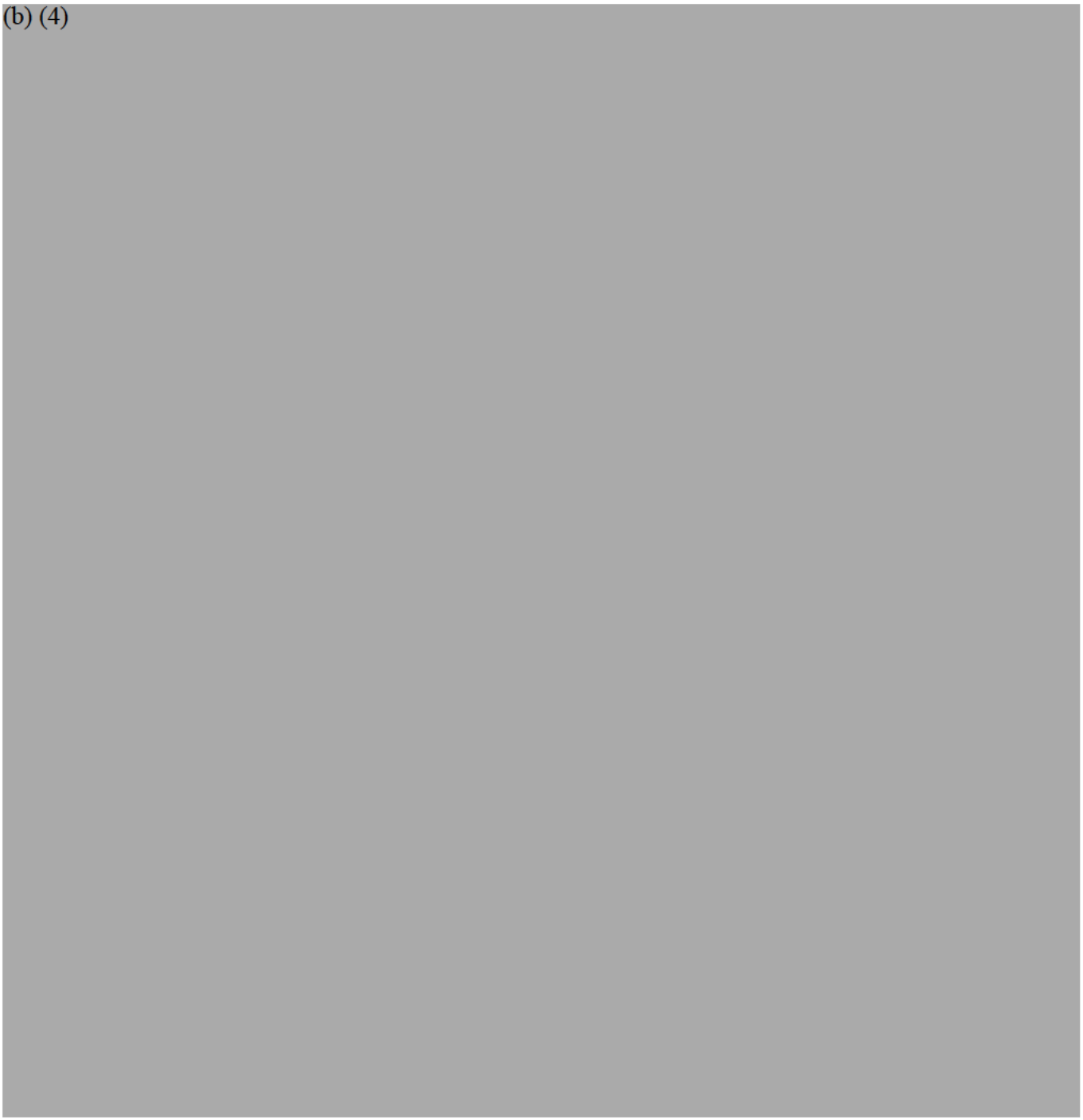

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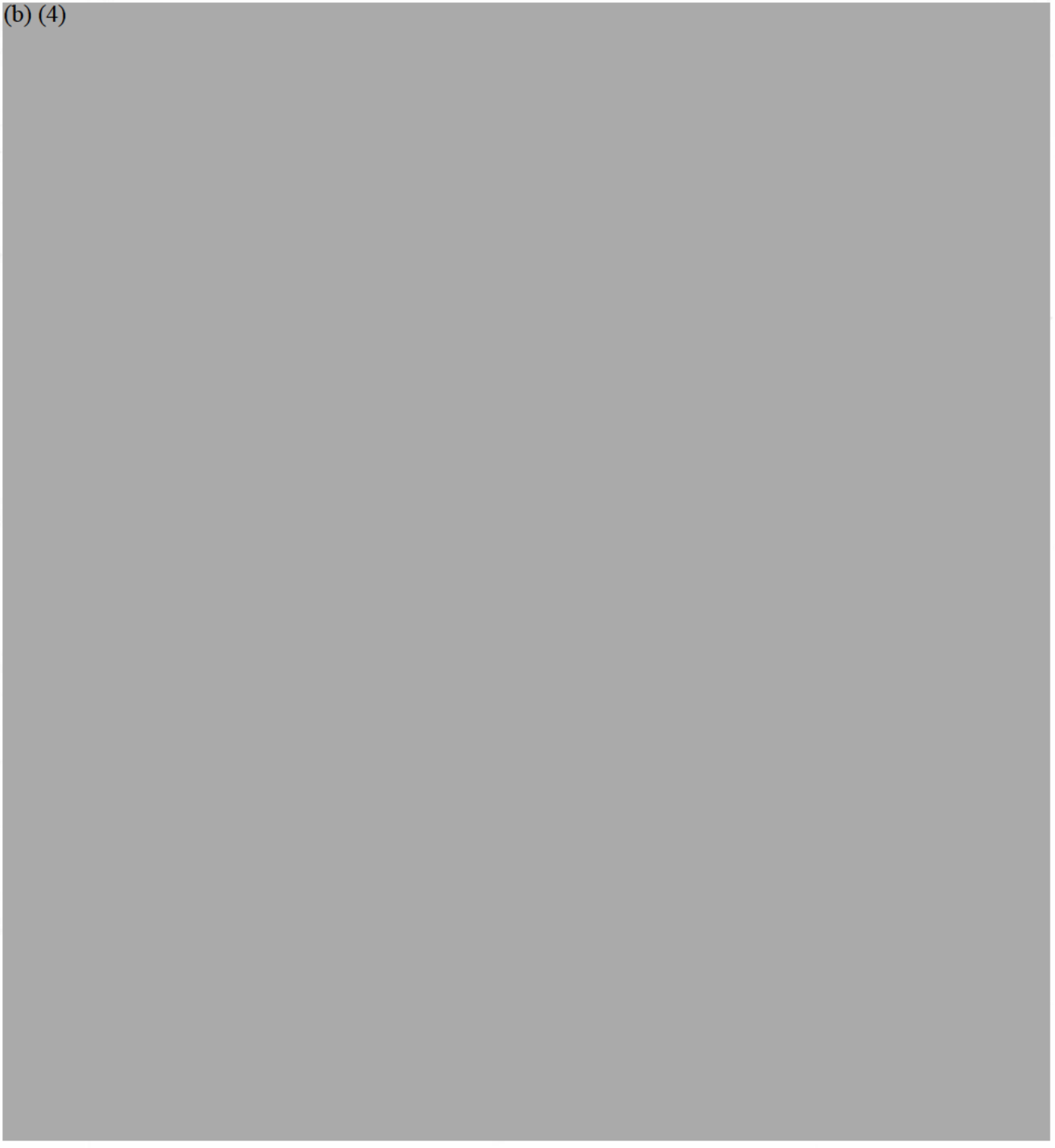

(b) (4)

(b) (4) Testing

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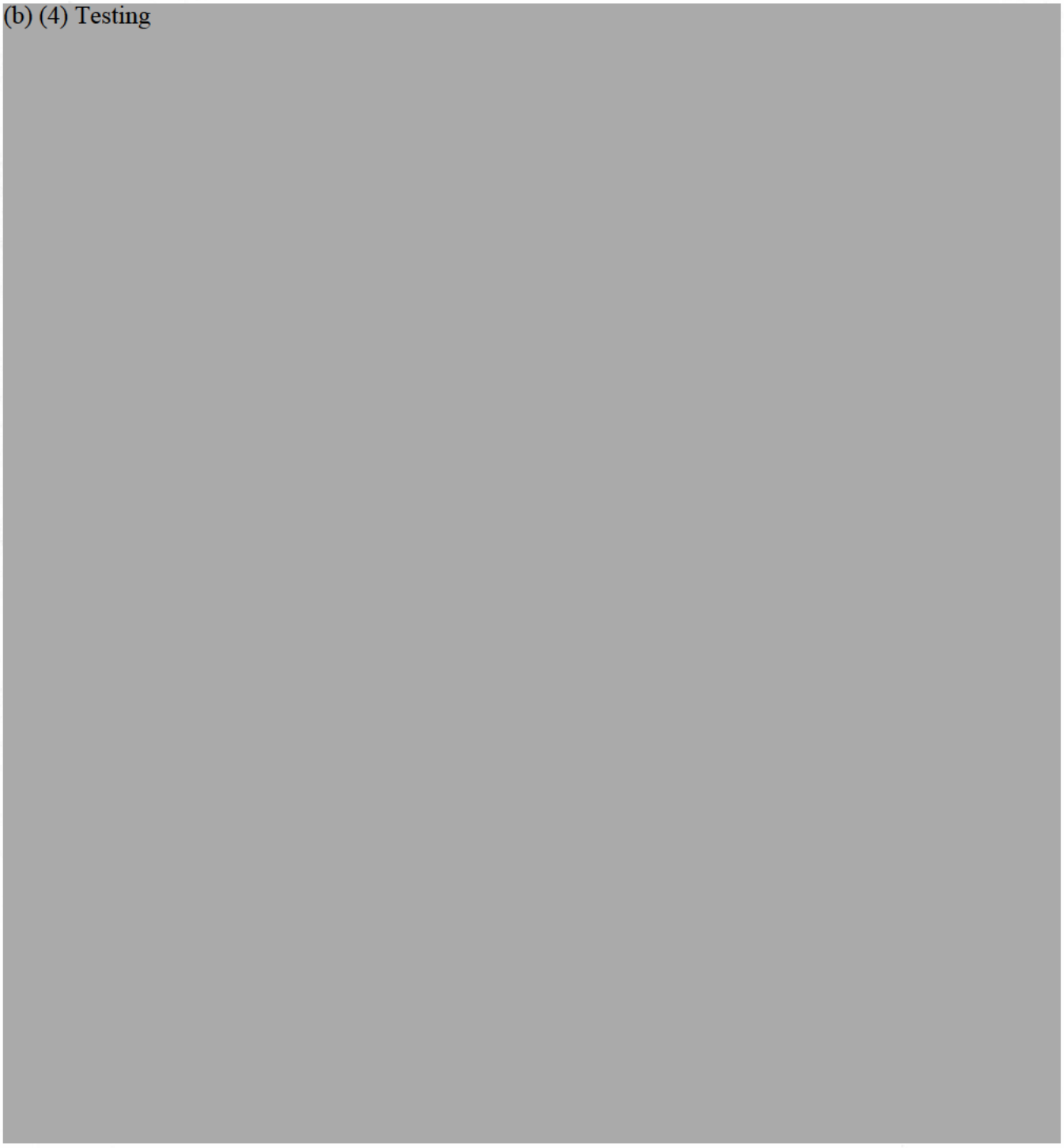
(b) (4) Testing



(b) (4) Testing

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(b) (4) Testing

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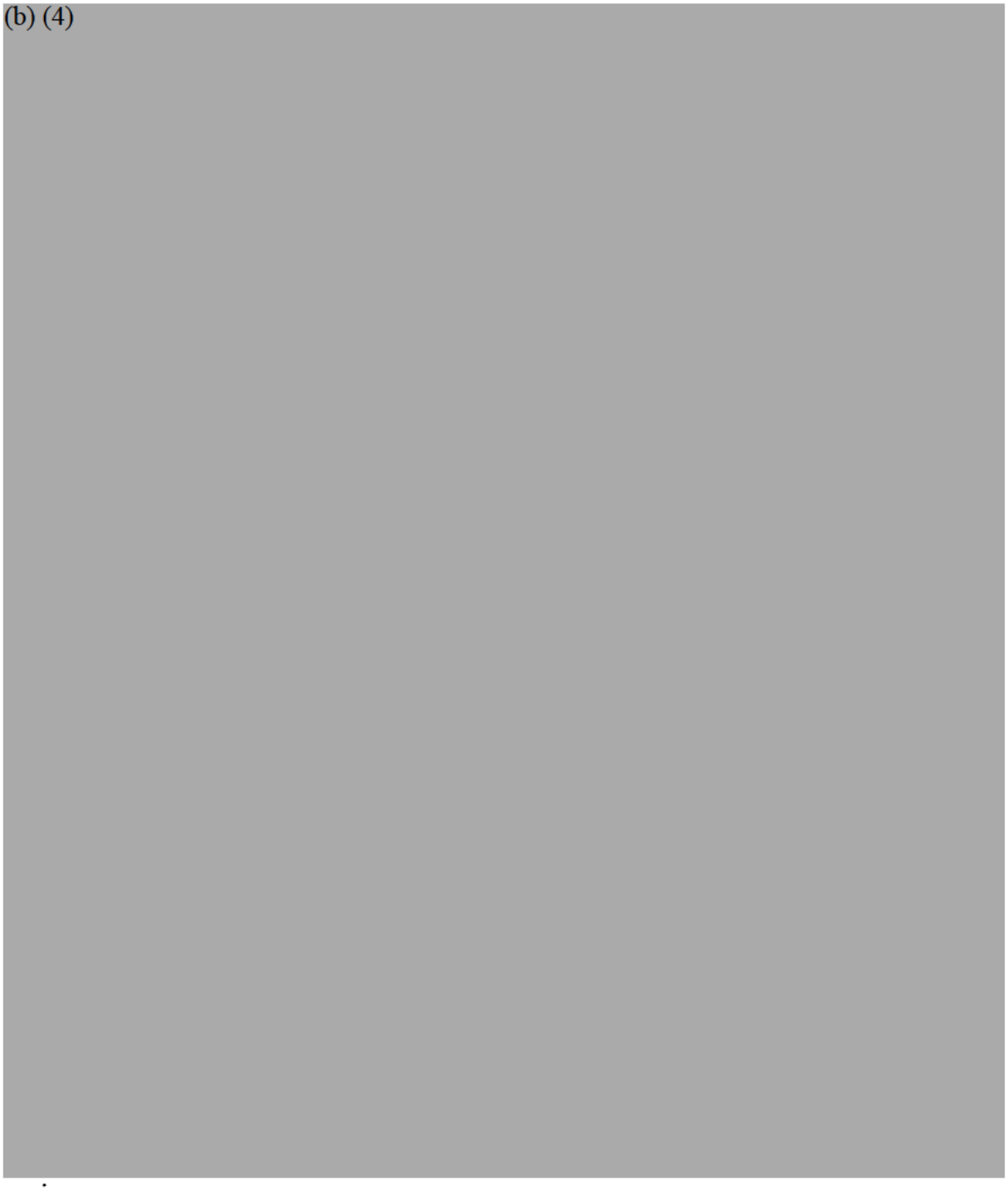

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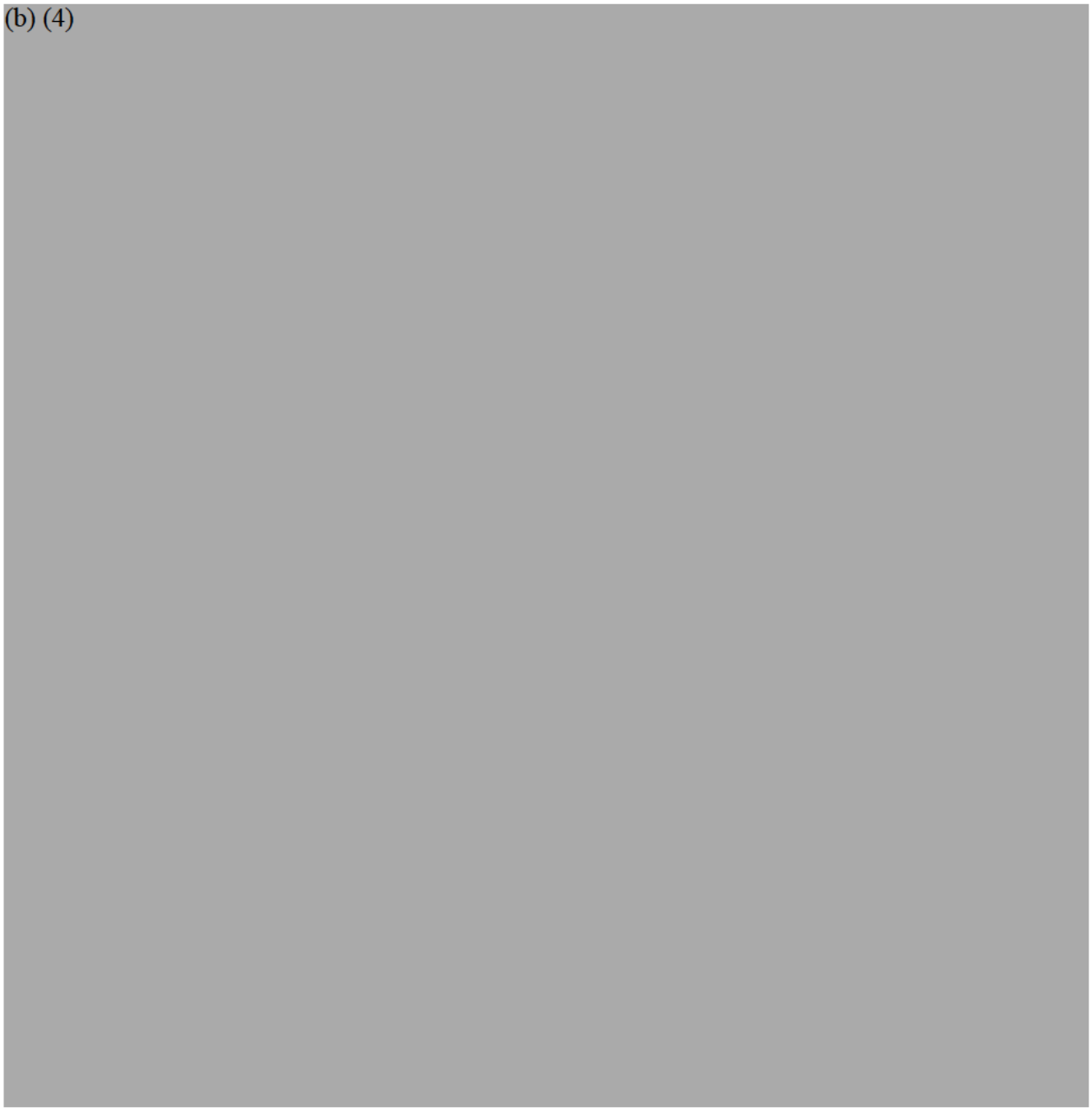

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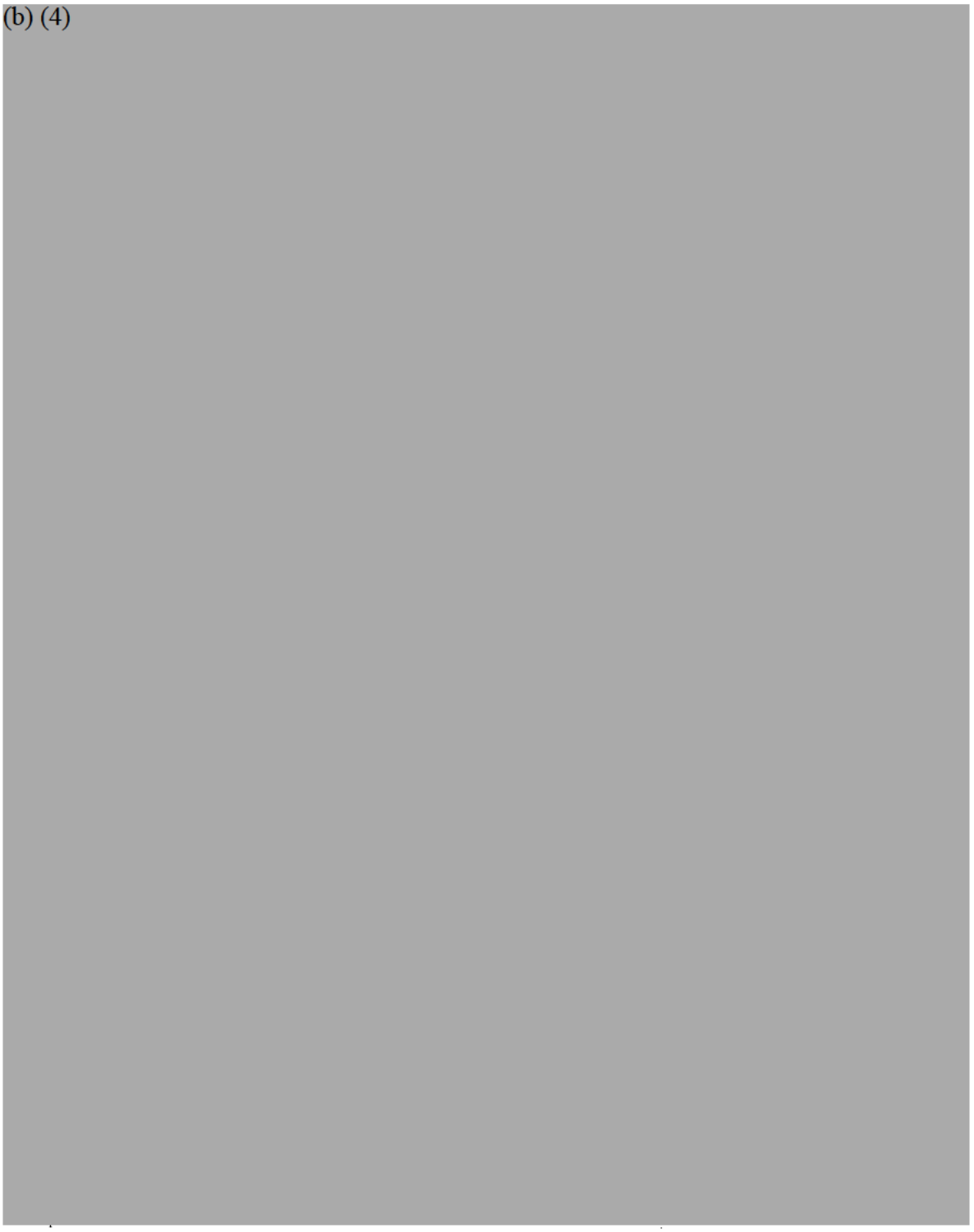

(b) (4)

[redacted]

XVII. Recommendation

It is recommended that this submission is SE.

Regulation Number: 21 CFR 880.2800(a)
Regulation Name: Sterilization process indicator/ Biological Sterilization process indicator
Regulatory Class: II
Product Code: FRC

Clarence W. Murray Iii III
Digitally signed by Clarence W. Murray III III
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300197254, cn=Clarence W. Murray III III
Date: 2013.03.14 18:53:28 -04'00'

Reviewer — Date

Elizabeth F. Claverie
2013.03.15 11:42:37 -04'00'

Branch Chief — Date

Tejashri S. Purohitsheth -S
2013.03.15 15:48:58 -04'00'

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Clarence W. Murray, III

Subject: 510(k) Number K121593 / S002

To: The Record

Please list CTS decision code TH

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Elizabeth P. Claro (Branch Chief) | INCB (Branch Code) | 12/13/12 (Date)

Final Review: _____ (Division Director) (Date)

(b) (4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K121593/S002

12/13/12

Date: December 13, 2012
To: The Record
From: Clarence W. Murray, III

Office: ODE
Division: DAGRID/INCB

510(k) Holder: 3M Health Care
Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack

(b) (4)

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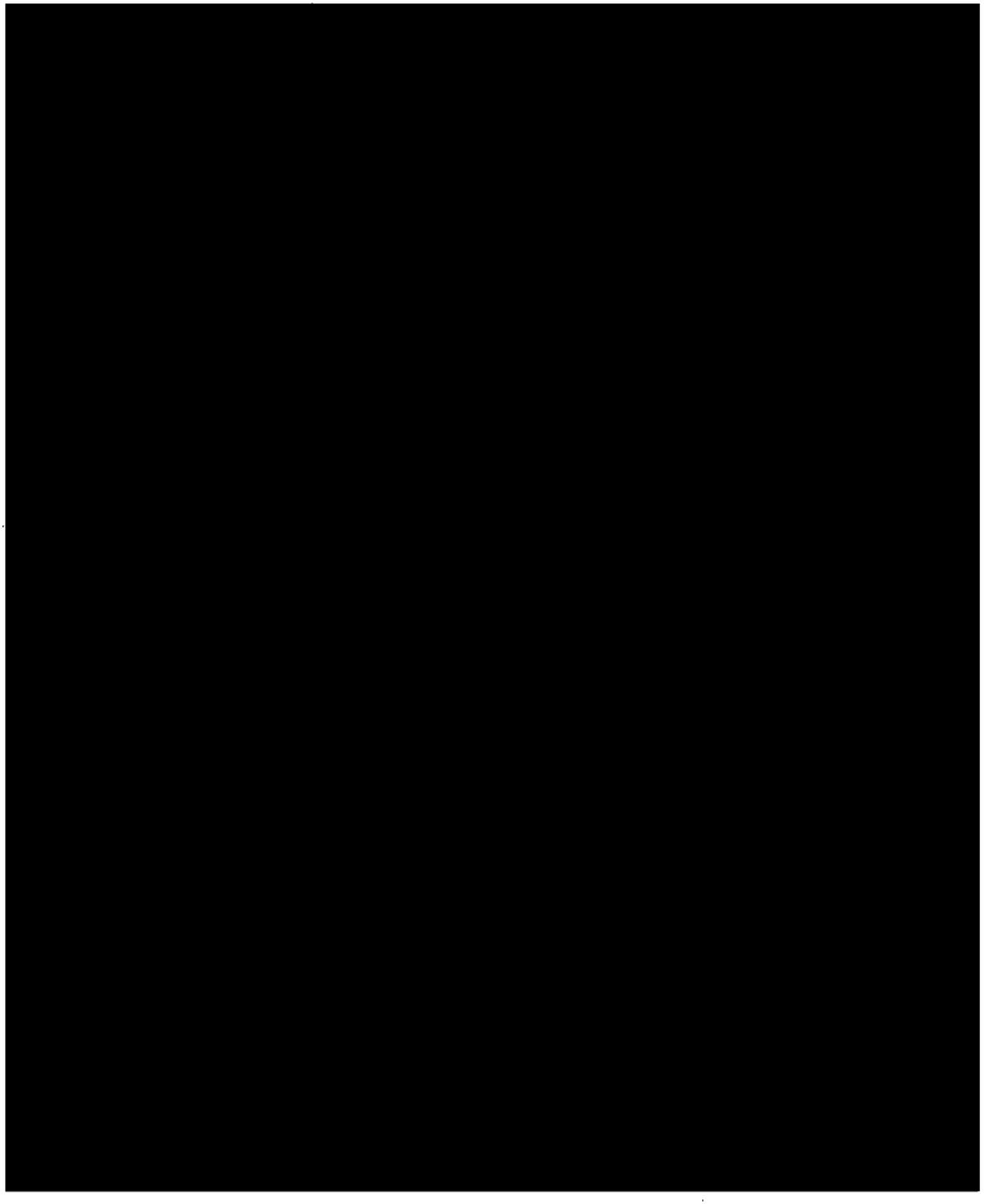

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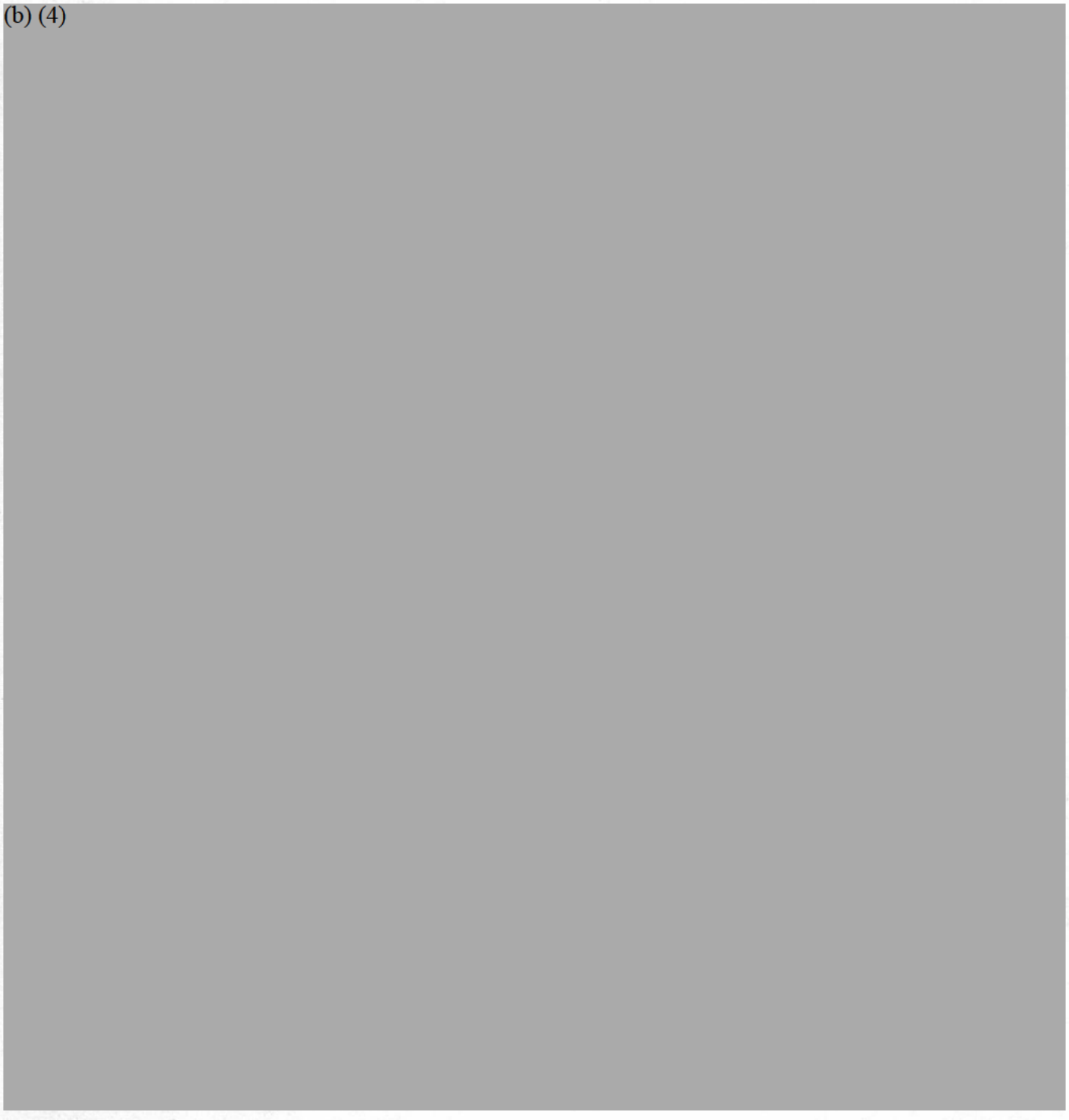

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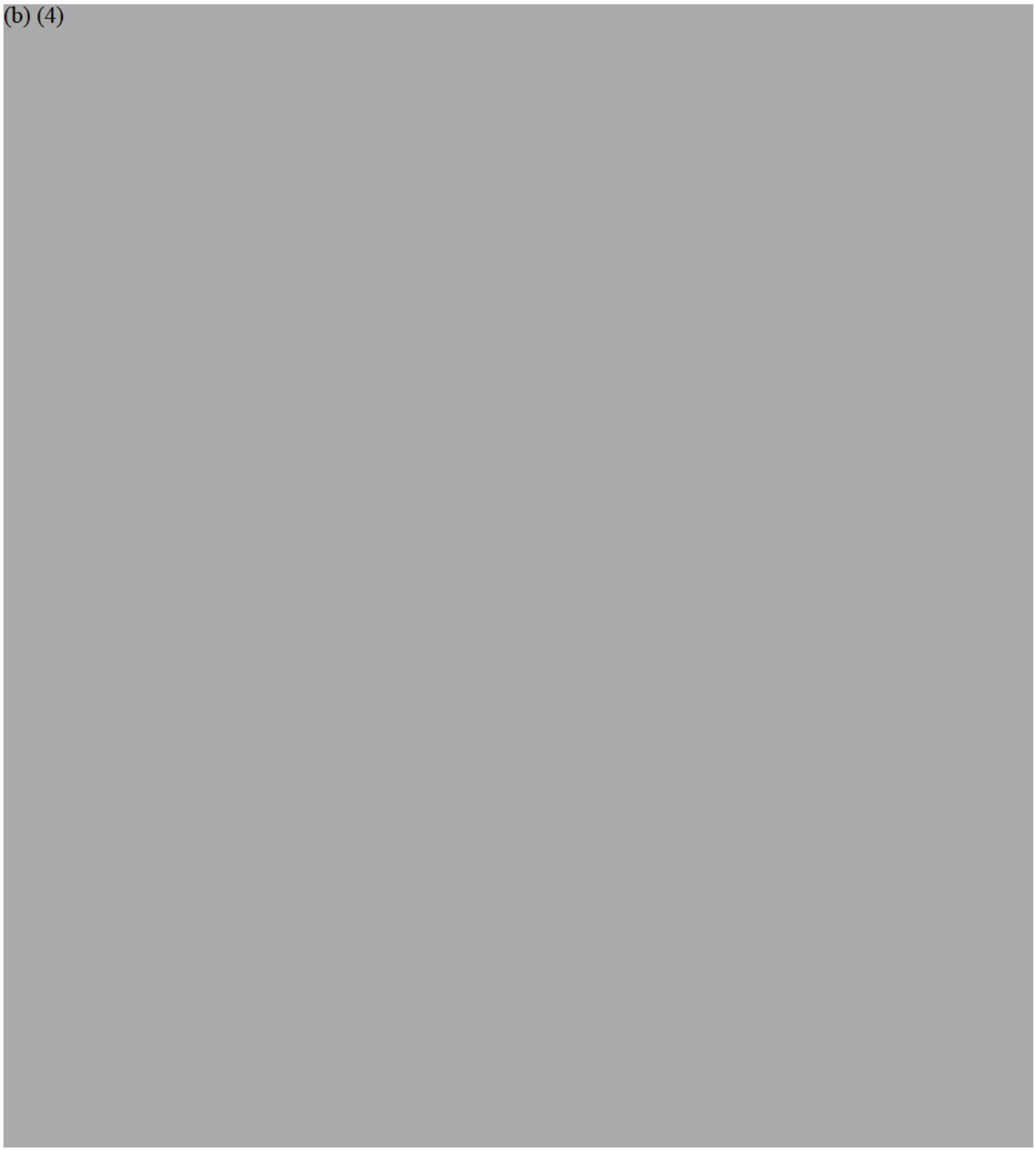

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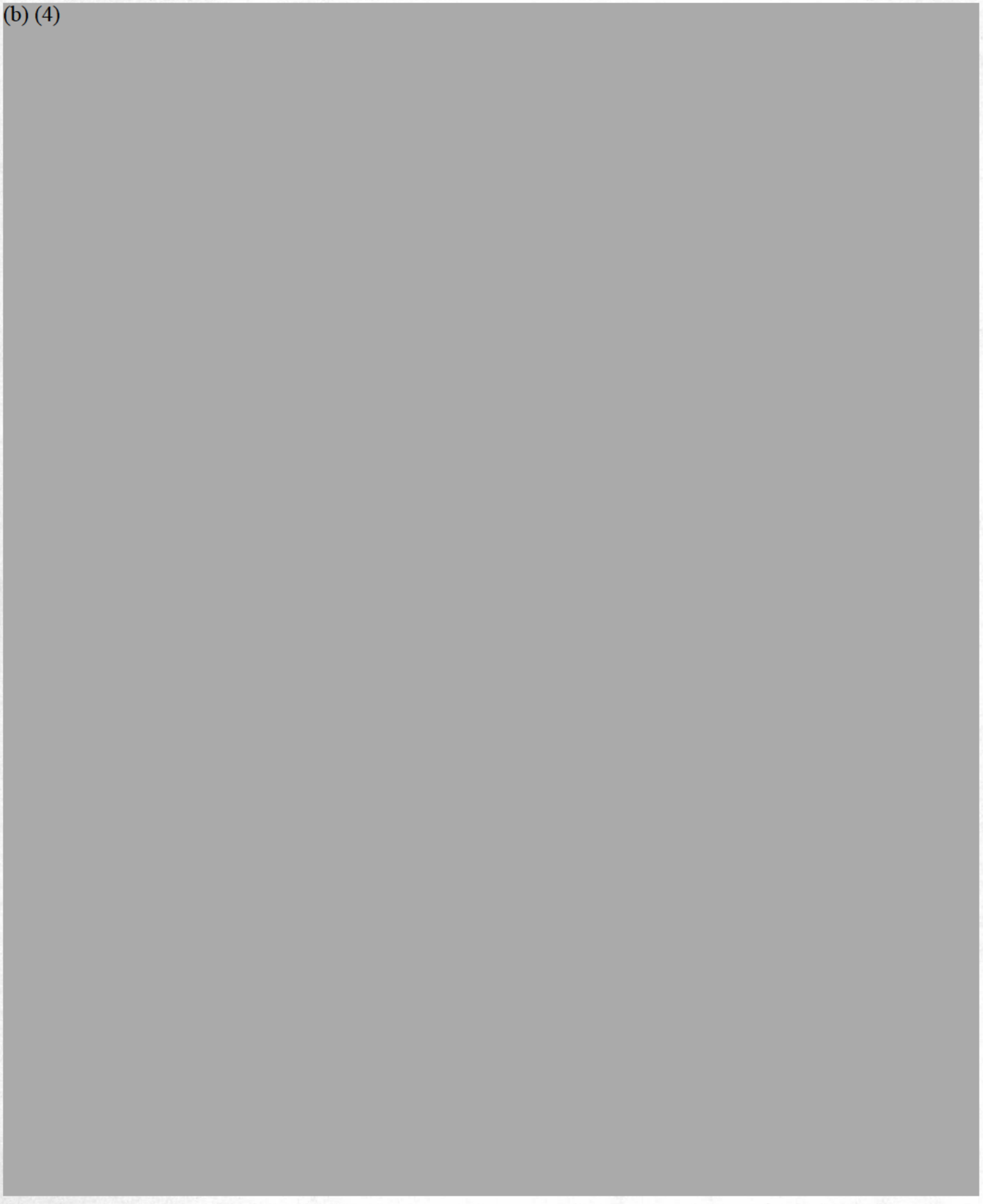

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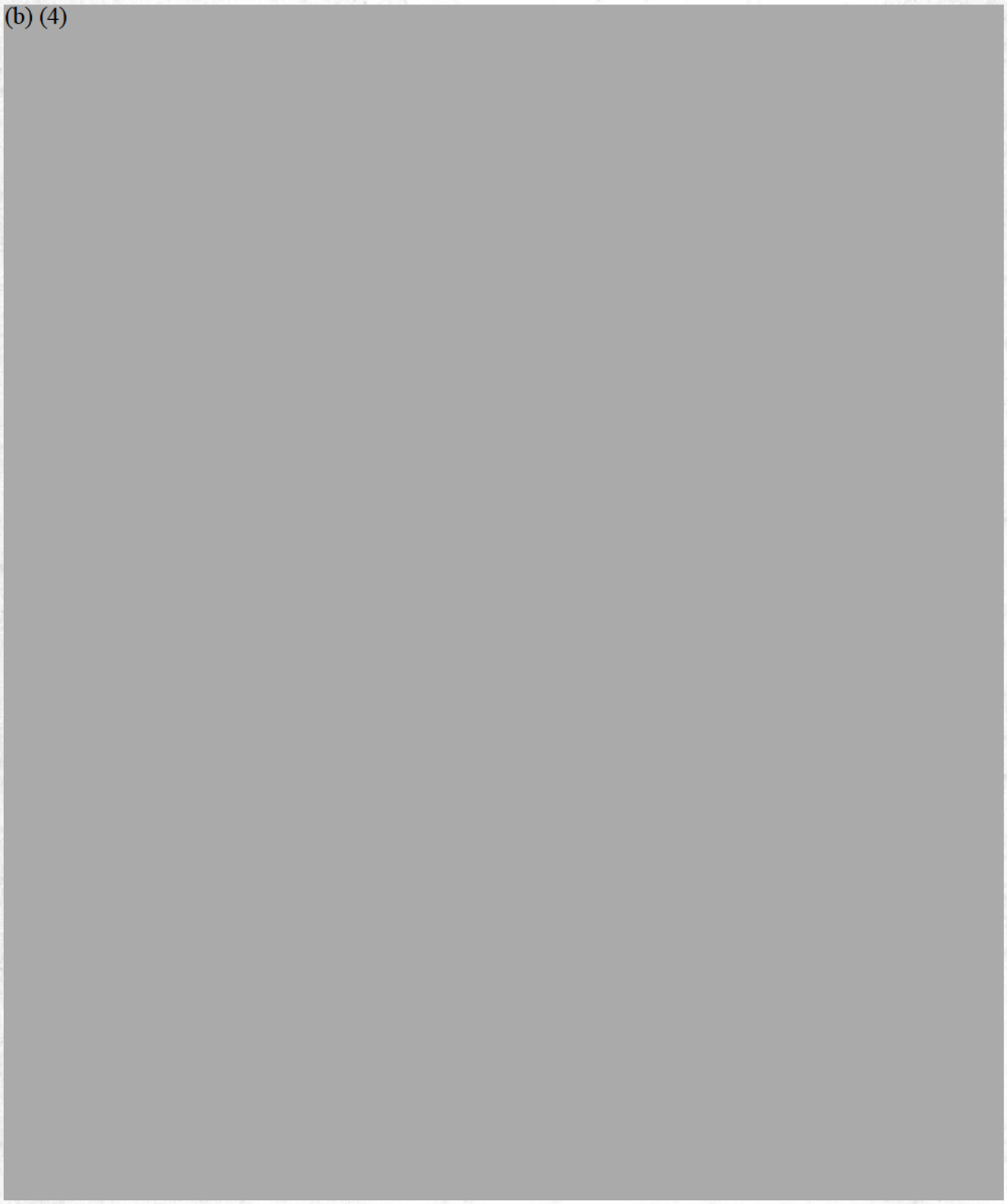

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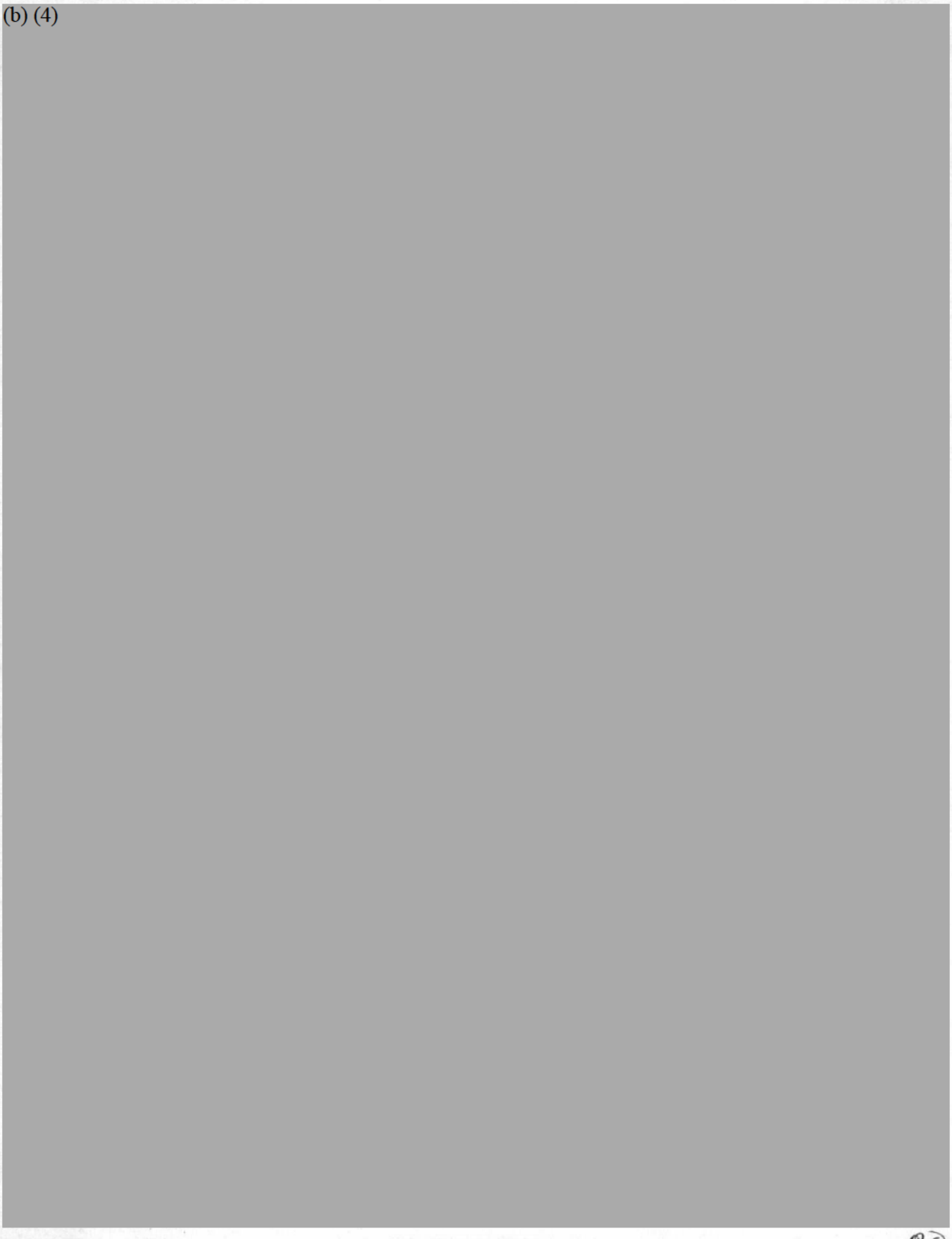

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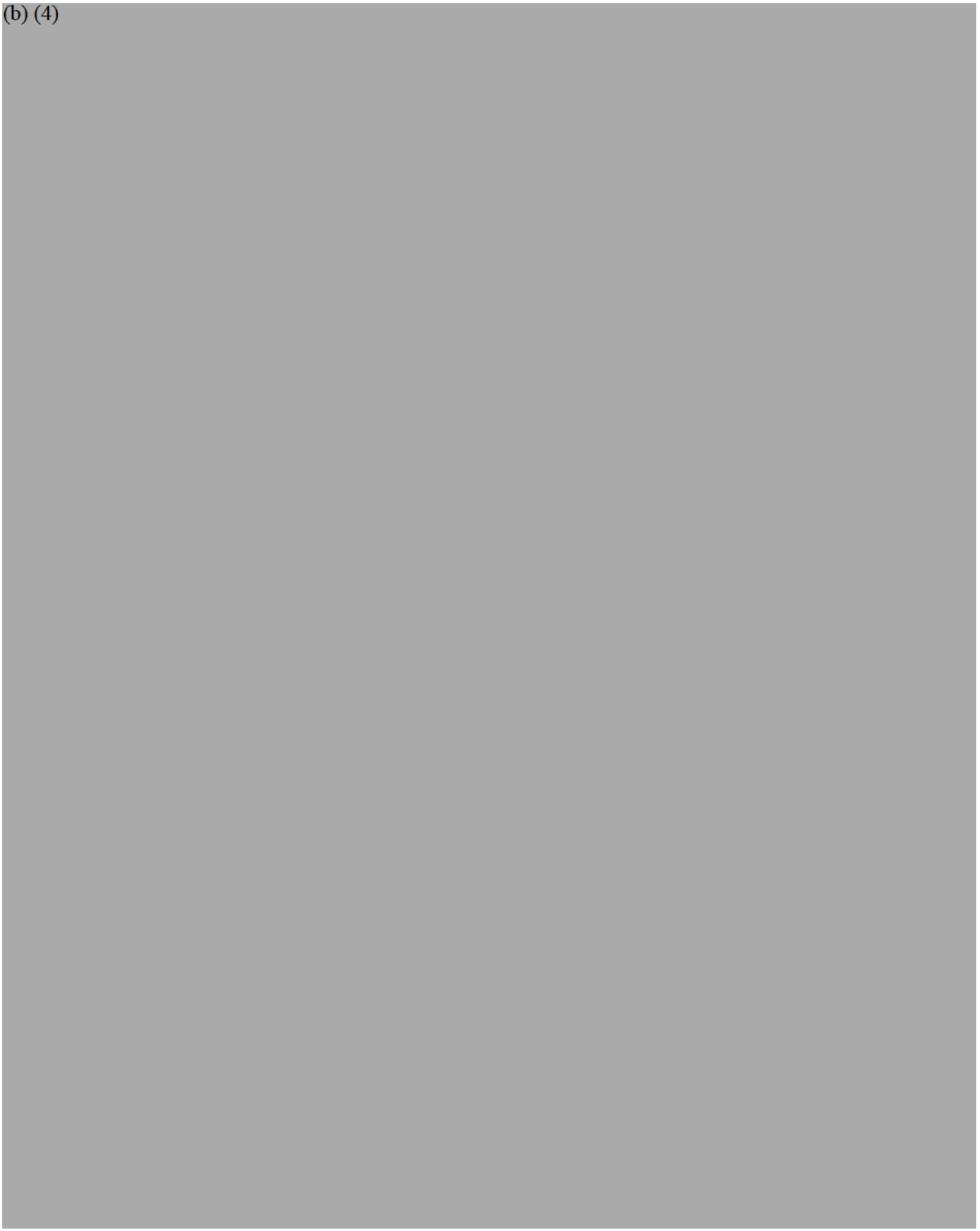

(b) (4)

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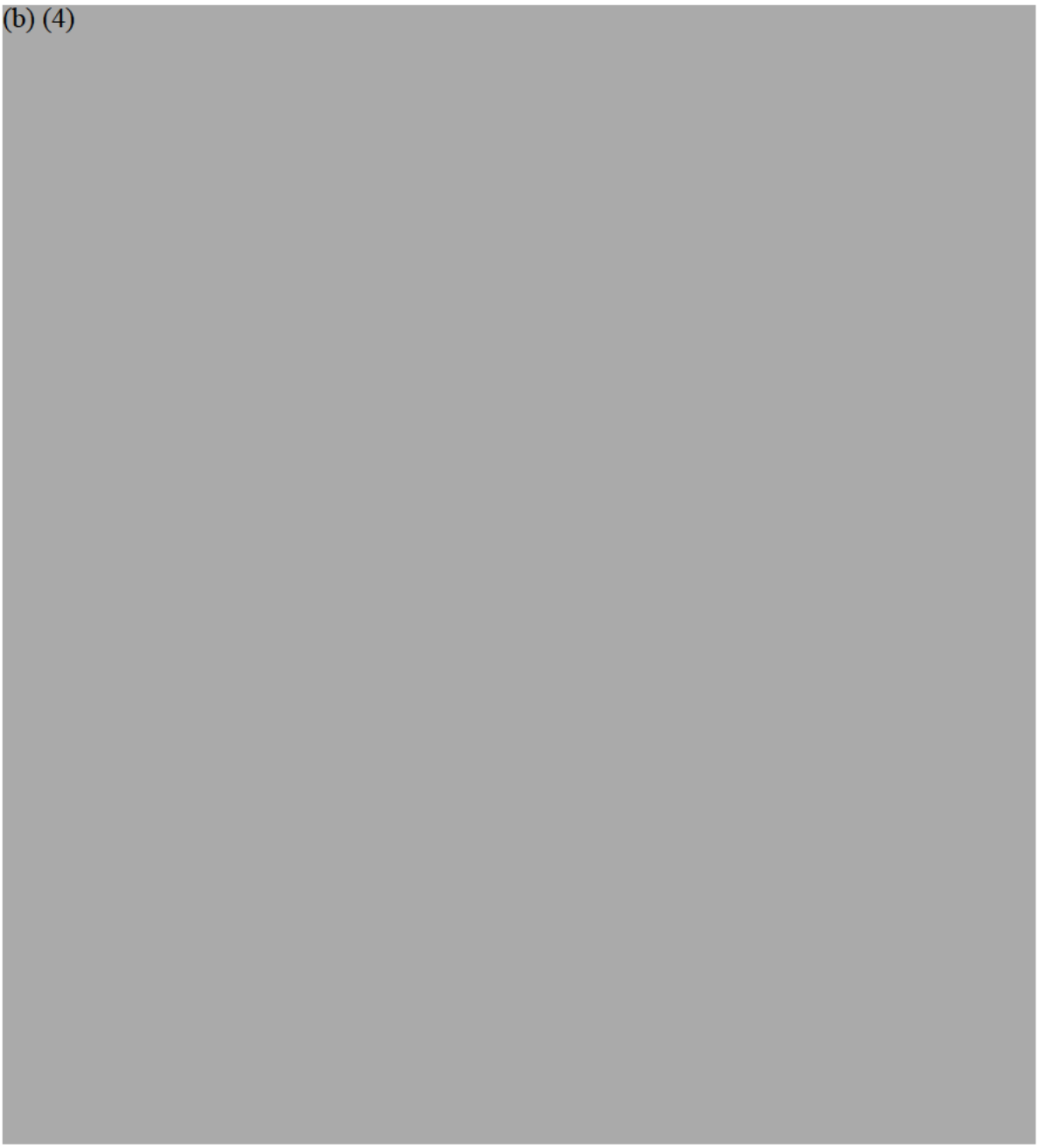
VI. Labeling

Labeling for AttestTM 1496V Super Rapid Readout Steam Challenge Pack

(b) (4)



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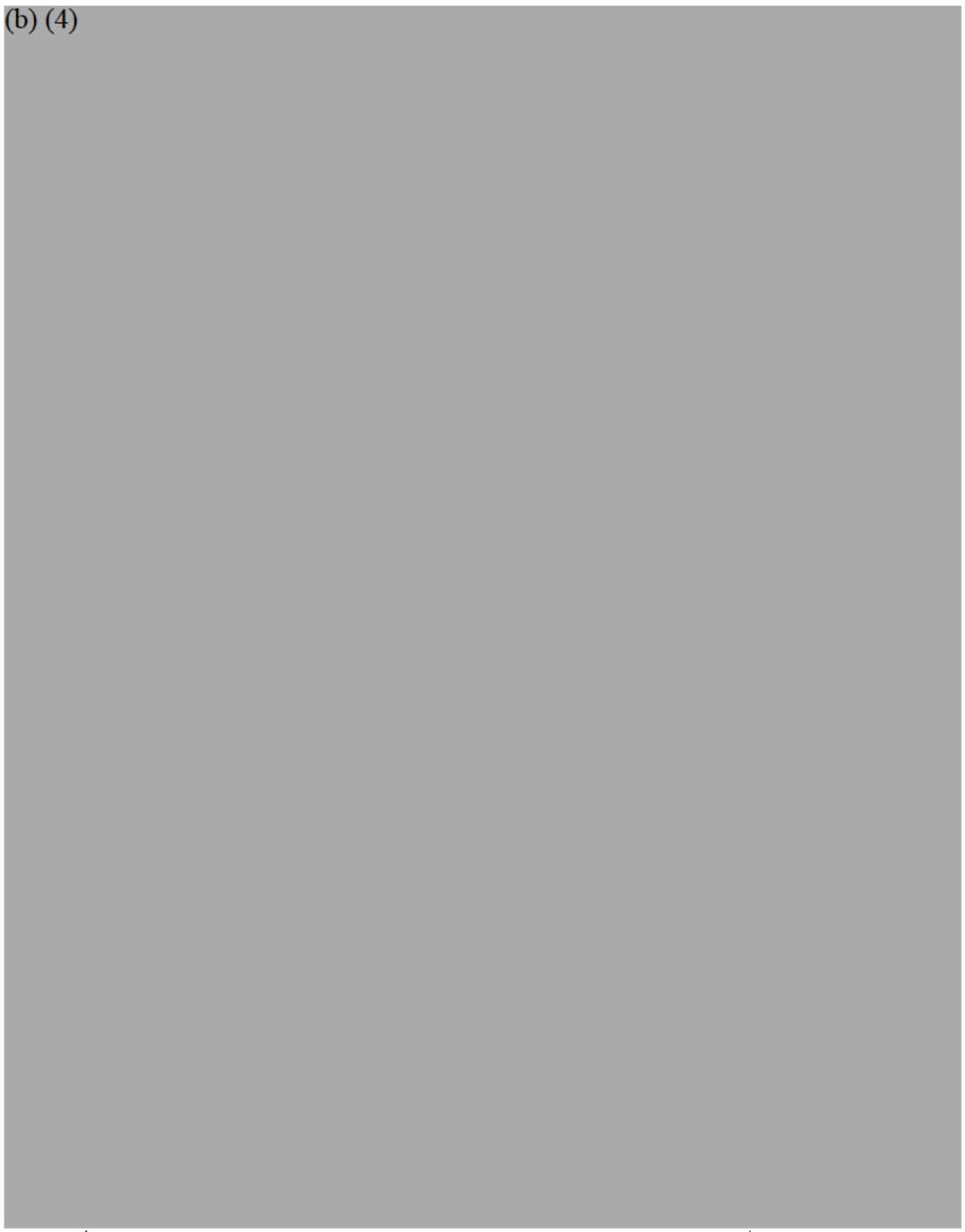

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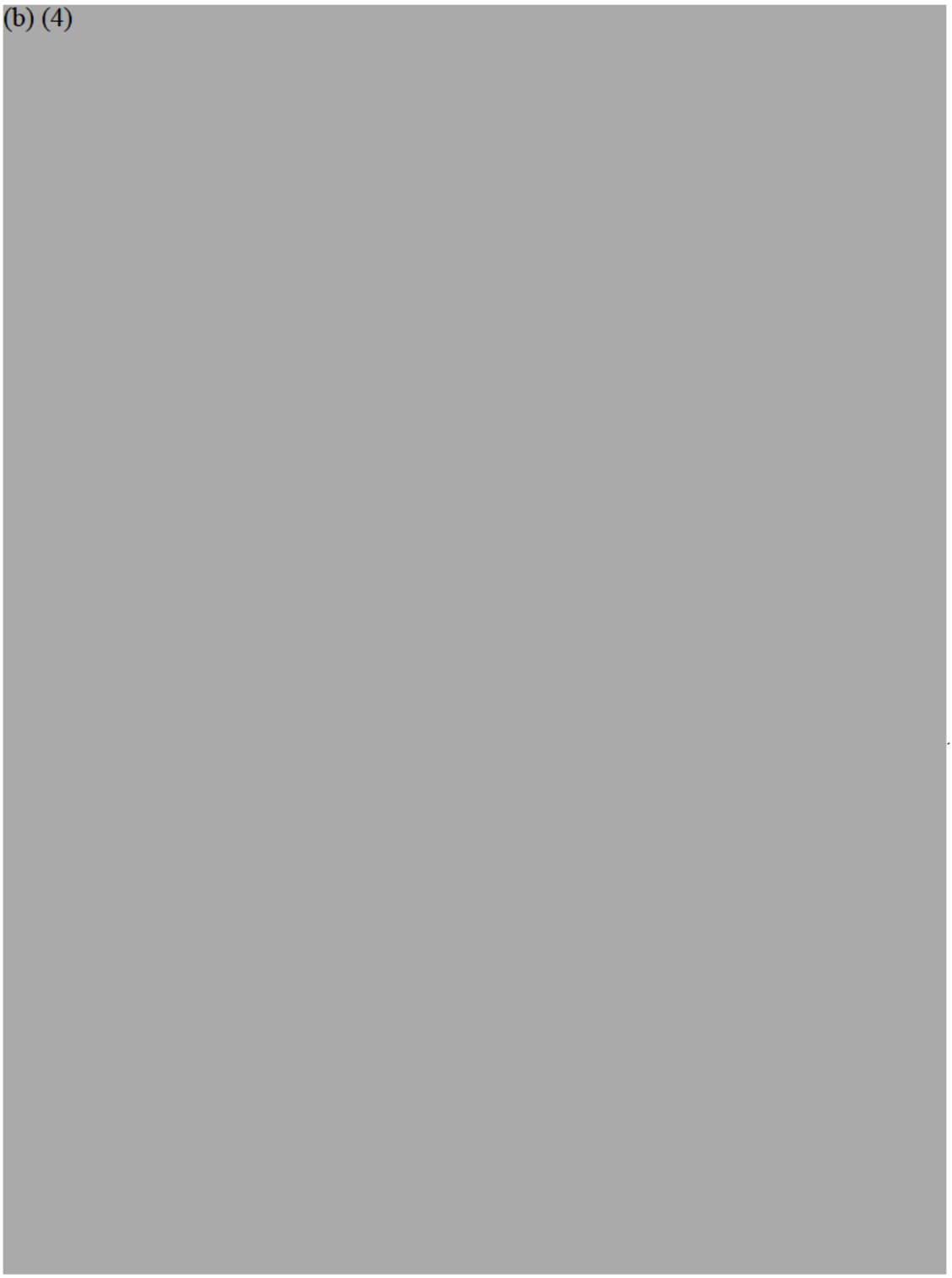

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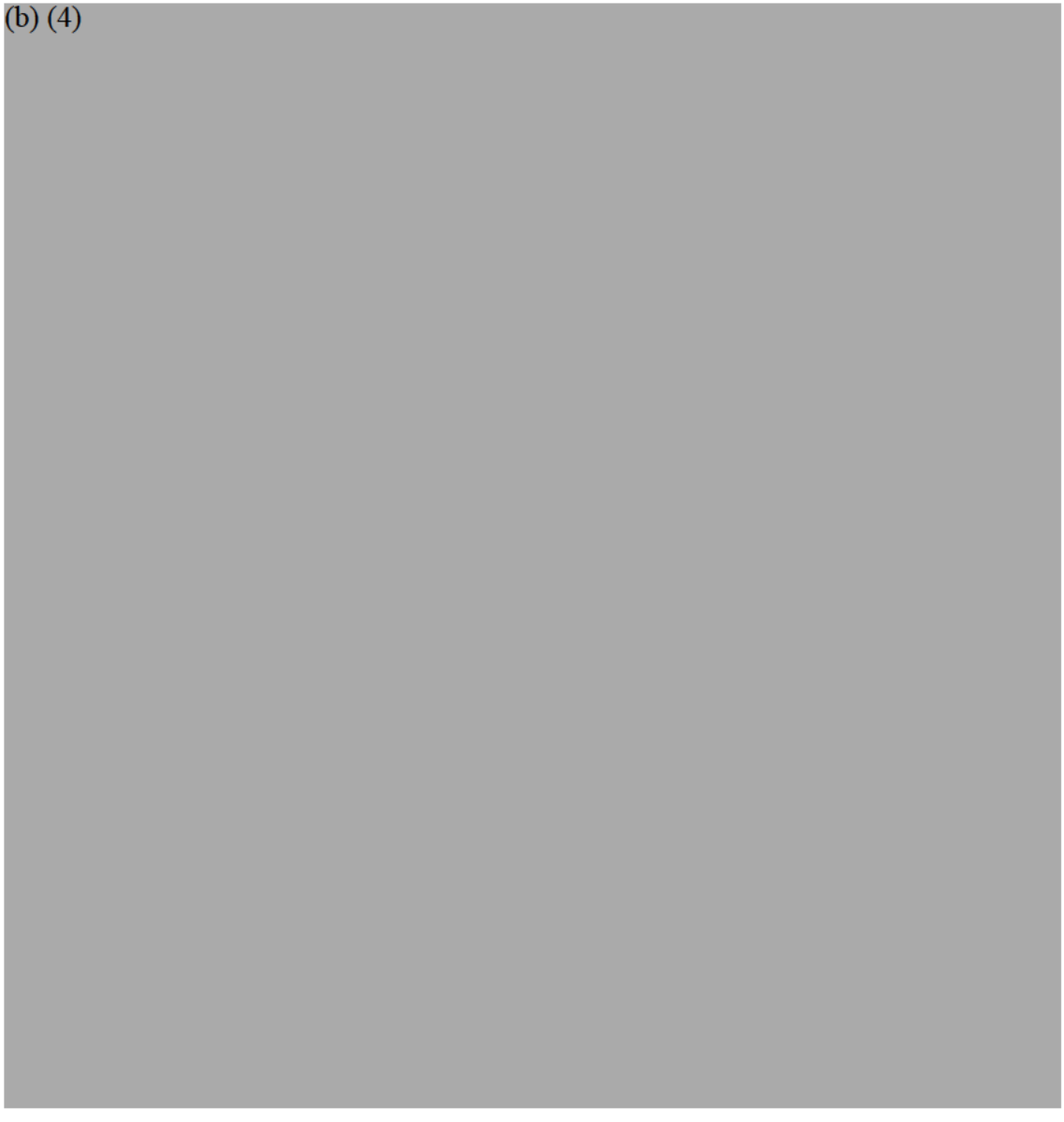

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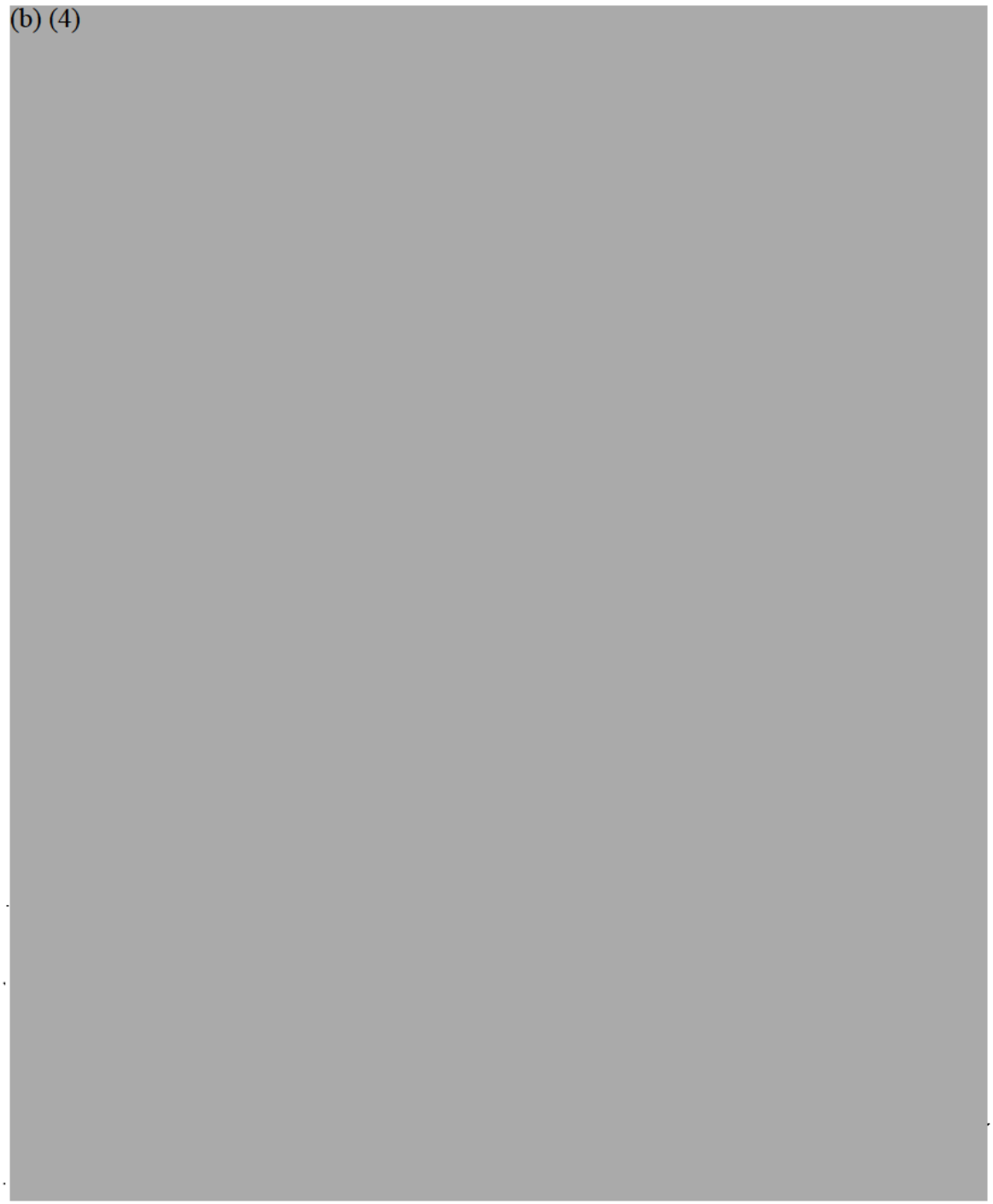

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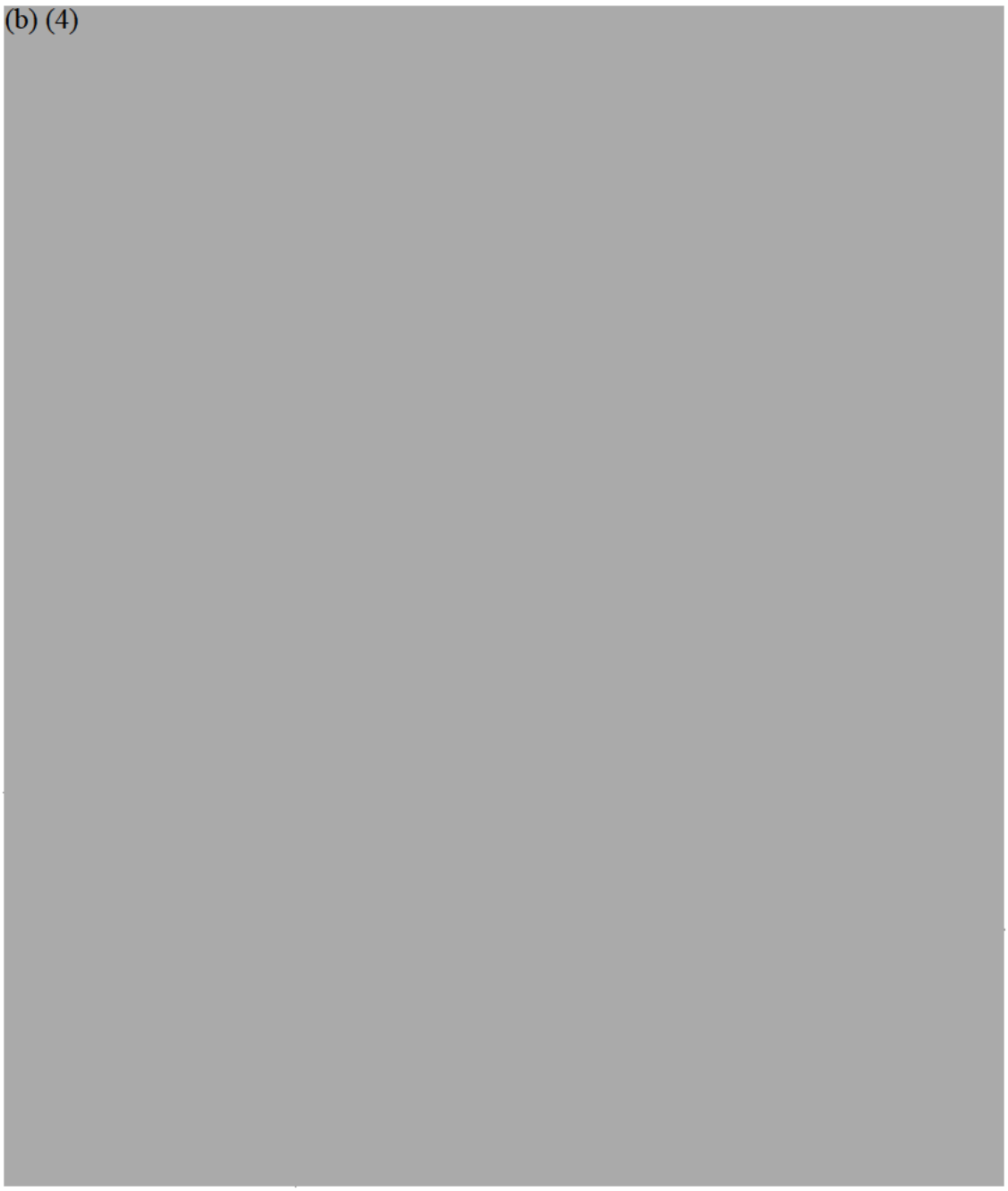

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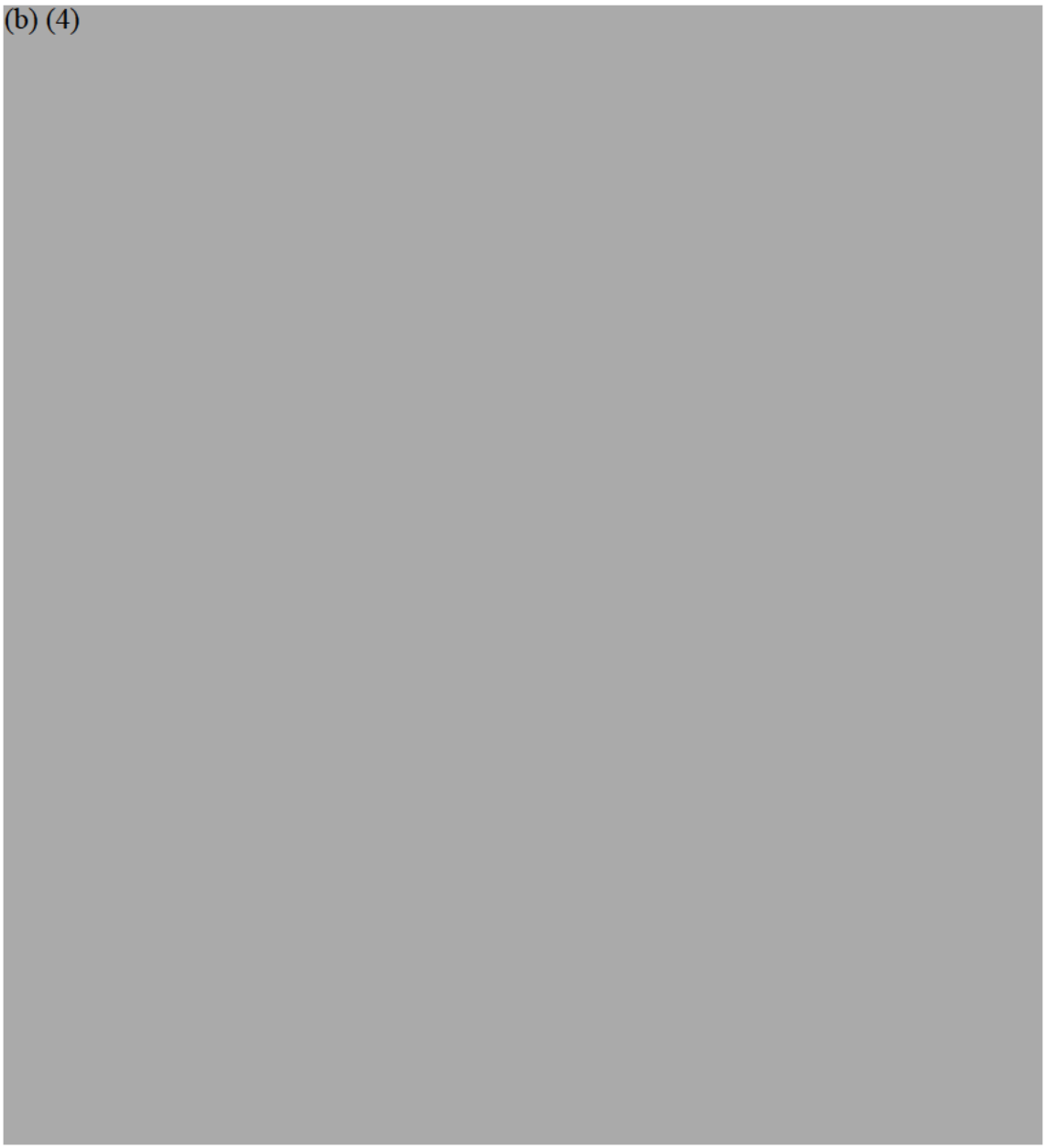

(b) (4)

Labeling for Attest™ 41482V Rapid 5 Steam-Plus Challenge Pack

(b) (4)

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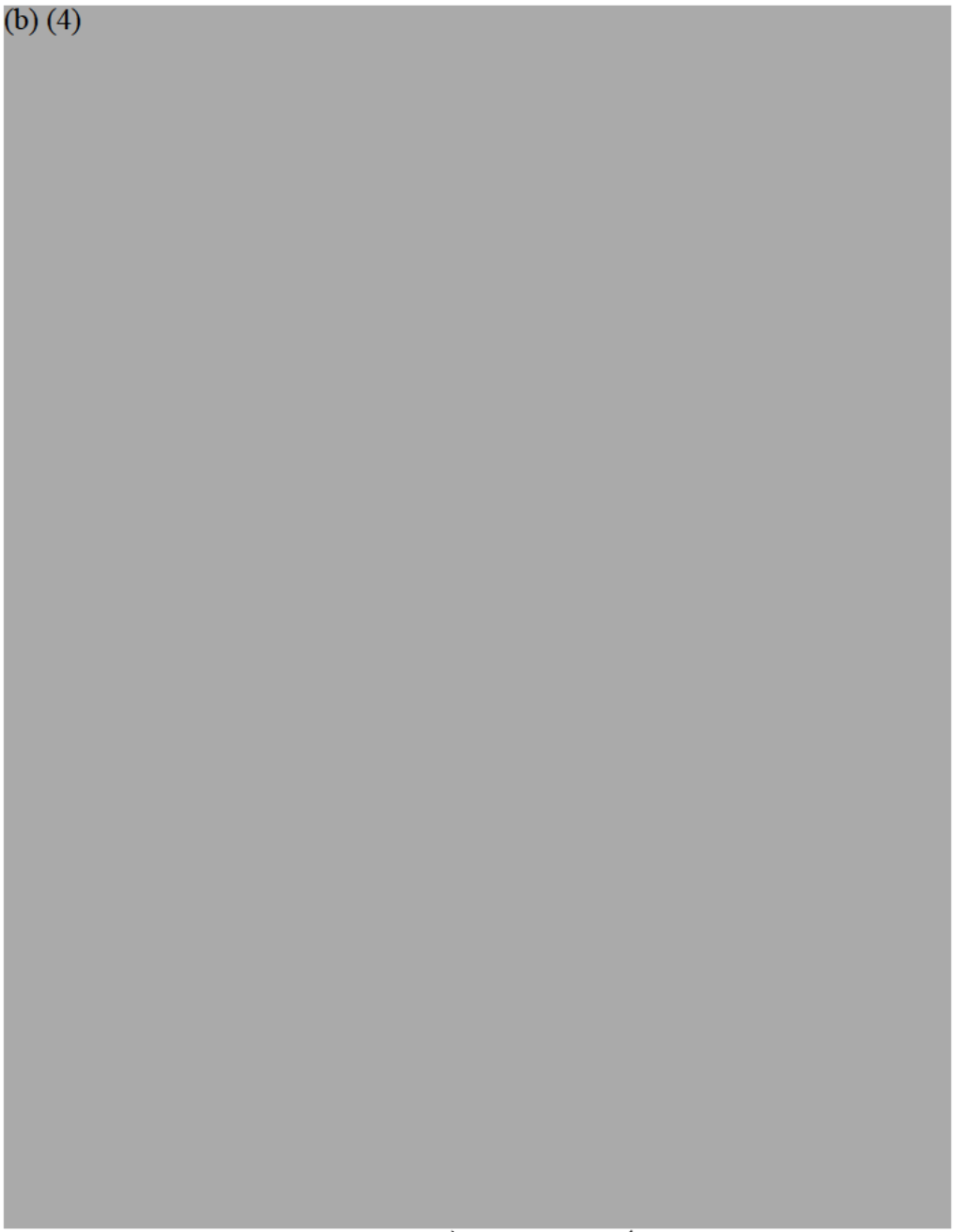

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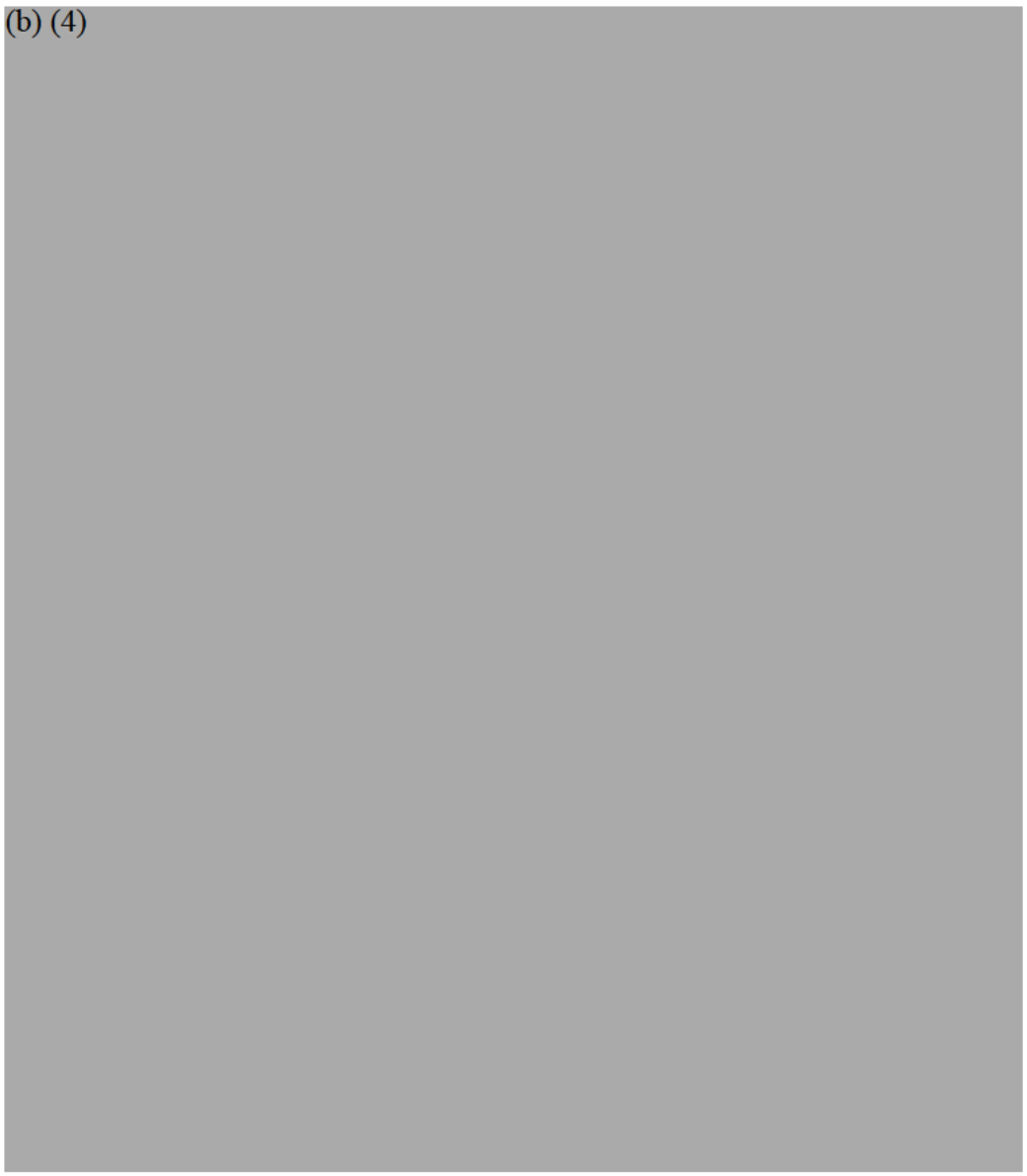

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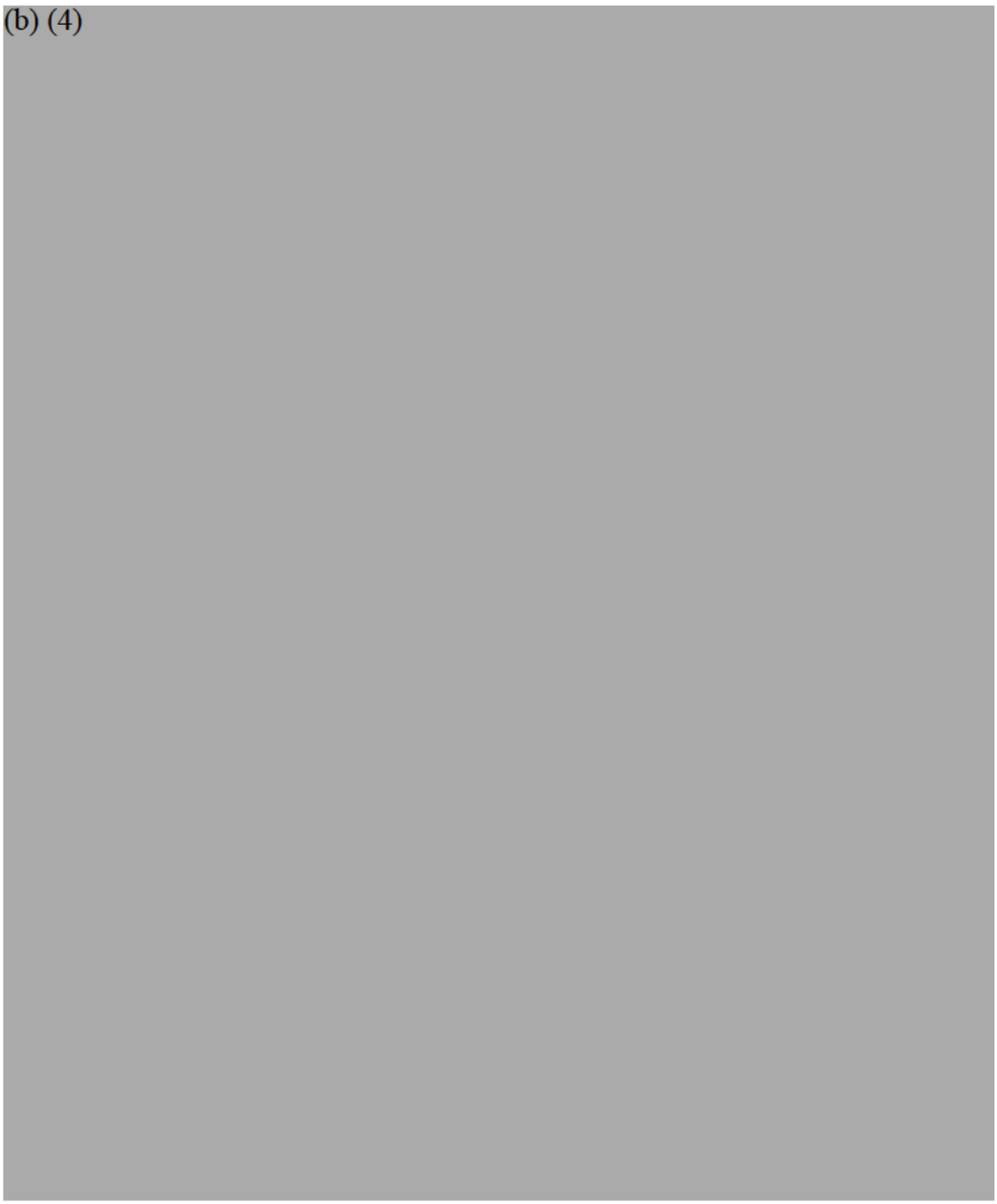

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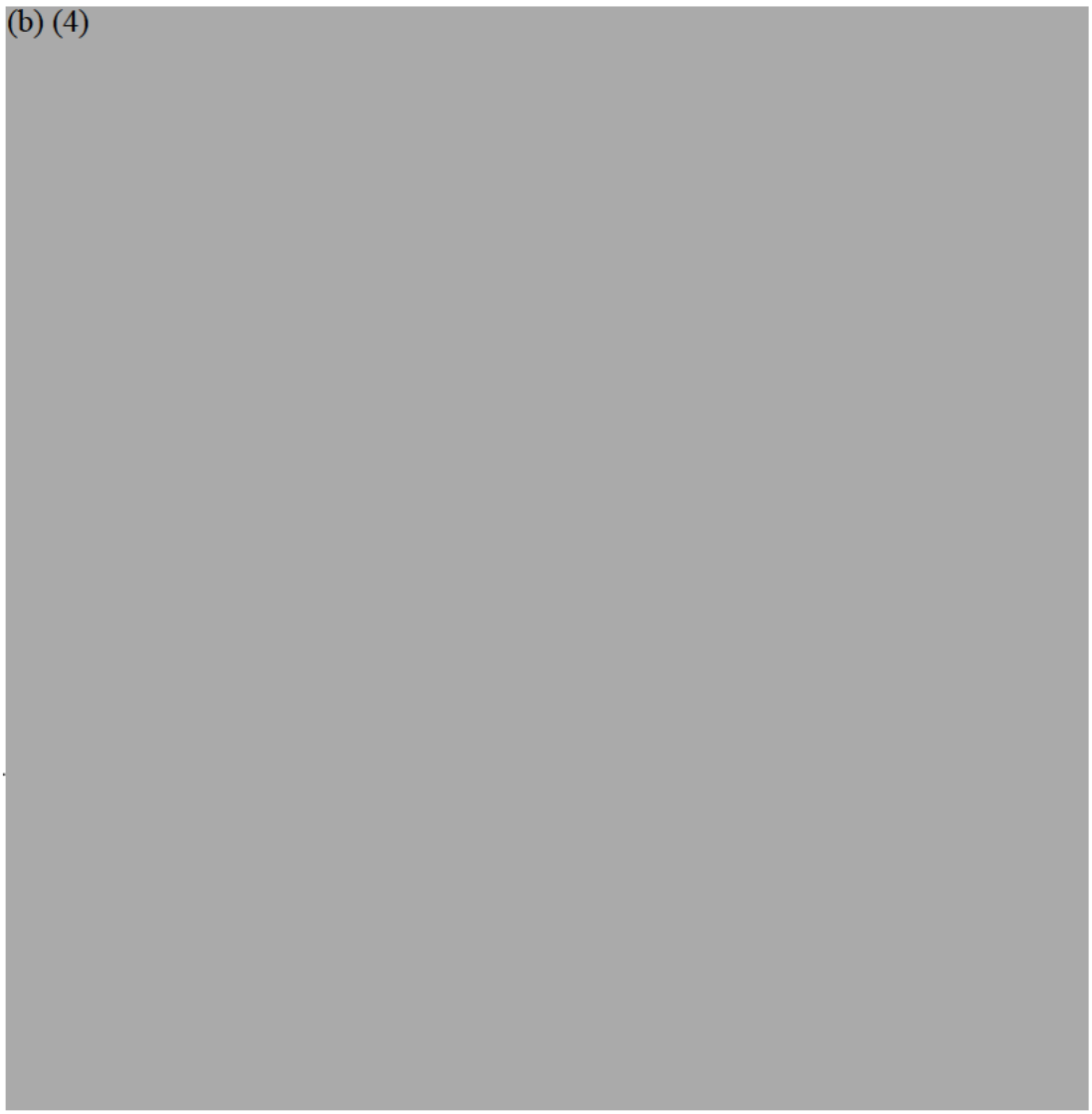

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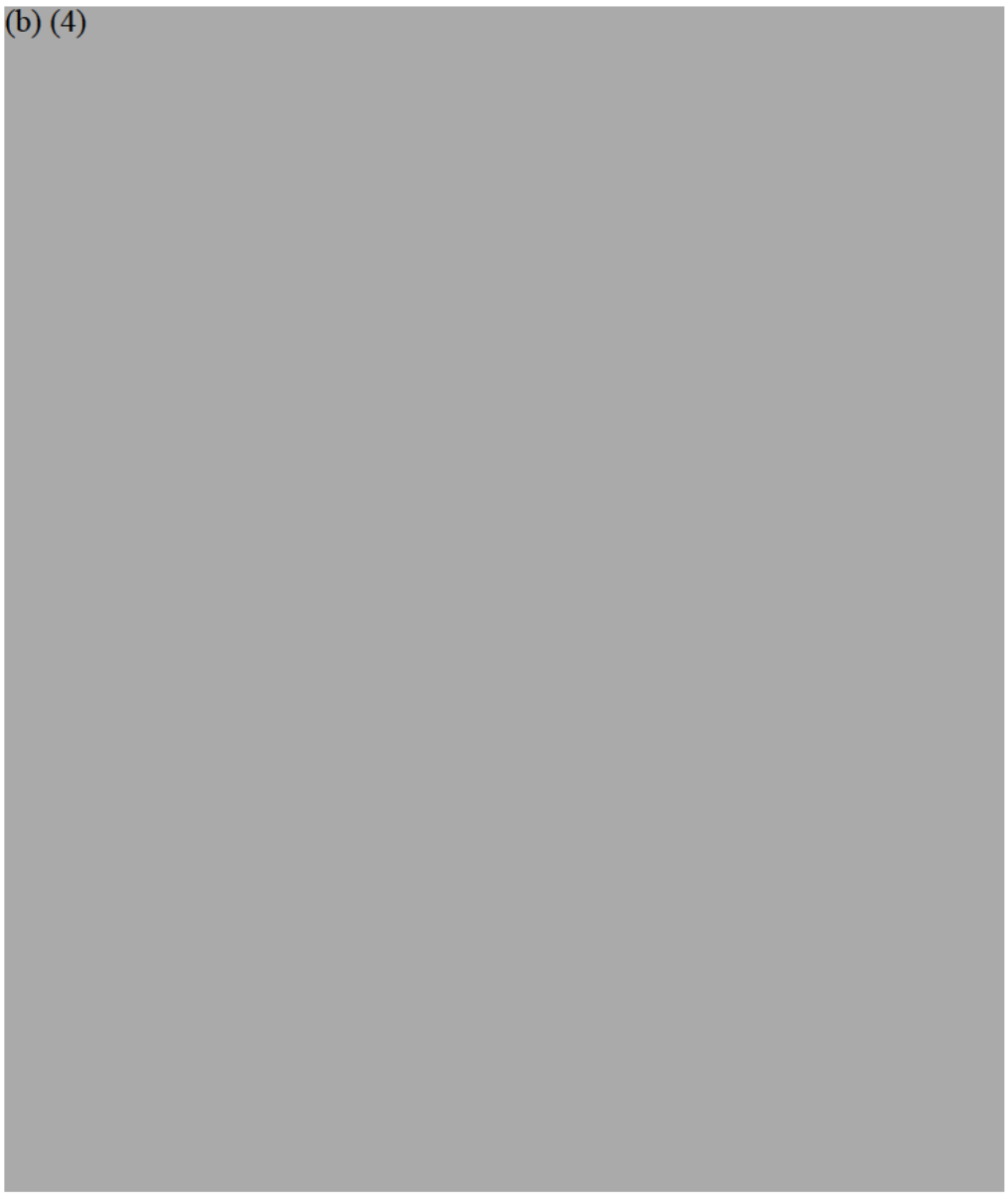

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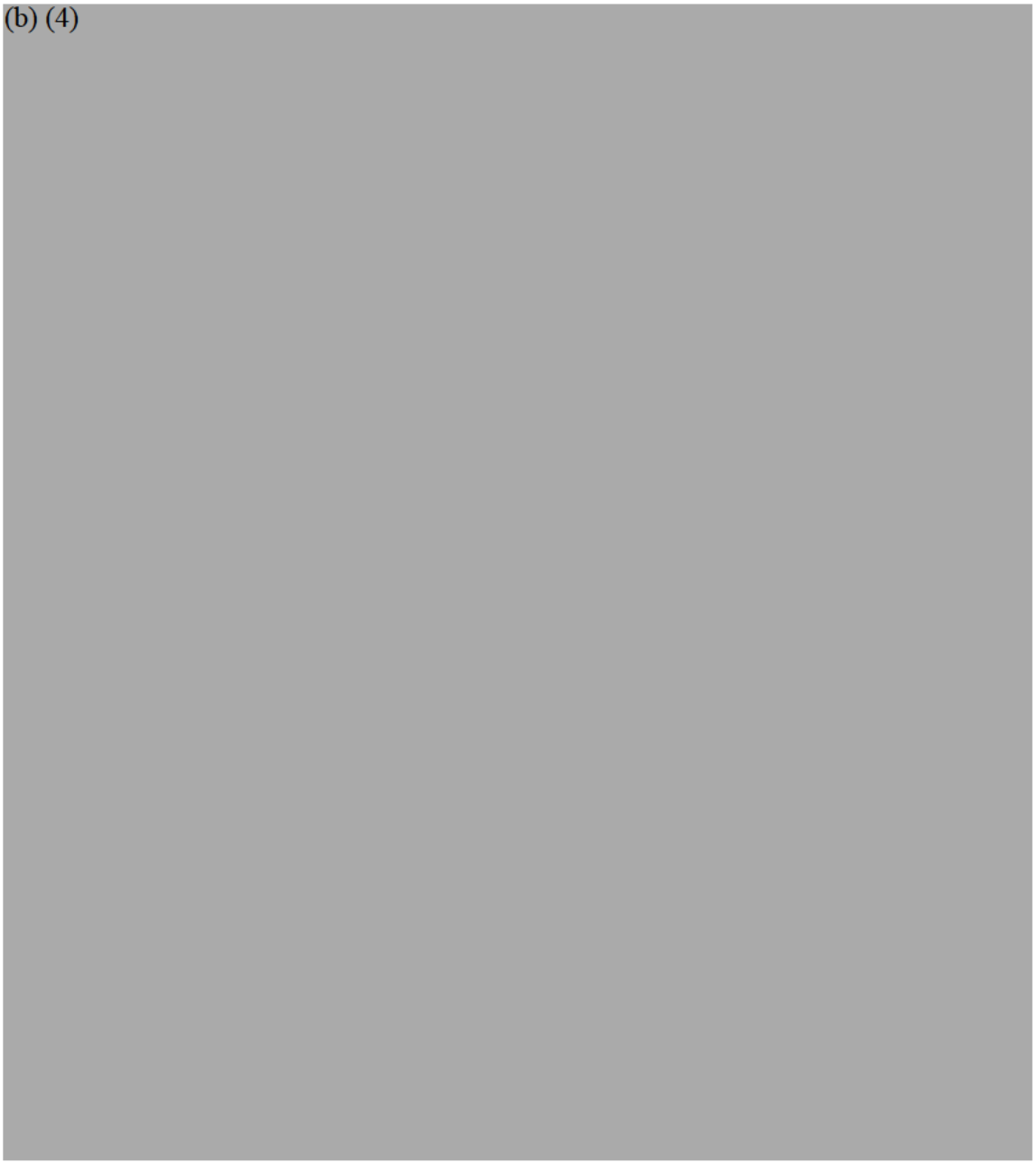

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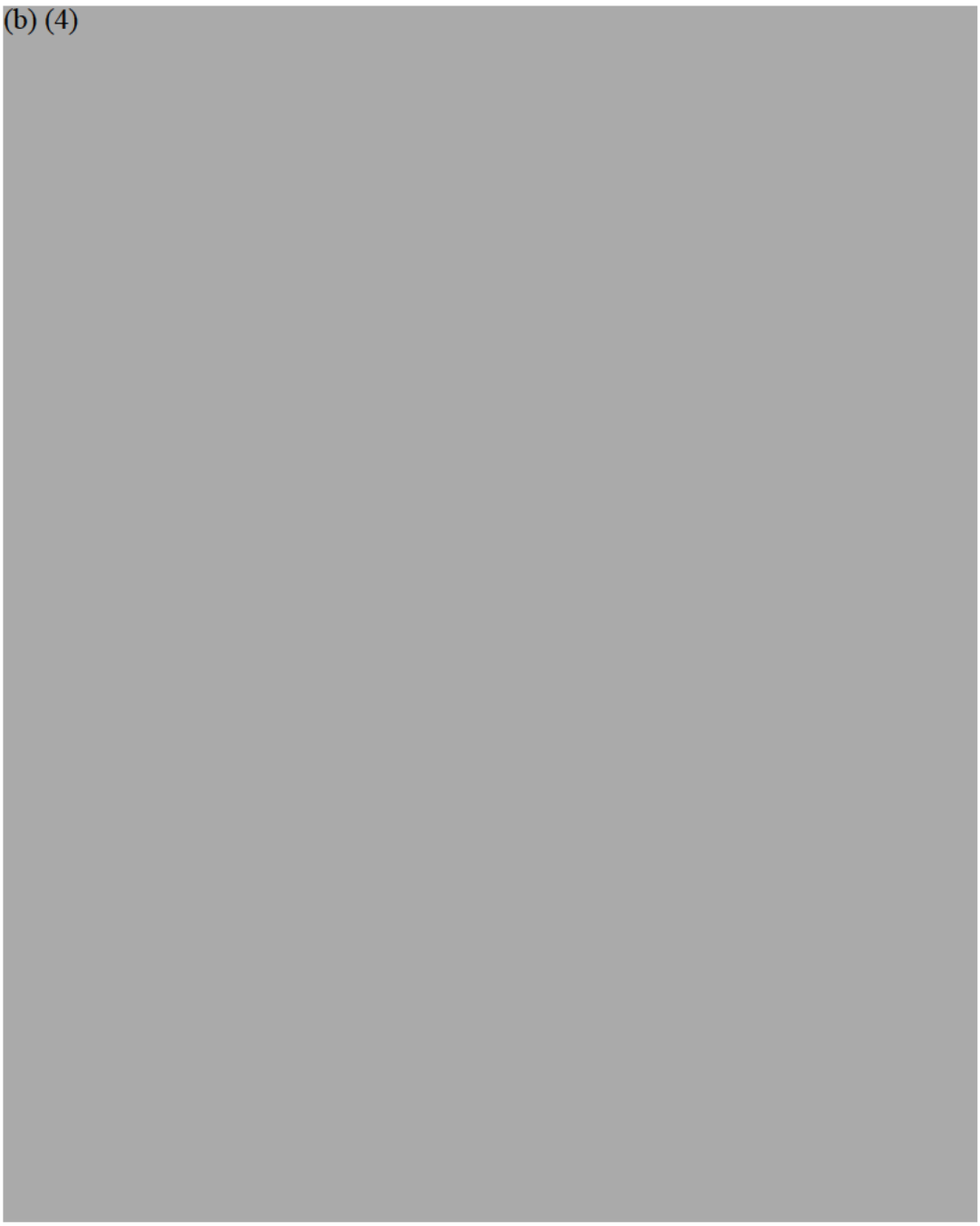

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IX. Software

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		

Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

(b) (4)

[redacted]

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

N/A

XI. Performance Testing – Bench

(b) (4)

[redacted]

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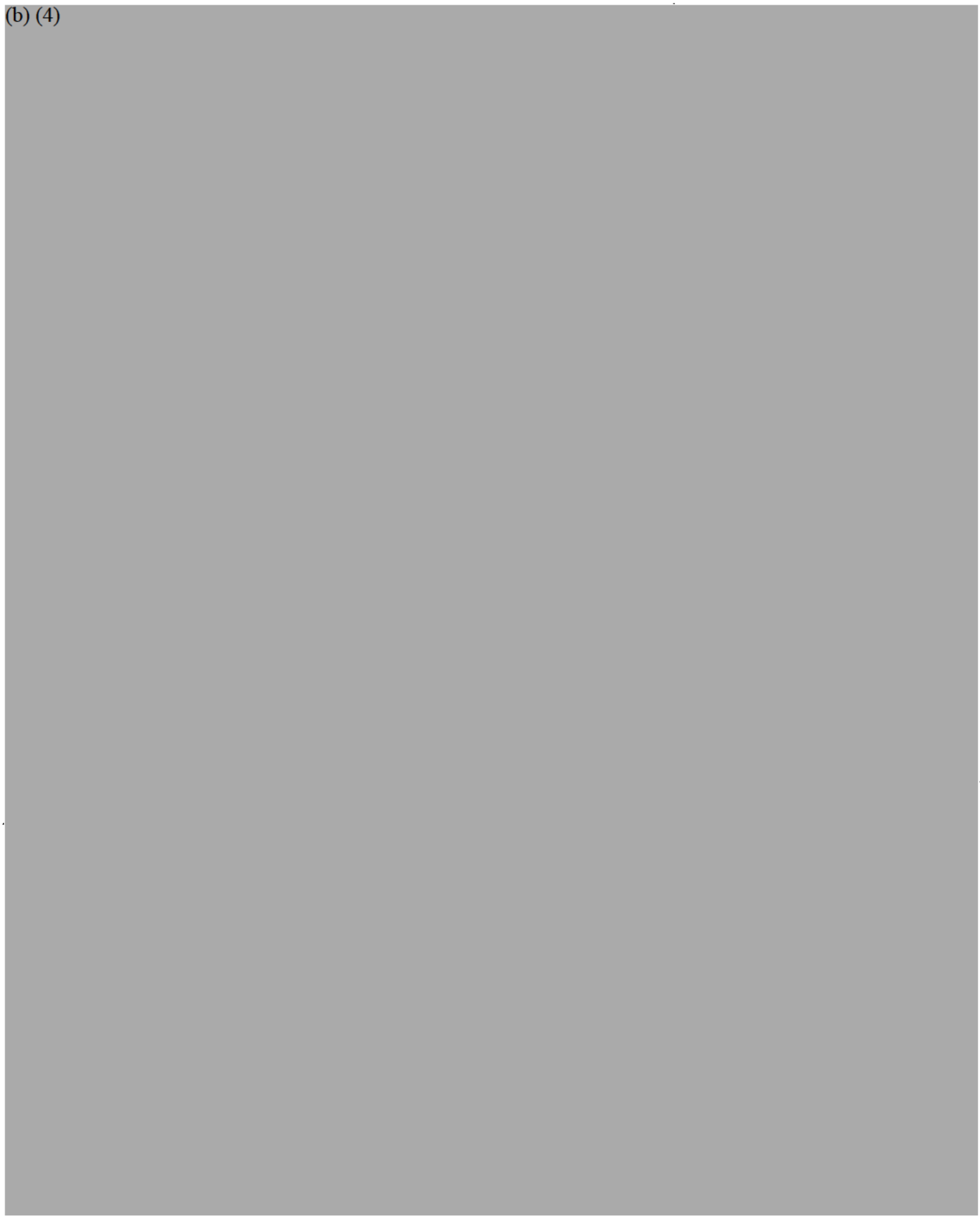

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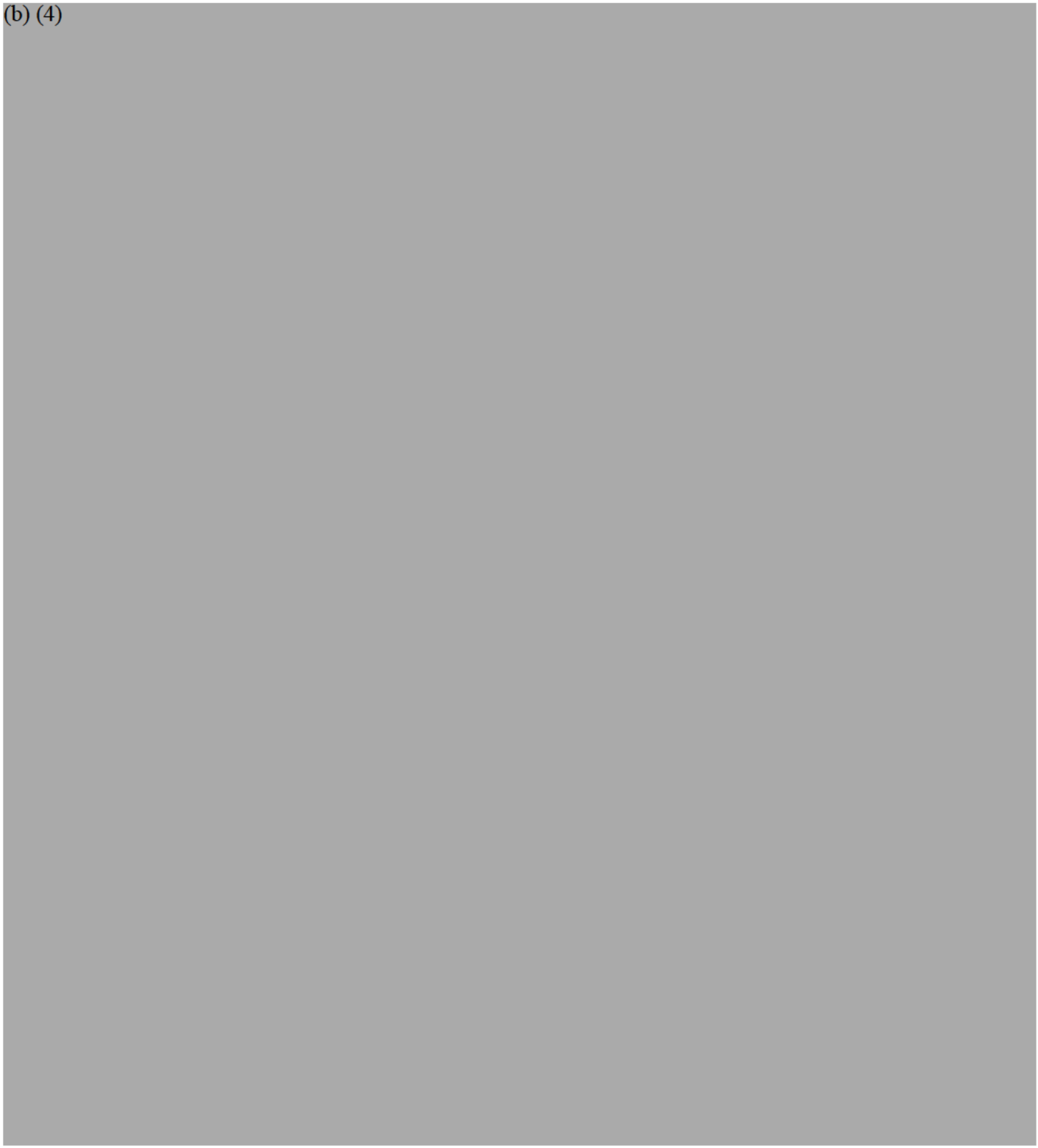

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[redacted]

XII. Performance Testing – Animal

N/A

XIII. Performance Testing – Clinical

N/A

(b) (4)

XIV. Substantial Equivalence Discussion

1. Same Indication Statement?	f **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	f **YES** = Stop **NSE**
3. Same Technological Characteristics?	f **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	f **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	f **NO** = Go To 8 f **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?	f **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	f **NO** = Stop **NSE**
8. Performance Data Available?	f **NO** = Request Data
9. Data Demonstrate Equivalence?	Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

(b) (4)

(b) (4)

Deficiencies from S001 Review:

Administrative

510(k) Summary

1. Please provide the product code in this summary.

The firm's December 6, 2012 S002 response to FDA:

3M included the product code in the 510(k) summary.

Reviewer Comments: The response is acceptable. ***The deficiency is resolved.***

(b) (4)

3. Please include a discussion of the similarities and differences between the subject devices and the predicate device.

The firm's December 6, 2012 S002 response to FDA:

3m included a table and discussion of the similarities and differences between the subject device and the predicate device.

Reviewer Comments: The response is acceptable. ***The deficiency is resolved.***

Indications for Use

(b) (4)

Predicate Device Comparison

(b) (4)

(b) (4)

Labeling

In regards to the labeling for your 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V:

(b) (4)

In regards to labeling for your 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V:

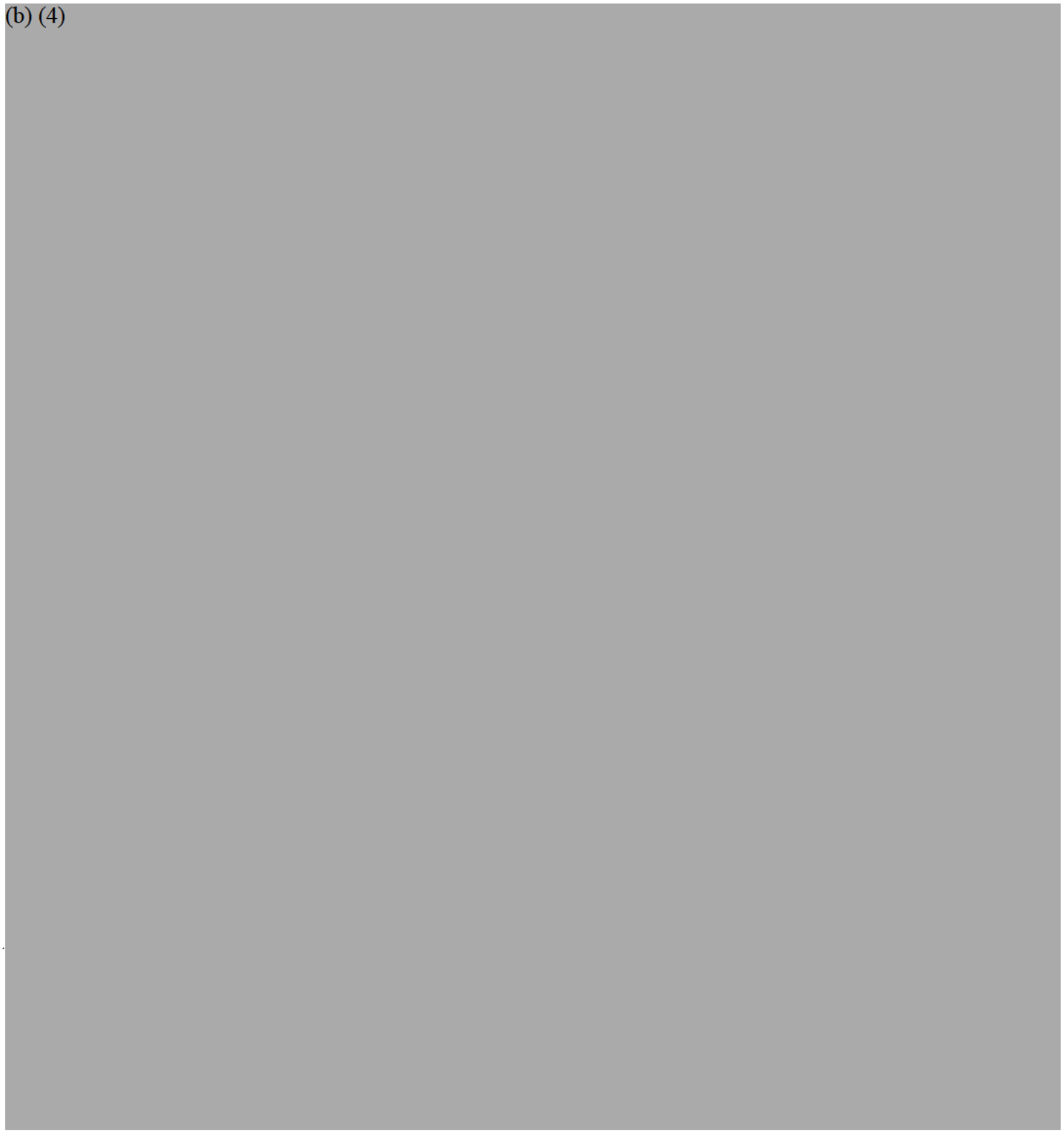
(b) (4)

(b) (4)

Labeling

(b) (4)

(b) (4)



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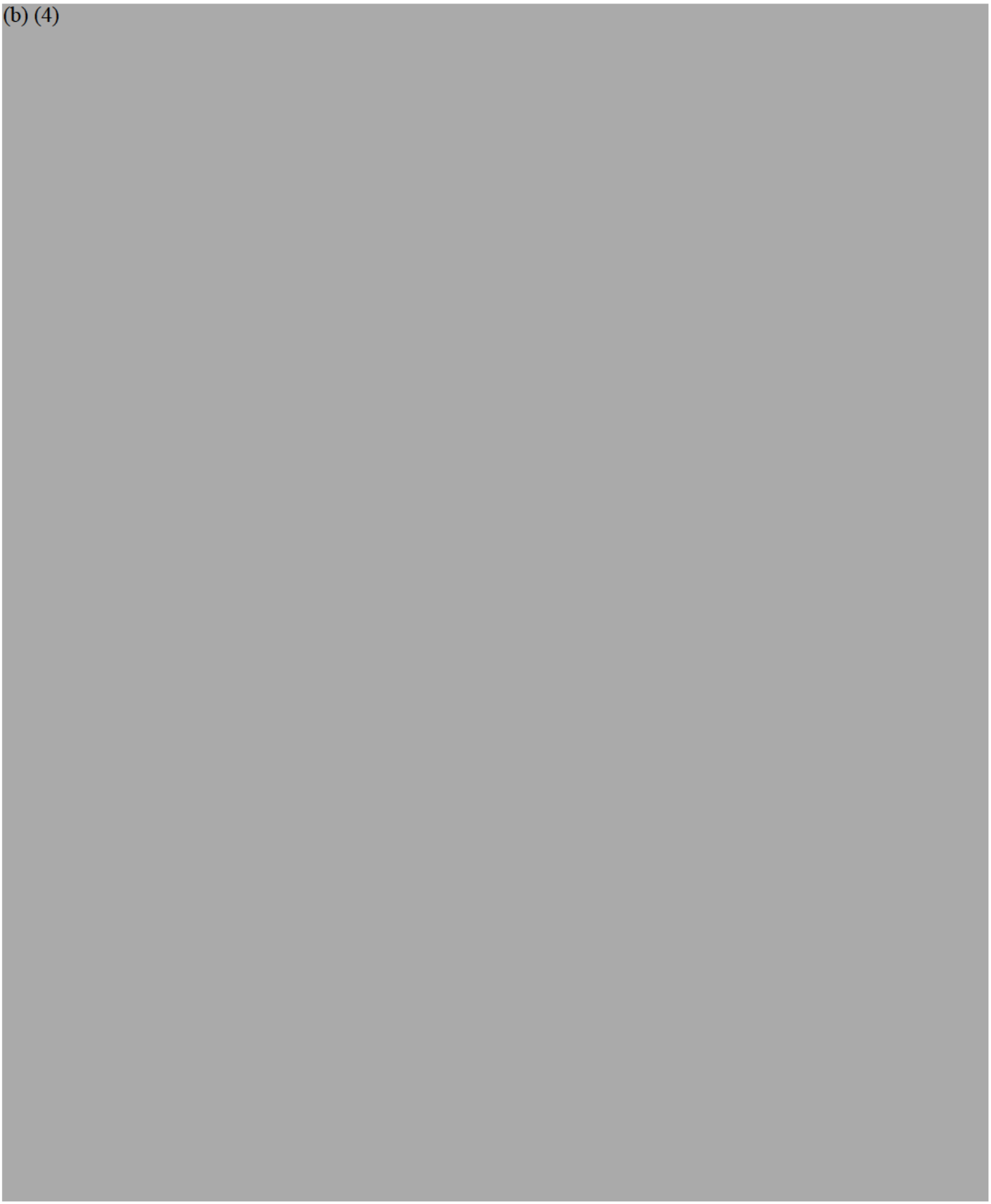

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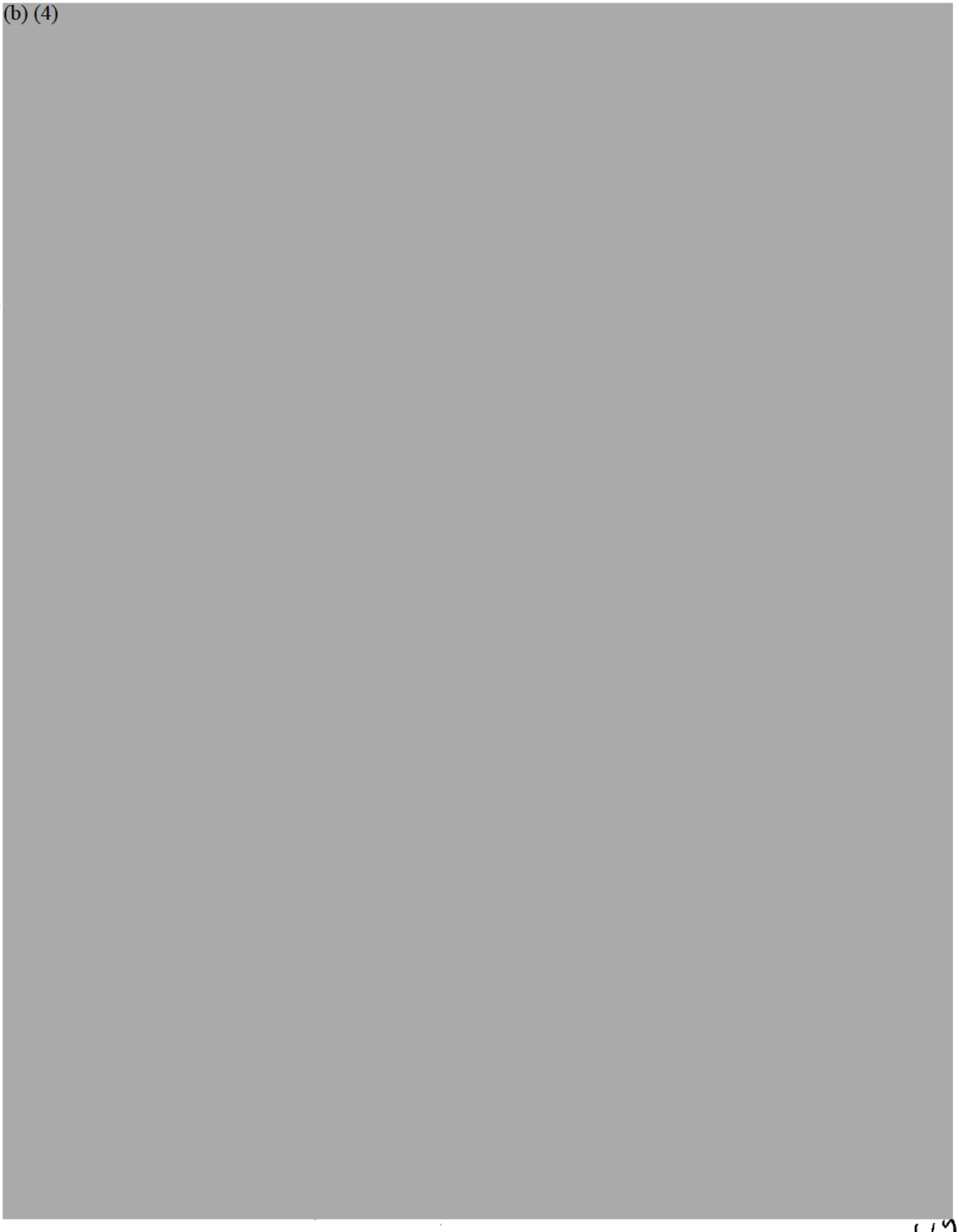

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XVII. Recommendation

Regulation Number: 21 CFR 880.2800(a)
Regulation Name: Sterilization process indicator/ Biological Sterilization process indicator
Regulatory Class: II
Product Code: FRC

Reviewer — Date: Dec. 13, 2012

Branch Chief — Date: 12/13/12

Murray III, Clarence

From: Murray III, Clarence
Sent: Thursday, December 13, 2012 3:28 PM
To: (b) (4), (b) (6)
Subject: K12593 - 3M AttestTM 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack

Premarket Notification [510(k)] Review
Traditional

K12593/S002

Date: (b) (4), (b) (6)
To:
From: Clarence Murray, III, Ph.D.
Office: ODE
Division: DAGRID/INCB

510(k) Holder: 3M Health Care
Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack
Cor (b) (4), (b) (6)
Pho
Fax
Em

(b) (4)

Dear (b) (4), (b) (6)
I am a request for additional information regarding your submission, K12593/S002, for the 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack. Please refer to the FDA guidance document, Biological Indicator (BI) Premarket Notification [510(k)] Submissions (October 4, 2007). So that I may continue the review of your submission, please provide the following information:

(b) (4)

[redacted]

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system.

Finally, please schedule a teleconference with FDA to discuss the above deficiencies prior to your formal response to this question.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system.

If you have any questions about the above request or you wish to discuss protocols, please contact me by phone at (301) 796-0270 or by email at clarence.murray@fda.hhs.gov.

Sincerely,

Clarence W. Murray, III, Ph.D.
Chemist
Infection Control Device Branch
FDA/CDRH/ODE/DAGRID
10903 New Hampshire Ave.
White Oak, Bldg. 66/ Room 2566
Silver Spring, MD 20993
301-796-0270 telephone
301-847-8109 fax

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Clarence W. Murray, III

Subject: 510(k) Number K121593/S001

To: The Record

Please list CTS decision code TH

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Elizabeth F. Claus-Walls (Branch Chief) INCB (Branch Code) 11/14/12 (Date)

Final Review: (Division Director) (Date)

286

(b) (4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K121593/S001

Date: November 14, 2012
To: The Record
From: Clarence W. Murray, III

Office: ODE
Division: DAGID/INCB

510(k) Holder: 3M Health Care
Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack
C(b) (4), (b) (6)
Ph
Fa
Er

I. Purpose and Submission Summary:

3M Health Care would like to introduce 3M Attest™ 1496V and 41482V Super Rapid Biological Indicator Challenge Packs for Steam into interstate commerce. The subject device is a biological indicator (Class II, 21 CFR § 880.2800(a), product code - FRC). The subject device is intended to monitor dynamic – air – removal (pre-vacuum) steam sterilization cycles. This submission was placed on telephone hold on July 17, 2012.

The submission was placed on telephone hold on November 14, 2012

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

The 510(k) summary for this submission is found on pages 10 - 13

Reviewer Comments: The firm has provided a 510(k) summary is this submission. The firm will be asked to provide the product code in this summary(b) (4)
(b) (4) Also the firm will be asked to include a discussion of the similarities and differences between the subject devices and the predicate device. This is not acceptable.

The firm will be asked the following:

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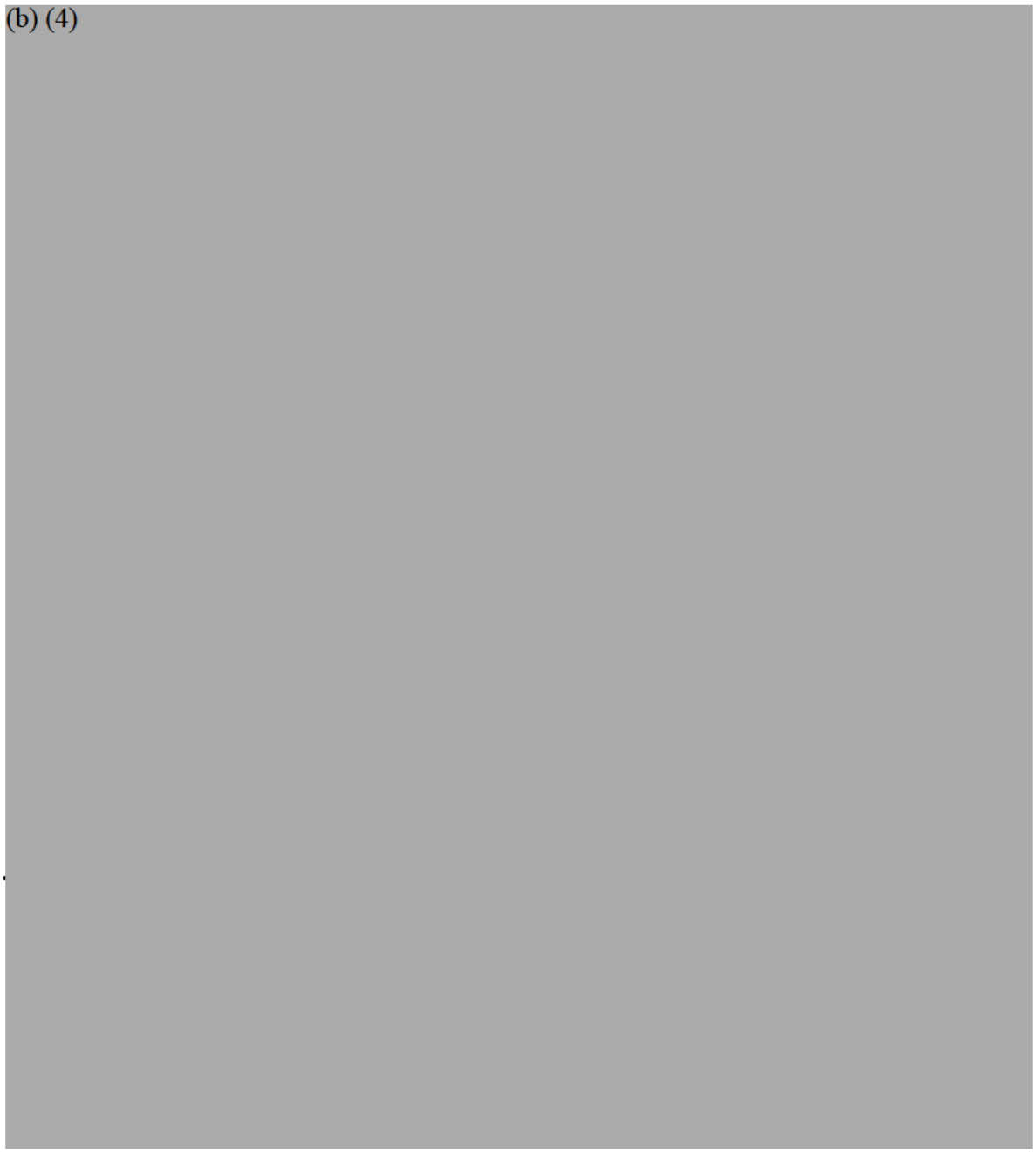
III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

(b) (4)

(b) (4)

(b) (4)



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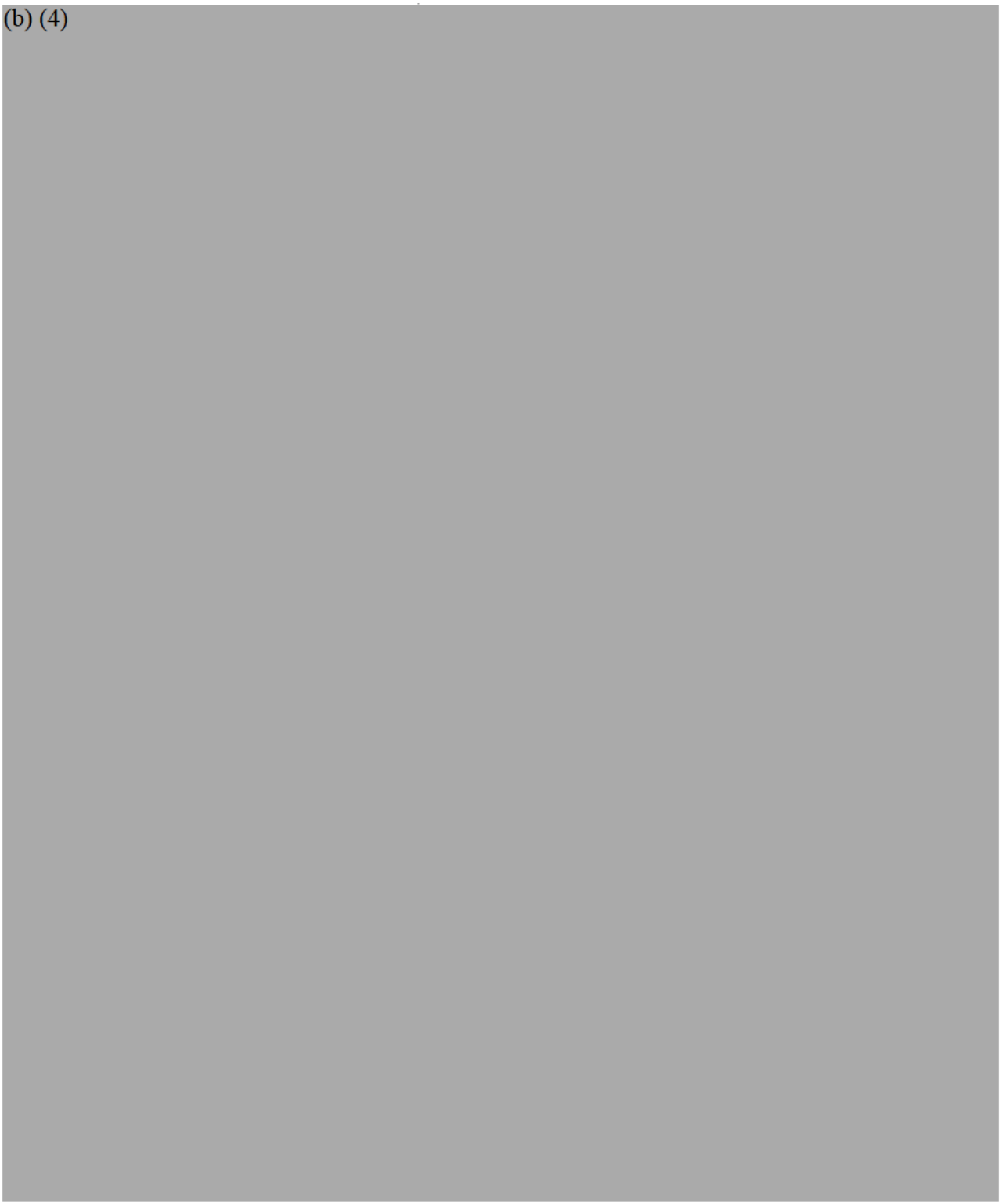

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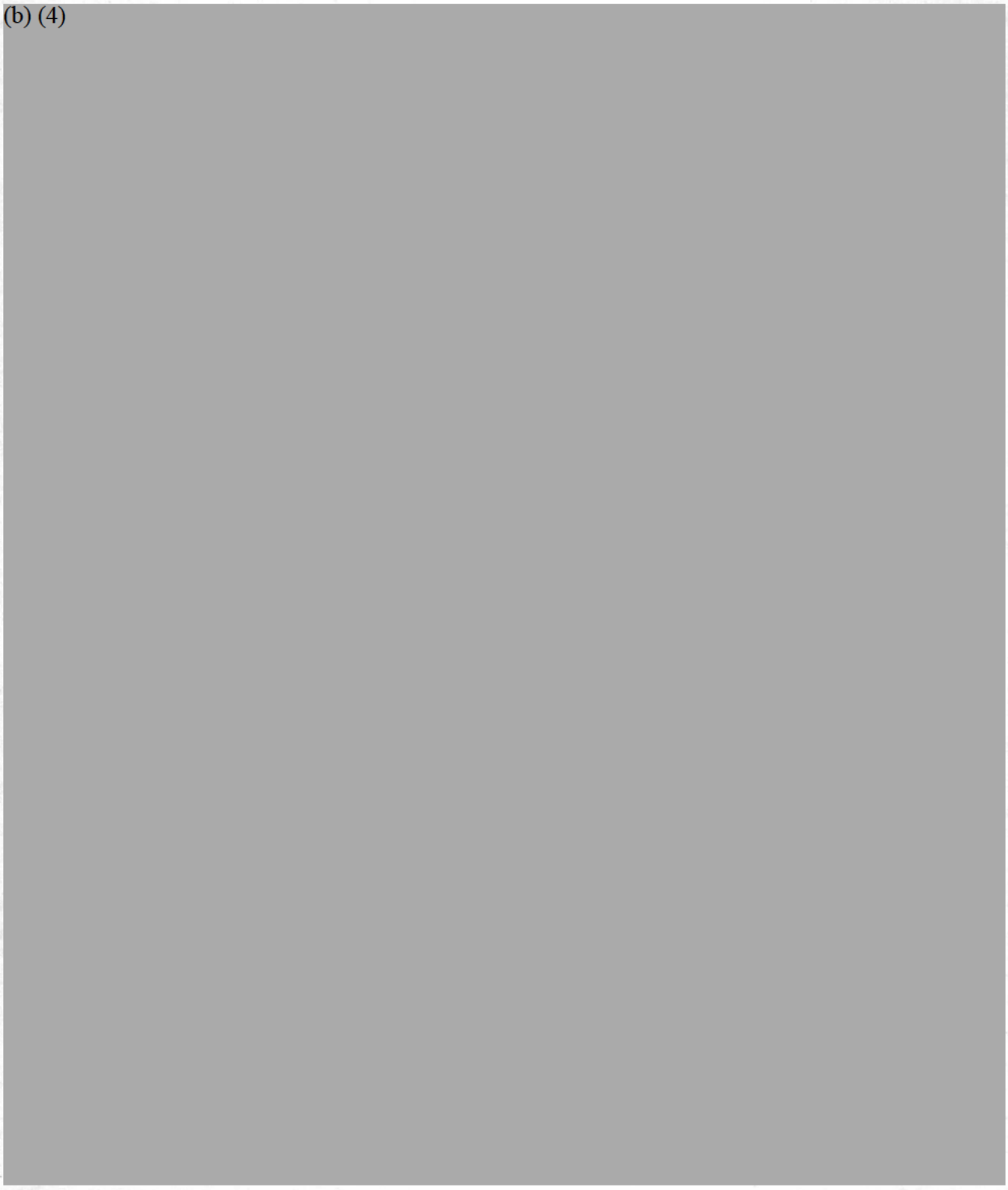

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(b) (4)

IV. Indications for Use

(b) (4)

(b) (4)

(b) (4)

The Attest™ 1496V Super Rapid Readout Steam and 41482V Super Rapid 5 Steam Plus Challenge Packs are substantially equivalent to the predicate

(b) (4)

(b) (4)

(b) (4)

The performance testing summaries provided demonstrate the products meet the requirements of their intended use for the indications claimed. There are no new questions of safety or effectiveness.

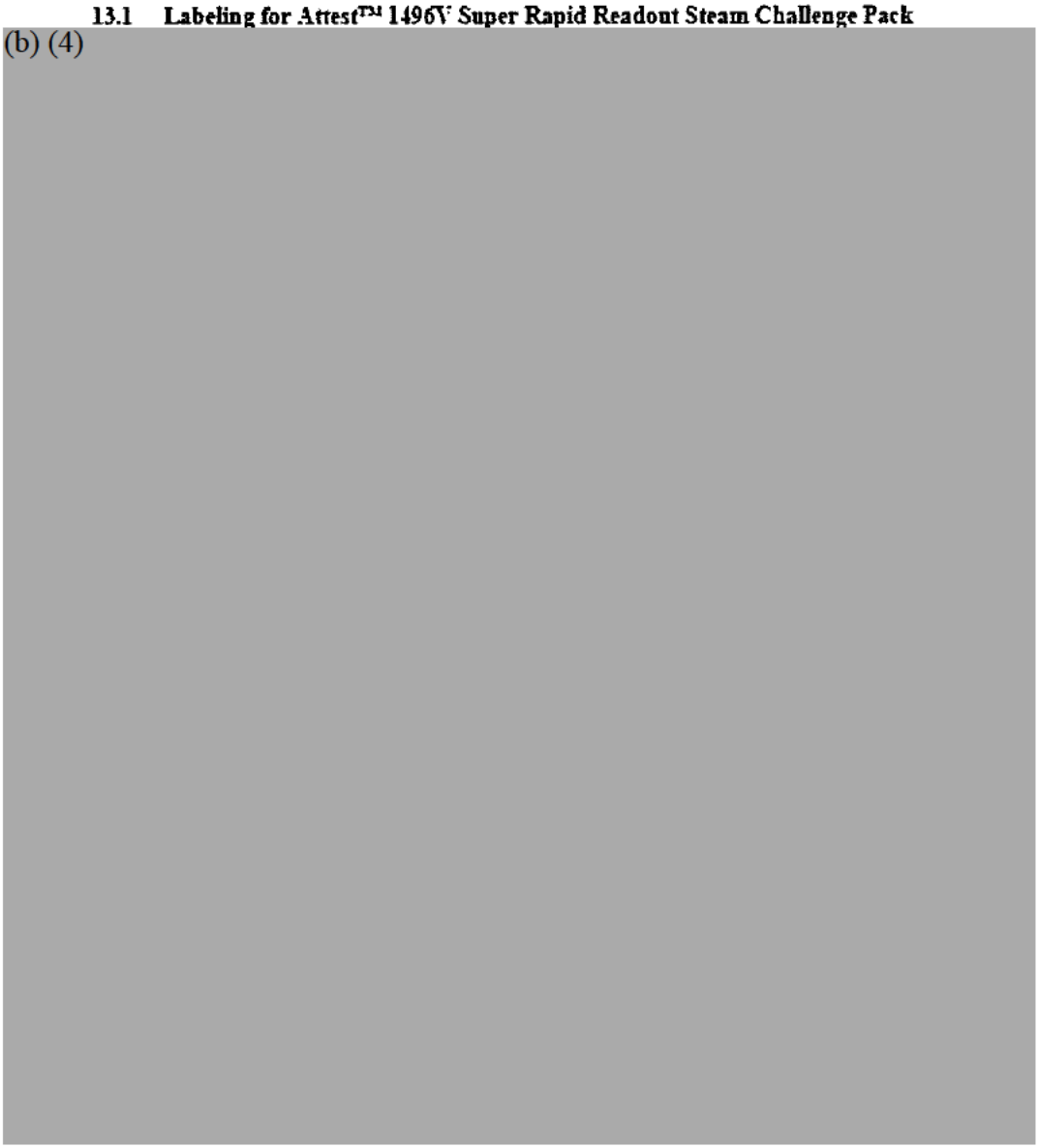
(b) (4)

VI. Labeling

Labeling for AttestTM 1496V Super Rapid Readout Steam Challenge Pack

13.1 Labeling for Attest™ 1496V Super Rapid Readout Steam Challenge Pack

(b) (4)



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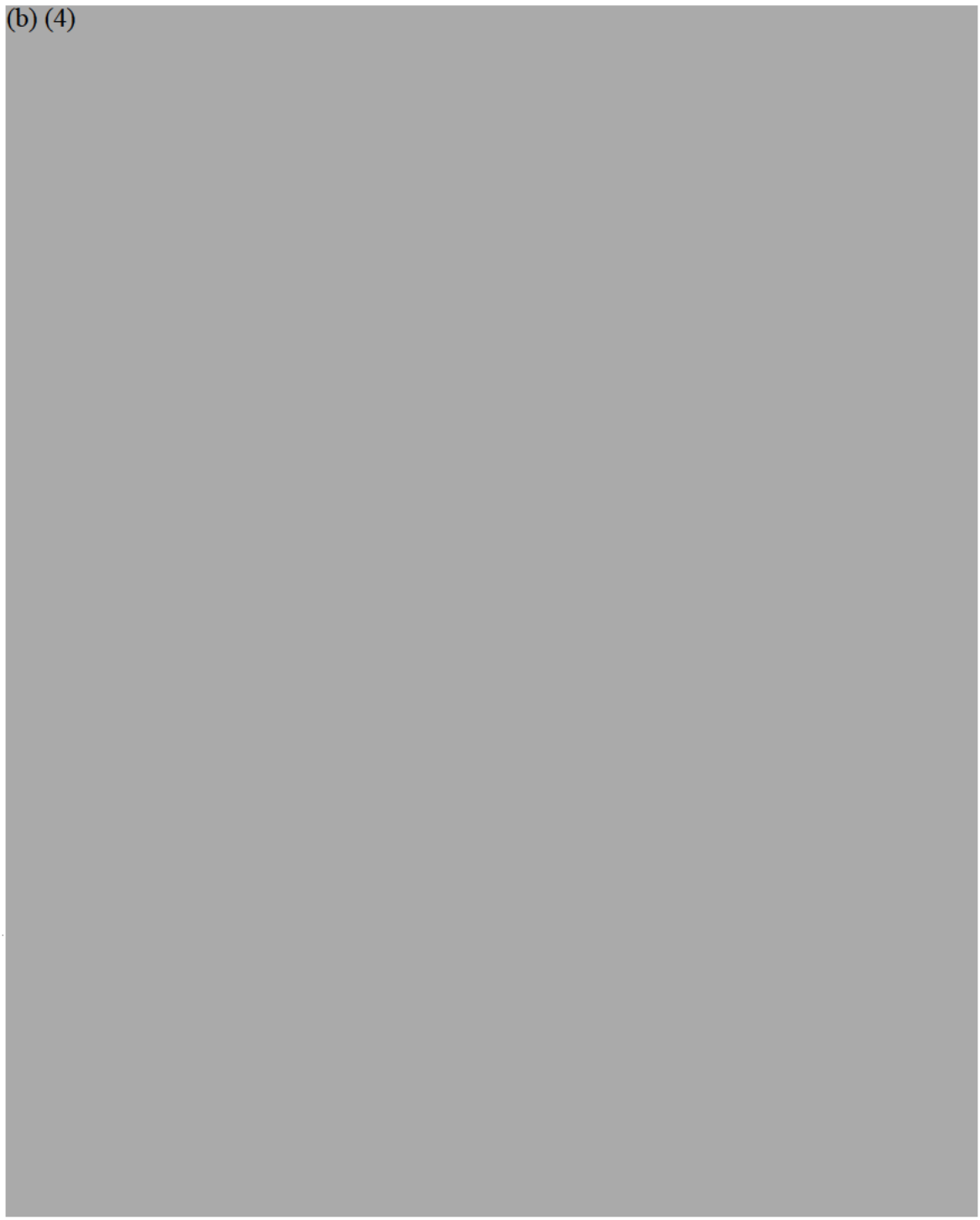

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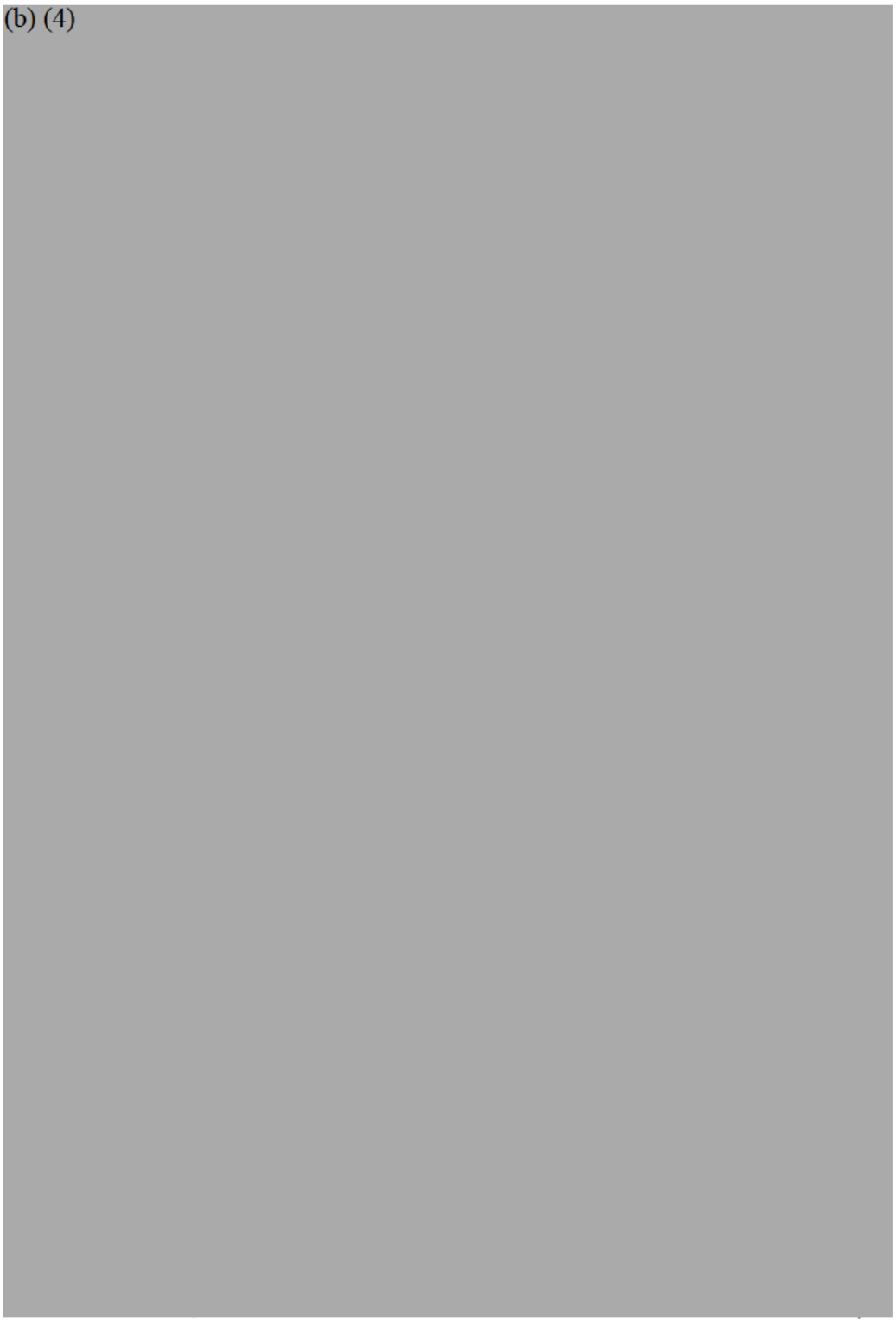

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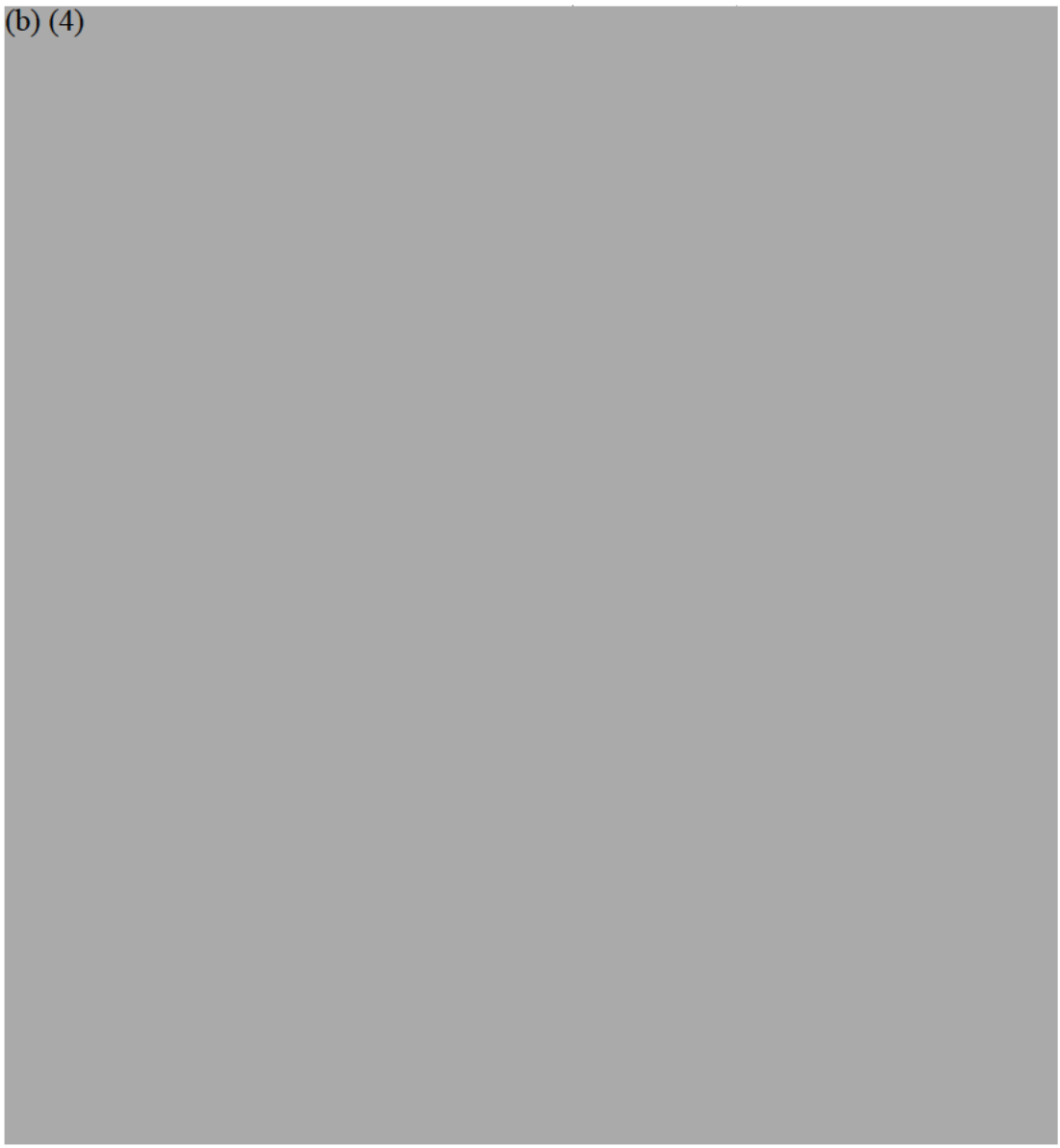

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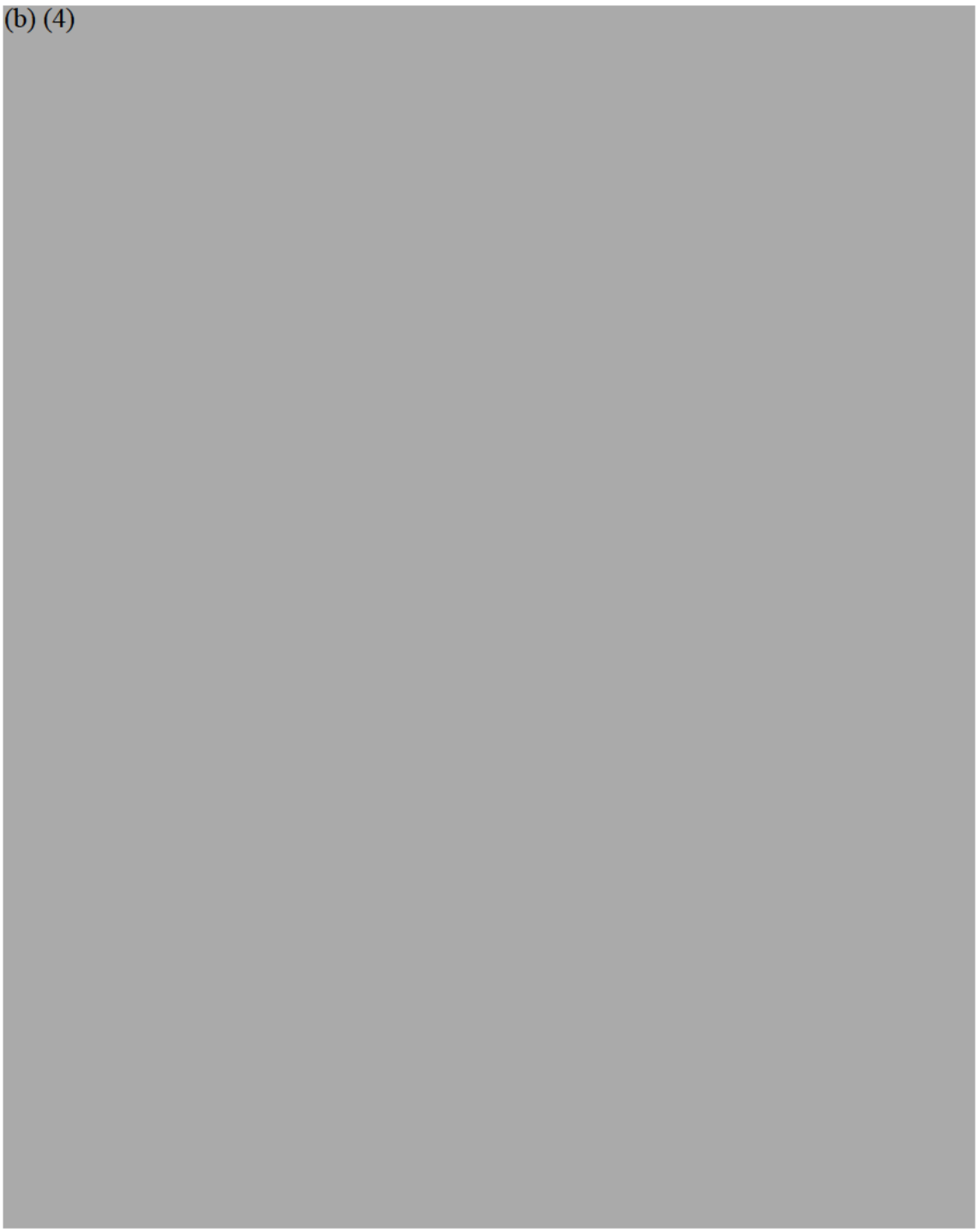

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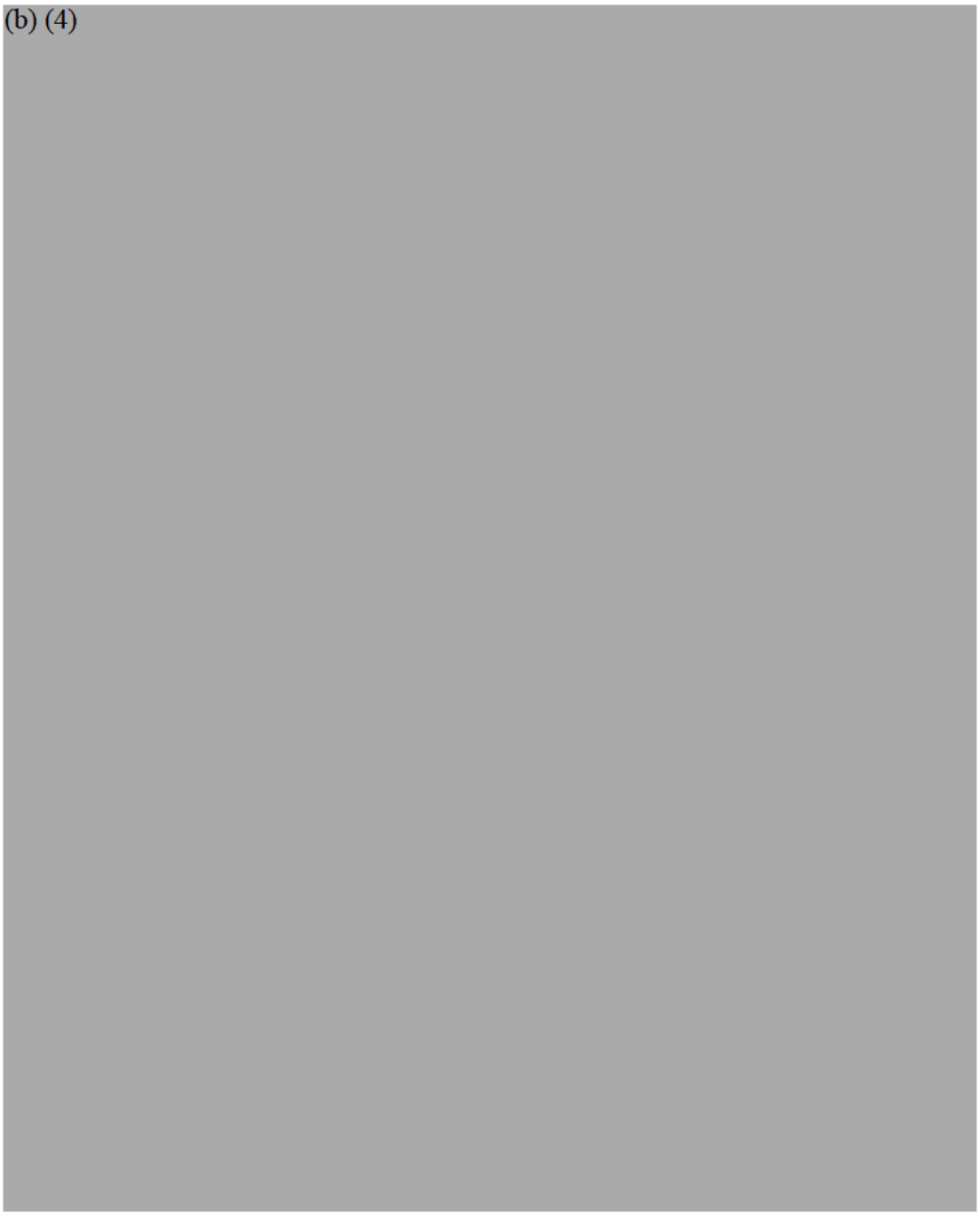

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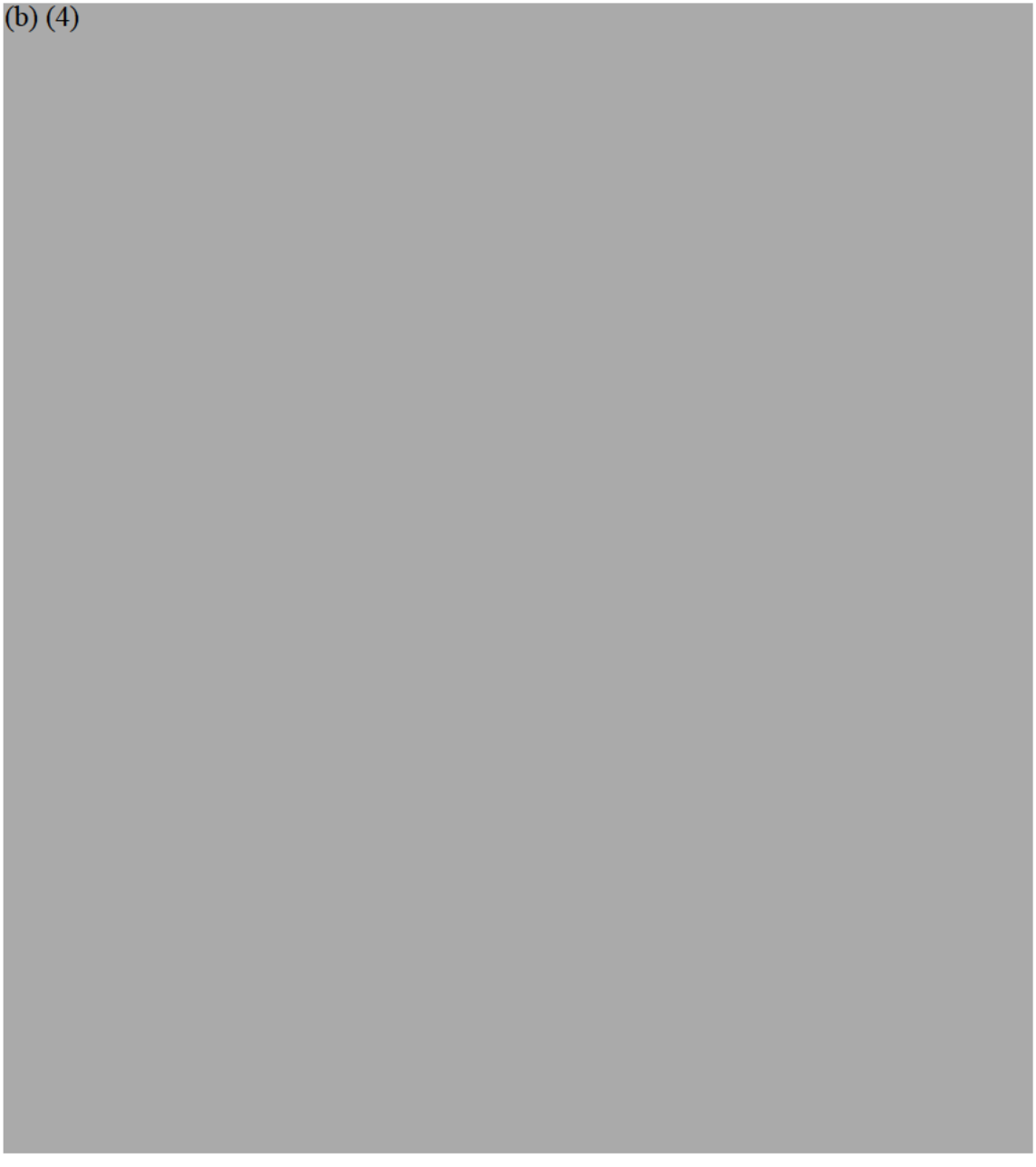
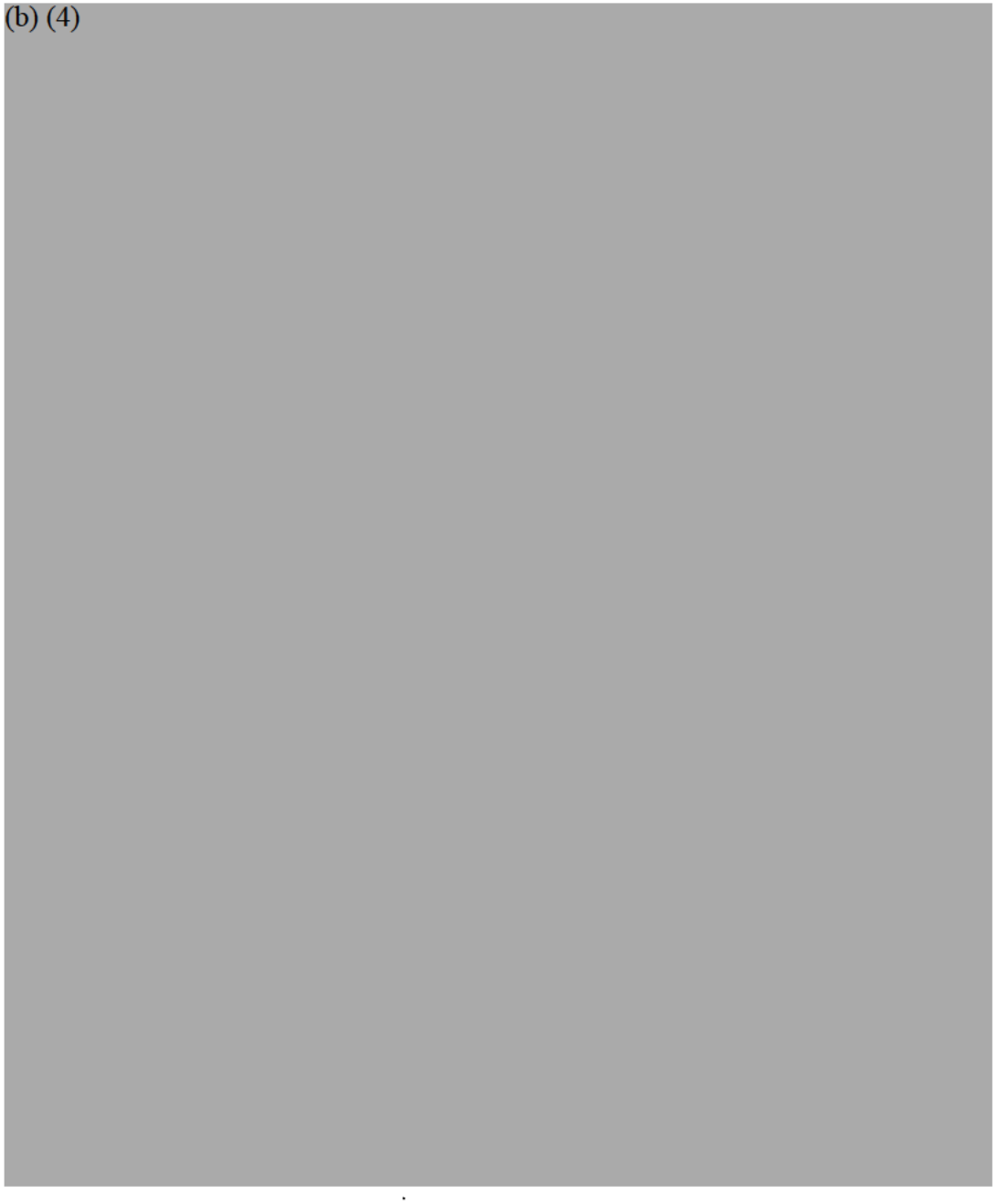


(b) (4)

Labeling for Attest™ 41482V Rapid 5 Steam-Plus Challenge Pack

(b) (4)

(b) (4)



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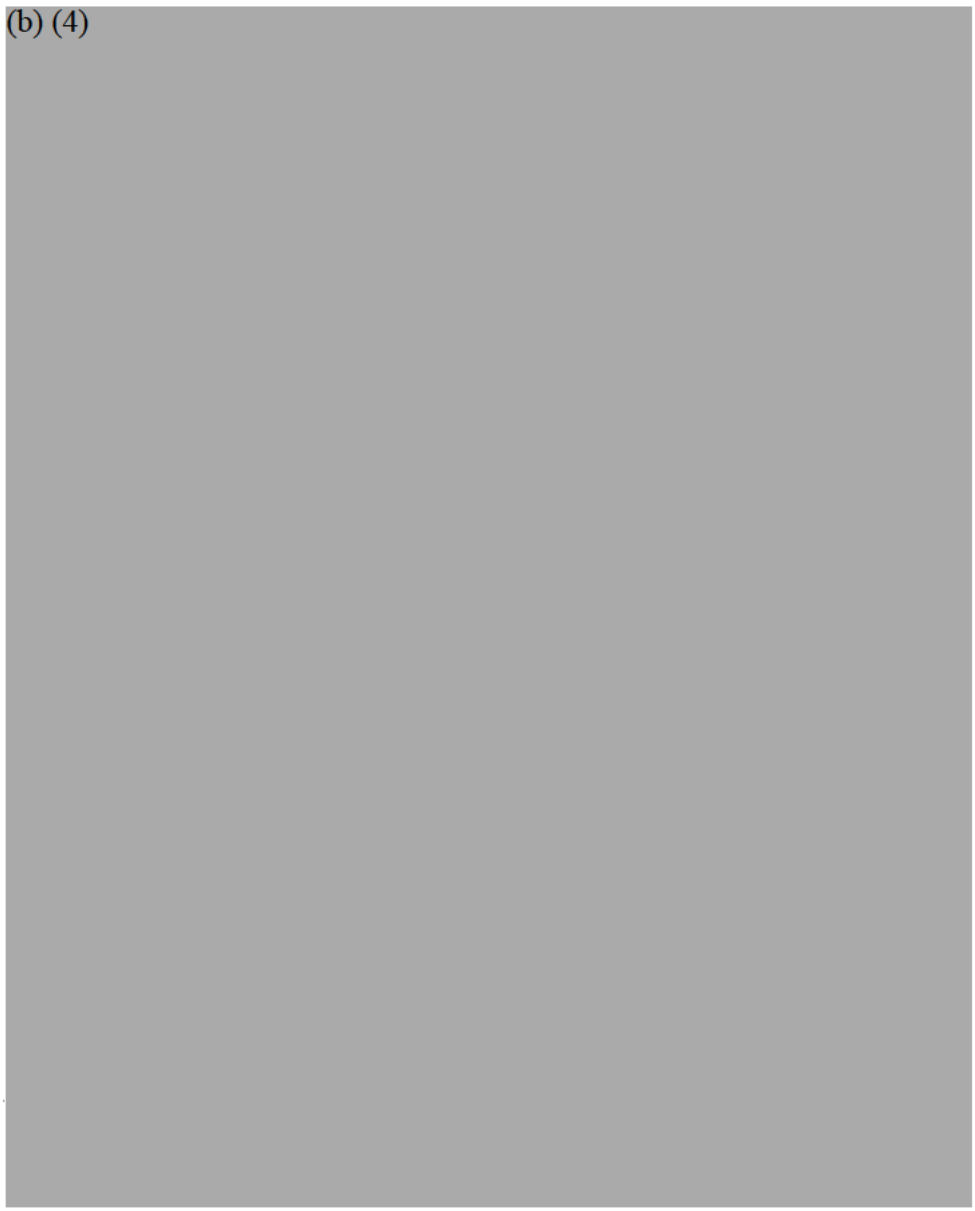
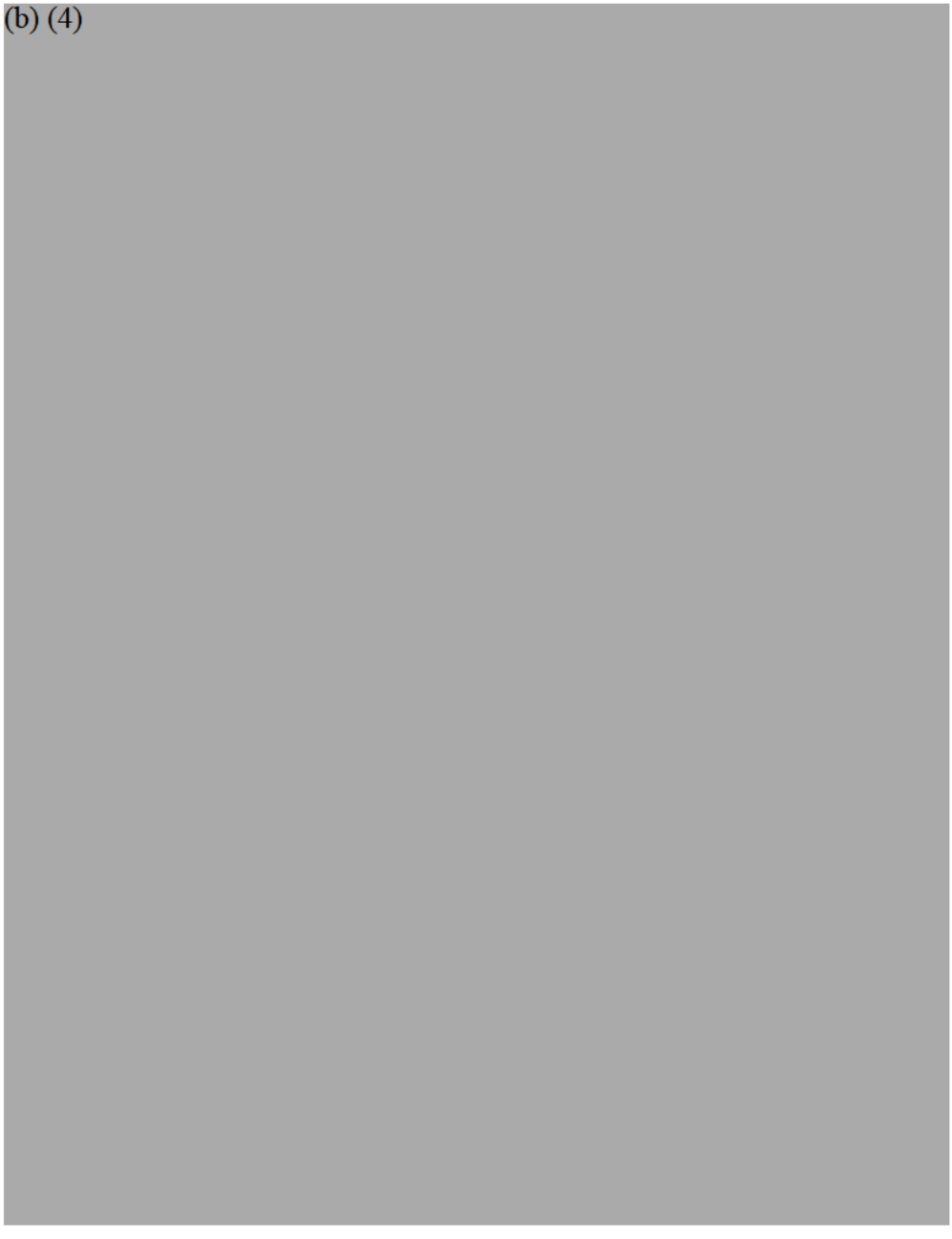


(b) (4)



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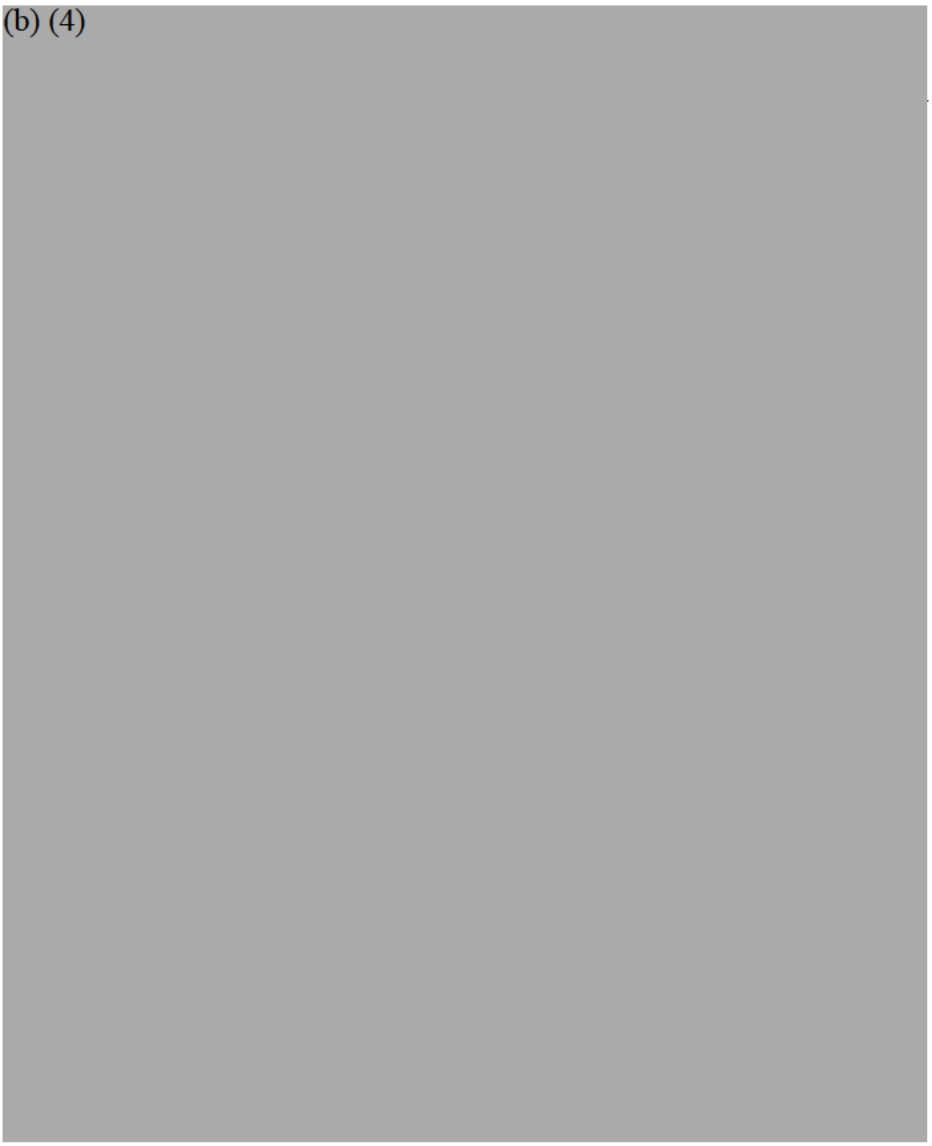
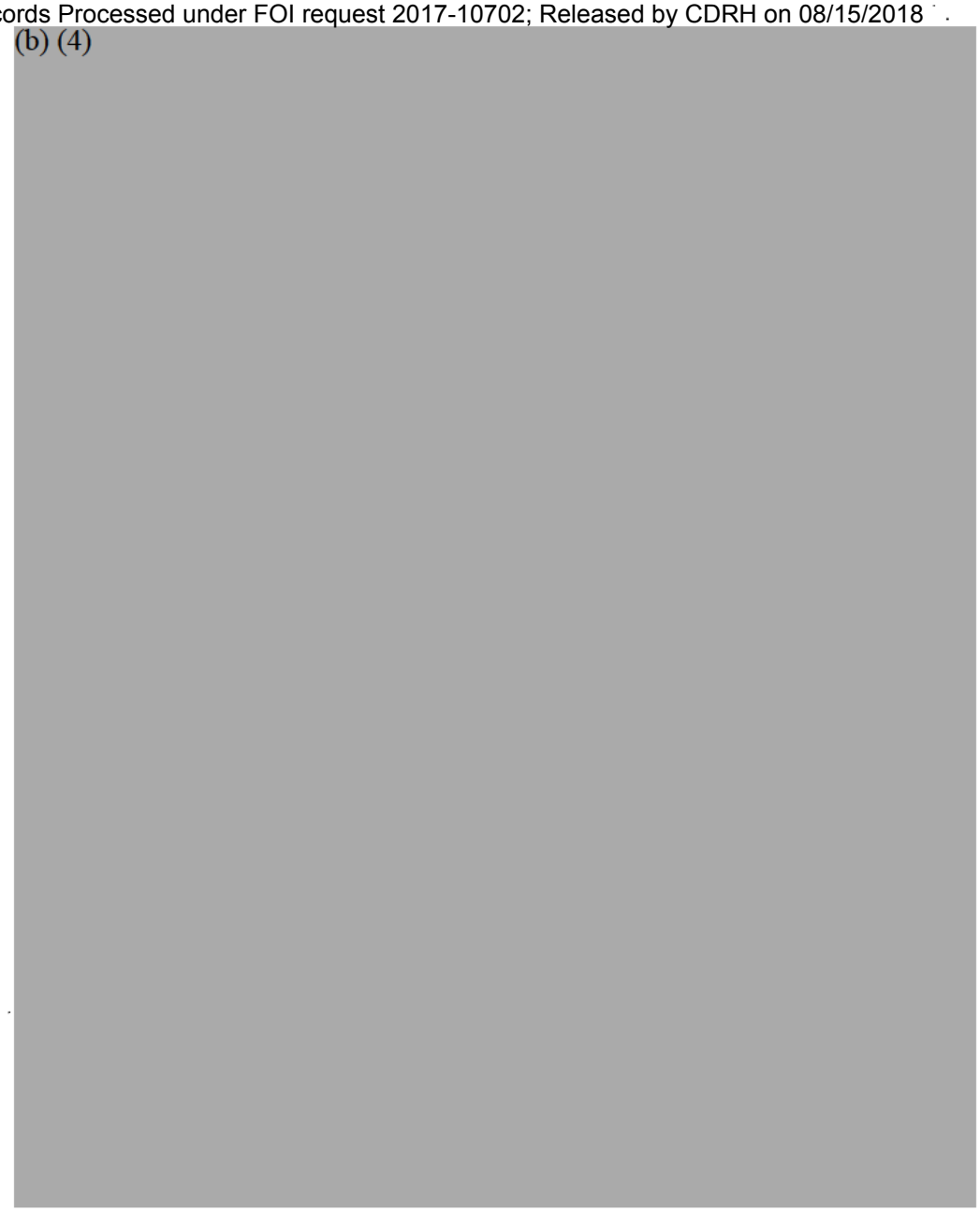


(b) (4)



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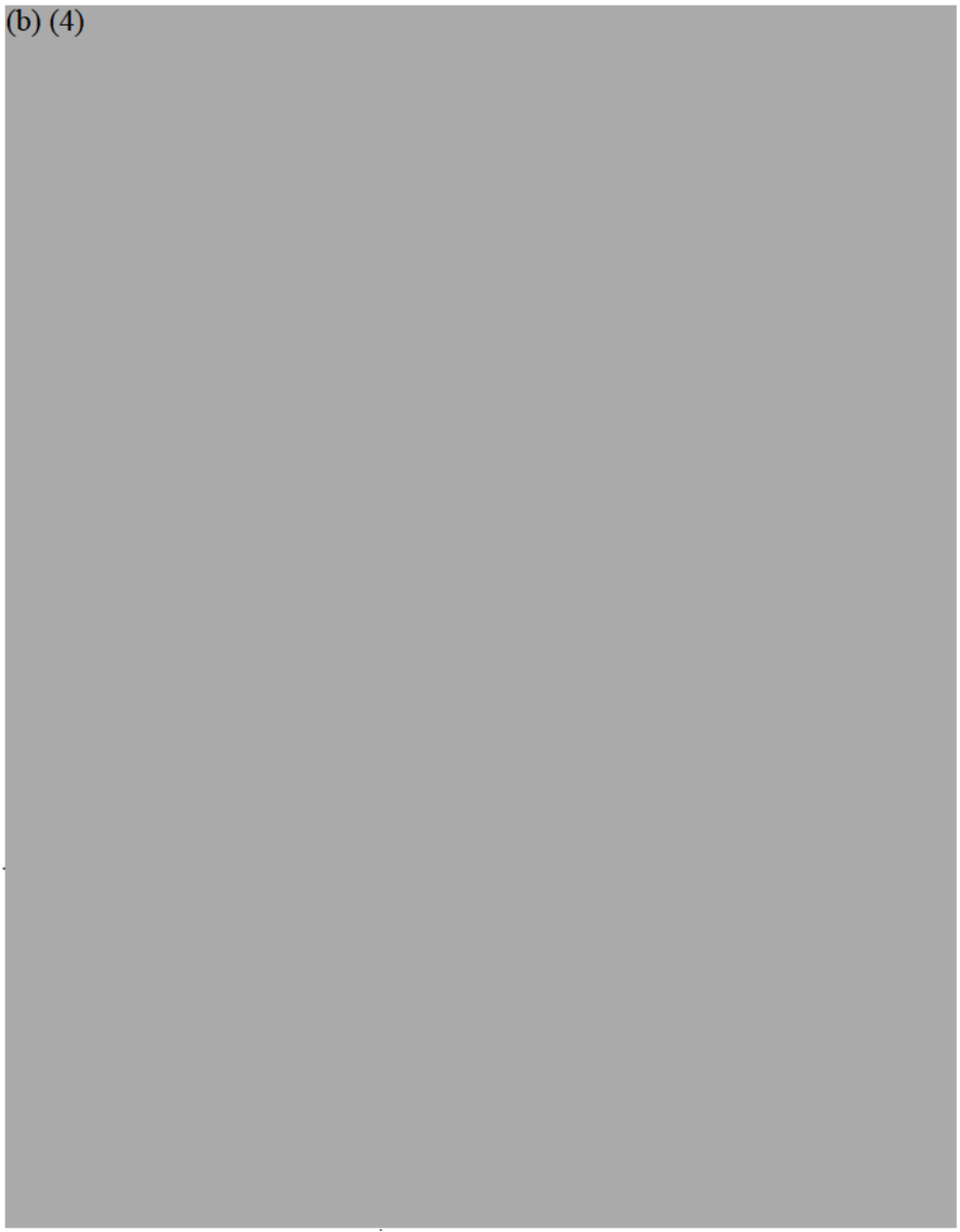


(b) (4)

(b) (4)

(b) (4)

VII. Sterilization/Shelf Life/Reuse

(b) (4)

(b) (4)

VIII. Biocompatibility

(b) (4)

(b) (4)

(b) (4)

IX. Software

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		

Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

(b) (4)

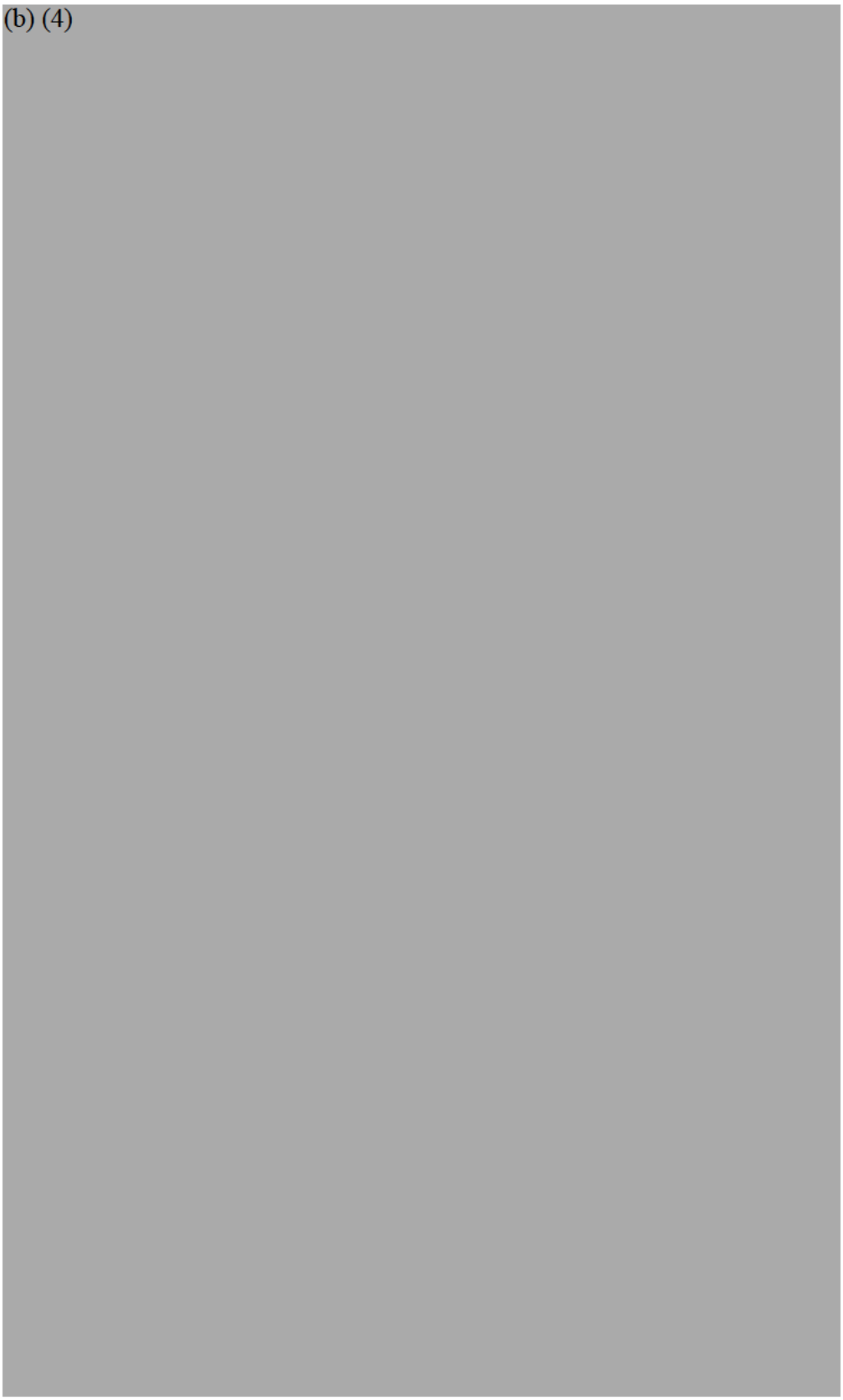
X. **Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

N/A

XI. **Performance Testing – Bench**

(b) (4)

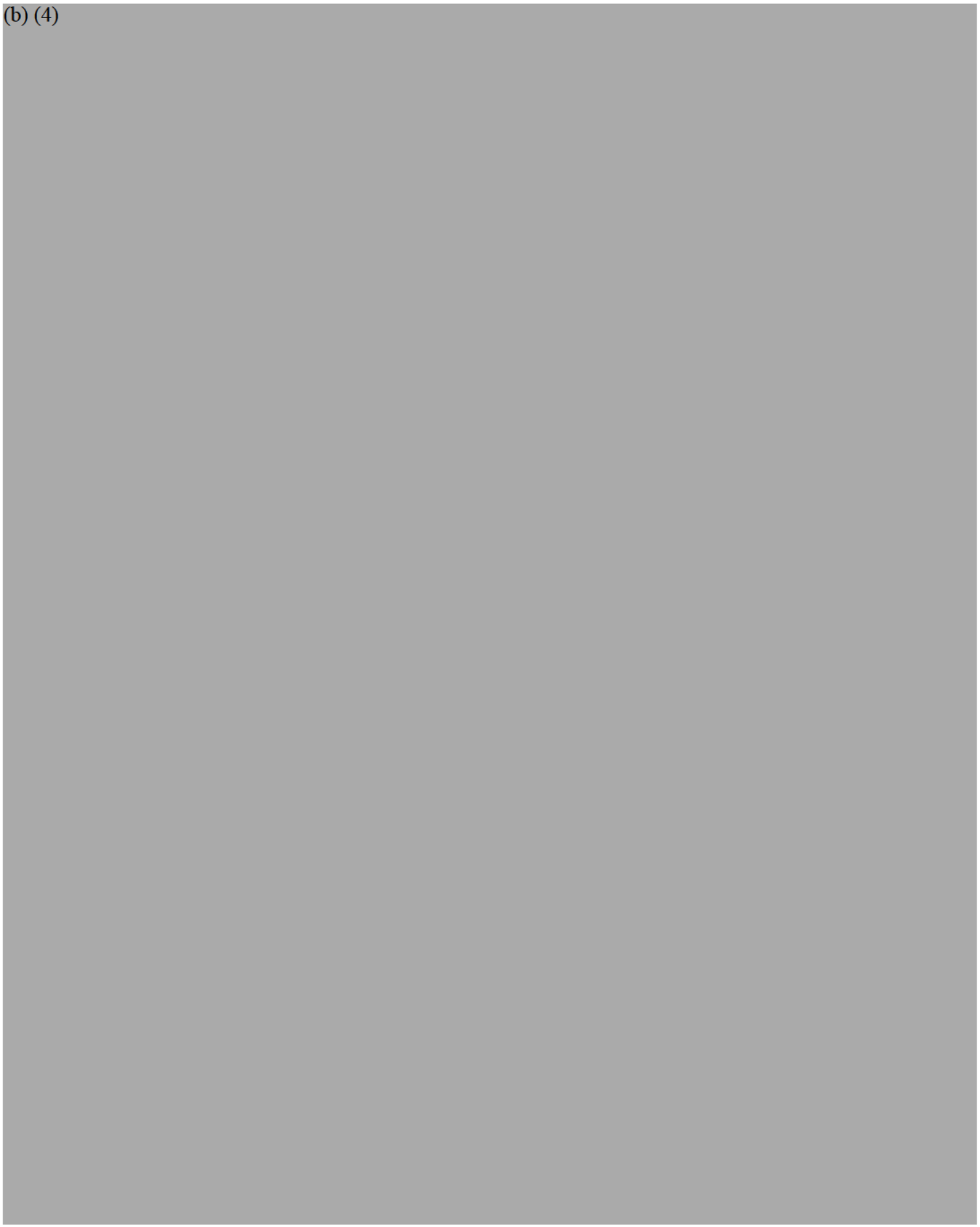
(b) (4)



(b) (4)

(b) (4)

(b) (4)



(b) (4)

[redacted]

XII. Performance Testing – Animal
N/A

XIII. Performance Testing – Clinical
N/A

XIV. Substantial Equivalence Discussion

(b) (4)

1. Same Indication Statement?	**YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	**YES** = Stop **NSE**
3. Same Technological Characteristics?	**YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	**YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	**NO** = Go To 8 **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?	**YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	**NO** = Stop **NSE**
8. Performance Data Available?	**NO** = Request Data
9. Data Demonstrate Equivalence?	inal Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

(b) (4)

Deficiencies from S001 Review:

Administrative

510(k) Summary

1. Please provide the product code in this summary.

(b) (4)

5. Please include a discussion of the similarities and differences between the subject devices and the predicate device.

Indications for Use

(b) (4)

Predicate Device Comparison

(b) (4)

Labeling

In regards to the labeling for your 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V:

(b) (4)

In regards to labeling for your 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V:

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(b) (4)

Sterilization/Shelf Life/Reuse

- Please include the shelf life data for the 1492V Attest™ Super Rapid Biological Indicator to establish the shelf life for both the 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs.

Performance Testing

In regards to your Study (b) (4)

(b) (4)

(b) (4) lease clarify whether if there were any changes to the biological indicator that was used in your udies and the biological indicator that was recently cleared by FDA

(b) (4)

In regards to your Study 2: (b) (4)

(b) (4)

(b) (4)

XVII. Recommendation

Regulation Number: 21 CFR 880.2800(a)
Regulation Name: Sterilization process indicator/ Biological Sterilization process indicator
Regulatory Class: II
Product Code: FRC

Reviewer — Date: 11/14/12

Branch Chief — Date: 11/14/12

Murray III, Clarence

From: Murray III, Clarence
Sent: Wednesday, November 14, 2012 3:20 PM
To: (b) (4), (b) (6)
Subject: K121593

Premarket Notification [510(k)] Review
Traditional

K121593/S001

Date: November 14, 2012
To: (b) (4), (b) (6) **Office:** ODE
From: Clarence Murray, III, Ph.D. **Division:** DAGID/INCB

510(k) Holder: 3M Health Care
Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack
Cor (b) (4), (b) (6)
Pho
Fax
Ema

November 14, 2012

Dear: (b) (4), (b) (6)

I am providing you a request for additional information regarding your submission, K121593/S001, for the 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack. Please refer to the FDA guidance document, Biological Indicator (BI) Premarket Notification [510(k)] Submissions (October 4, 2007). So that I may continue the review of your submission, please provide the following information:

Administrative

510(k) Summary

1. Please provide the product code in this summary.
2. (b) (4)
3. Please include a discussion of the similarities and differences between the subject devices and the predicate device.

Indications for Use

4. (b) (4)

Predicate Device Comparison

5. (b) (4)

Labeling

In regards to the labeling for your 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V:

6. Please include the (b) (4) for your (b) (4) cycles
7. (b) (4)
8. Please revise the IFU statement in the proposed labeling to include (b) (4)

In regards to labeling for your 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V:

9. Please include (b) (4)
10. Please remove the language regarding the Class 5 integrating indicator because the Agency does not recognize this class of integrating indicators.
11. Please revise the IFU statement in the label to include the (b) (4)

Sterilization/Shelf Life/Reuse

12. Please include the shelf life data for the 1492V Attest™ Super Rapid Biological Indicator to establish the shelf life for both the 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs.

Performance Testing

In regards to your Study 1: (b) (4)

13. Please clarify whether if there were any changes to the biological indicator that was used in your studies and the biological indicator that was recently cleared by FDA
14. (b) (4)
15. Please provide the raw data and provide all the details for the results shown in this summary table to support the conclusions (b) (4)
16. Please provide the raw data and provide all the details for the results shown in this summary table to support the conclusions mad (b) (4)

In regards to your Study 2: (b) (4)

17. Please provide a rationale for (b) (4)
18. Please provide the rationale for usin (b) (4) in this study when in your previous stud (b) (4)
19. (b) (4)
20. Please provide the raw data and provide all the details for the results shown in this summary table to support the conclusions made (b) (4)

General Comments:

(b) (4) Please revise Table 3 under study 2 to denote that the (b) (4)

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22. Please provide a rationale for the (b) (4) (b) (4)

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system.

Finally, please be aware that other deficiencies may arise in this submission from the review of your K121593/S001 submission.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system.

If you have any questions about the above request or you wish to discuss protocols, please contact me by phone at (301) 796-0270 or by email at clarence.murray@fda.hhs.gov.

Sincerely,

Clarence W. Murray, III, Ph.D.
Chemist
Infection Control Device Branch
FDA/CDRH/ODE/DAGID
10903 New Hampshire Ave.
White Oak, Bldg. 66/ Room 2566
Silver Spring, MD 20993
301-796-0270 telephone
301-847-8109 fax

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Clarence W. Murray, III

Subject: 510(k) Number K121593

To: The Record

Please list CTS decision code TH

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold)
- ☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):	YES	NO
Indications for Use Page — *Attach IFU*		
510(k) Summary /510(k) Statement — *Attach Summary*		
Truthful and Accurate Statement. — *Must be present for a Final Decision*		
Is the device Class III?		
If yes, does firm include Class III Summary? — *Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC		
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		
Is this device intended for pediatric use only?		
Is this a prescription device? (If both prescription & OTC, check both boxes.)		
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		
Is clinical data necessary to support the review of this 510(k)?		
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was		

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**

(*If unclassified, see 510(k) Staff)

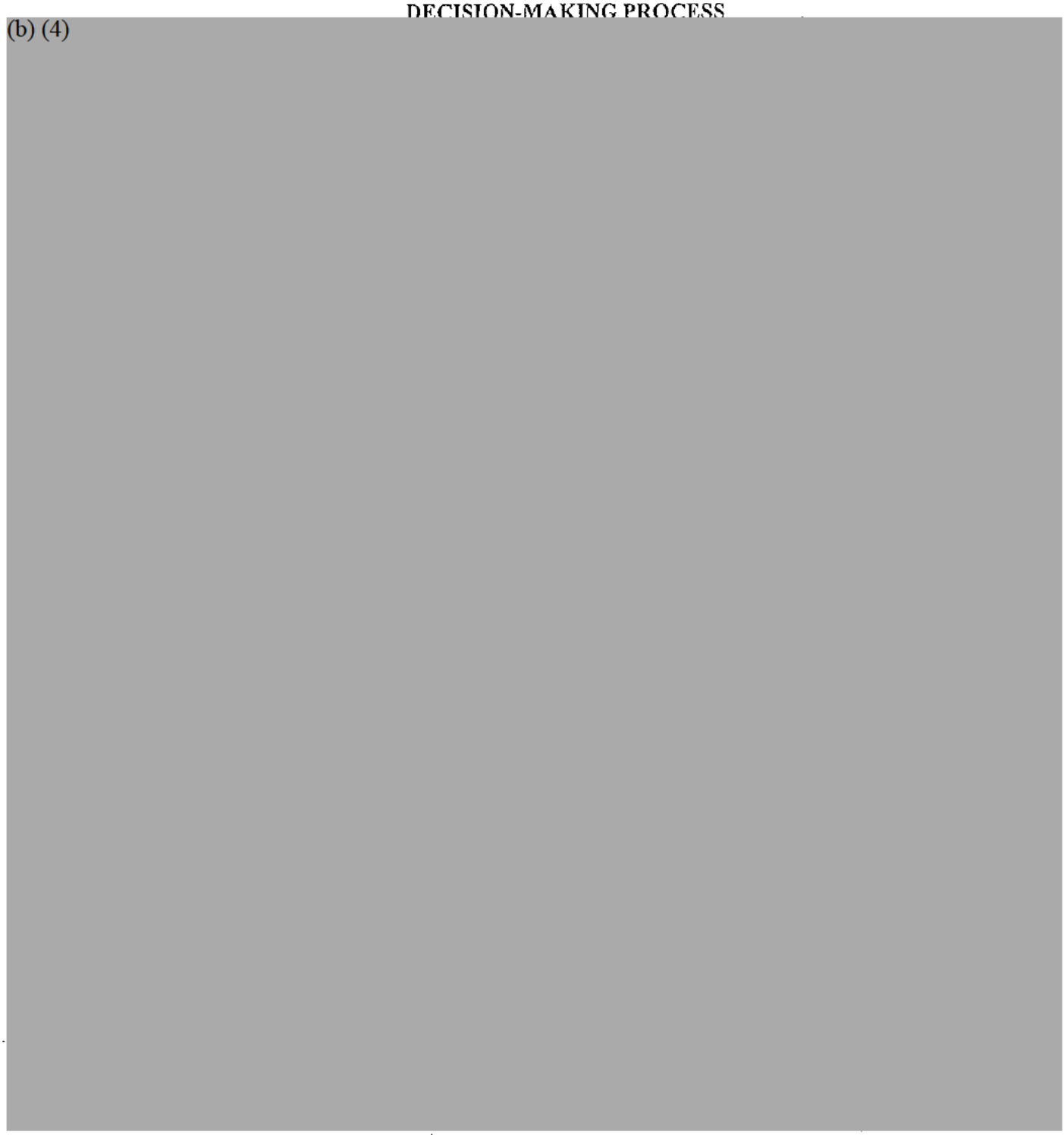
Additional Product Codes:

Review: _____ (Branch Chief) _____ (Branch Code) 7/17/12 (Date)

Final Review: _____ (Division Director) (Date)

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

(b) (4)



* 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 maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K121593

Date: July 17, 2012
To: The Record
From: Clarence W. Murray, III

Office: ODE
Division: DAGID/INCB

510(k) Holder: 3M Health Care
Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack
Cor (b) (4), (b) (6)
Pho
Fax
Em

I. Purpose and Submission Summary:

3M Health Care would like to introduce 3M Attest™ 1496V and 41482V Super Rapid Biological Indicator Challenge Packs for Steam into interstate commerce. The subject device is a biological indicator (Class II, 21 CFR § 880.2800(a), product code - FRC). The subject device is intended to monitor dynamic – air – removal (pre-vacuum) steam sterilization cycles. This submission was placed on telephone hold on July 17, 2012.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	

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	Yes	No	N/A
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

Device Summary:

The 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs are designed to routinely challenge dynamic-air-removal (pre-vacuum) steam sterilization processes in healthcare facilities. The challenge packs have the same Intended Use as the predicate 3M AttestTM Steam-Plus Pac(b) (4) (b) (4) 25496) and are similar in design.

The challenge packs consist of (b) (4) (b) (4) (b) (4) The pack is (b) (4) Each pack has a process indicator on the outside of the pack that changes from yellow to brown or darker when exposed to steam. This disposable pack has been designed to present a challenge to the steam sterilization process that is equivalent to or more resistant than the towel pack biological indicator challenge device recommended by the AAMI.

Each Attest™ 1496V challenge Pack contains an Attest™ 1492V Super Rapid Readout Biological Indicator and a record keeping sheet. Each Attest™ 41482V Challenge Pack contains an Attest™ 1492V Super Rapid Readout Biological Indicator, a SteriGage™ chemical integrator, and a record keeping sheet. Attest™ 1492V biological indicator controls are provided with both challenge packs.

Biological Indicator Designed and AttestTM Super Rapid Readout Technology:

The AttestTM 1492V Super Rapid Readout Biological Indicator (1492V Super Rapid BI or 1492V SRBI) contained within the 1496V and 41482V challenge packs utilizes the AttestTM Super Rapid Readout Technology(b) (4) (b) (4)

The 1492V is a new model of the Super Rapid biological Indicator currently under review for dynamic-air-removal (pre-vacuum) steam sterilization cycles (K121484).

Mechanism:

(b) (4) The super readout technology (b) (4) enzyme system, which is generated naturally within growing G. stearothermo (b) (4) (b) (4) (b) (4) e detection of fluorescence upon incubation of the 1492V Super Rapid BI (b) (4) tes a steam sterilization failure. The indicators also contain a pH indicator hich turns yellow in the presence o(b) (4) stearothermophilus organism.

(b) (4)

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(b) (4)

Chemical Integrator Design

SteriGage™ chemical integrators contain a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked ACCEPT and REJECT; the extent of migration depends on steam, time, and temperature. SteriGage™ has been cleared under K101249.

Device Description and Drawing provided by the firm:

The 1496V and 41482V Challenge Packs are similar in design to the predicate 3M Attest™ Steam-Plus Pack cleared under K925496. Both contain a laminated sheet, die cut paper sheets, and index cards that form the bulk of the challenge pack. (b) (4)

(b) (4)

Table 2 shows the composition of the Super Rapid Challenge Packs as compared to the predicate device Attest™ Steam-Plus Pack cleared under K925496.

(b) (4)

Diagrams showing the composition of the 3M Attest™ 1496V and 41482V Challenge Packs are provided on the following page. (b) (4)

(b) (4)

The construction of the packs contains:

(b) (4)

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(b) (4)

(b) (4)

The process indicator dot on the Challenge Pack label (1496V and 41482V) turn from yellow to brown or darker when processed in 270°F and 275°F prevacuum cycles. The process indicator is used by the customer to verify that the Challenge Pack was exposed to steam. It does not verify that the cycle was complete or that sterilization conditions were met.

The process indicator ink chemistry is shown below: (b) (4)

(b) (4) After reaction

with steam, the indicator turns brown. (b) (4)

(b) (4)

(b) (4)

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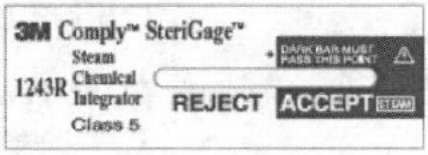
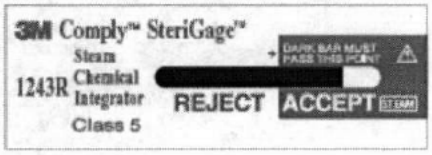
(b) (4)

Design of the SteriGage™ Chemical Integrator (in 41482V only)

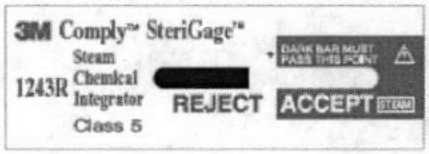
3M SteriGage™ Steam Chemical Integrators are single-use chemical indicators consisting of a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. Upon exposure to steam, the chemical pellet melts and migrates as a dark color along the paper wick as a moving front. The migration is visible through a window marked ACCEPT or REJECT; the extent of migration depends on steam, time, and temperature.



Unexposed



After a passing cycle



After a failing cycle

Design of the Attest™ 1492V Super Rapid BI (SRBI)

The 1492V Super Rapid BI (SRBI) has been submitted as a separate 510(k), K121484. The basic design is similar to many current self-contained biological [redacted] (b) (4) (b) (4) of the SRBI serve to secure the spore carrier and growth media ampoule within the tube. The sterilant enters the BI through entry ports on the cap. During activation, the cap is depressed fully onto the sleeve which crushes the growth media ampoule, allowing the liquid growth media to flow down to the spores. After activation, the cap [redacted] (b) (4) (b) (4) contains the liquid growth media within the SRBI. (b) (4)

[redacted] (b) (4) (b) (4) ne Process Indicator on top of the cap and undergoes a color change from

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pink to light brown upon exposure to steam, allowing the user to identify processed from unprocessed biological indicators.

The media ampoule i[redacted] and contains the growth media which consists of a [redacted]

A diagram showing the component parts is provided below.

[redacted]

Reviewer Comments: It is noted that the subject devices uses the 3M 1492V Super Rapid BI (SRBI) which is currently under review. The 1492V Super Rapid BI is the subject of a separate 510(K), K121484 and thus the BI described in this submission is not FDA approved Biological Indicator. The firm will be asked to provide a F[redacted]I that can be used in the subject devices of this current 510(K). It is also noted that the only [redacted]ntains the 3M SteriGage™ Steam Chemical Integrator. ***This is not acceptable***.

Please provide a FDA cleared Biological Indicator for use in your challenge pack.

IV. Indications for Use

The 3M Attest™ Super Rapid Readout Steam Challenge Pack 1496V and the 3M Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V in conjunction with the 3M Attest™ Auto-reader 490 to qualify or monitor 270°F (132°C) and 275°F (135°C) dynamic-air-removal (pre-vacuum) steam sterilization cycles.

The 3M Attest™ Super Rapid Readout Biological Indicator 1492V contained in the challenge pack provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

Reviewer Comments: The firm stated that their two challenge packs are to be used to monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles at 270°F (132°C) and 275°F (135°C). However [redacted] ***is is acceptable***.

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V. Predicate Device Comparison

Element	(b) (4)
Intended Use	
Biological Indicator	
Indication for Use • Method of Sterilization • Process Parameters	
Organism in BI	
Viable Spore Population of BI	
Resistance Comparison to the AAMI ST79 Towel Pack	
Chemical Integrator	
Process Indicator on Pack Label	
Shelf-life	

The Attest™ 1496V Super Rapid Readout Steam and 41482V Super Rapid 5 Steam-Plus Challenge (b) (4) ate test pack device 3M Attest™ Steam-Plus Pack, cleared under K925496, in terms of intended use and technological characteristics.

The differences between the Attest™ Super Rapid Challenge Packs and the predicate device are:

(b) (4)

The performance testing summaries provided demonstrate the products meet the requirements of their intended use for the indications claimed. There are no new questions of safety or effectiveness.

(b) (4)

bject device with 3M Attest™ Steam-Plus Pack, 925496). The subject device uses a biological indicator that is currently under review as the subject device for K121484. The firm will be asked to use a FDA cleared biological indicator in their subject device. ***This is not acceptable.***

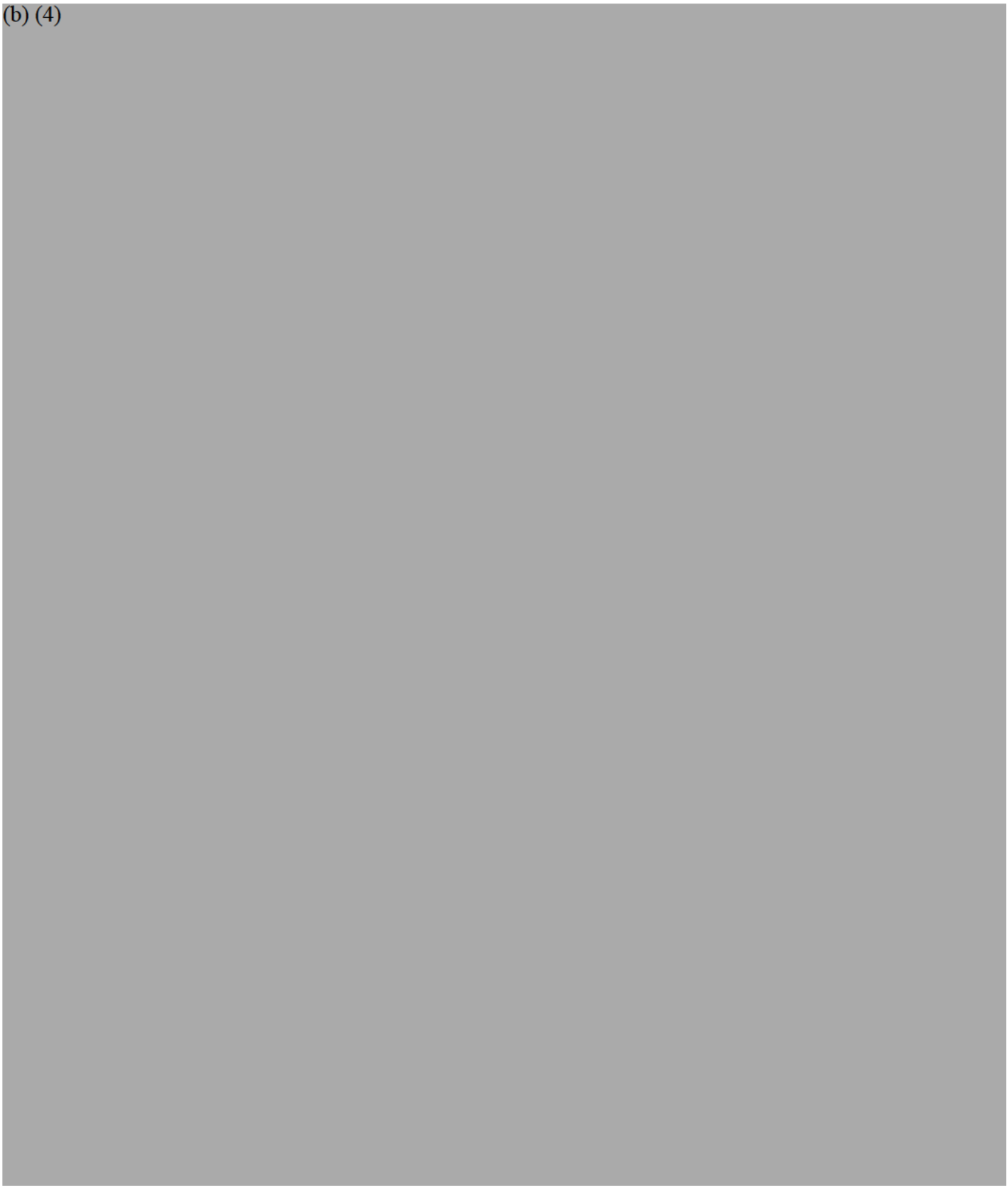
Please provide a FDA cleared Biological Indicator for use in your challenge pack.

VI. Labeling

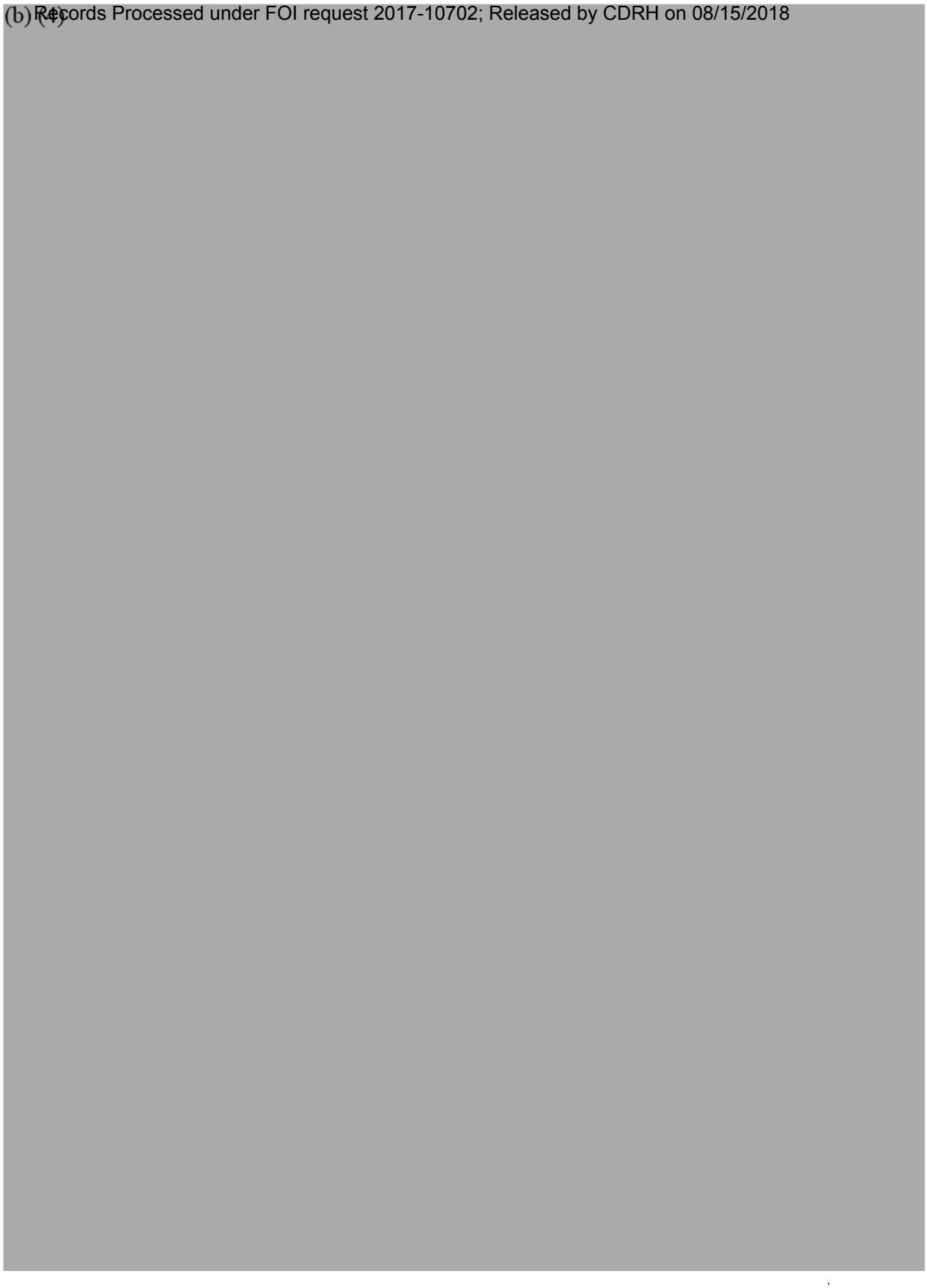
(b) (4)

352

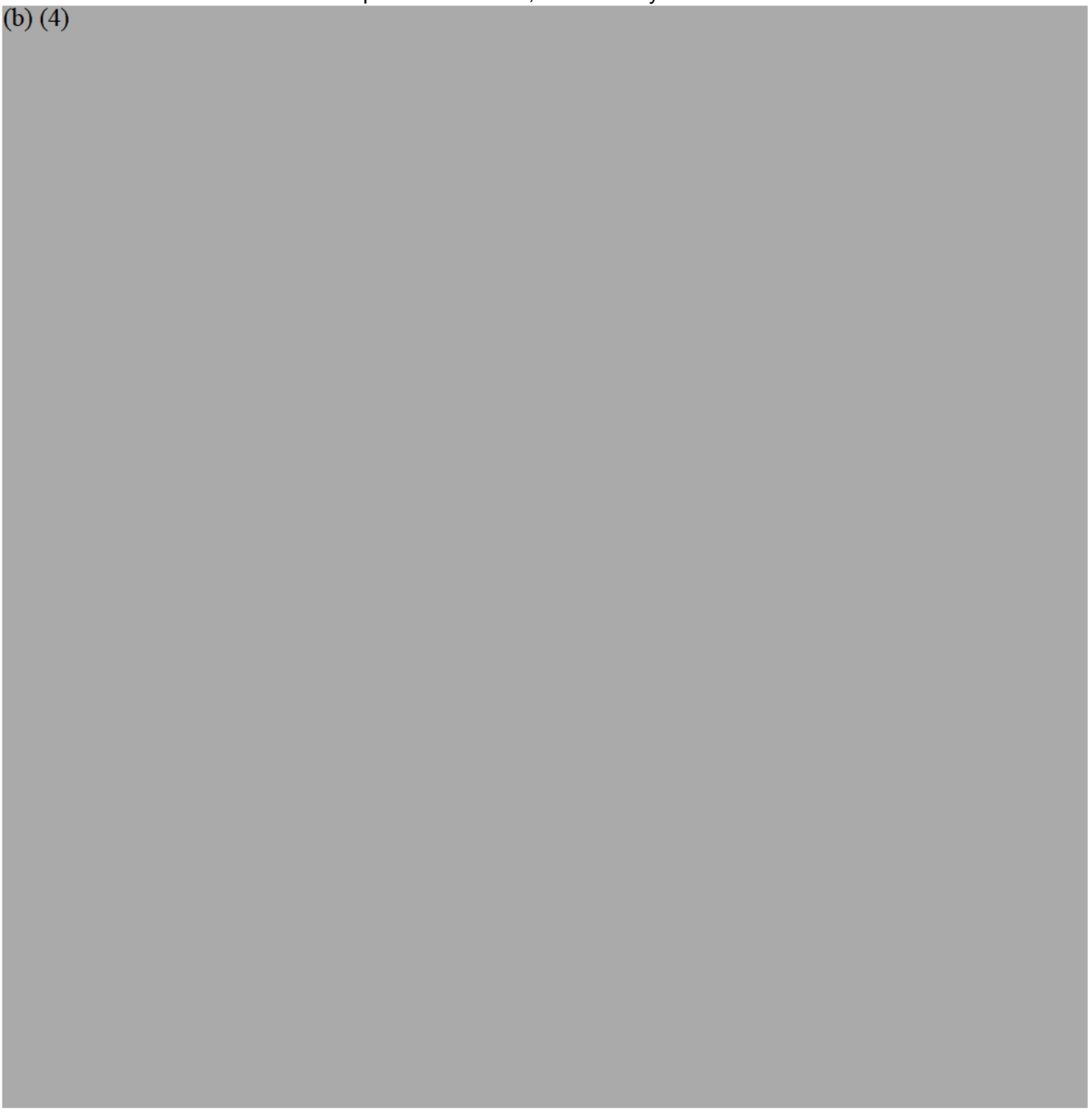
(b) (4)



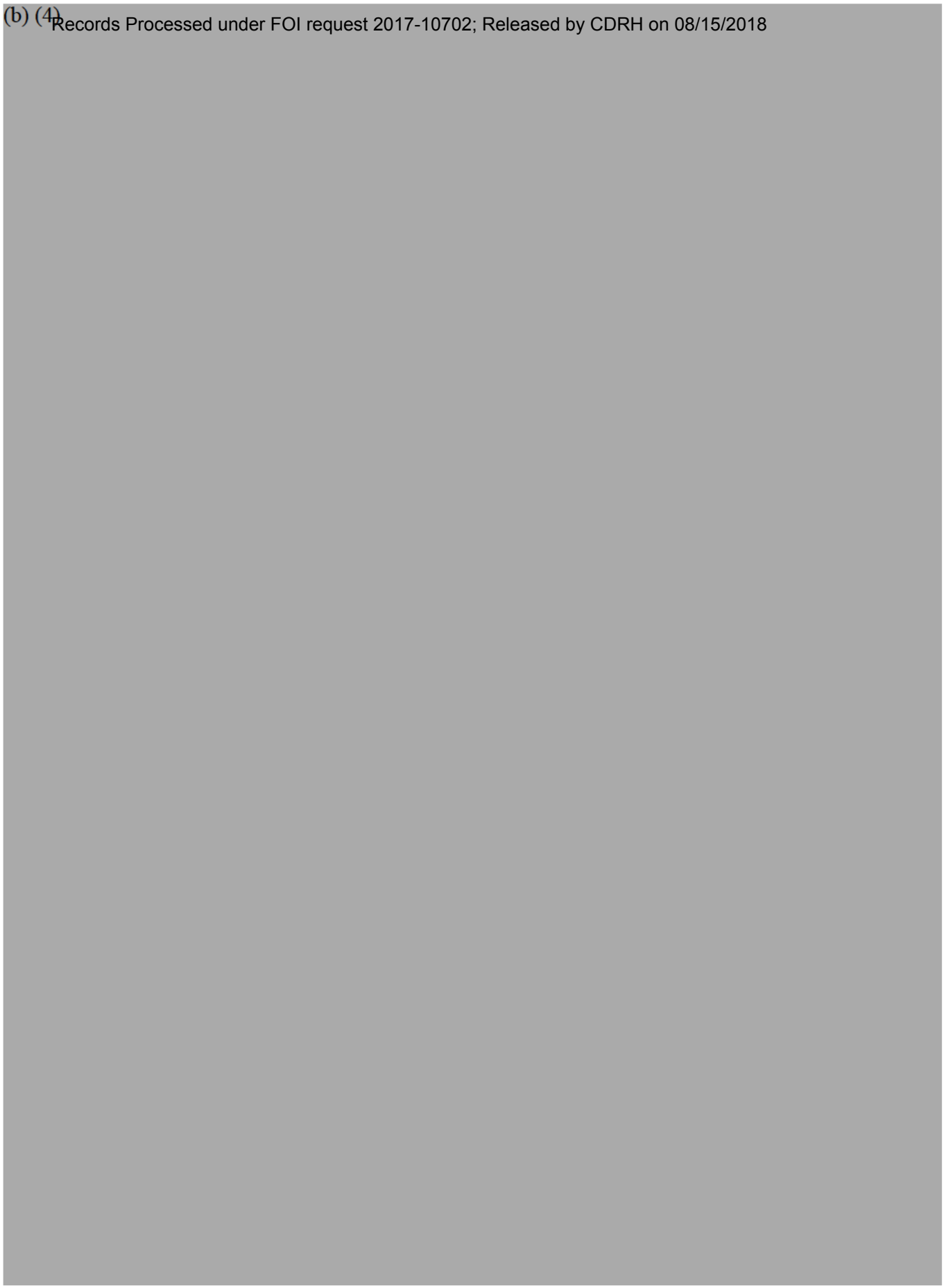
(b) (4)



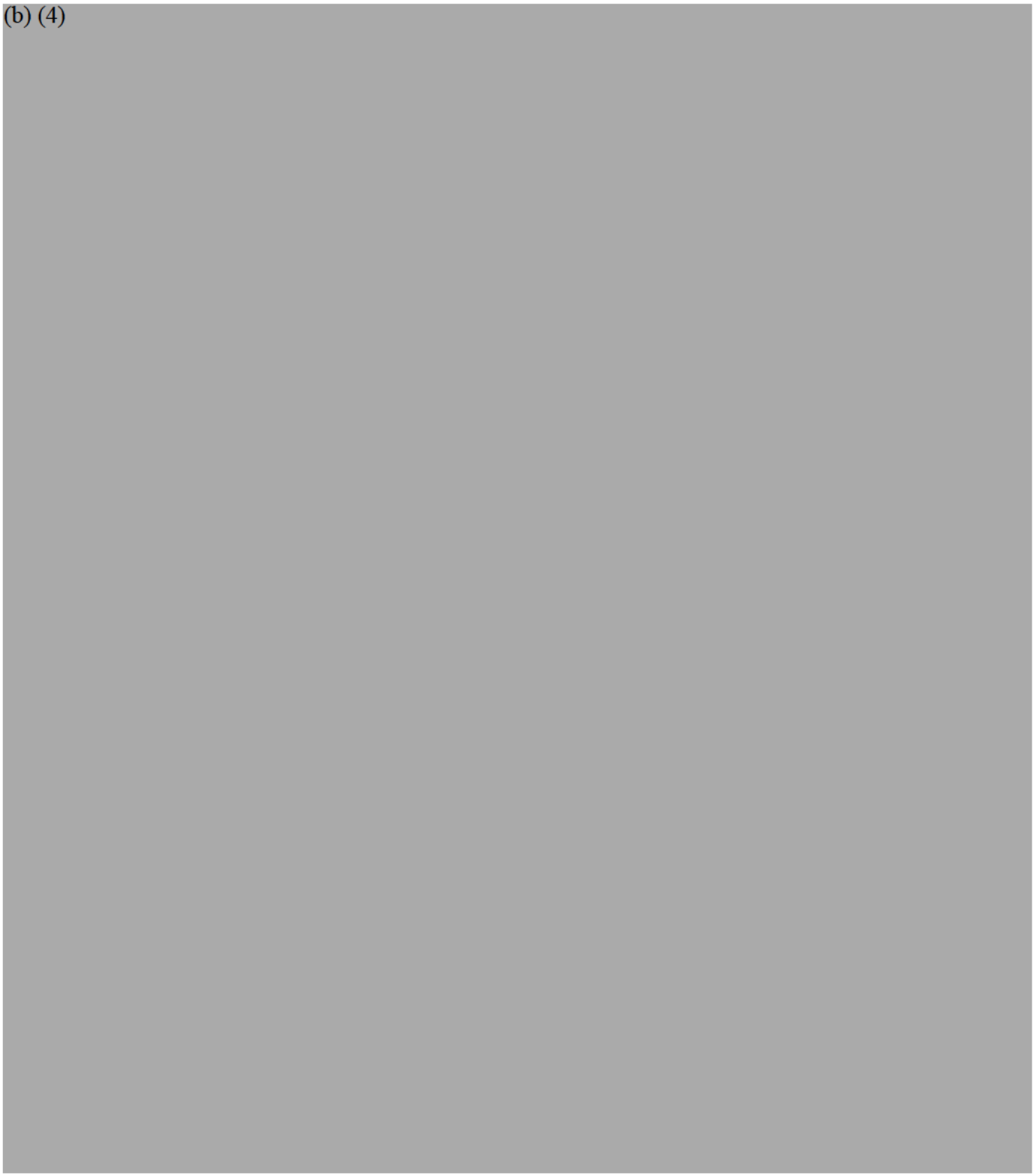
(b) (4)



[redacted]



(b) (4)

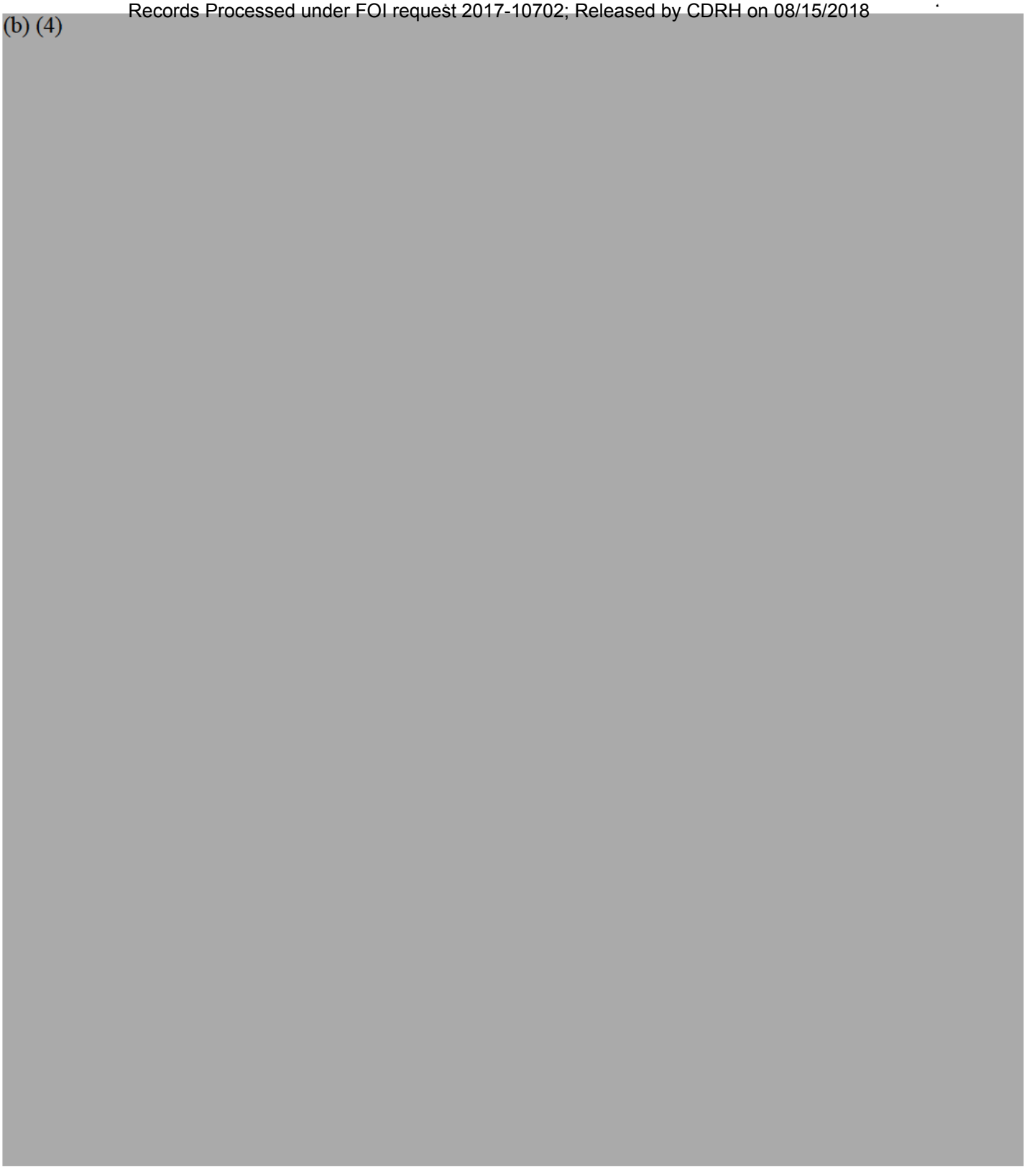


(b) (4)

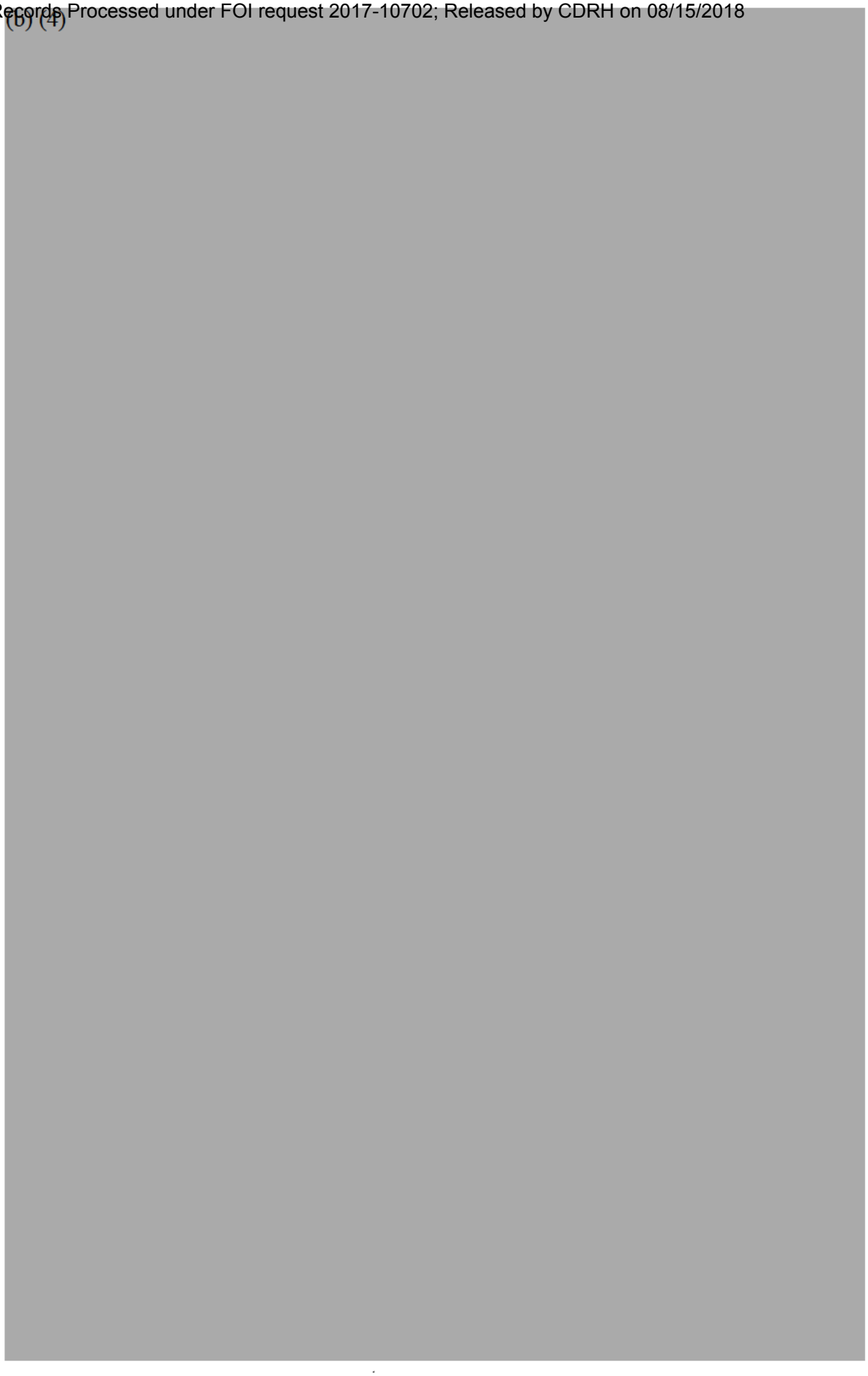
(b) (4)

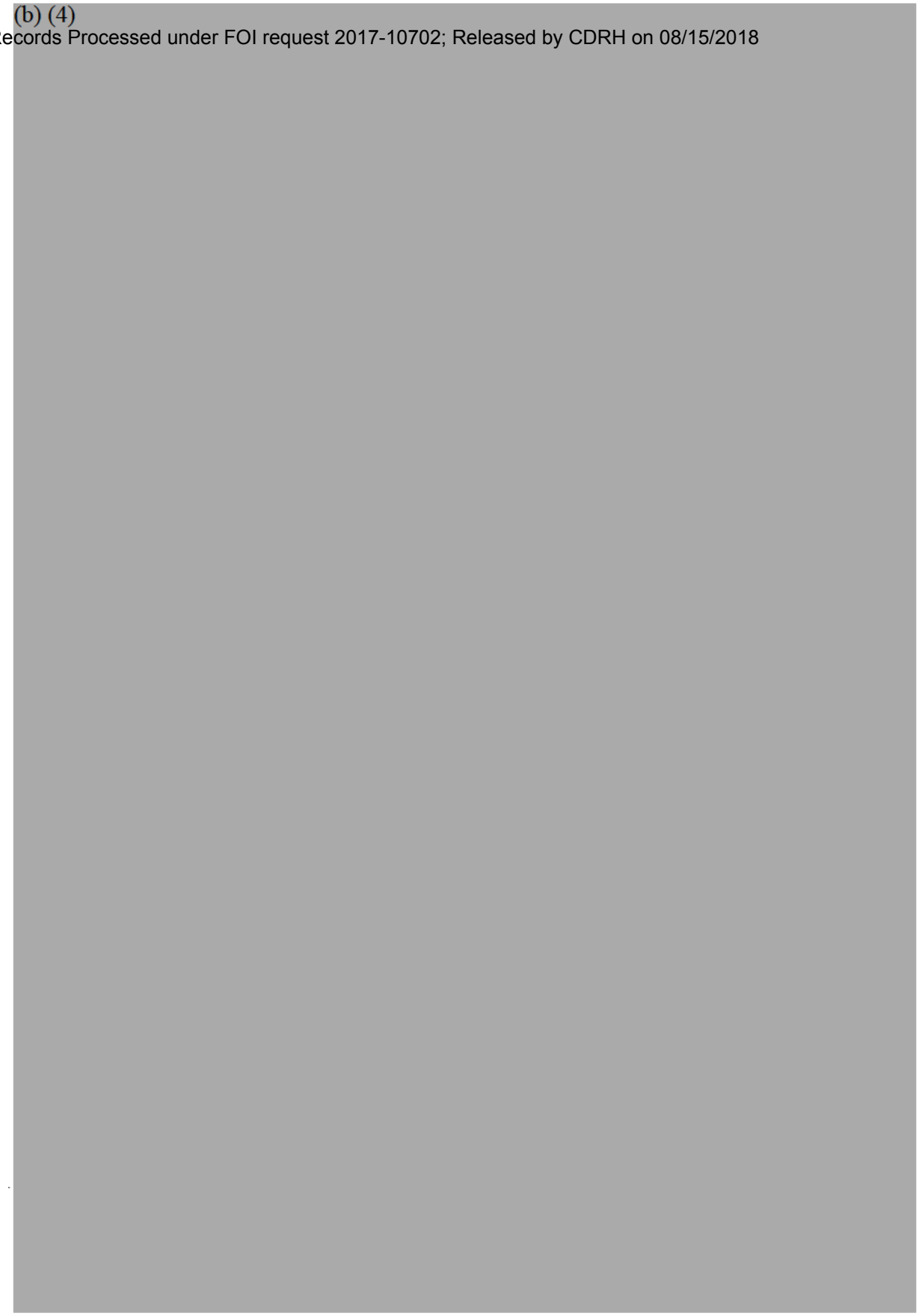
(b) (4)

(b) (4)

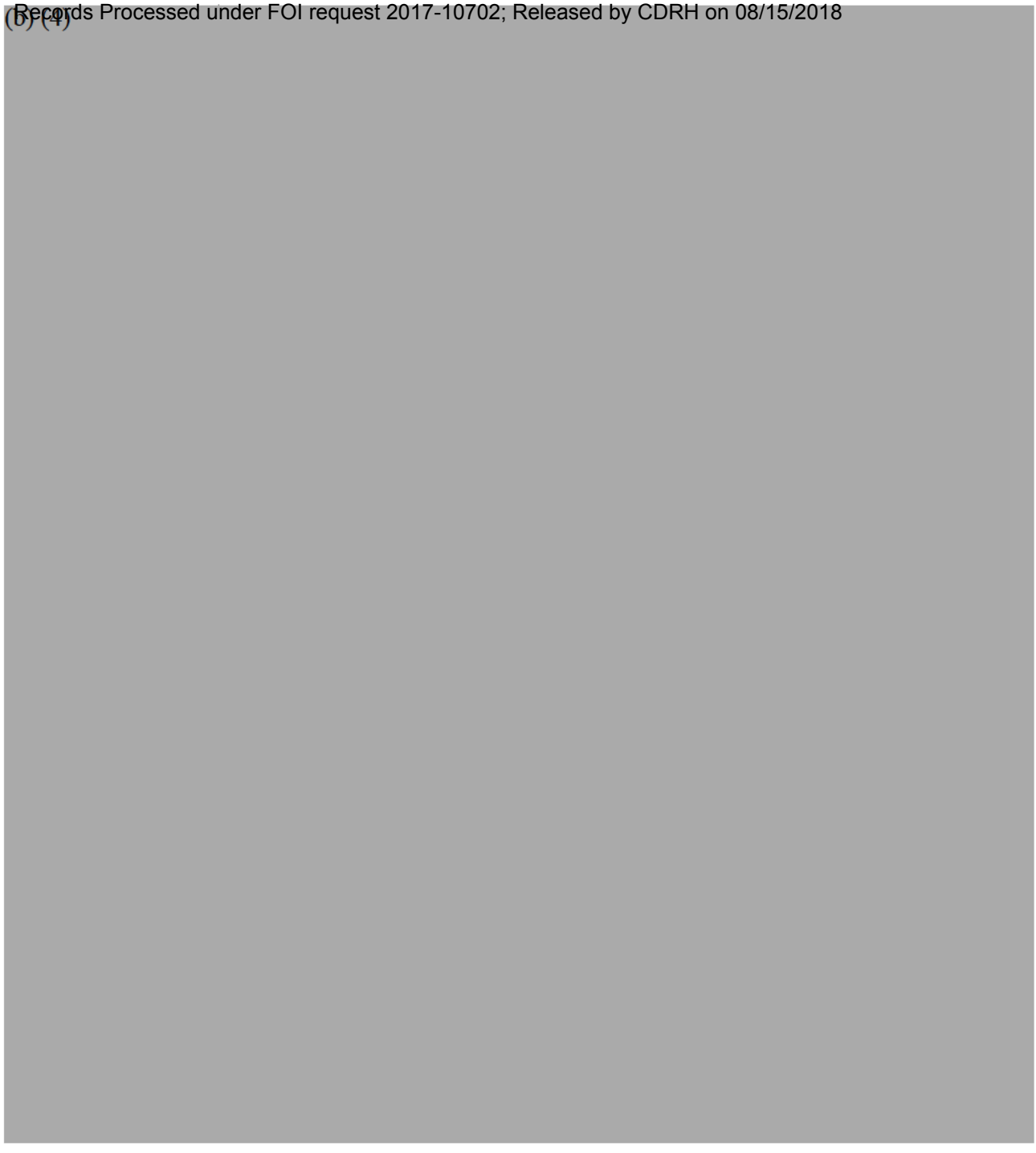


(b) (4)



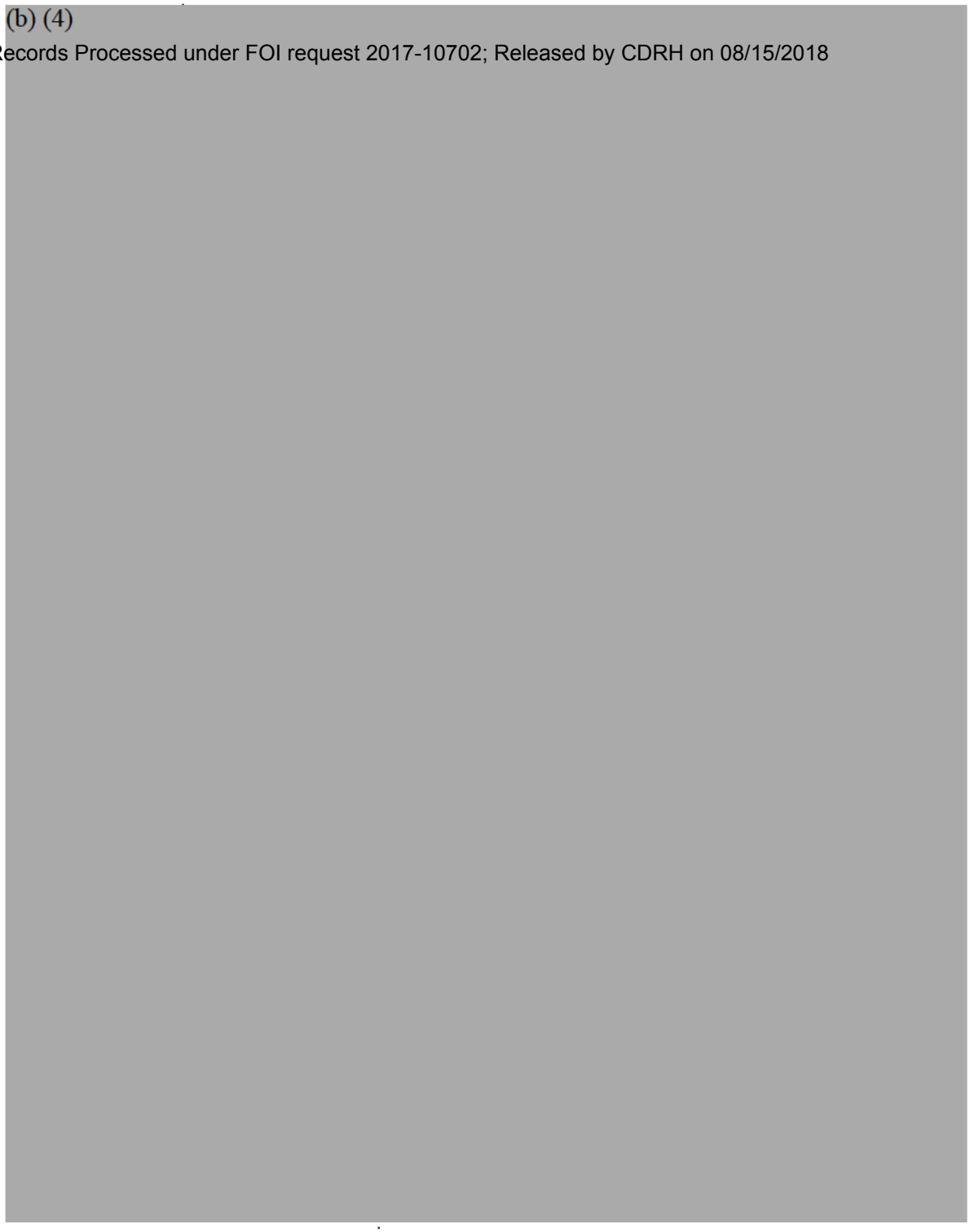


(b) (4)



(b) (4)

(b) (4)



[redacted]

(b) (4)

[redacted]

VII. Sterilization/Shelf Life/Reuse

14.0 Sterilization and Shelf Life

14.1 Sterilization

3M Attest™ 1496V and 41482V Super Rapid Challenge Packs are non-sterile devices.

14.2 Shelf Life

(b) (4)

(b) (4)

(b) (4)

1492V Attest™ Super Rapid Biological (b) (4) The shelf life of the
rectangular SteriGage™ chemical integrato (b) (4) The shelf life of the Challenge
Pack (b) (4)

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Reviewer Comment: The shelf life data could not be evaluated because the firm has based the shelf life on the biological indicator that is currently under review as the subject device for K121484. The firm will be asked to provide shelf life data for this subject device that uses a FDA cleared biological indicator. ***This is not acceptable.***

Please provide a FDA cleared biological indicator for use in your challenge pack to demonstrate the shelf life data for this subject device.

VIII. Biocompatibility

(b) (4)

(b) (4)

(b) (4)

has been reviewed. Because the challenge packs in this submission uses a biological indicator that has not been cleared by FDA. The firm will be asked to provide a FDA biological indicator so that the biocompatibility of the entire challenge pack may be assessed. ***This is not acceptable.***

Please provide a FDA cleared biological indicator for use in your challege pack.

IX. Software

Version:		
Level of Concern:		
	Yes	**No**
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

N/A

XI. Performance Testing – Bench

1496V and 41482V Challenge Packs

(b) (4)

AAMI Towel Packs

AAMI Towel Packs were constructed per ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 with towels of approxima(b) (4) s folded lengthwise into thirds and then folded widthwise in one manner. Towels were placed(b) (4)(b) (4) (b) (4) form a stack that was approximate pack was taped in a manner that resulted in

(b) (4)

The AAMI Towel Packs were prepared with gical towels.(b) (4) (b) (4) (4) After folding, the AAMI

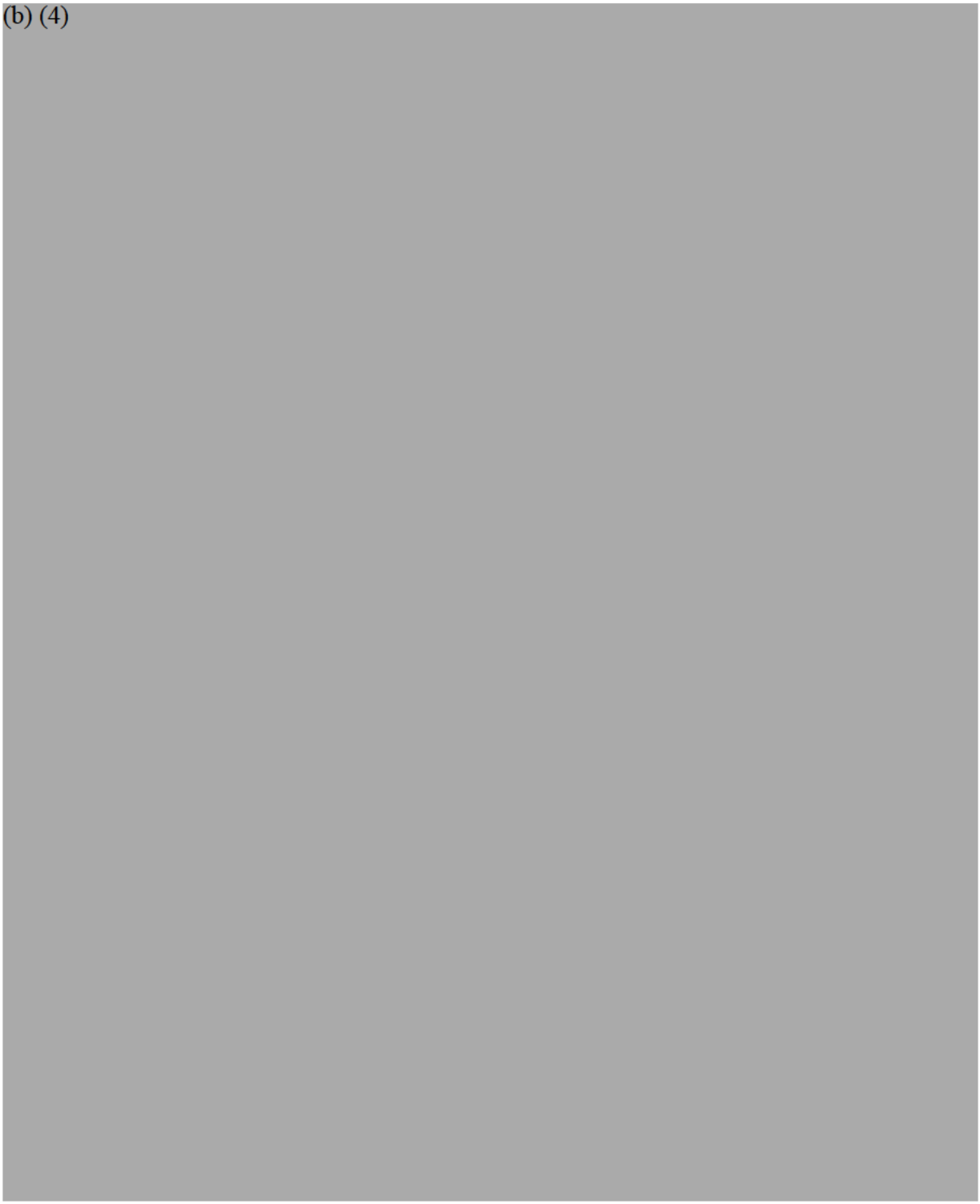
AAMI Towel Packs were loaded with Attest™ 1492V SRBIs and where appropriate SteriGage™. Attest™ 1492V SRBIs (and SteriGage™) were placed between the (b) (4) 1492V SRBIs weighed a(b) (4) (b) (4)

12.2 Equipment

Attest™ 1496V and 41482V Challenge Packs were evaluated(b) (4) (b) (4) these sterilizers are provided.

(b) (4)

(b) (4)



12.3 Performance Testing Protocols and Results

The table below summarizes the test protocols, acceptance criteria, cycle types and

(b) (4)

(b) (4)

Reviewer Comments: The subject device uses a biological indicator that is currently under review as the subject device for K121484. The firm will be asked to use a FDA cleared biological indicator in their subject device. ***This is not acceptable.***

Please provide a FDA cleared Biological Indicator for use in your challenge pack.

XII. Performance Testing – Animal
N/A

XIII. Performance Testing – Clinical
N/A

XIV. Substantial Equivalence Discussion

(b) (4)

1. Same Indication Statement?
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?
3. Same Technological Characteristics?
4. Could The New Characteristics Affect Safety Or Effectiveness?
5. Descriptive Characteristics Precise Enough?
6. New Types Of Safety Or Effectiveness Questions
7. Accepted Scientific Methods Exist?
8. Performance Data Available?
9. Data Demonstrate Equivalence?

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please

complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

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

XV. Deficiencies

Deficiency 1: The firm has provided 3M Attest™ 1496V and 41482V Super Rapid Biological Indicator Challenge Packs that uses the Attest™ 1492V biological indicator that currently under review for dynamic-air-removal (pre-vacuum) steam sterilization cycles (K121484).The firm will be asked to provide a 510(k) number for the biological indicator that has been cleared by FDA.

Please clarify whether the Attest™ 1492V biological indicator used with the subject challenge pack is FDA cleared. Please provide the 510(k) number for the biological indicator that has been cleared by the FDA. In the event the biological indicator is not cleared by the FDA, please submit your response when the biological indicator has been cleared by FDA.

XVI. Contact History

A deficiency email was sent to the firm on July 17, 2012

XVII. Recommendation

Regulation Number: 21 CFR 880.2800(a)
Regulation Name: Sterilization process indicator/ Biological Sterilization process indicator
Regulatory Class: II
Product Code: FRC

Reviewer — July 17, 2012 — Date

Branch Chief — 7/17/12 — Date

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Murray III, Clarence

From: Murray III, Clarence
Sent: [redacted]
To: (b) (4), (b) (6)
Subject: K121593: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack

Premarket Notification [510(k)] Review
Traditional

K121593

Date: July 17, 2012
To: (b) (4), (b) (5)
From: Clarence Murray, III, Ph.D.

Office: ODE
Division: DAGID/INCB

510(k) Holder: 3M Health Care
Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack
Cor (b) (4), (b) (6)
Pho
Fax
Em

July, 17, 2012

(b) (4), (b) (6)
Dea

Our review of your 510(k) submission, K121593, 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack show an area of deficiency that need to be resolved before we can conclude our review of your subject devices. Please address the following concern:

Deficiency 1: Please clarify whether the Attest™ 1492V biological indicator used with the two subject challenge pack is FDA cleared. Please provide the 510(k) number for the biological indicator that has been cleared by the FDA. In the event the biological indicator is not cleared by the FDA, please submit your response when the biological indicator has been cleared by FDA.

Finally, please be aware that other deficiencies may arise in this submission from the review of your K121593 submission.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system.

If you have any questions about the above request or you wish to discuss protocols, please contact me by phone at (301) 796-0270 or by email at clarence.murray@fda.hhs.gov.

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Sincerely,

Clarence W. Murray, III, Ph.D.
Chemist
Infection Control Device Branch
FDA/CDRH/ODE/DAGID
10903 New Hampshire Ave.
White Oak, Bldg. 66/ Room 2566
Silver Spring, MD 20993
301-796-0270 telephone
301-847-8109 fax

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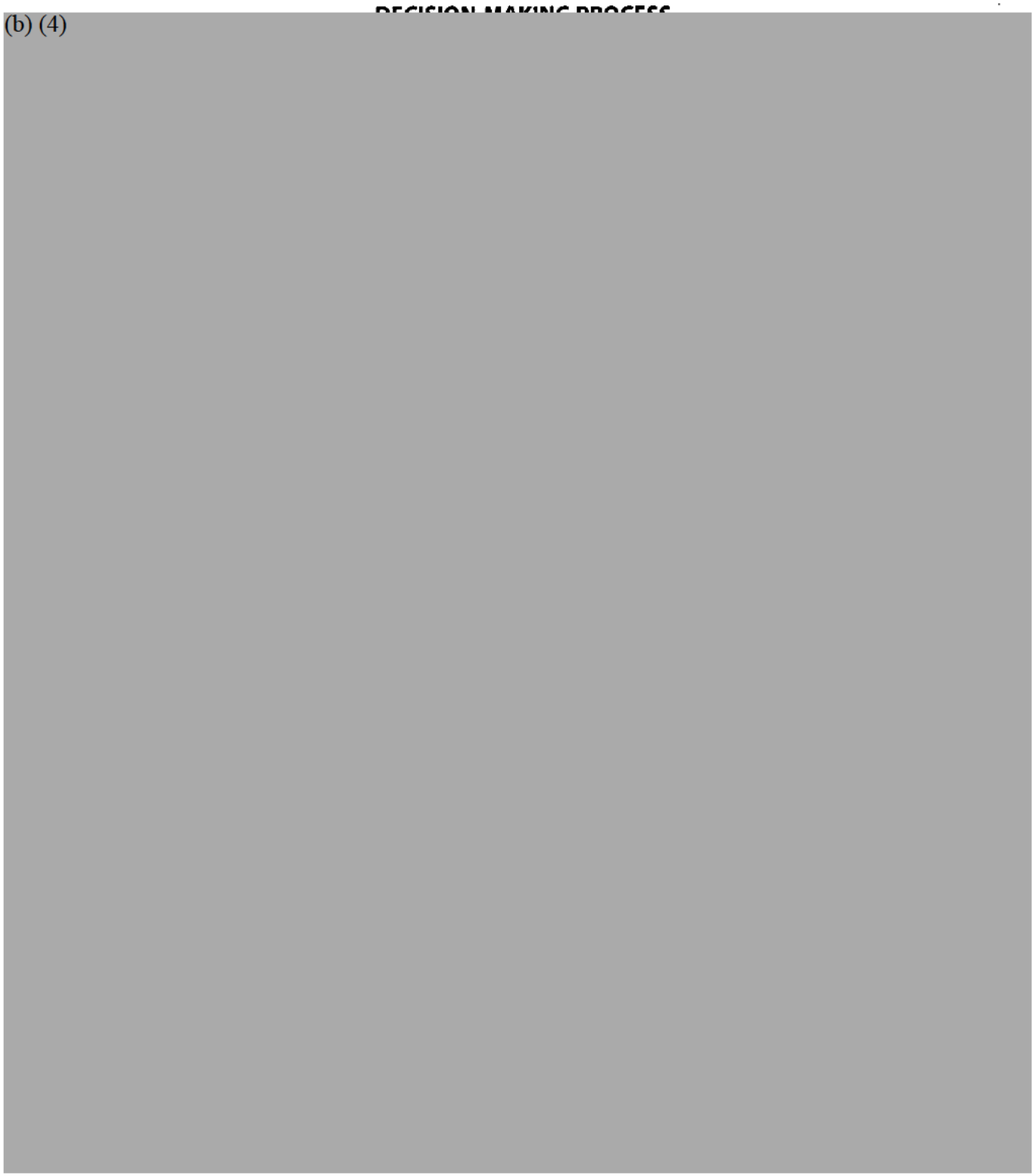
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS

(b) (4)



* 510(k) Submissions compare new device 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 literature.

K121593/S002

3M

Dr. Clarence Murray, III
Infection Control Devices Branch
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – W066-0609
Silver Spring, MD 20993-0002

March 1, 2013

Re: K121593, 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack, S002

Dear Dr. Murray,

As we discussed in the telephone conversation of February 26, 2013, I am enclosing 3M's responses to the Agency's questions related to the 510(k) K121593, Premarket Notification for 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack.

The Agency's questions took the form of a deficiency letter (December 13, 2013) and subsequent requests made during the interactive review (email of January 25, 2013 and telephone conversation of January 29, 2013). The 3M responses to each are provided within this submission.

This document is submitted as one paper copy and an electronic copy that is an exact duplicate of the paper copy. Please contact me at the number provided if you should have any questions concerning this submission.

Regards,

(b) (4), (b) (6)

Regulatory Affairs Manager
(b) (4)
St. Paul, MN 55144
(b) (4), (b) (6)

19

Dr. Clarence Murray, III
Infection Control Devices Branch
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – W066-0609
Silver Spring, MD 20993-0002

March 1, 2013

Re: K121593, 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack, S002

Dear Dr. Murray,

As we discussed in the telephone conversation of February 26, 2013, I am enclosing 3M's responses to the Agency's questions related to the 510(k) K121593, Premarket Notification for 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack.

The Agency's questions took the form of a deficiency letter (December 13, 2013) and subsequent requests made during the interactive review (email of January 25, 2013 and telephone conversation of January 29, 2013). The 3M responses to each are provided within this submission.

This document is submitted as one paper copy and an electronic copy that is an exact duplicate of the paper copy. Please contact me at the number provided if you should have any questions concerning this submission.

Regards,

(b) (4), (b) (5)

Regulatory Affairs Manager
(b) (4)
St. Paul, MN 55144
(b) (4), (b) (6)

Questions from Deficiency Letter of December 13, 2012

Deficiency 1: On November 14, 2012, you were asked to provide a rationale for using exposure (b) (4) *Once again, please provide a rationale for using the following* (b) (4)

(b) (4)

3M Response:

The FDA guidance requires demonstration of t(b) (4)he test pack(b) (4)he (b) (4)

Based on the Agency's feedback, a comparison o(b) (4)
(b) (4)

(b) (4)

(b) (4)

Deficiency 2:

(b) (4)

3M Response:

(b) (4)

Deficiency 3: On November 14, 2012 3M was asked to explain the result shown in the table below that is highlighted in the red box. Your rationale for (b) (4) (b) (4) (b) (4) *If this statement is the case, Please provide a rationale for why* (b) (4) (b) (4) *Please provide t* (b) (4) *our tables 6 and 7. Please schedule a teleconference with FDA to discuss table 7 prior to your formal response to this question.*

(b) (4)

3M Response:

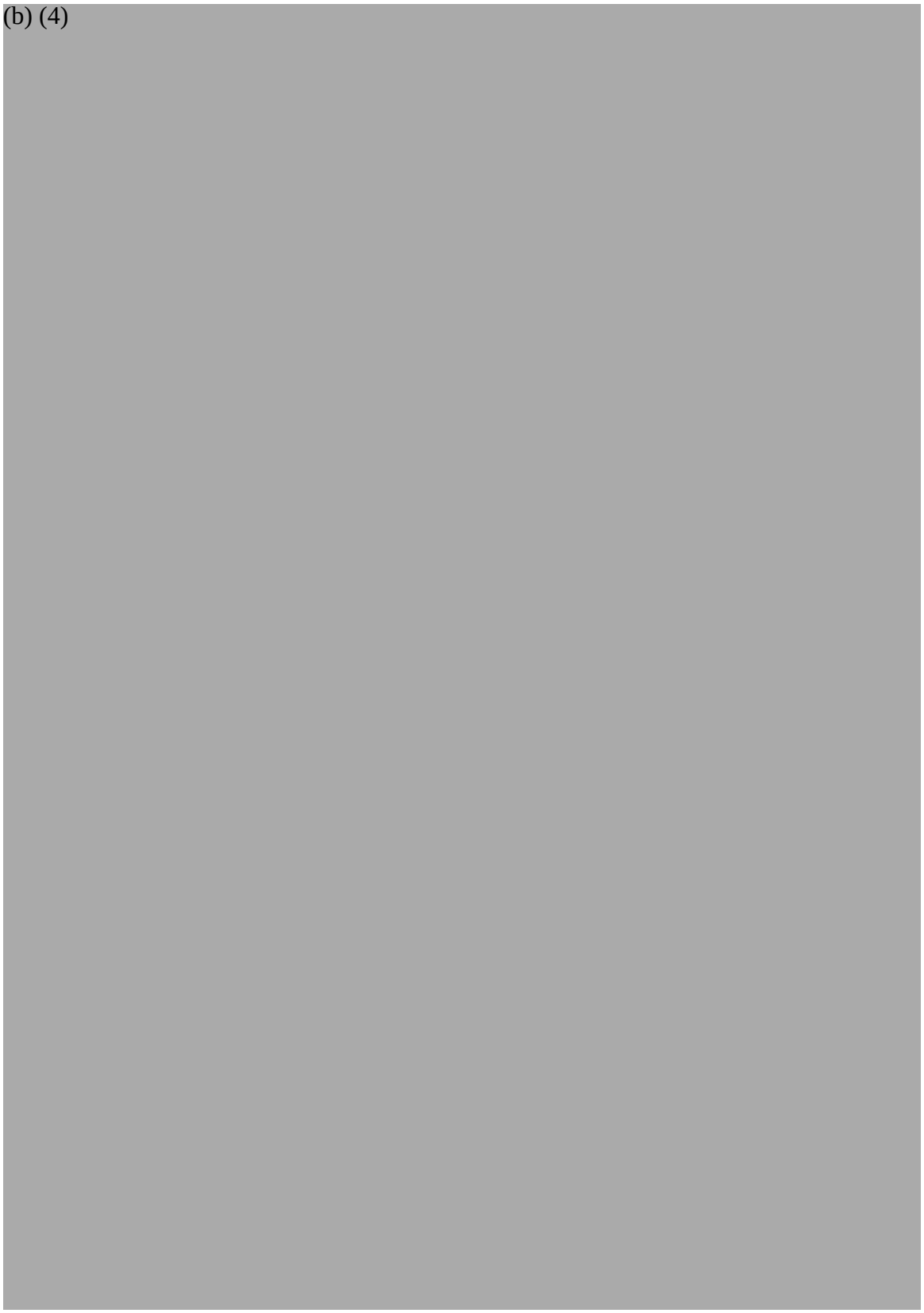
(b) (4)

As part of the interactive review, additional questions were raised surrounding the choice of exposure time (b) (4) In the teleconference of January 29, 2013, 3M explained that (b) (4) (b) (4) (b) (4) The subsequen(b) (4) ere chosen to demonstrate the increased resistance of the (b) (4) (b) (4)

Given the Agency's feedb (b) (4) , 3M decided to (b) (4) (b) (4) testing the 1492V biological indicator's resistanc (b) (4) The results are provided as part of the response to Question 1.

Another request made as part of the interactive review was to clarify whether th(b) (4)
(b) (4)
(b) (4) is also exposed t(b) (4)
(b) (4)
(b) (4) e
summary table was presented as part of the response to Deficiency 1. The exposure times needed to
generate(b) (4) ong with the results at each exposure are provided belo(b) (4)
(b) (4)

(b) (4)



Additional requests from teleconference of January 29, 2013

As a result of the teleconference of January 29, 2013, the Agency made a request for additional information, which is provided below.

1. Comparison of (b) (4) *with cleared cycles* (b) (4)

3M Response:

The Agency had requested a tabular comparison of the cycles that have been used to generate data in this submission. The table below summarizes the operating parameters (b) (4)

(b) (4)

2. *Explain the difference in th[redacted] when compared to that of the [redacted] n Figure 7;* [redacted]

3M Response:

As part of the interactive review, questions were raised surrounding the data presented in Table 7 of the original submission[redacted]

The[redacted]

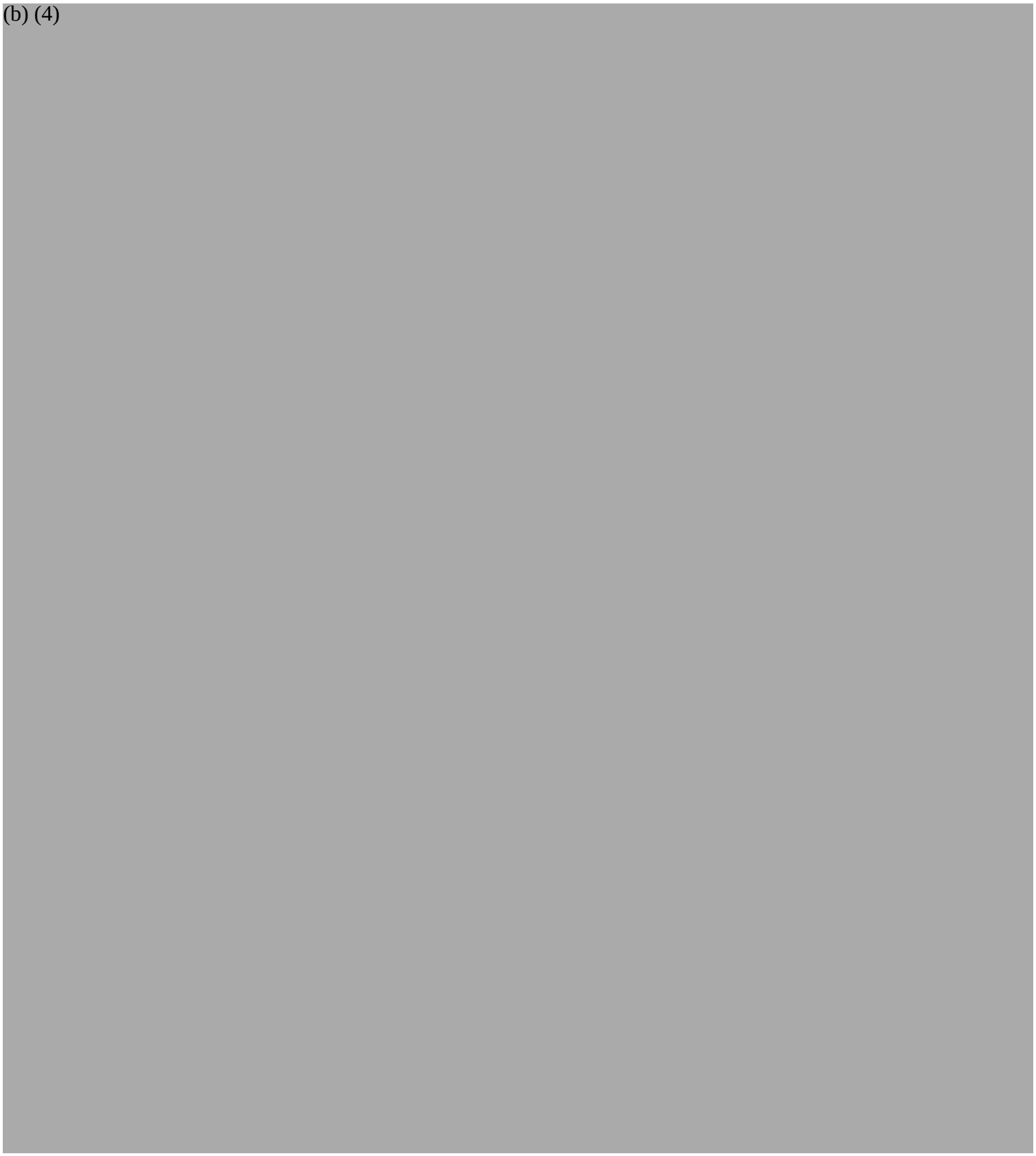
Attest™ Rapid Readout technology provide[redacted] o ensure the[redacted] as been confirmed b[redacted] The[redacted]

3. Provide data for the Fluorescent results from you (b) (4) *testing.*

3M Response:

(b) (4)

(b) (4)



Discussion of the results

(b) (4)

It is important to note that the results obtained for the

(b) (4)

As with th(b) (4)

The correspondence of th(b) (4) (b) (4) resul(b) (4)

(b) (4) Th(b) (4) ponse is a direct result of

spores(b) (4)

(b) (4)

(b) (4)

ized in the Attest™ Rapid Readout biological indicators and

sponse have been characterized in numerous peer-reviewed

publicatio(b) (4)

(b) (4)

(b) (4)

In previous reviews of the Rapid Readout technology, the Agency has stated

> "As we indicated during the call, CDRH believes that the procedures described in the 1986 'F
> f (b) (4)
> o
>
> (b) (4)

References:

(b) (4)

(b) (4)

I performance in the hospital sterilizers

3M Response:

(b) (4)

As requested in the teleconference of January 29, 2013, th (b) (4)
indicator was tested in the same hospital sterilizer cycles as the
(b) (4) (b) (4)
(b) (4) Tables 4 and 5. The 1492V BI data has now been add
tables as a revision.

Conclusion:

This supplement is a summary of the exchange during the interactive review of (b) (4) 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack.

As outlined in the 2007 Guidance for Biological Indicators, the following criteria should be met for a test pack.

1. The performance of the BI in the test pack is equivalent to the performance of the AAMI reference test pack

   Criteria met: The AAMI reference for steam sterilization is the 16 Towel Pack. The Challenge Packs have demonstrated equivalent or greater resistance to the 16 Towel Pack through testing in the cleared 132°C/270°F and 135°C/275°F prevacuum cycles.

(b) (4)

(b) (4) (b) (4)

Supplement S001, and this supplement, 3M has demonstrated the Challenge Packs have fully met the FDA's requirements as outlined in the 2007 Guidance for Biological Indicators.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 24, 2012

(b) (4), (b) (6)
ST. PA (b) (4), (b) (6))0
ATTN:

510k Number: K121593

Product: 3M ATTEST (TM) SUPER RADID REA

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

329

Pugh, Dominique *

From: Microsoft Outlook
To: (b) (4), (b) (6)
Sent: Wednesday, October 24, 2012 12:00 PM
Subject: Relayed: K121593 AI Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

(b) (4), (b) (6)

Subject: K121593 AI Letter

K121593/S001

K-17

Dr. Clarence Murray, III
Infection Control Devices Branch
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – W066-0609
Silver Spring, MD 20993-0002

October 23, 2012

Re: K121593, 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack

Dear Dr. Murray,

As requested in your email dated July 17, 2012, please find enclosed 3M's written response to your question related to the 510(k) K121593, Premarket Notification for 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack. The clearance information for the biological indicator used in the challenge packs is provided.

This document is submitted as two paper copies. Please contact me at the number provided if you should have any questions concerning this submission.

Regards,

(b) (4), (b) (6)

Regulatory Affairs Manager
(b) (4)
St. Paul, MN 55144
(b) (4), (b) (6)

(b) (4)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2012

3M (b) (4), (b) (6)
C/C
Regulatory Affairs
(b) (4)
St. Paul, Minnesota 55144

Re: K121484
Trade/Device Name: 3M Attest™ 1492V Super Rapid Readout Biological Indicator for Steam, 3M Attest™ 490 Auto Reader
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: October 17, 2012
Received: October 18, 2012

Dea (b) (4), (b) (6)

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

332

510(k) Number: K121484

Device Name: 3M Attest™ 1492V Super Rapid Readout Biological Indicator for Steam
3M Attest™ 490 Auto-reader

Indications for Use:

Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ Auto-reader 490 to qualify or monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles of 4 minutes at 270°F (132°C) and 3 minutes at 275°F (135°C).

The 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K121484

Jones, Ashlee *

From: (b) (4), (b) (6)
To:
Sent: Wednesday, December 05, 2012 12:22 PM
Subject: Relayed: K121593 AI Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

(b) (4), (b) (6)

Subject: K121593 AI Letter

121

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 05, 2012

(b) (4), (b) (6)
ATTN: (b) (4), (b) (6)

510k Number: K121593

Product: 3M ATTEST (TM) SUPER RADID REA

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Attachment

Attachment for Submission Number(s):

K121593/S002

The list below identifies the reason(s) why your eCopy failed FDA's eCopy validation process. All of these items need to be addressed or your eCopy will not pass the validation process.

1. **The following PDF file(s) have an invalid naming convention (e.g., numbering scheme incorrect, no underscore between number and descriptive name, descriptive name includes prohibited special characteristics):**

   3M Response to Deficiency Letter of 14Nov2012 K121593 S001.pdf

123

K121

3M

Dr. Clarence Murray, III
Infection Control Devices Branch
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – W066-0609
Silver Spring, MD 20993-0002

December 3, 2012

Re: K121593, 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and 41482V Super Rapid 5 Steam-Plus Challenge Pack, S001

Dear Dr. Murray,

As requested in your email dated November 14, 2012, please find enclosed 3M's written response to your questions related to the 510(k) K121593, Premarket Notification for 3M™ Attest™ 1496V Super Rapid Readout Steam Challenge Pack and the 41482V Super Rapid 5 Steam-Plus Challenge Pack. In additional to responses to each deficiency question, this supplement includes revisions to the following documents:

- Indications for Use
- 510(k) Summary
- Instructions for Use

This document is submitted as one paper copy and an electronic version that is an exact duplicate of the paper copy. Please contact me at the number provided if you should have any questions concerning this submission.

Regards,

(b) (4), (b) (6)

Regulatory Affairs Manager,
3M Health Care
(b) (4)
St. Paul, MN 55144

(b) (4), (b) (6)

124

510(k) Summary

1. *Please provide the product code in this summary.*
2. (b) (4)
3. *Please include a discussion of the similarities and differences between the subject devices and the predicate device.*

3M Response to Questions 1 to 3:

Please see (b) (4) for a modified 510(k) Summary that includes the following:

- Addition of the product code
- (b) (4)
- Addition of a discussion of the similarities and differences between the 1496V and 41482V Challenge Packs and the predicate device.

Indications for Use

4. (b) (4)

(b) (4)

Predicate Device Comparison

5. *Please verify the shelf life of your BI and if there is a change in the shelf life then please revise your predicate comparison table to include the new shelf life for the BI to be used in this subject device.*

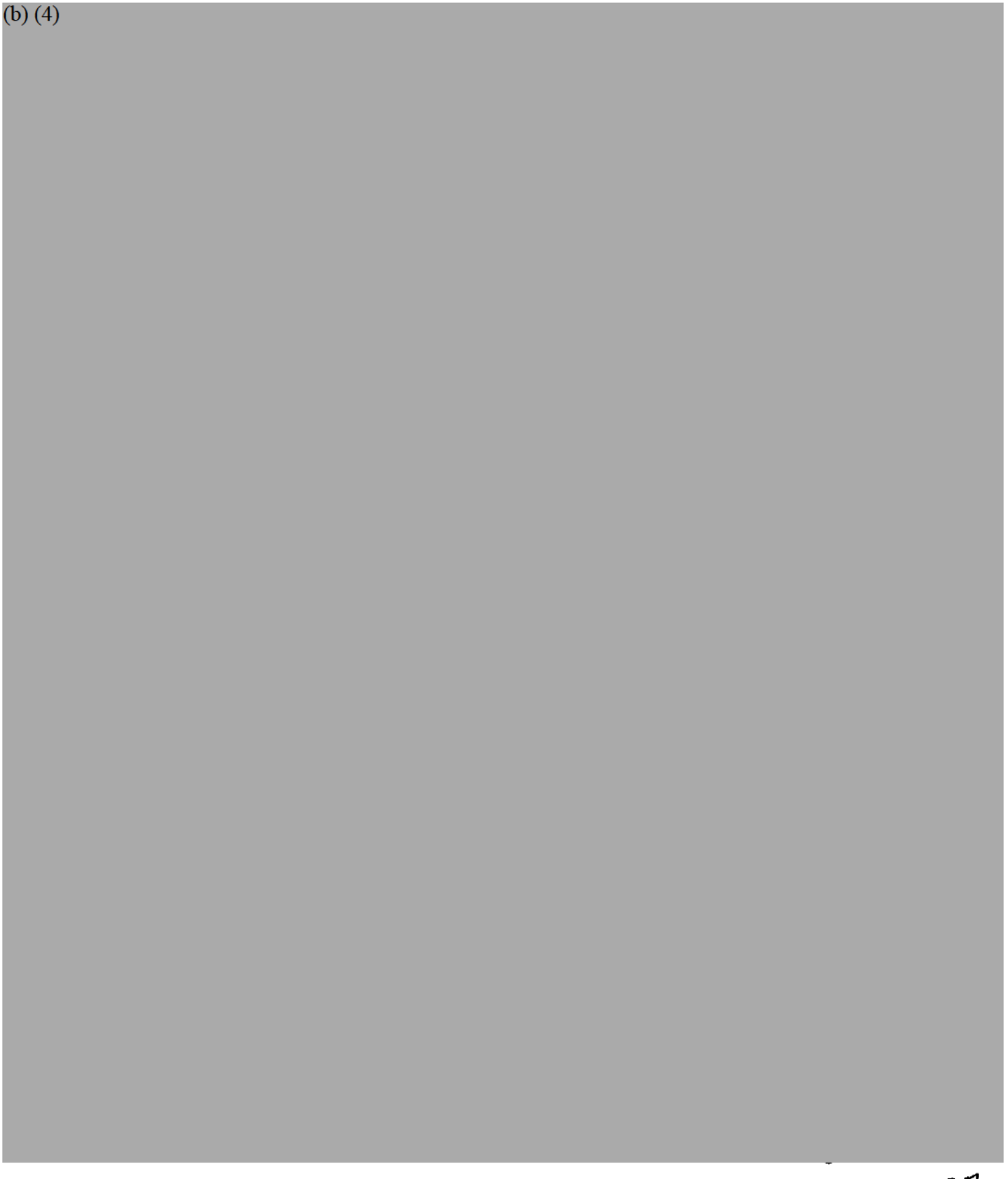
3M Response to Question 5:

The design of both the 1496V and 41482V Challenge Packs incorporates a 1492V Biological Indicator (BI). In the case of 41482V Challenge Pack, a SteriGage™ chemical integrator is also included.

(b) (4)

126

(b) (4)



Labeling

In regards to the labeling for your 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V:

(b) (4)

3M Response to Questions 6 to 8:

Please see **Attachment C** for a revised Instructions for Use statement for the 1496V Challenge Pack which includes the revised Indications for Use statement that states the

(b) (4)

In regards to labeling for your 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V:

(b) (4)

3M Response to Questions 9 to 11:

Please se (b) (4) or a revised Instructions for Use statement for the 41482V Challenge Pack which includes the revised Indications for Use statemen (b) (4)

(b) (4)

The SteriGage chemical integrator meets **both** the FDA requirements for a chemical integrator as stated in FDA's *Premarket Notification [510(k)] Submissions for Chemical Indicators: Guidance for Industry and FDA Staff*, December 19, 2003 and the requirements within ANSI/AAMI/ISO 11140-1:2005/(R)2010 *Sterilization of health care products – Chemical indicators, Part 1: General Requirements* for a Class 5 integrating integrator.

(b) (4)

(b) (4)

(b) (4)

omply

with the requirements of ANSI/AAMI ST-79 *Comprehensive guide to steam sterilization & sterility assurance in health care facilitie*

(b) (4)

(b) (4)

(b) (4)

Sterilization/Shelf Life/Reuse

12. *Please include the shelf life data for the 1492V Attest™ Super Rapid Biological Indicator to establish the shelf life for both the 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs.*

3M Response to Question 12:

(b) (4)

Please see (b) (4) the shelf life study provided within (b) (4) supports the (b) (4)

130

Performance Testing

(b) (4)

In regards to your Study 1

(b) (4)

13. *Please clarify whether if there were any changes to the biological indicator that was used in your studies and the biological indicator that was recently cleared by FDA.*

(b) (4)

15. *Please provide the raw data and provide all the details for the results shown in this summary table to support the conclusions made at 132°C.*
16. *Please provide the raw data and provide all the details for the results shown in this summary table to support the conclusions made at 135°C.*

3M Response to Questions 13 to 16:

(b) (4)

3M would like to clarify the following

(b) (4)

- There is no difference between the 1492V Biological Indicator used in the studies ission and the 1492V Biological Indicator recently cleared under

(b) (4)

(b) (4)

(b) (4)

(b) (4)

he following statement is provided in AAMI ST79:

(b) (4)

(b) (4)

course of this study for both 132°C and 135°C cycles are now provided as

(b) (4)

along with th

(b) (4)

132

(b) (4)

In regards to your Study 2

(b) (4)

20. Please provide the raw data and provide all the details for the results shown in this summary table to support the conclusions made at 132°C and 135°C.

3M Response to Questions 17-20:

(b) (4)

(b) (4)

(b) (4)

(b) (4)

The DA-cleared cycles in

(b) (4)

(b) (4)

(b) (4)

approximate cycle.

133

(b) (4)

General Comments:

21. *Please revise Table 3 under study 2 to denote that the 132°C and 135°C cycles are* (b) (4)

22. (b) (4)

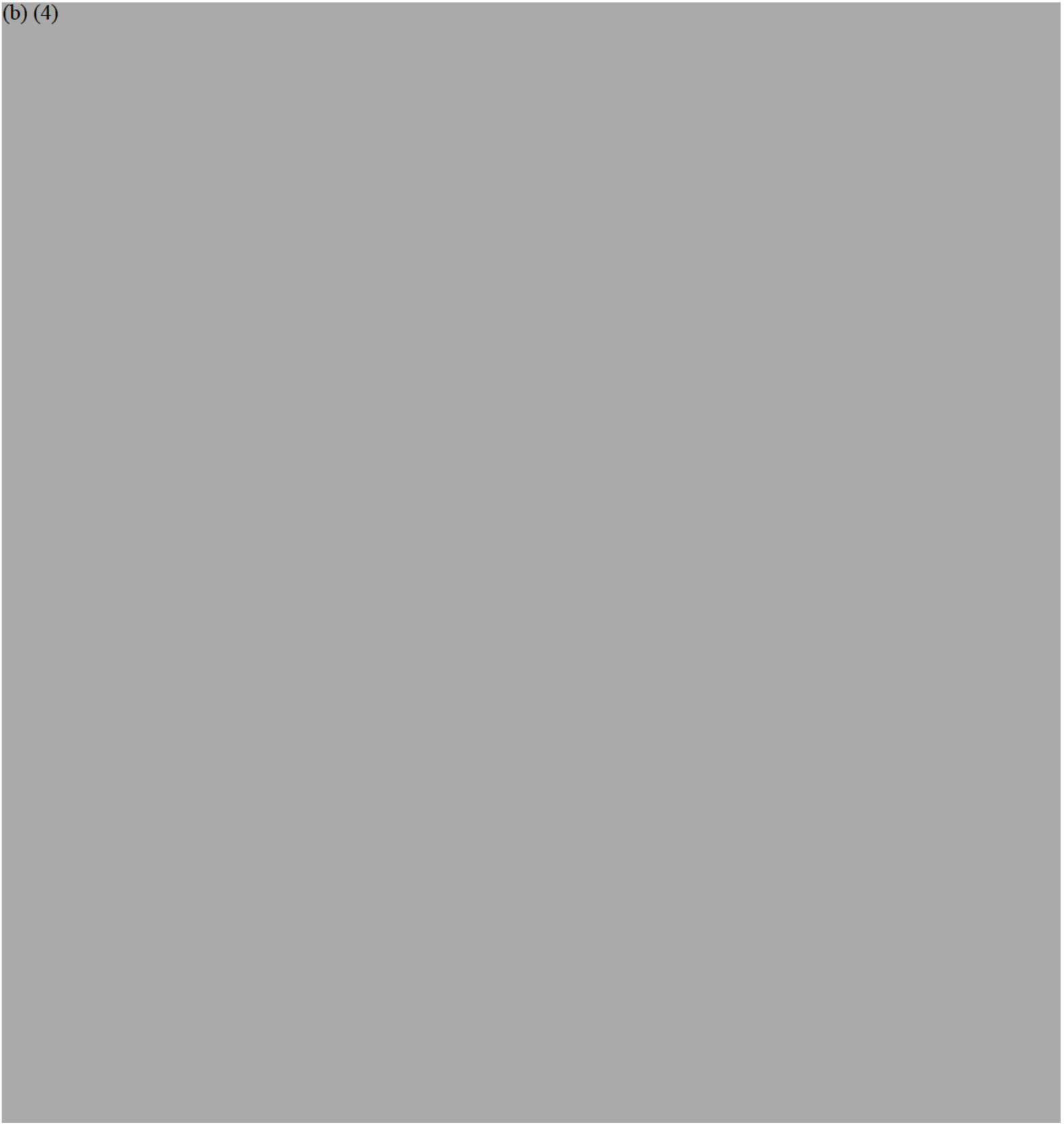
3M Response to Questions 21 and 22:

(b) (4)

(b) (4)

135

(b) (4)



Attachment A: Updated 510(k) Summary

Premarket Notification (510(k)) Summary

3M

Sponsor Information:

3M Health Care
(b) (4), (b) (6)
St. Paul, MN 55144-1000

Contact Person: (b) (4), (b) (6)
Regulatory Affairs Manager
Phone Number: (b) (4), (b) (6)
FAX Number:

Date of Summary: March 14, 2013

Device Name and Classification:

Common or Usual Name: Sterilization Biological Indicator

Proprietary Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack
3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack

Classification Name: Indicator, Biological Sterilization Process
(21 CFR § 880.2800(a))

Product Code: FRC

Product Class: Class II

Predicate Devices: (b) (4)
3M Attest™ Steam-Plus Pack (b) (4)
cleared under K92549(
3M Attest™ 1492V Super Rapid Readout Biological Indicator for Steam and 3M Attest™ 490 Auto-reader (K121484)

Description of Device:

The 3M Attest™ 1496V Super Rapid Readout Steam and 41482V Super Rapid 5 Steam-Plus Challenge Packs are specifically designed to qualify or routinely challenge 270°F (132°C) and 275°F (135°C) dynamic-air-removal (pre-vacuum) steam sterilization cycles in healthcare facilities.

Similarities to the predicate device

The 1496V and 41482V Challenge Packs are similar in design to the predicate device the 3M Attest™ Steam-Plus Pack. The packs consist of (b) (4)
(b) (4)
(b) (4)
The Challenge Packs and the predicate device all contain a biological indicator. The 41482V Challenge Pack and the predicate device also contain a SteriGage™ chemical integrator. The SteriGage™ integrator offers an immediate Accept/Reject reading that allows for implant load early release in emergency situations as defined in AAMI ST-79. Each Challenge Pack has a chemical process indicator on the outside of the device that changes from yellow to brown or darker when exposed to steam.

Differences from the predicate device

Each 1496V test pack contains an Attest™ 1492V Super Rapid Biological Indicator (1492V SRBI) while the 41482V Super Rapid 5 Steam-Plus Challenge Pack contains a 1492V SRBI and a SteriGage™ steam chemical integrator. The predicate device contains an Attest™ 1262 Biological Indicator with a visual pH color change result at 48 hours and a SteriGage™ steam chemical integrator. The 1492V SRBI is specifically designed for a rapid fluorescent result when used in conjunction with the 3M Attest™ 490 Auto-reader. A fluorescence change indicates a steam sterilization process failure. Attest™ 1492V SRBI controls are provided with the Challenge Packs.

(b) (4)

Indications for Use:

Use the 3M Attest™ Super Rapid Readout Steam Challenge Pack 1496V and the 3M Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V in conjunction with the 3M Attest™ Auto-reader 490 to qualify or monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles of 270°F (132°C) at 4 minutes and 275°F (135°C) at 3 minutes.

The 3M Attest™ Super Rapid Readout Biological Indicator 1492V contained in the challenge pack provides a final fluorescent result in 1 hour. (b) (4) visual pH color change result is observed in 48 hours.

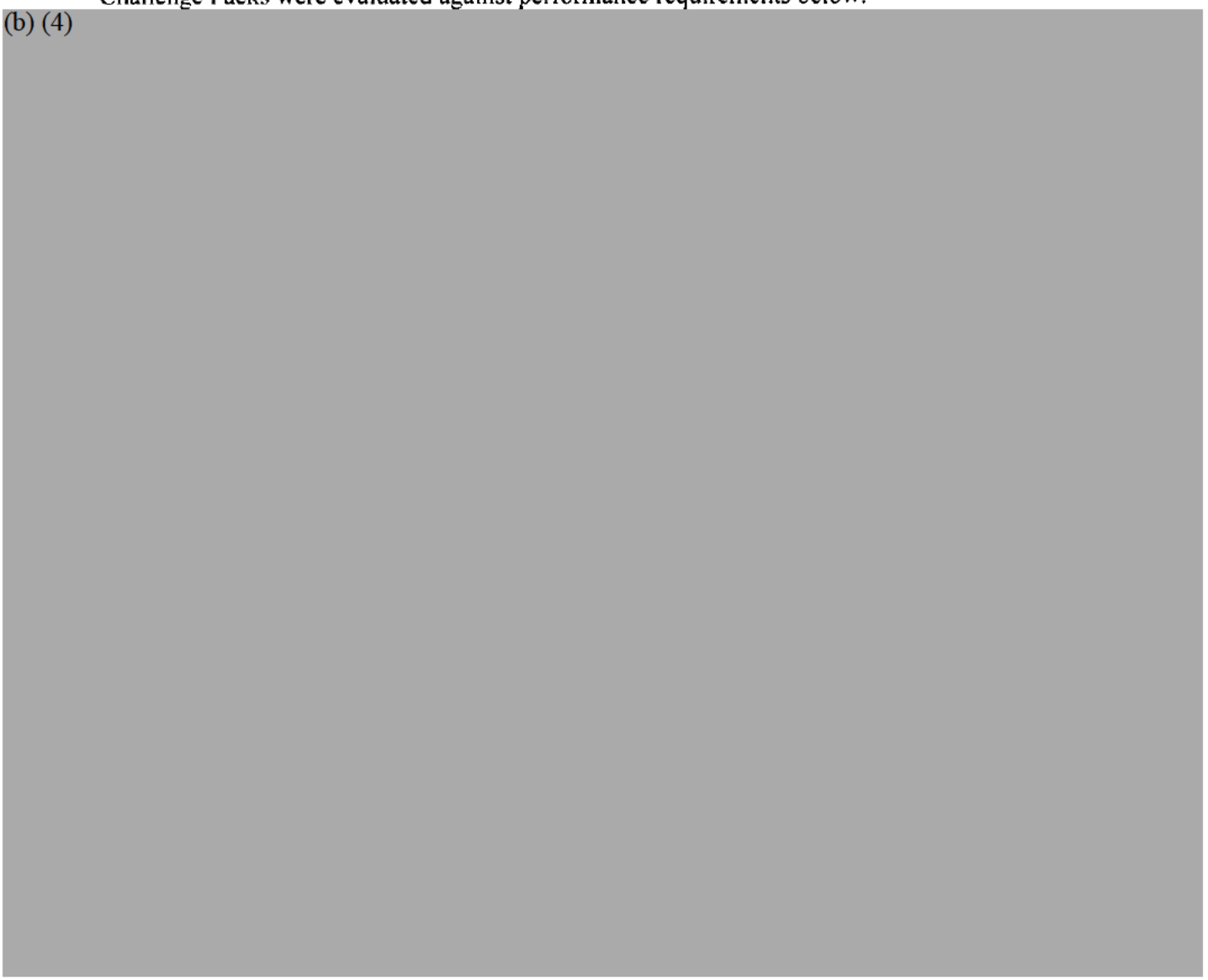
Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Testing was conducted on the indicators and the challenge packs following the FDA guidance and standards below:

(b) (4)

Multiple lots of 3M Attest™ Super Rapid Challenge Packs were prepared containing multiple lots of 1492V Super Rapid BIs and SteriGage™ chemical integrators. The Challenge Packs were evaluated against performance requirements below.

(b) (4)



Conclusion

The 3M Attest™ 1496V and 41482V Super Rapid Challenge Packs and the 3M Attest™ 490 Auto-reader meet all applicable voluntary performance standards and are substantially equivalent to the predicate device in terms of their intended use, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

Attachment B: Indications for Use Statement

510(k) Number: K121593

Device Name: 3M Attest™ 1496V Super Rapid Readout Steam Challenge Pack
3M Attest™ 41482V Super Rapid 5 Steam-Plus Challenge Pack

Indications for Use:

Use the 3M Attest™ Super Rapid Readout Steam Challenge Pack 1496V and the 3M Attest™ Super Rapid 5 Steam-Plus Steam Challenge Pack 41482V in conjunction with the 3M Attest™ Auto-reader 490 to qualify or monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles of 270°F (132°C) at 4 minutes and 275°F (135°C) at 3 minutes.

The 3M Attest™ Super Rapid Readout Biological Indicator 1492V contained in the challenge pack provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(b) (4)

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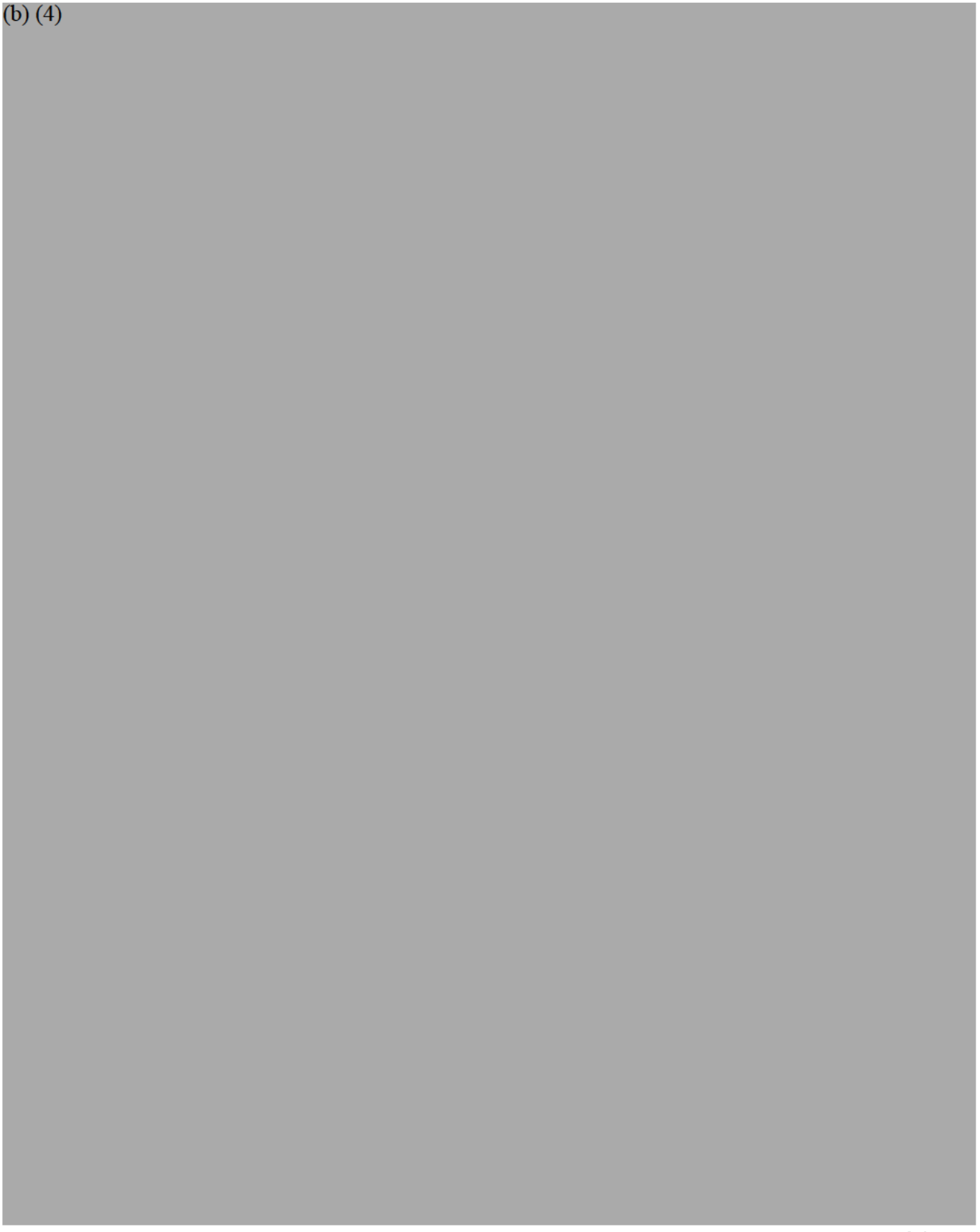

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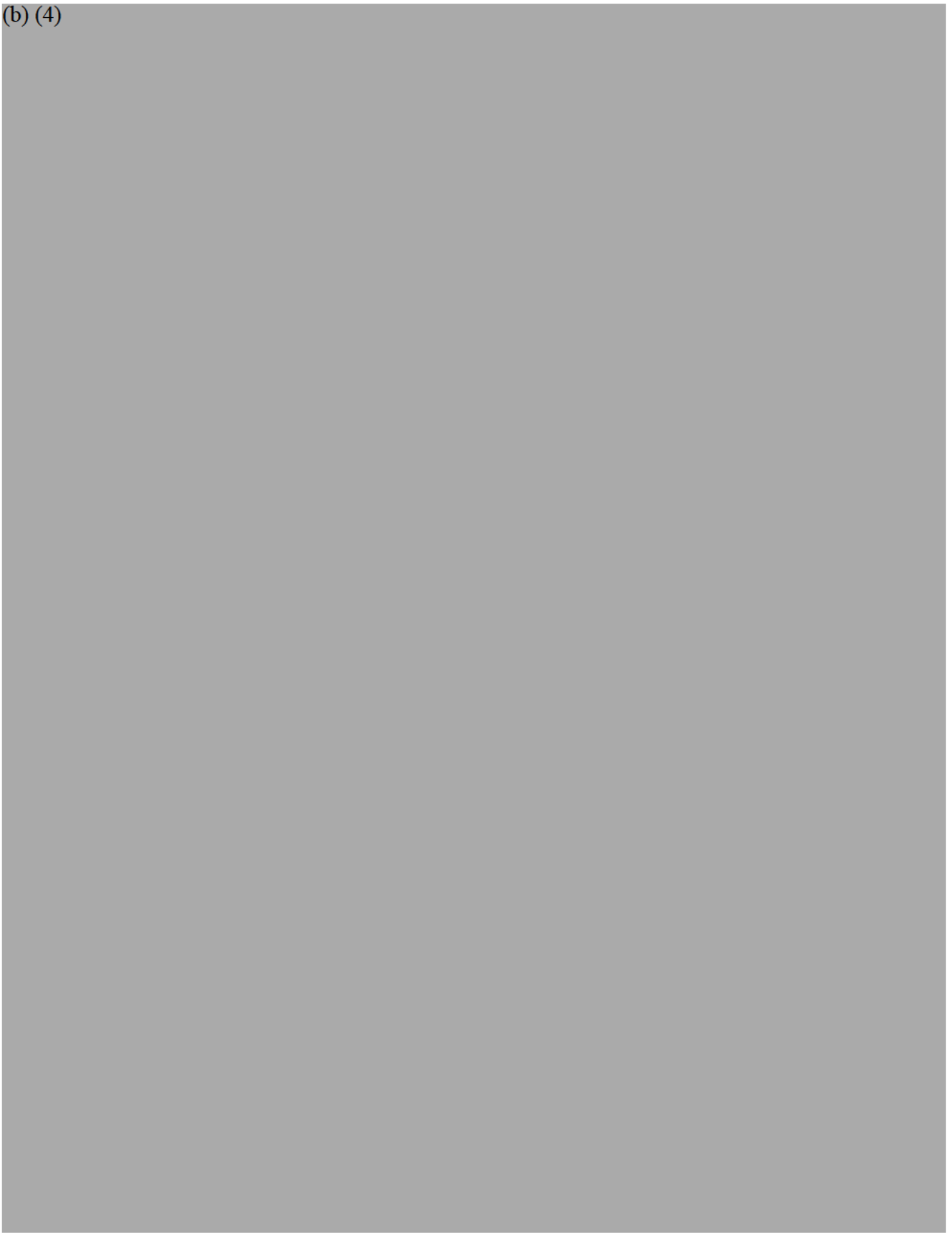

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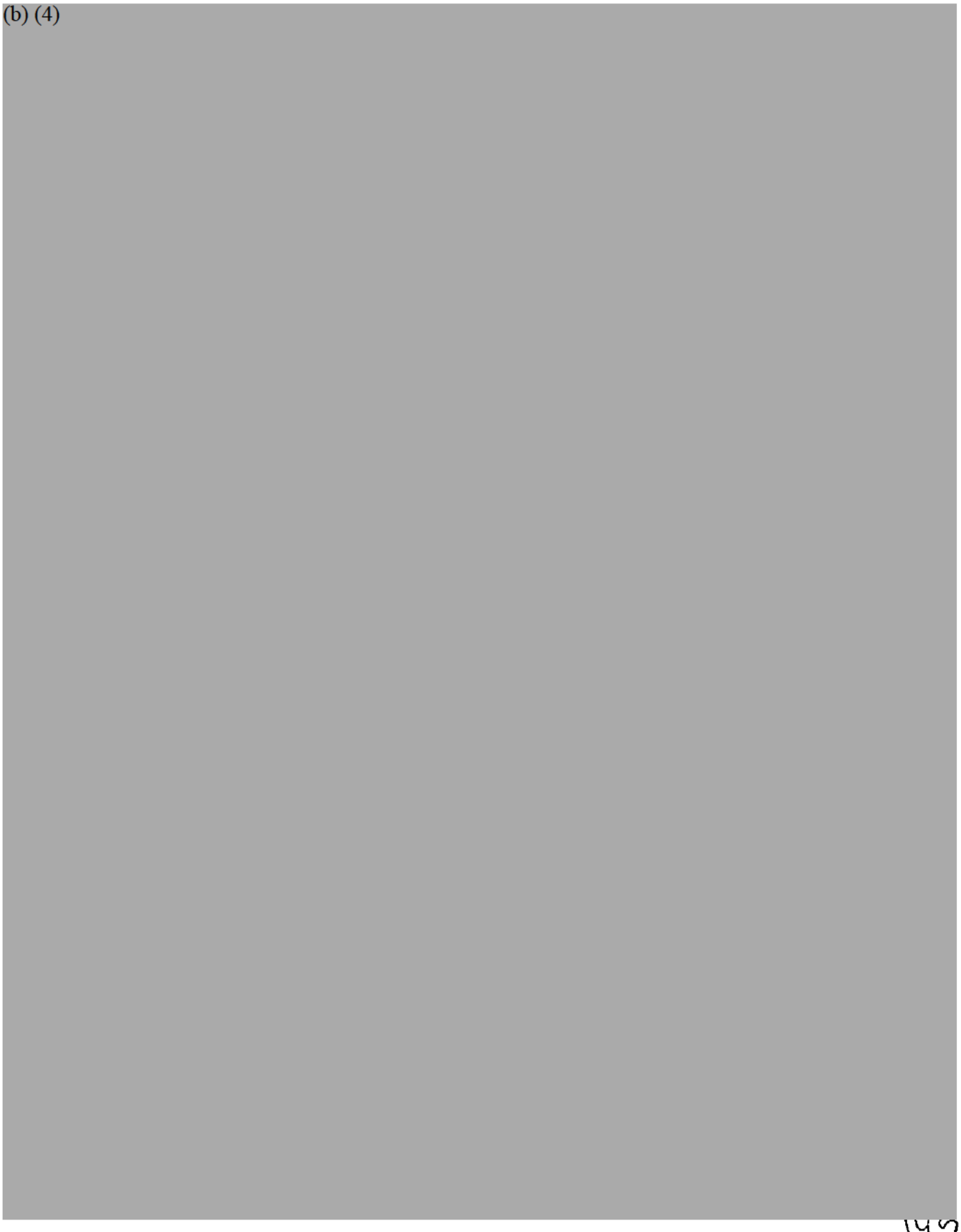

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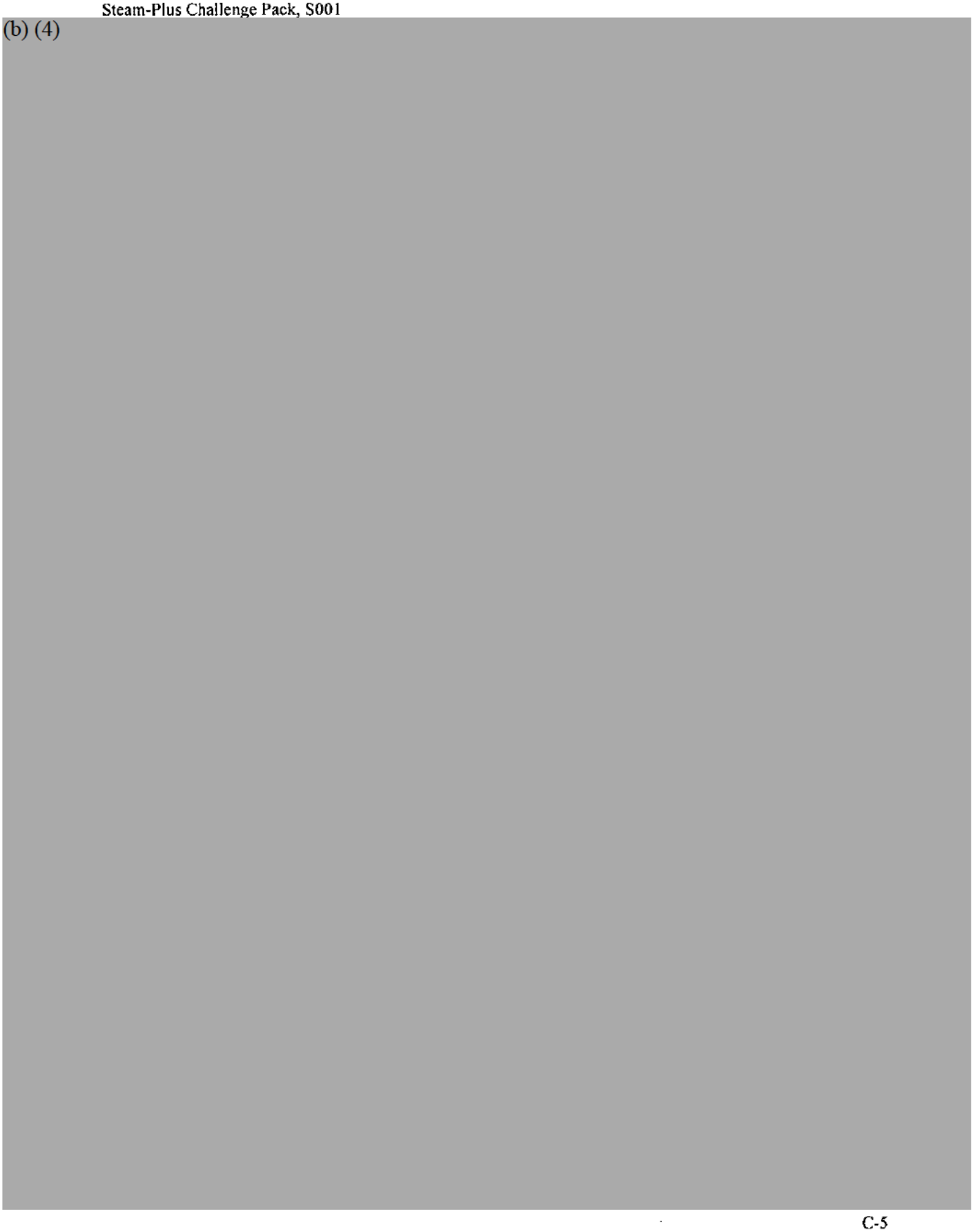

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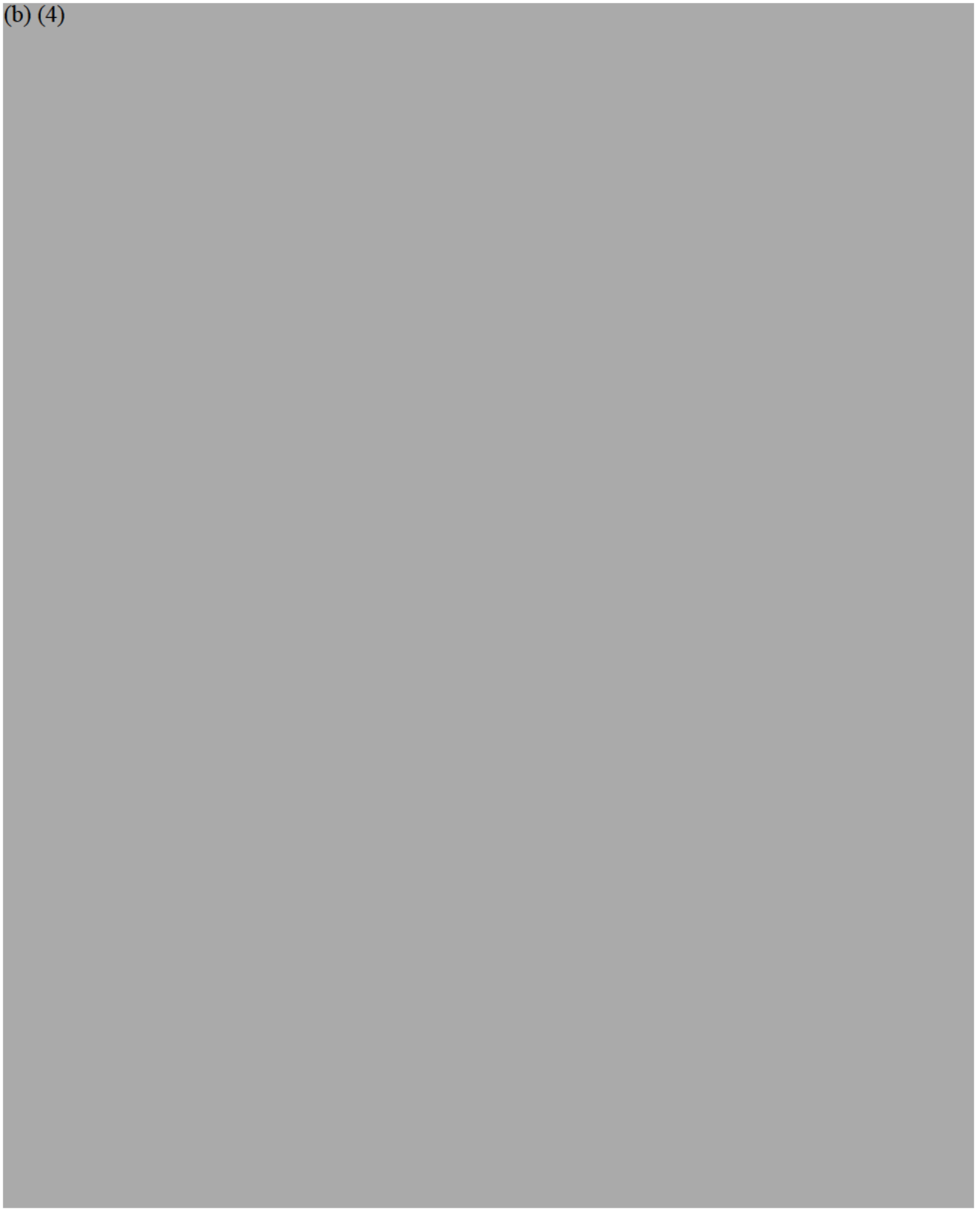

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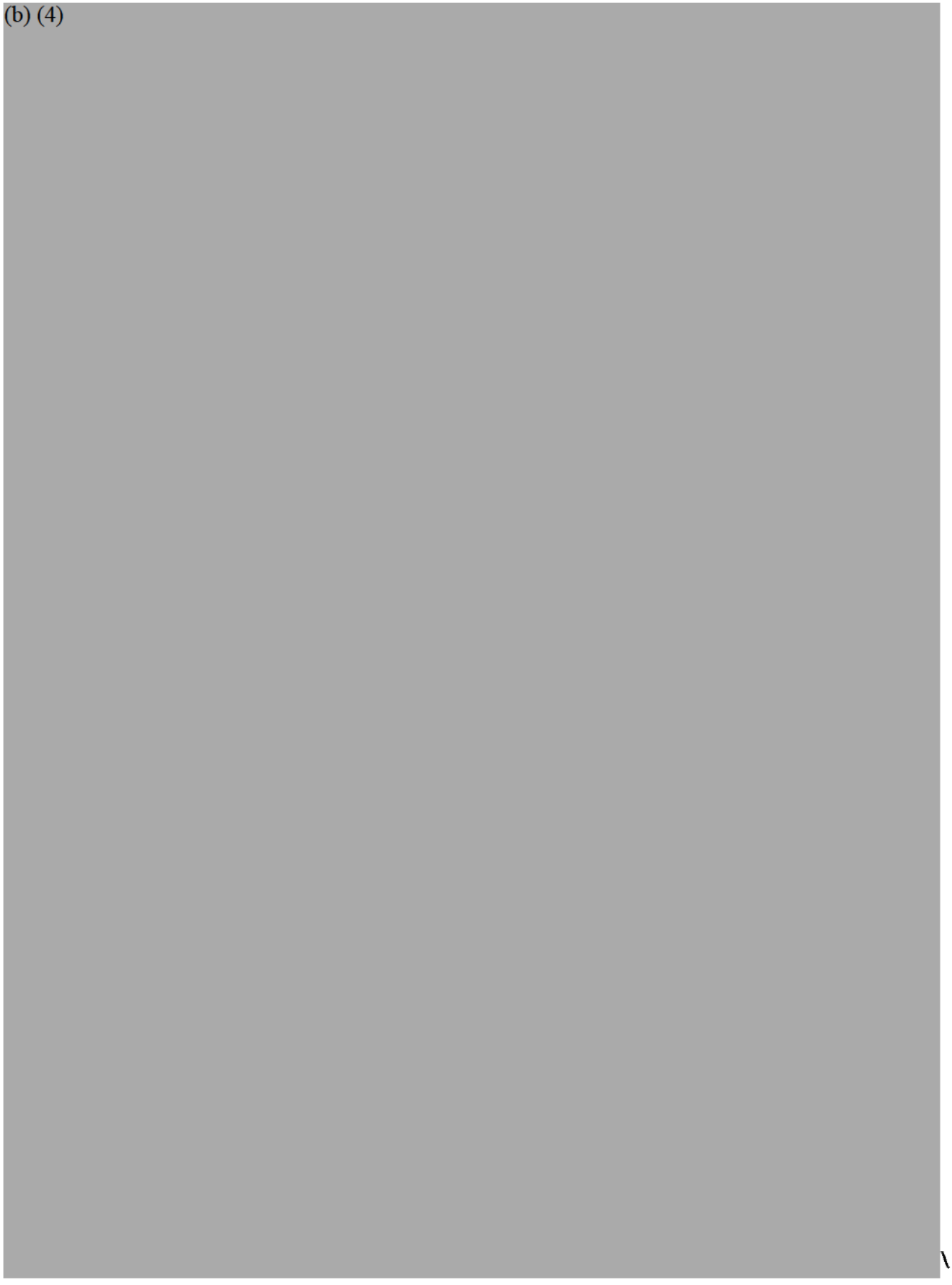

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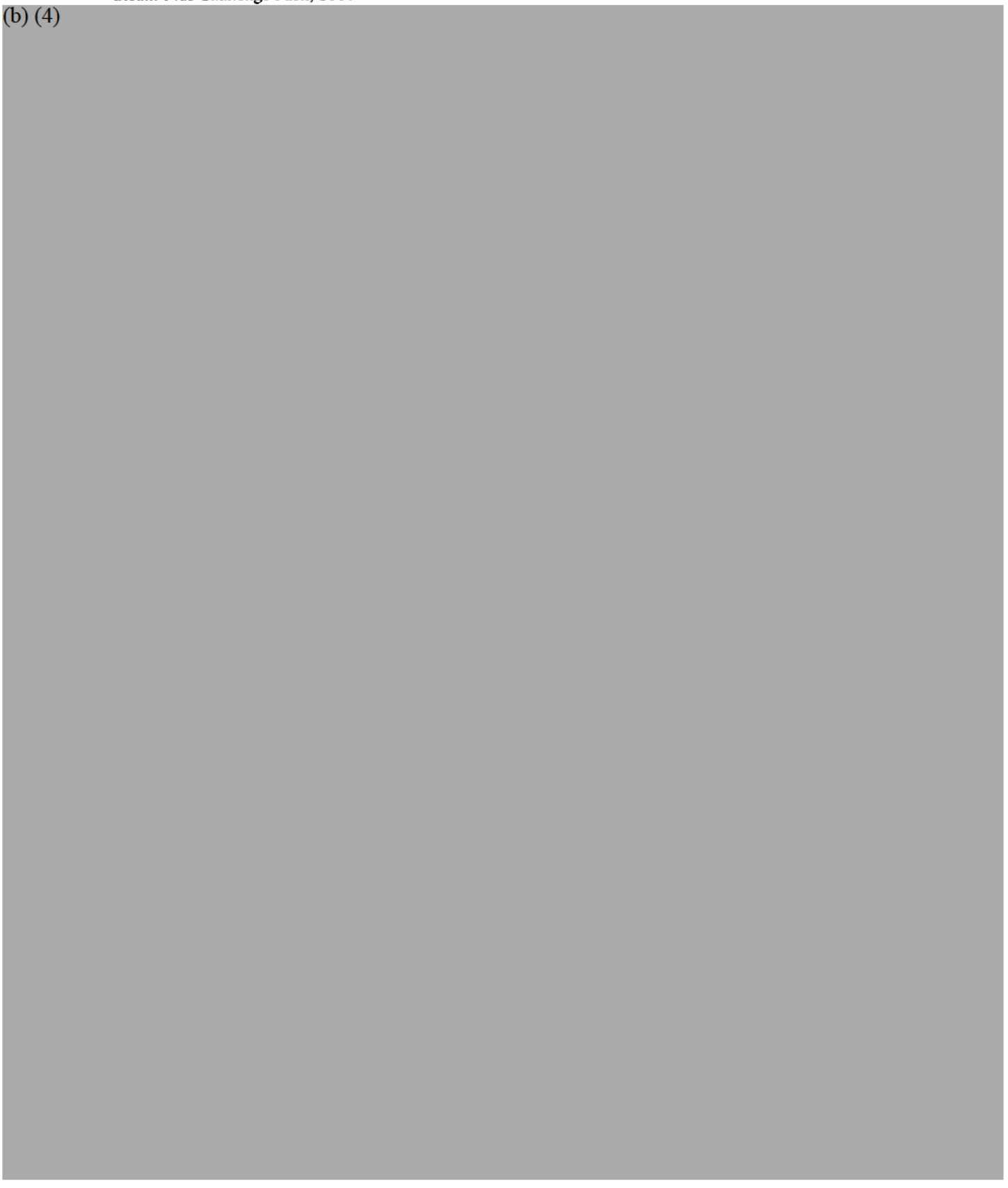

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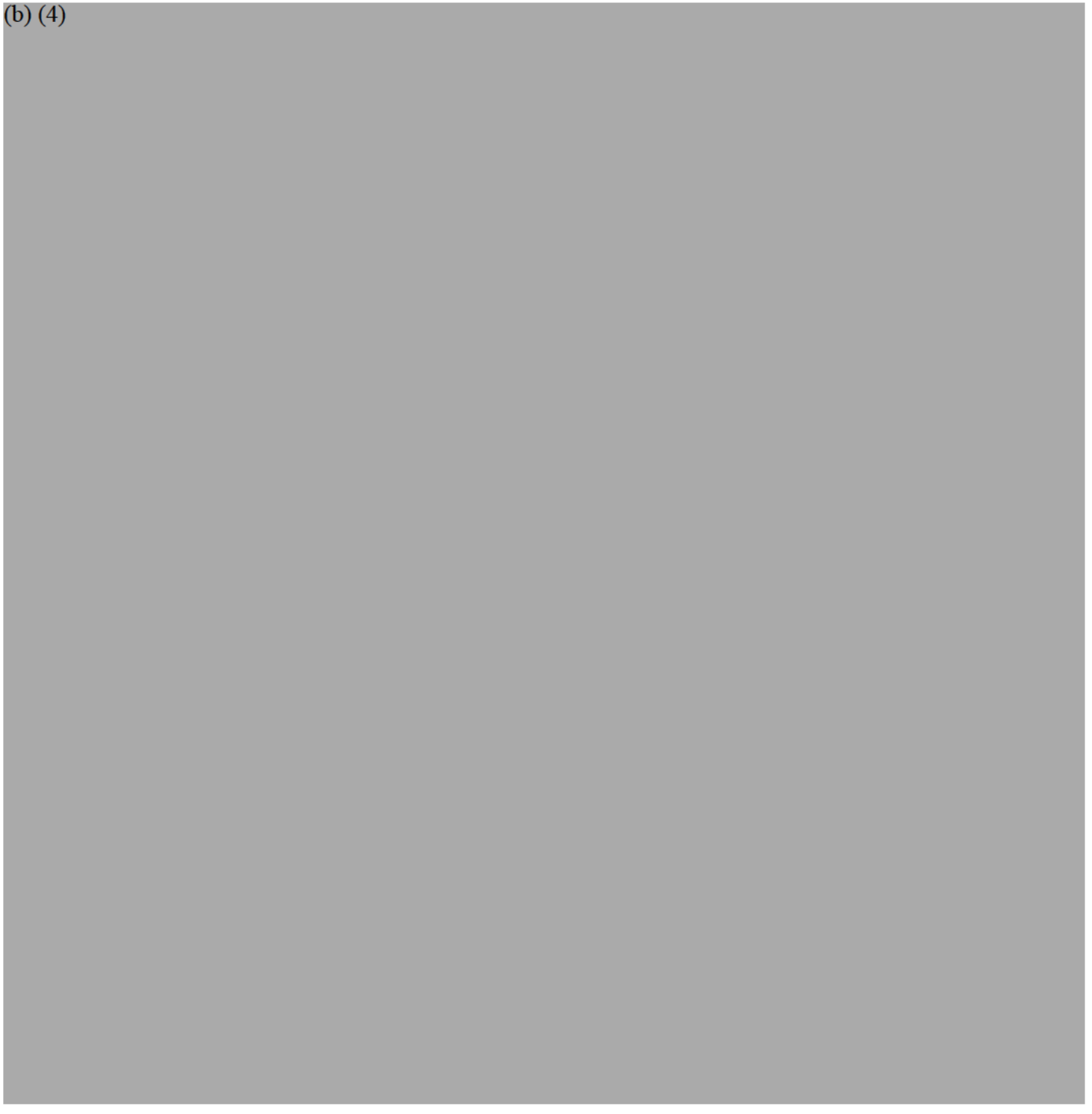

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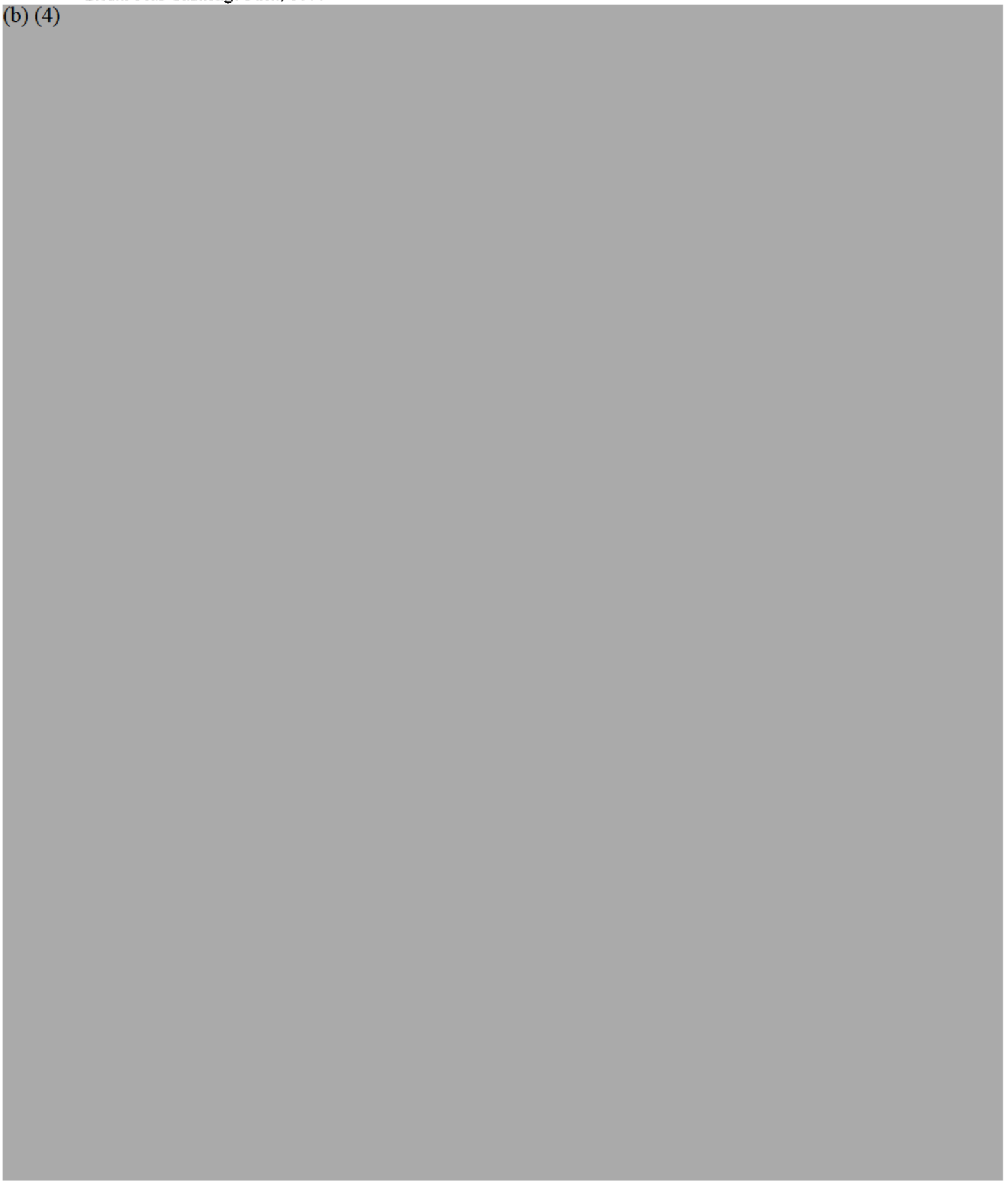

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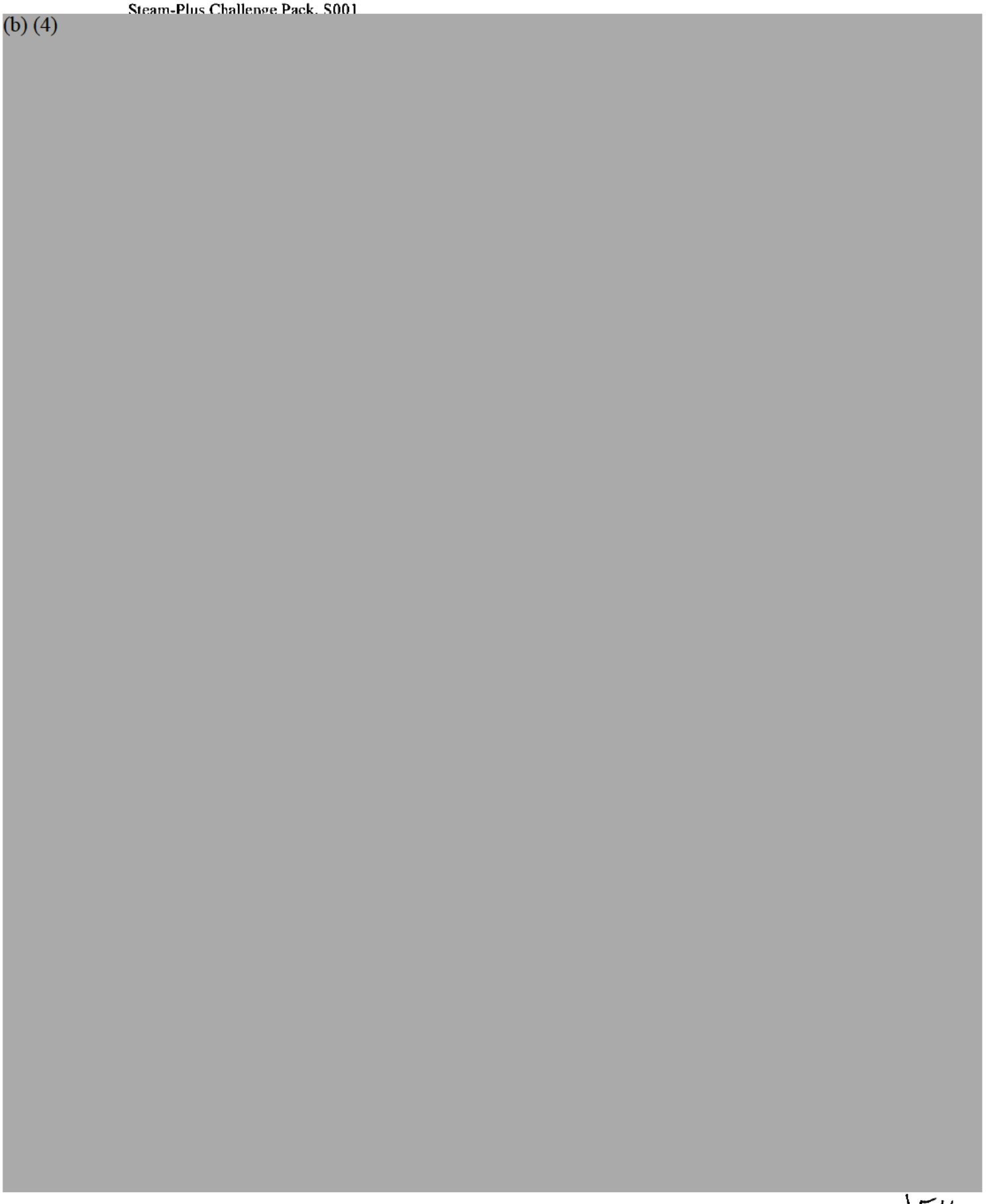

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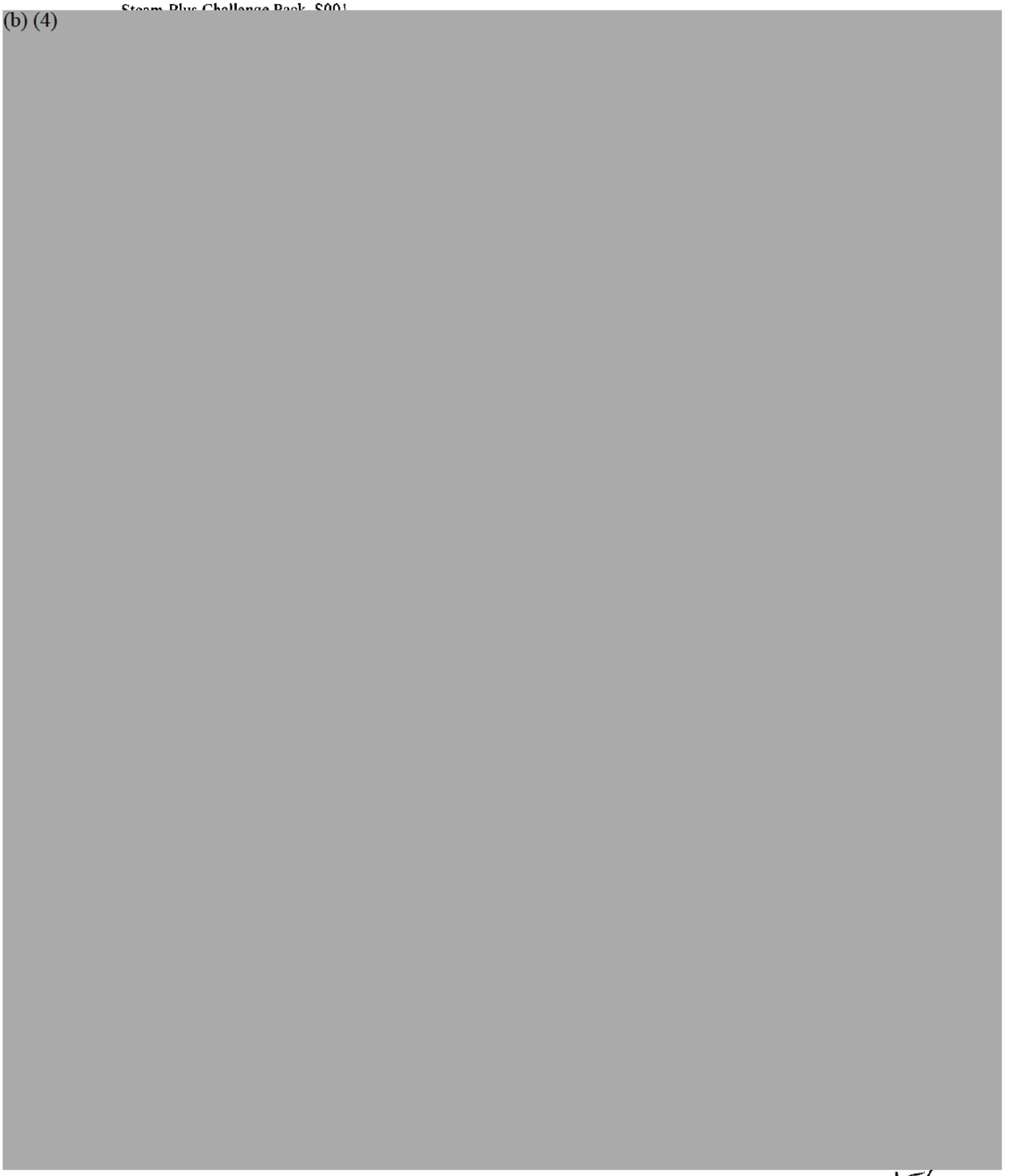

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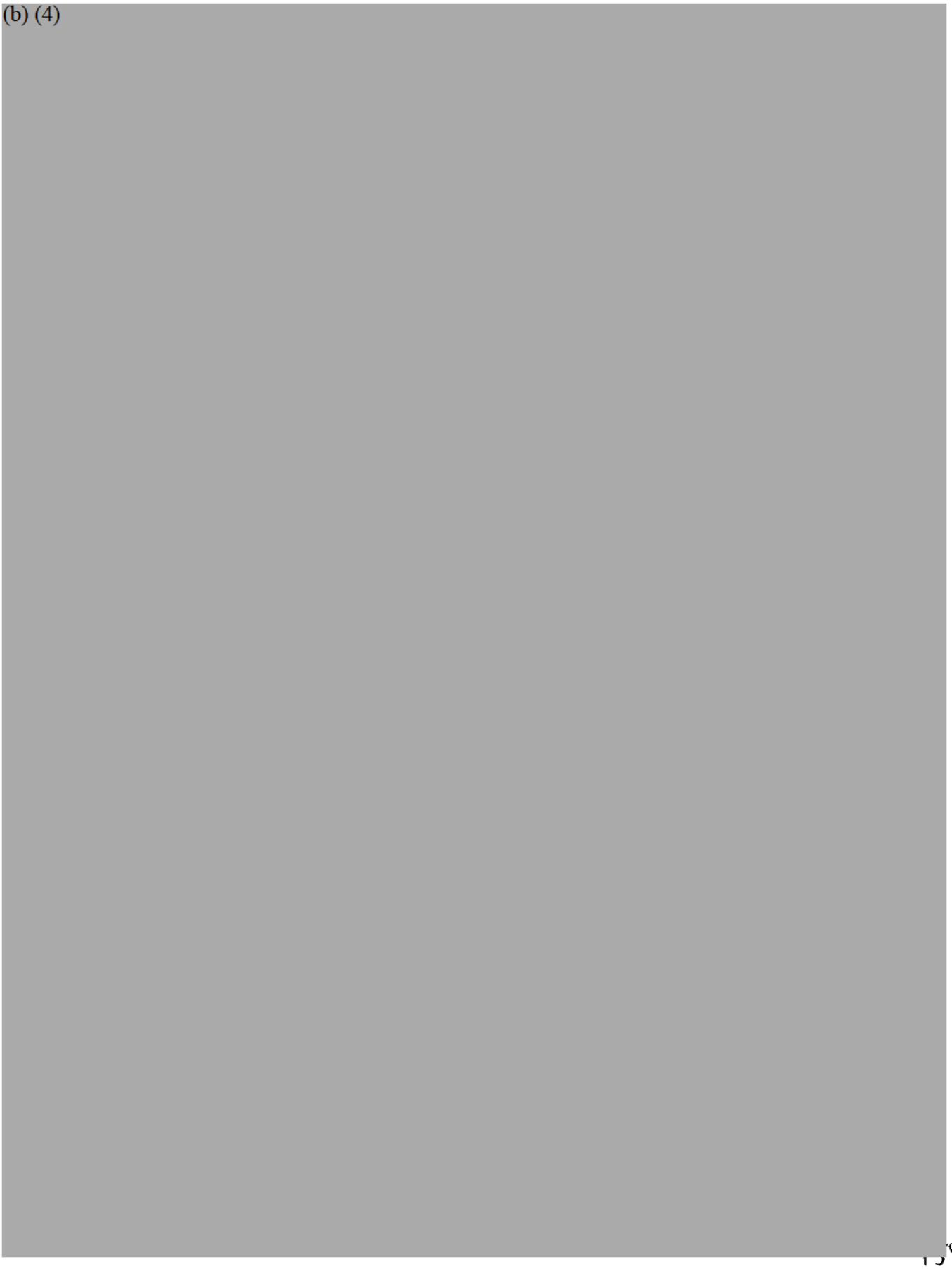

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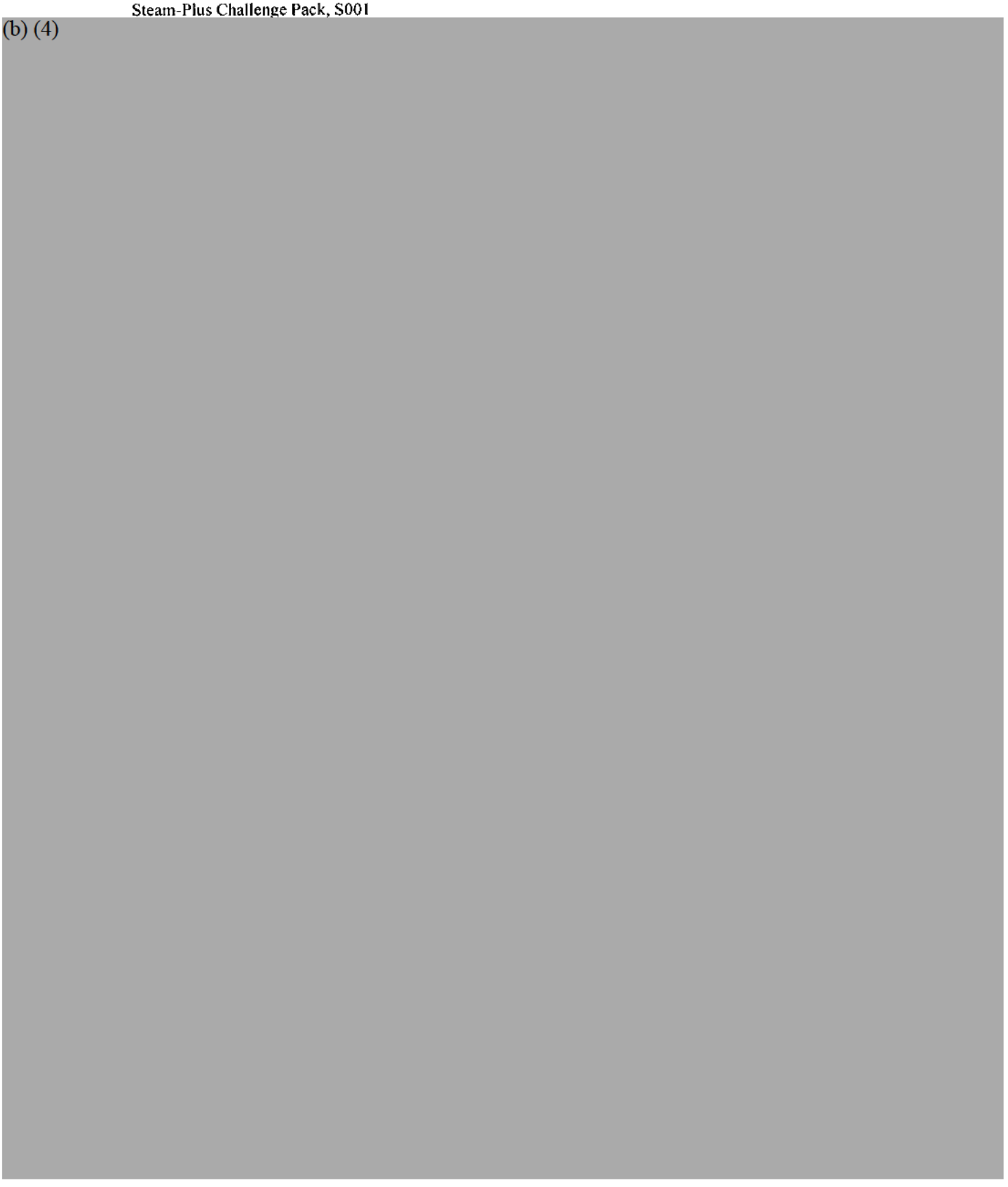

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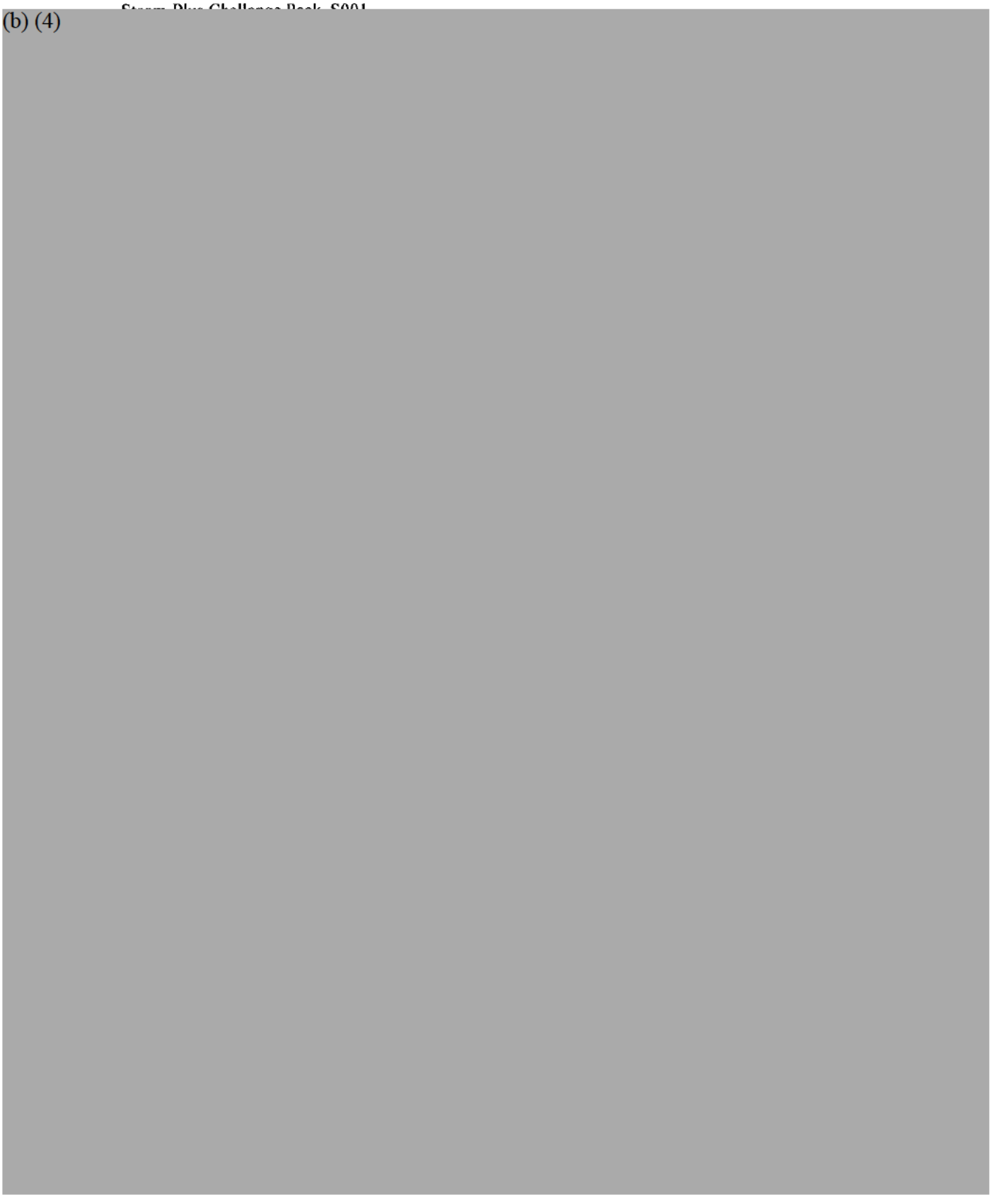

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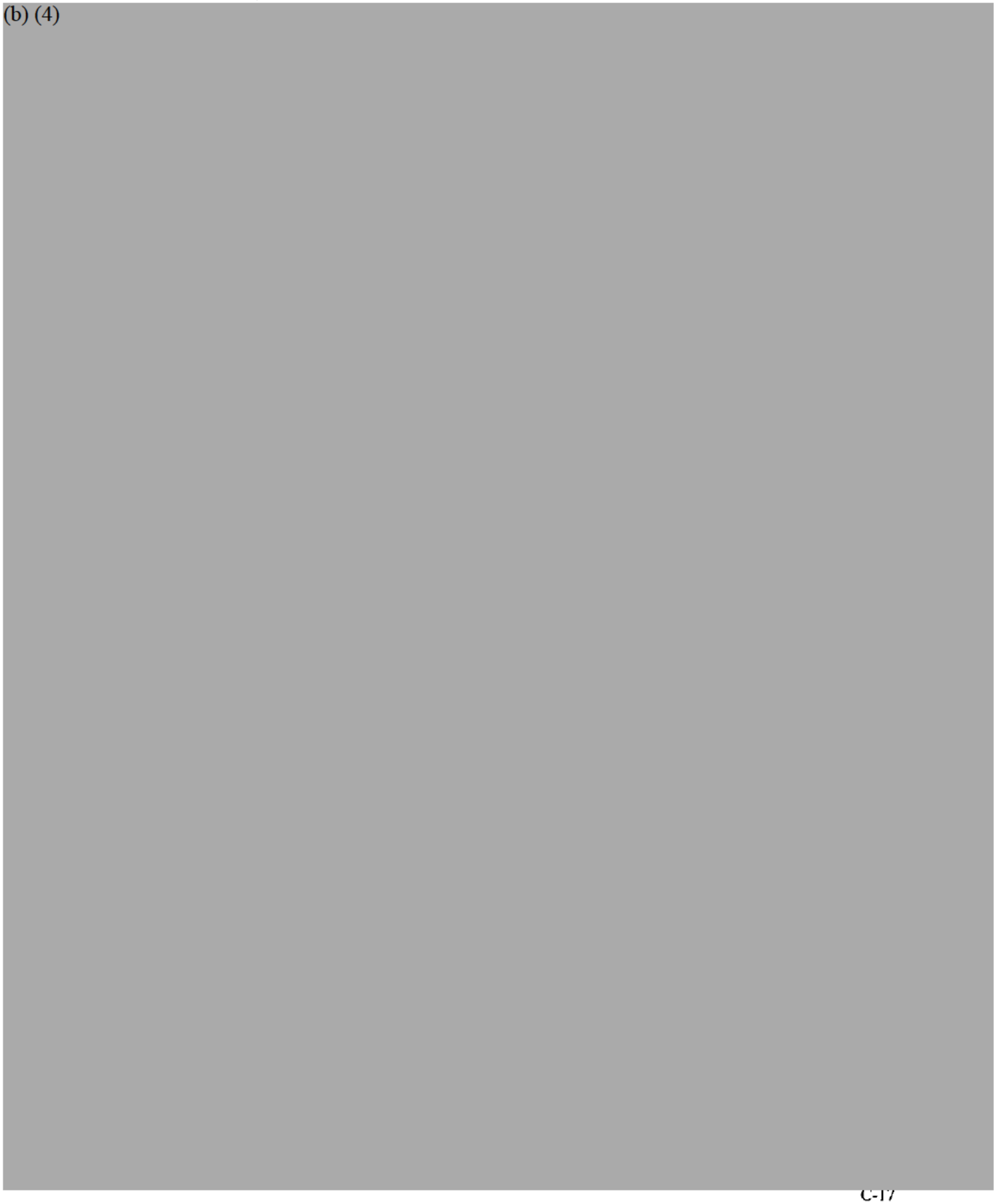
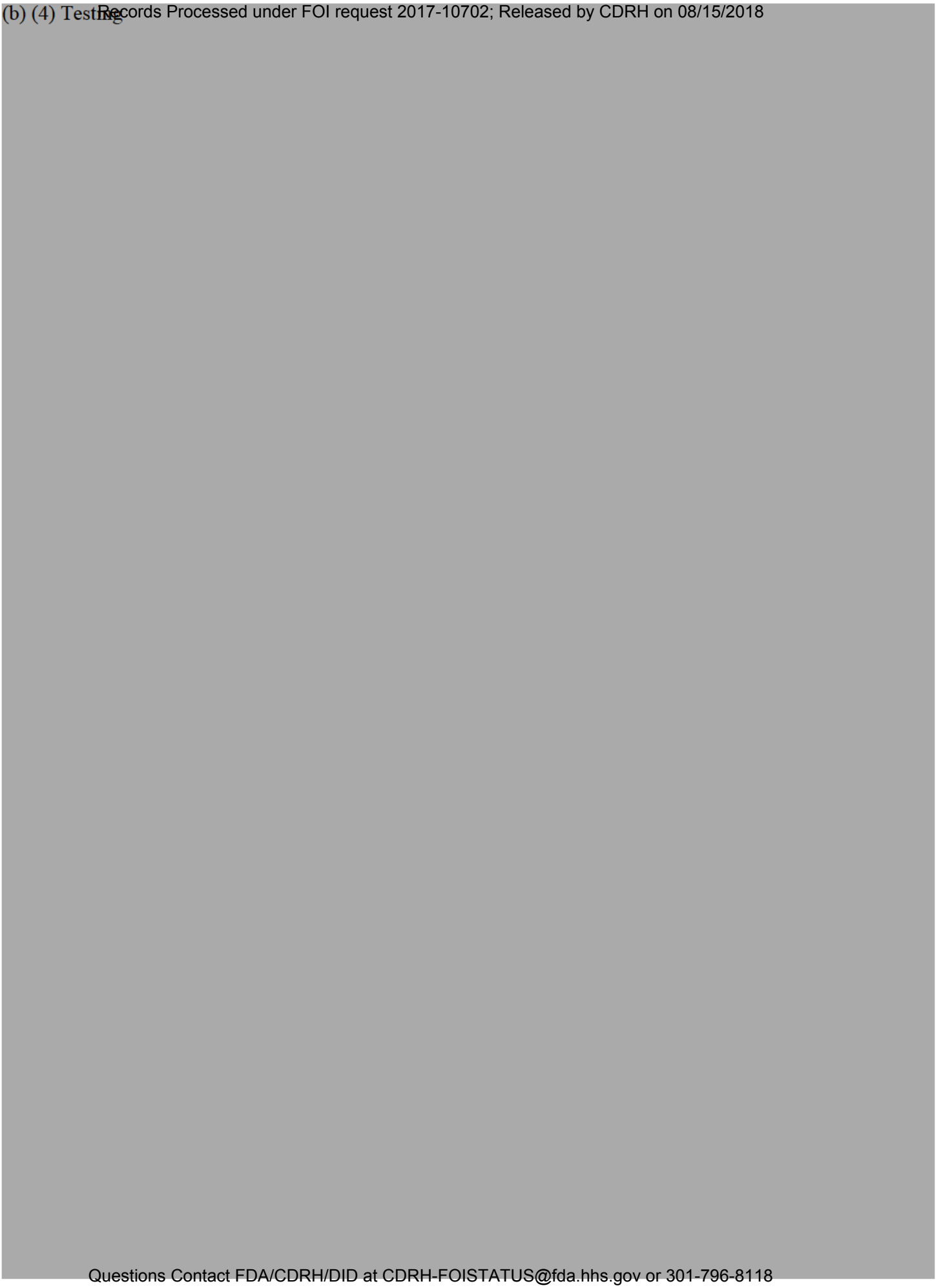


(b) (4)

(b) (4) Materials, (b) (4) Protocols

(b) (4)



Attachment E: 510(k) Summary for K101249

510(k) Summary

K101249

SEP 0 8 2010

3M

Sponsor Information:

3M Health Care
(b) (4), (b) (6)
St. Paul, MN 55144-1000

Contact Person: (b) (4), (b) (6)
Regulatory Affairs

Phone Number: (b) (4), (b) (6)
FAX Number:

Date of Summary: August 16, 2010

Device Name and Classification:

Common or Usual Name:	Sterilization Process Indicators for Steam
Proprietary Name:	3M™ Comply™ SteriGage™ 1243RA, 1243RB, and 1243RE Chemical Integrators for Steam
Classification Name:	Indicator, Physical/Chemical Sterilization Process (21 CFR § 880.2800(b))
Performance Standards:	There are no mandatory performance standards

Predicate Device:

3M™ Comply™ SteriGage™ Chemical Integrator (formerly InfoChem SteriGage™ Chemical Integrator)

Description of Device:

3M Comply SteriGage 1243RA, 1243RB, and 1243RE Steam Chemical Integrators are single-use chemical indicators consisting of a paper wick and steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked ACCEPT or REJECT; the extent of migration depends on steam, time, and temperature.

Indications for Use:

The 3M™ Comply™ SteriGage™ 1243RA, 1243RB, 1243RE Chemical Integrators for Steam are designed for pack control monitoring of the following cycles.

Cycle Type	Temperature	Exposure Time
Gravity	250 °F/121 °C	≥ 30 minutes
Gravity	270 °F/132 °C	≥ 3 minutes
Vacuum-assisted (prevacuum)	270 °F/132 °C	≥ 4 minutes (wrapped) ≥ 3 minutes (unwrapped)
Vacuum-assisted (prevacuum)	273 °F/134 °C	≥ 4 minutes (wrapped) ≥ 3.5 minutes (unwrapped)
Vacuum-assisted (prevacuum)	275 °F/135 °C	≥ 3 minutes

The Minimum Stated Values for SteriGage as determined using a resistometer are shown below.

Minimum Stated Values for SteriGage

250° F 121° C	270° F 132° C	273° F 134° C	275° F 135° C
16.5 minutes	2.0 minutes	1.4 minutes	1.1 minute

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Testing on multiple lots confirmed that the new model of 3M™ Comply™ SteriGage™ Chemical Integrator for Steam complies with the chemical integrator performance requirements of FDA's *Premarket Notification [510(k)] Submissions for Chemical Indicators: Guidance for Industry and FDA Staff*, December 19, 2003 and ANSI/AAMI/ISO 11140-1:2005 *Sterilization of health care products – Chemical indicators, Part 1: General Requirements (for Class 5).* Stated values were obtained

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using a test vessel compliant to ANSI/AAMI/ISO 18472:2006 *Sterilization of Health Care Product-Biological and Chemical Indicators: Test Equipment.*

Summary of Nonclinical Testing

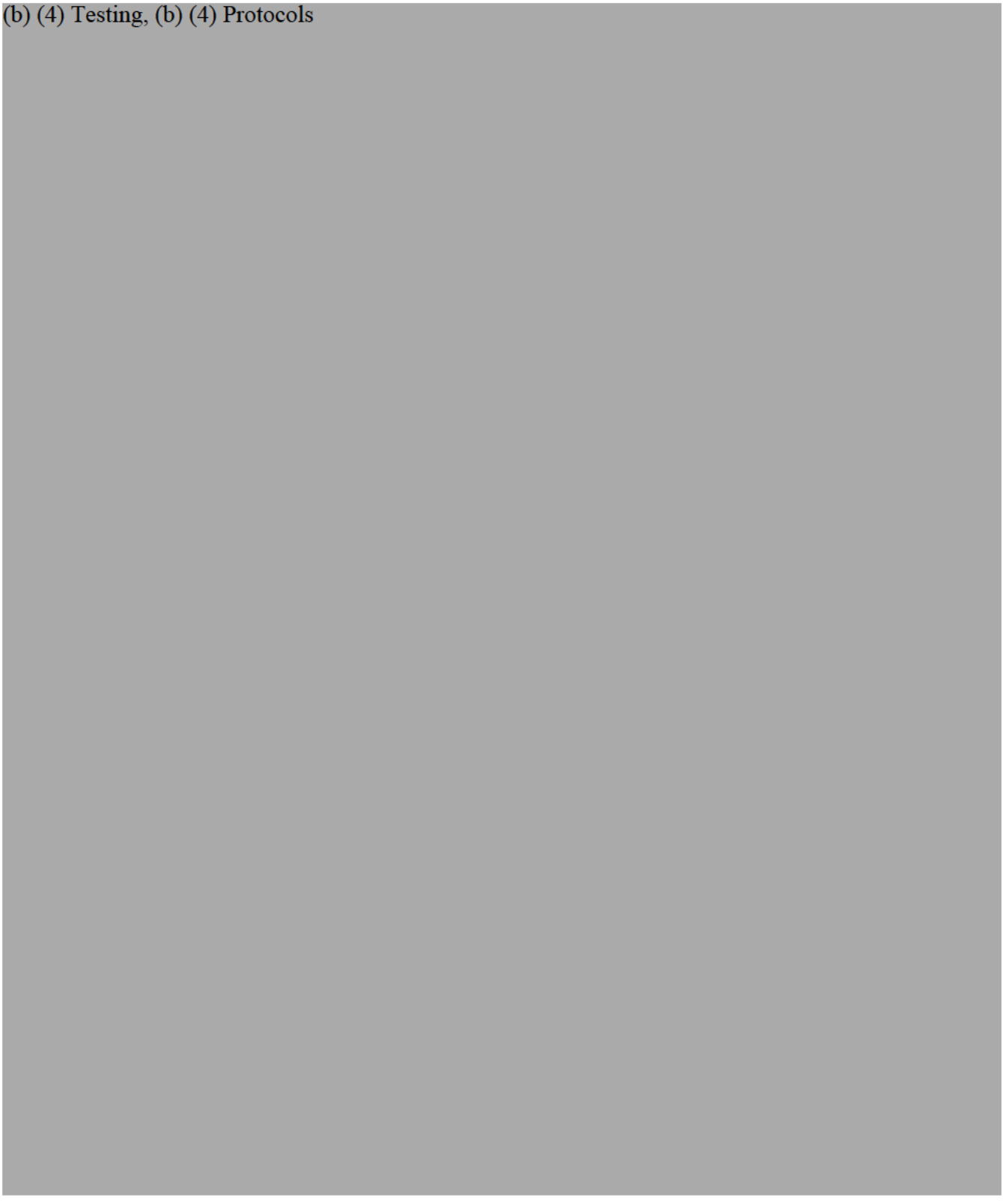
Test	Acceptance Criteria	Results
Stated Values in Resistometer	See Minimum Stated Values	Passed
Dry Heat	Shows 'Reject' at 137 – 138 °C, 30 min	Passed
Comparison to BI	Shows 'Reject' at conditions where BI fails, Shows 'Accept' only at conditions where BI passes	Passed
Endpoint Stability	An 'Accept' result or a 'Reject' result does not change after storage for 6 months	Passed

The testing summarized above showed that the new model of 3M™ Comply™ SteriGage™ Chemical Integrator for Steam is substantially equivalent to the predicate device, the current 3M™ Comply™ SteriGage™ Chemical Integrator, cleared under K771080 in terms of design, intended use, indications for use, composition, physical properties and technological characteristics. The only difference between the predicate and the new integrators is the change in the shape of the product from trapezoidal to rectangular. There are no new questions of safety or effectiveness.

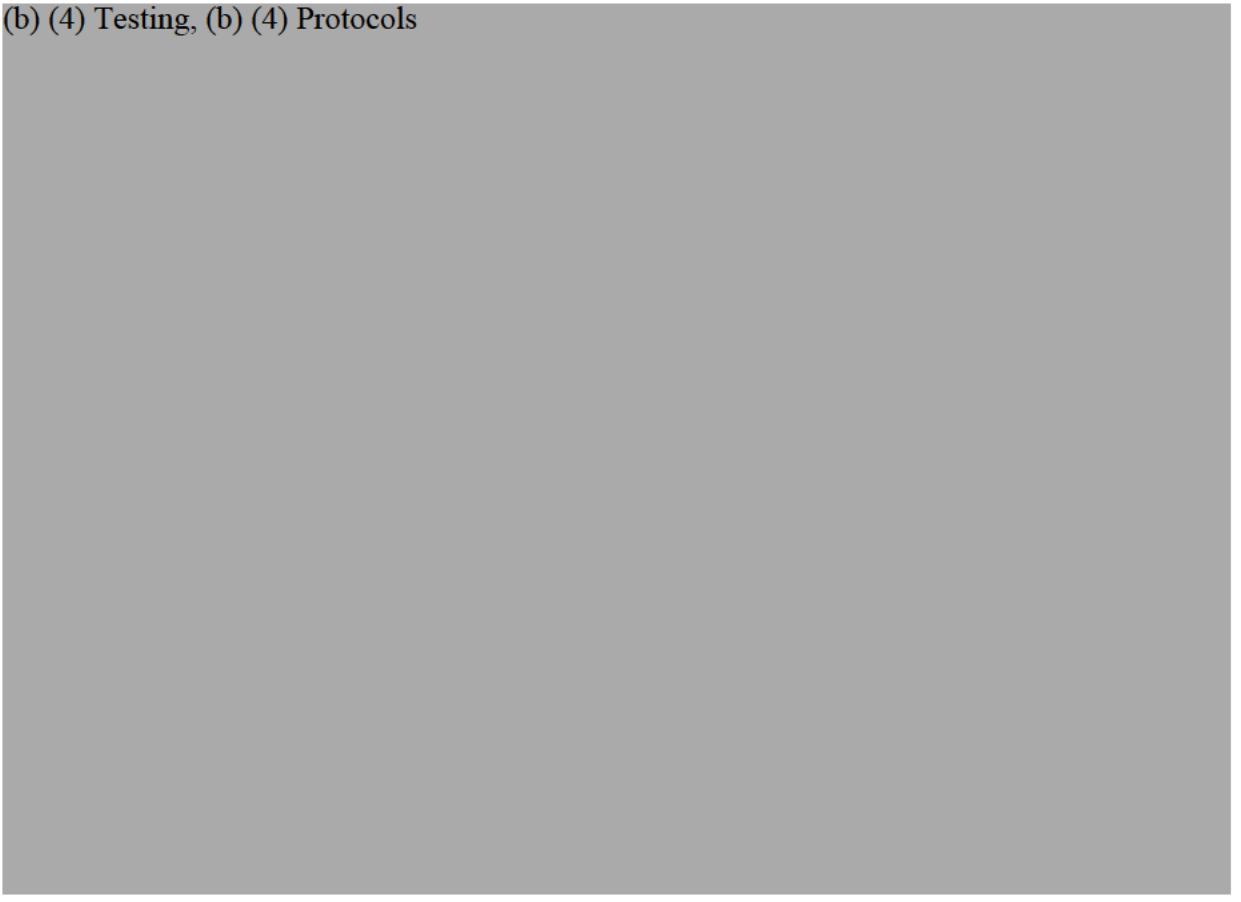
(b) (4) Testing

The following pages contain the (b) (4) for the 1492V BI and submitted as par(b) (4) s Section 14.2.1. (b) (4)
(b) (4)

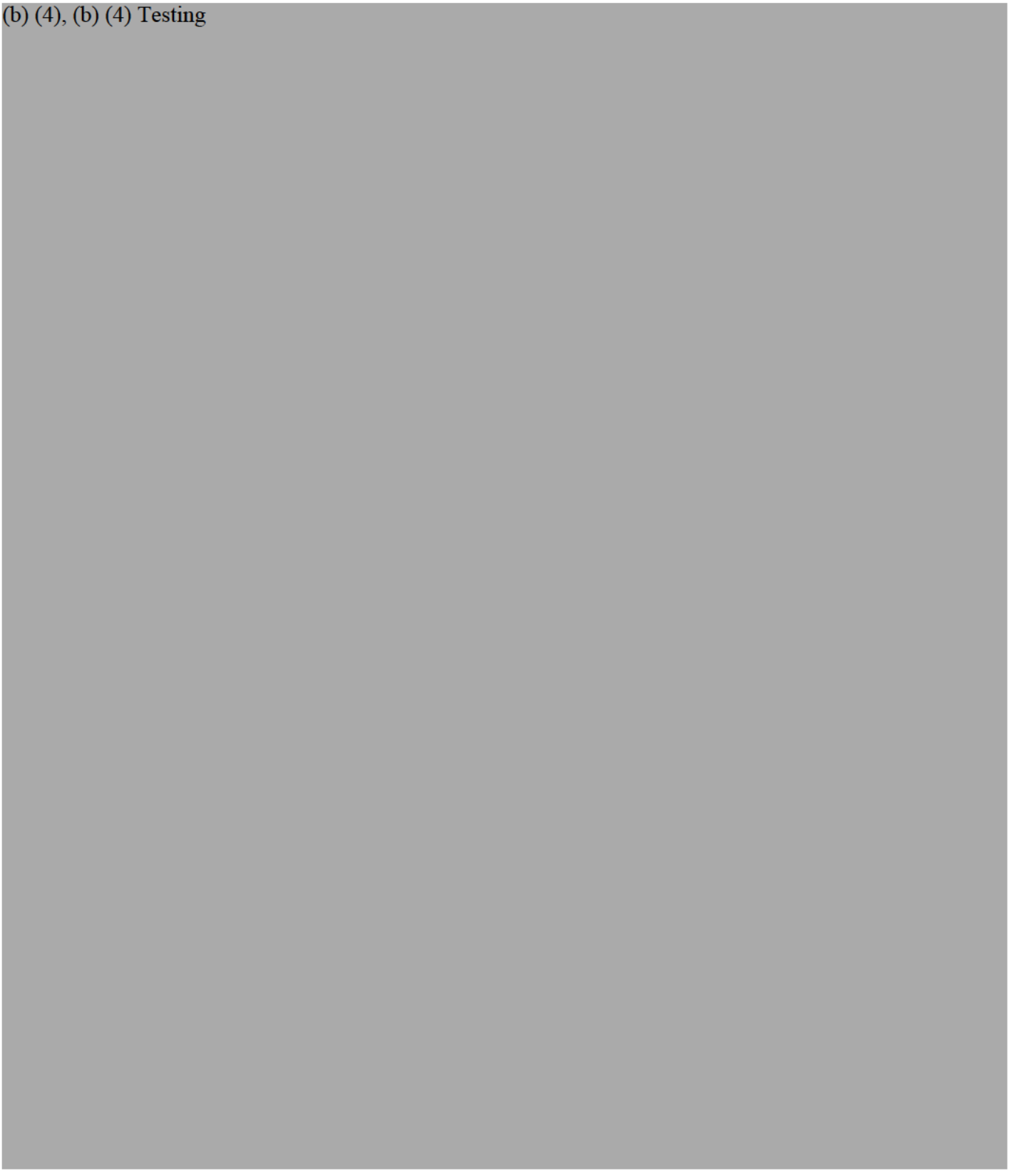
(b) (4) Testing, (b) (4) Protocols



(b) (4) Testing, (b) (4) Protocols



(b) (4), (b) (4) Testing



(b) (4) Testing

Results and Discussion

Population

(b) (4)

Summary of Population Results

(b) (4)

In all samples evaluated the population for each carrier was greater than the minimum population requirement(b) (4)

(b) (4)

D-Value

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

Conclusions

(b) (4)
(b) (4)

All test results passed the acceptance criteria for Population and D-value.

14.2.1.2 Study XI: (b) (4) Study with Design Verification Lots 1, 2, and 3

Materials

Three lots were evaluated after storag(b) (4)
(b) (4)

Equipment

(b) (4)

Methodology

Population (b) (4)
(b) (4)

D-value
(b) (4)

178

Results and Discussion

Population (Total Viable Spore Count)

(b) (4) Testing

Spore Population of 1492V SRBI through 3 Months of Aging at 25°C/60% RH

(b) (4)

(b) (4)

The spore population of 1492V SRBIs remained within

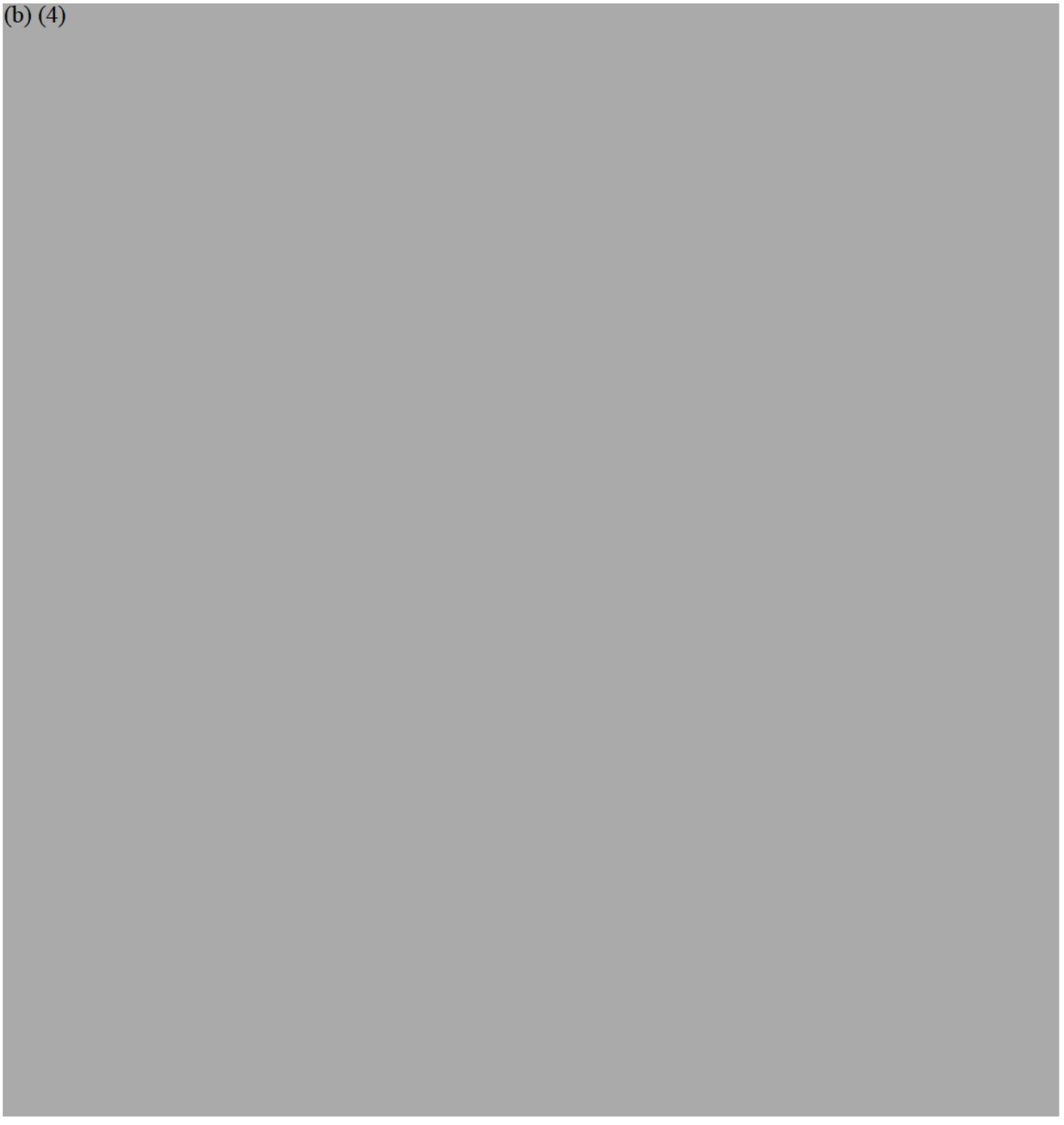
(b) (4)

D-value

The D-value results for the 132°C exposure temperature is shown first, followed by the results for 135°C for each of the 3 Design Verification lots.

(b) (4)

(b) (4)



(b) (4)

(b) (4)

(b) (4)

The data from the 3 month pullpoint after storage

(b) (4)

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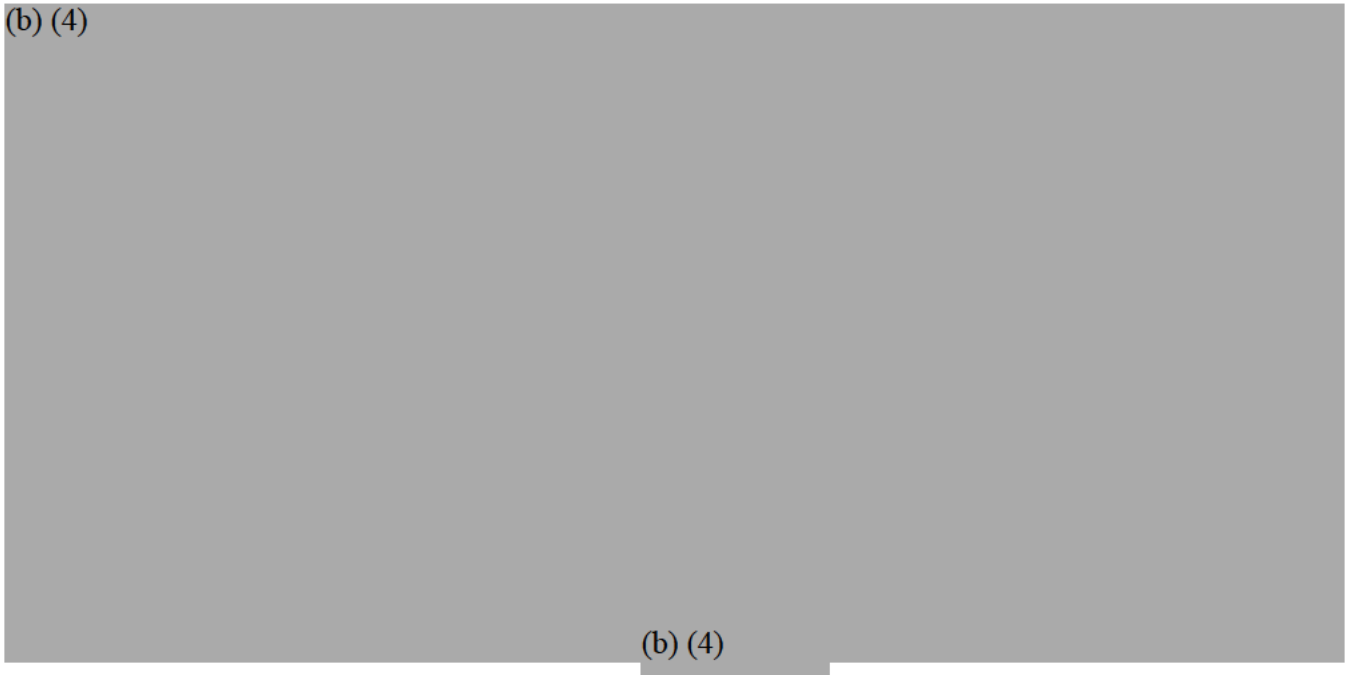
Conclusions

The 1492V Design Verification lots had Population and D-value characteristics that met the acceptance criteria (b) (4)

(b) (4)

Future Testing

(b) (4)



(b) (4)

Acceptance Criteria for 1492V Study

(b) (4)

Additional (b) (4) Data for 1492V BI (Provided as part of Deficiency Response)

(b) (4)

1.0 (b) (4) Population

Population studies were carried out in order to demonstrate that the population of Attest™ 1492V Biological Indicators (BIs) remained stable with little variation after the date of manufacture

(b) (4)

2.0 Resistance Characteristics

Resistance Studies

D-value

(b) (4)

D-Value Testing of 1492V BIs (b) (4)

(b) (4)

(b) (4)

D-Value Testing of 1492V BIs at

(b) (4)

(b) (4) Testing

[redacted]

Conclusions

The Attest 1492V Biological Indicator population and resistance characteristics met the acceptance crit(b) (4)

(b) (4) Testing

[redacted]

(b) (4) Testing

Summary Table of (b) (4) Testing for Attest 1492V

(b) (4) Testing

Attachment G: Study I (b) (4) Comparison of 1496V and 41482V Challenge Packs with AAMI Towel Pack (Raw data sheets included)

The following pages contain Study I, a comparison of the Challenge Packs with the AAMI Towel Pack in a standard 132°C/270°F and 135°C/275°F prevacuum steam sterilization cycles (provided in the original submission as Section 12.3.1). Raw data sheets are included covering the data in the summary tables within the report.

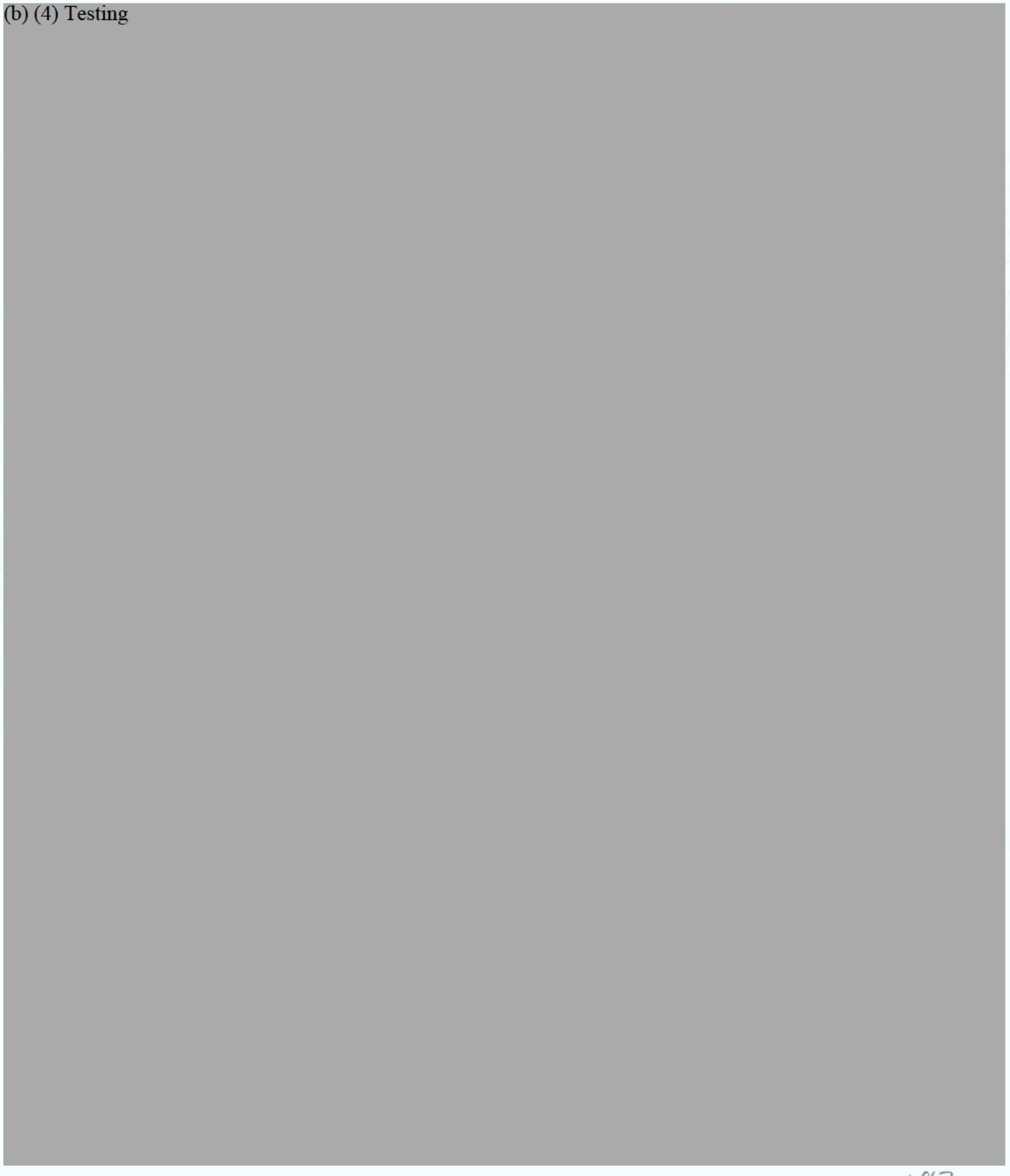
Raw Data Sheets

The data sheets record general test information such as the date of the test, the sterilizer used, the cycle type, the cycle temperature and exposure time, the operator, and the specific test results from the 1492V biological indicator (BI) in each Challenge Pack and the SteriGage chemical integrator, if present (in the 41482V Challenge Pack only).

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing



(b) (4) Testing

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12.3.1 Study 1: (b) (4) Testing, (b) omparison of 1496V and 41482V Challenge Packs with AAMI Towel Pack

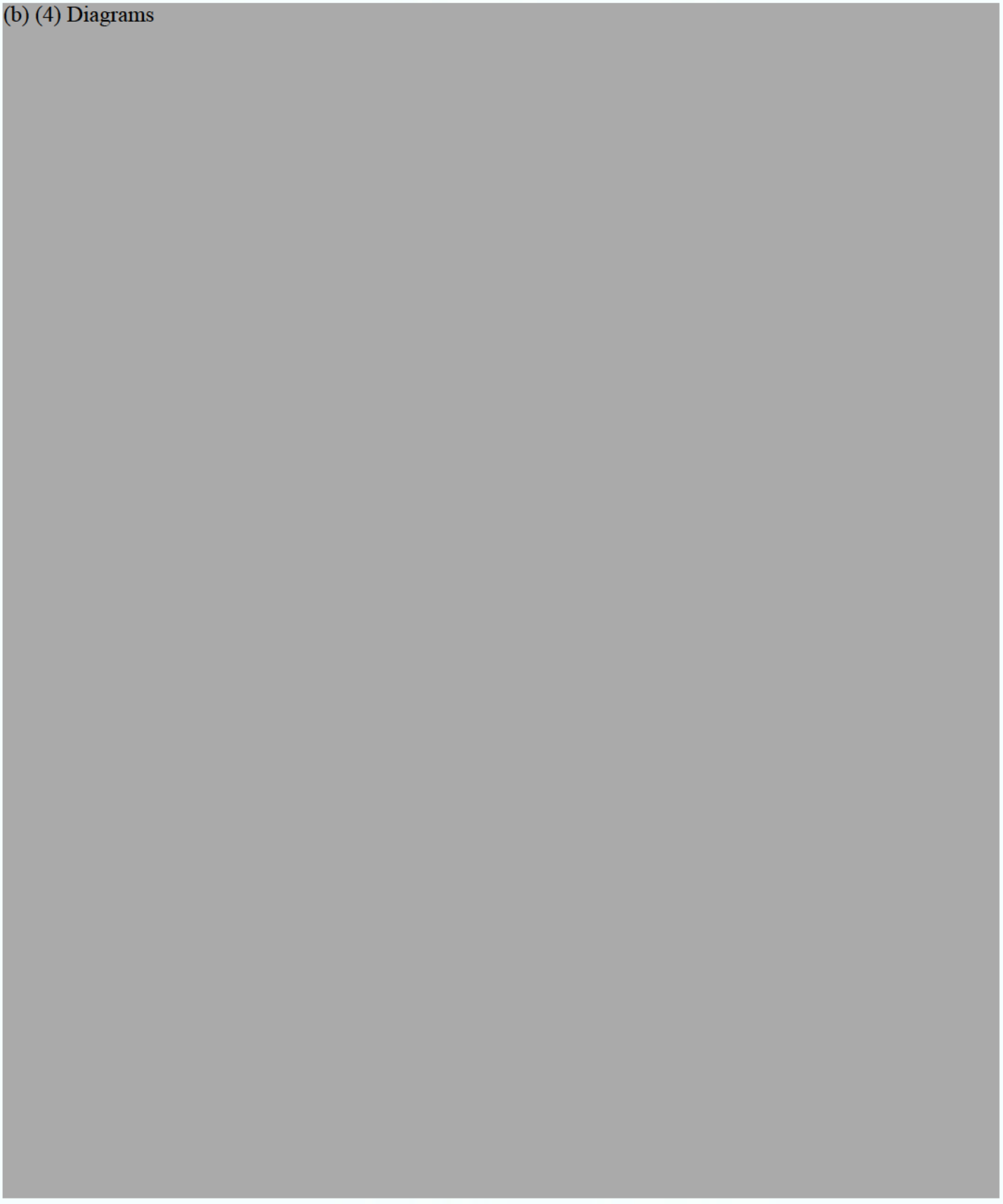
Objective:

This study was designed to compare (b) (4) 96V and 41482V Challenge Packs to the AAMI Towel Pack in 132°C/270°F prevacuum steam sterilization cycles and 135°C/275°F prevacuum steam sterilization cycles

Protocol:

(b) (4) Protocols

(b) (4) Diagrams



(b) (4) Testing

Acceptance Criteria:

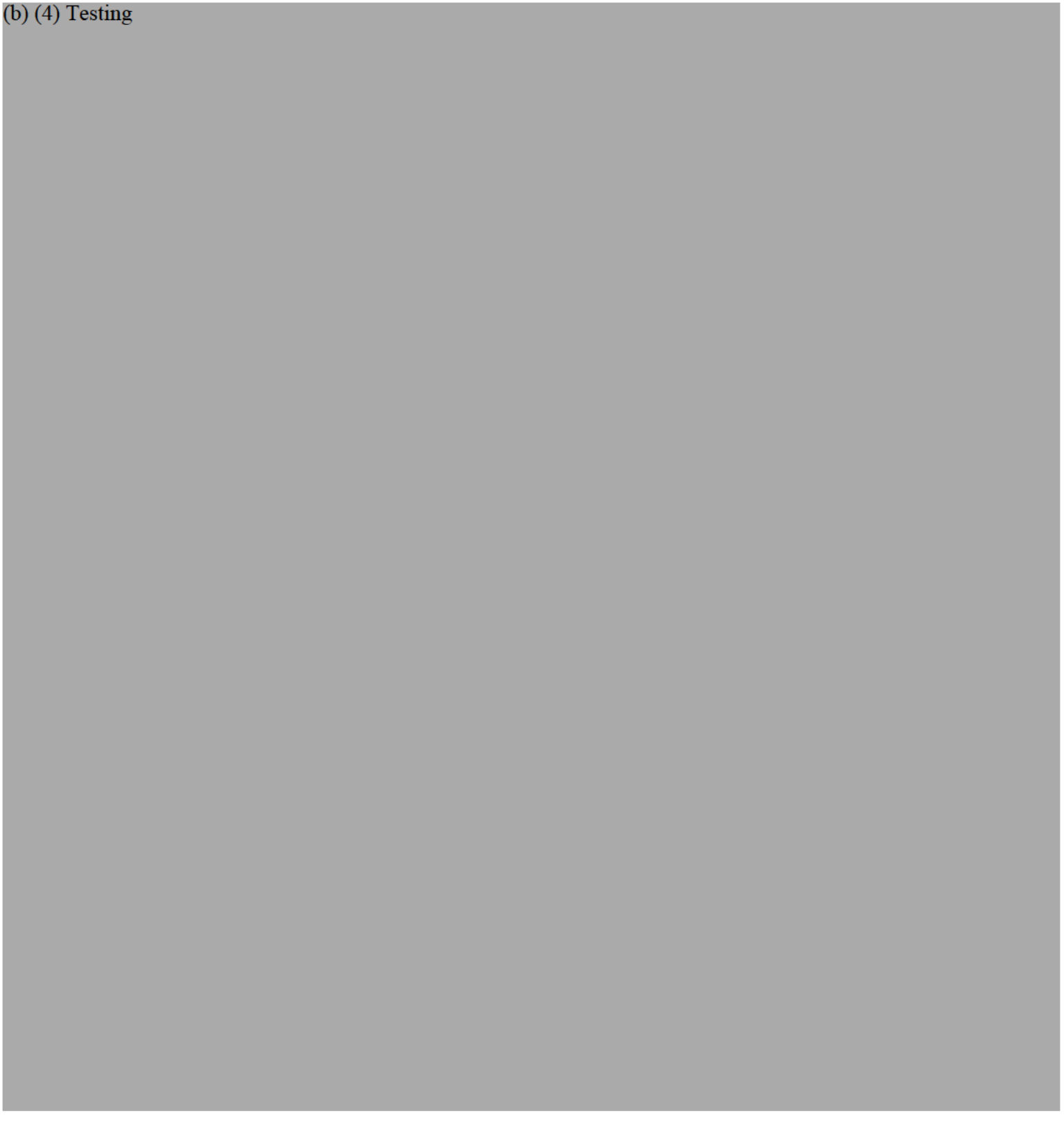
(b) (4) Testing

Results and Discussion:

(b) (4) Testing

(97

(b) (4) Testing



Conclusions:

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(b) (4) Testing

(b) (4) Testing

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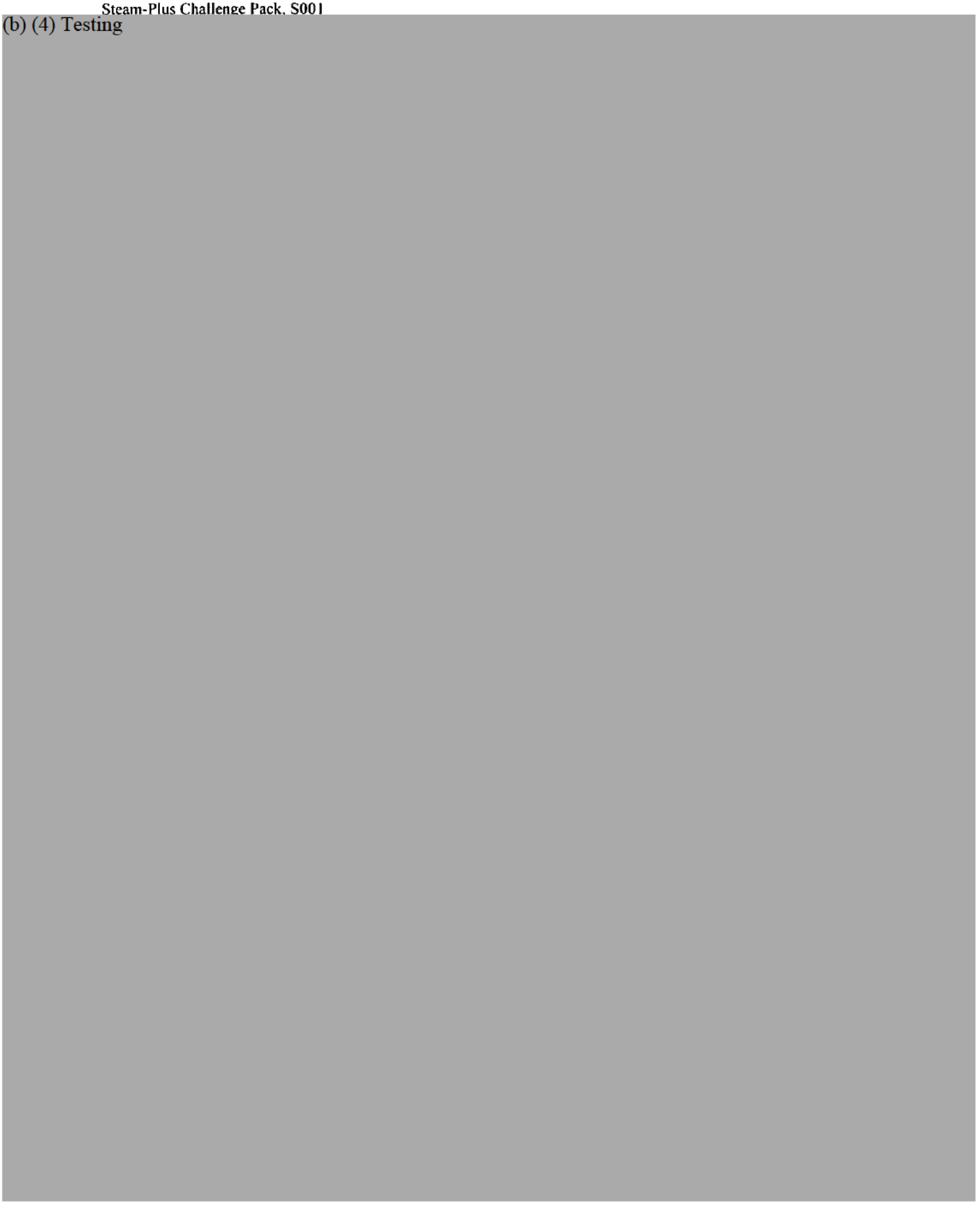
(b) (4) Testing



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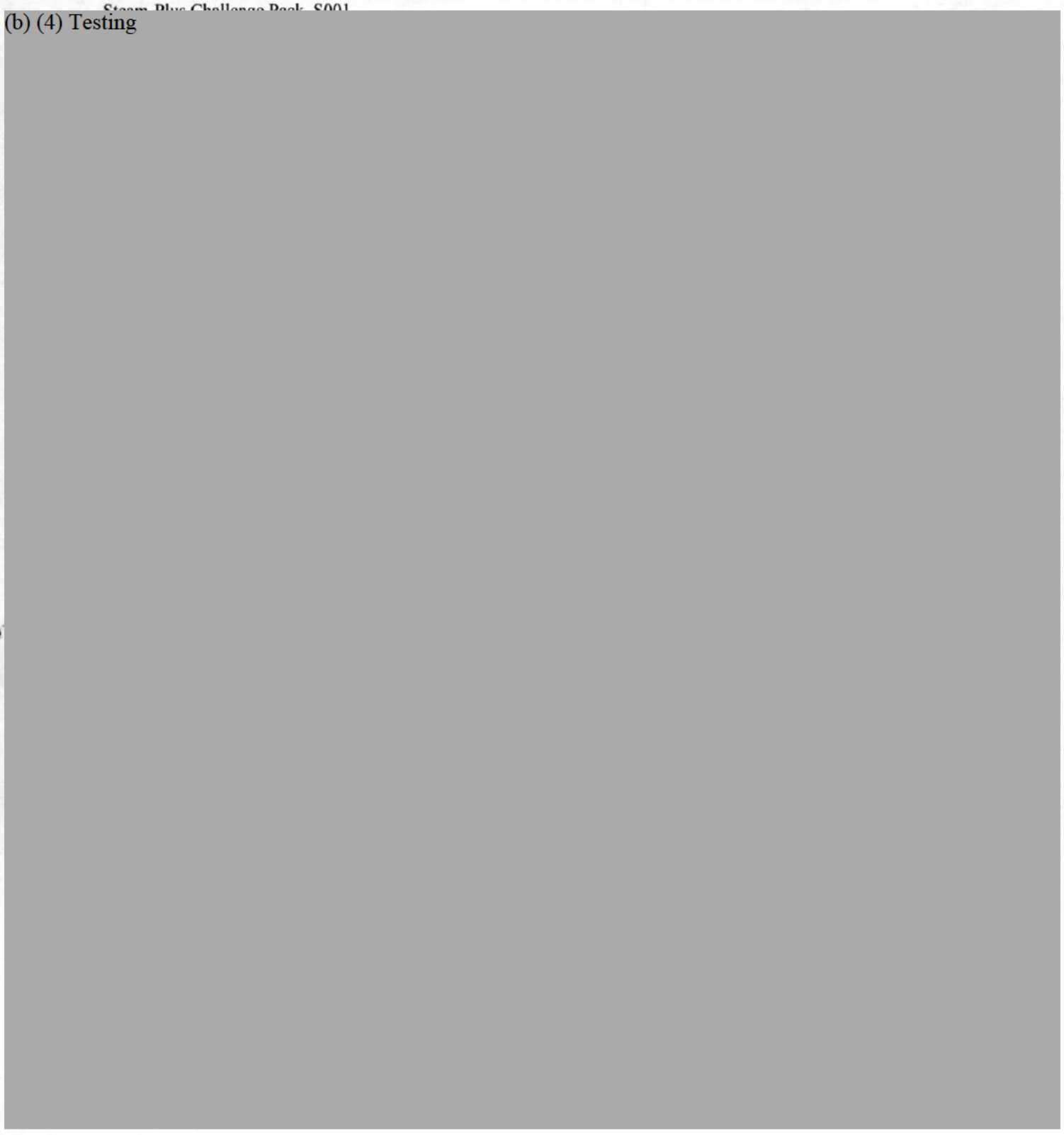
(b) (4) Testing



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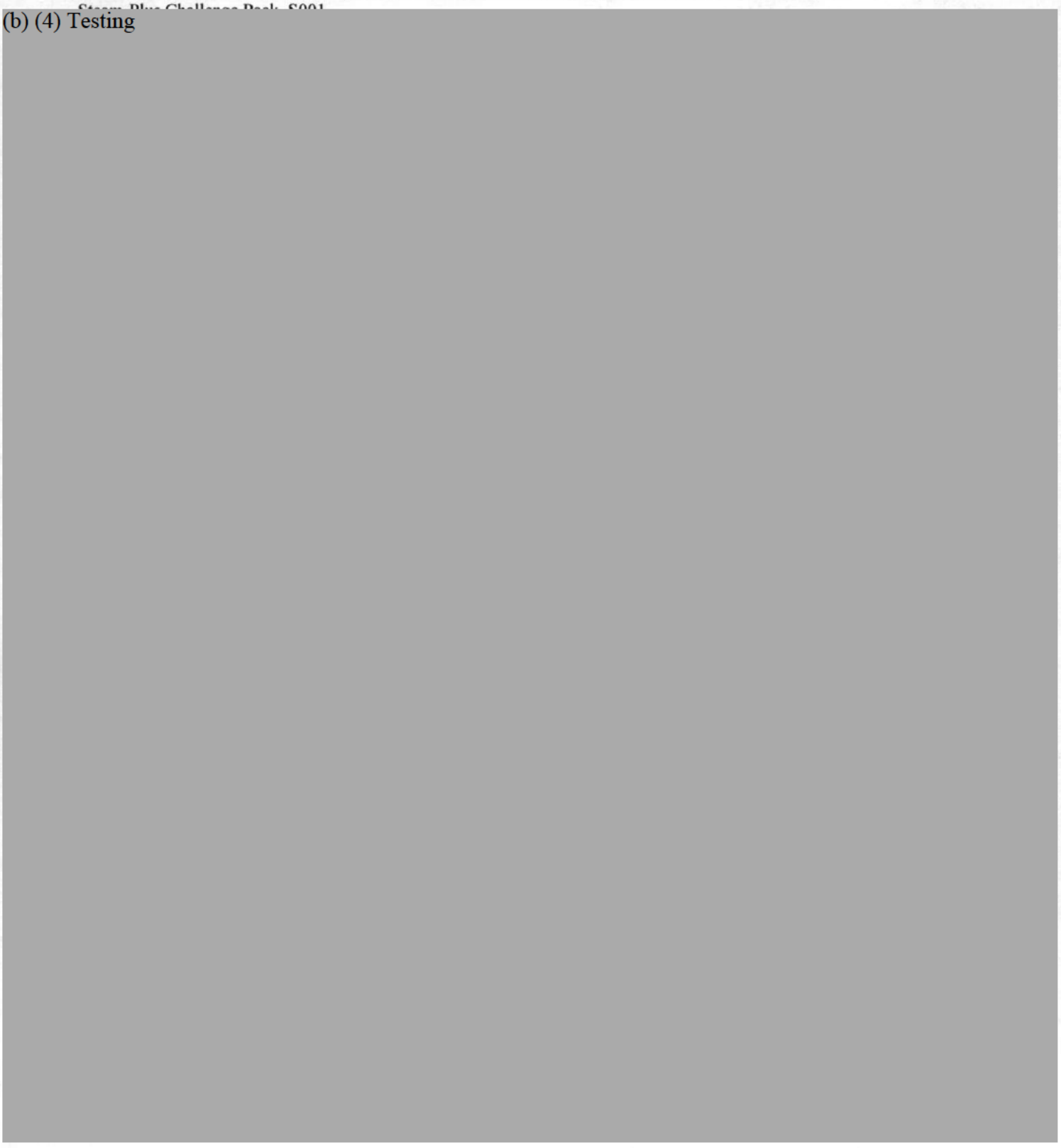

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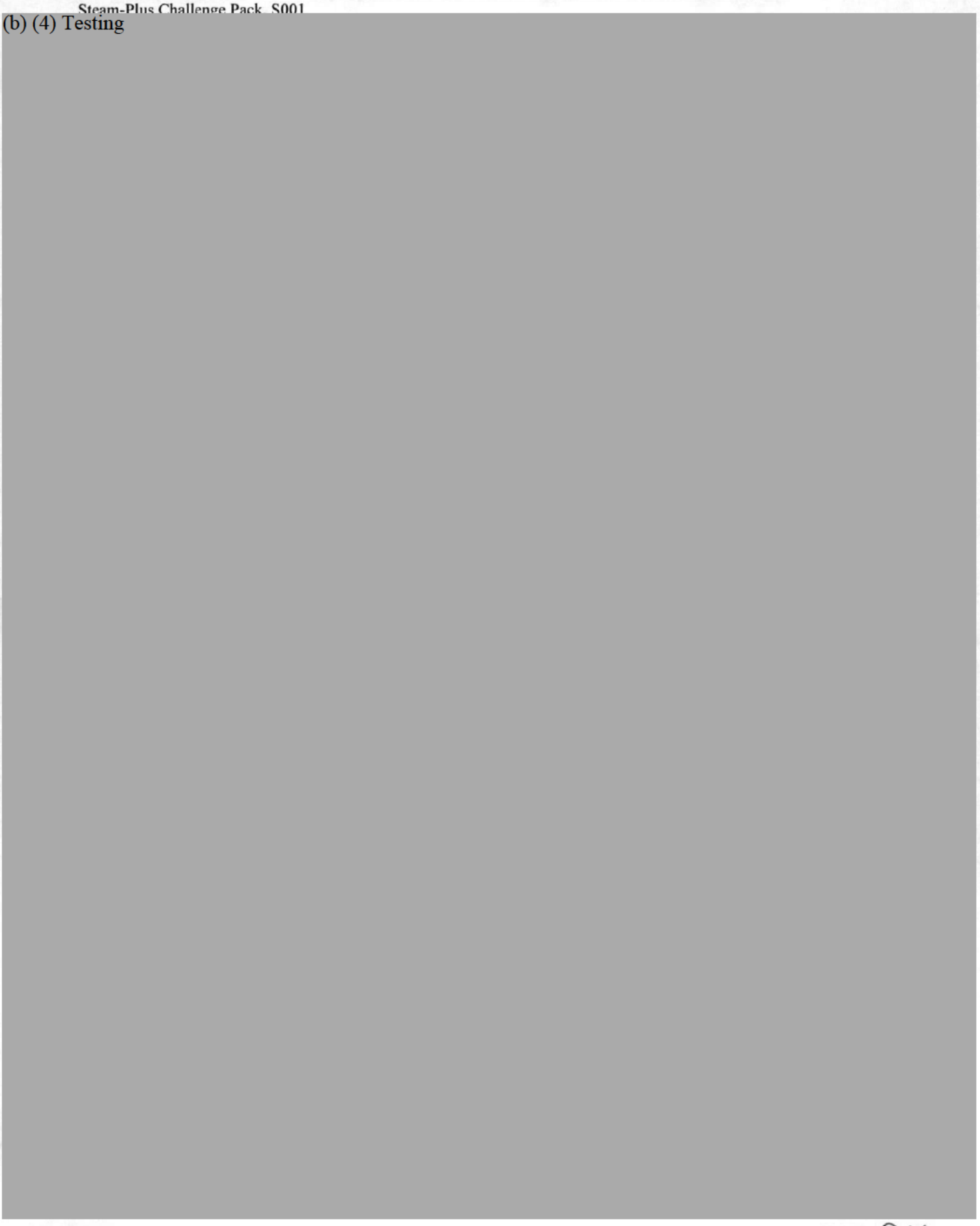

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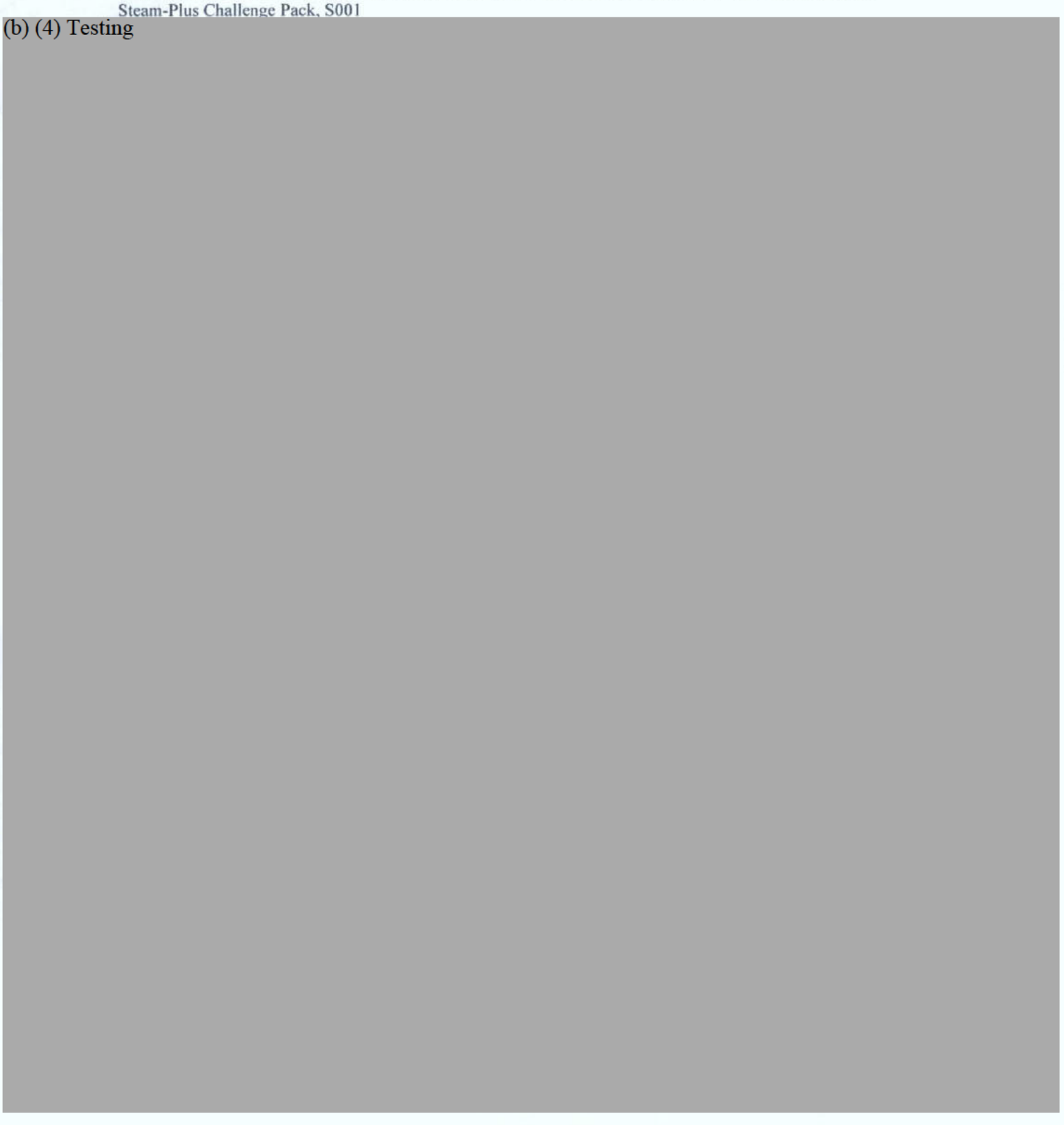
(b) (4) Testing



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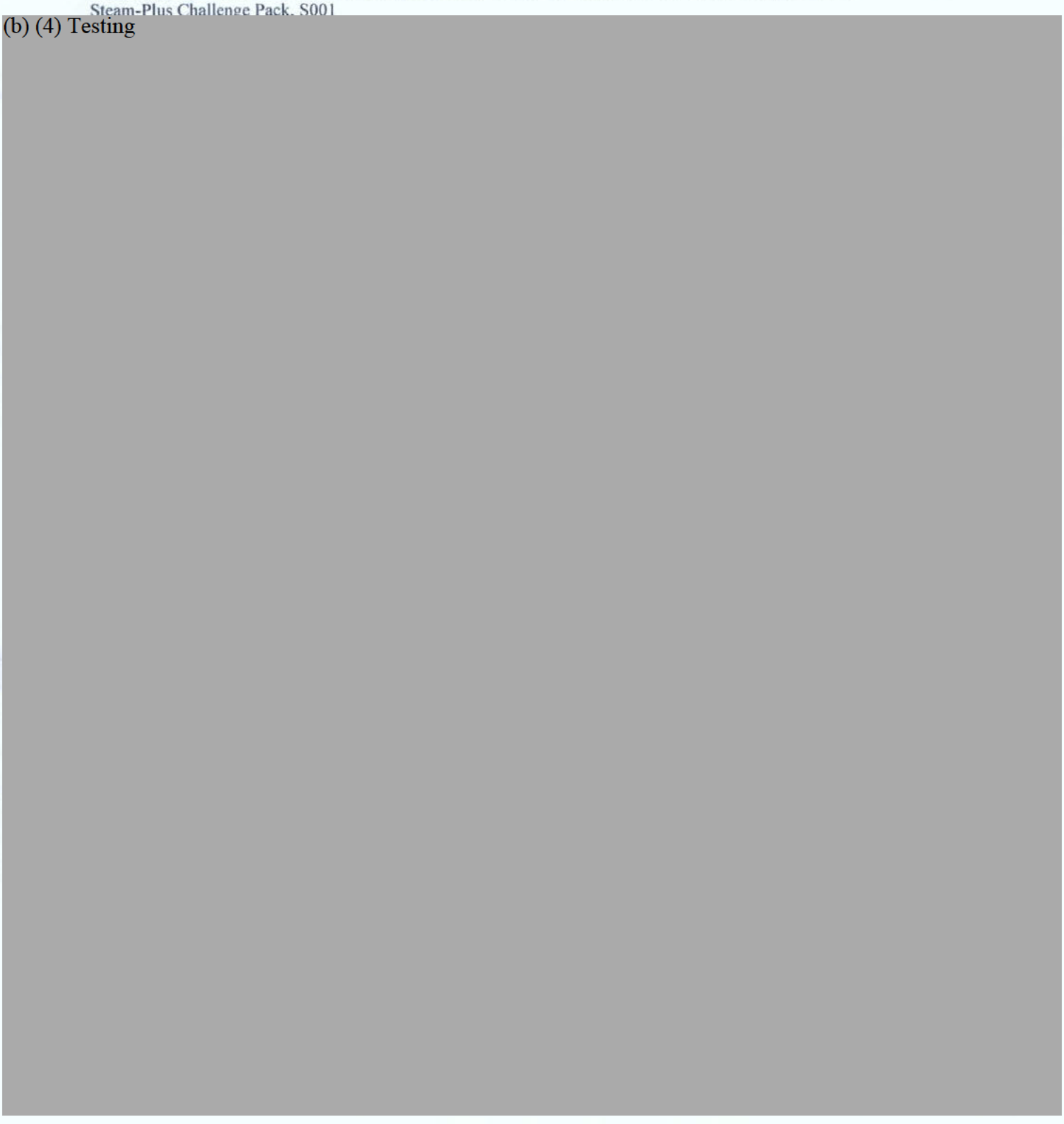

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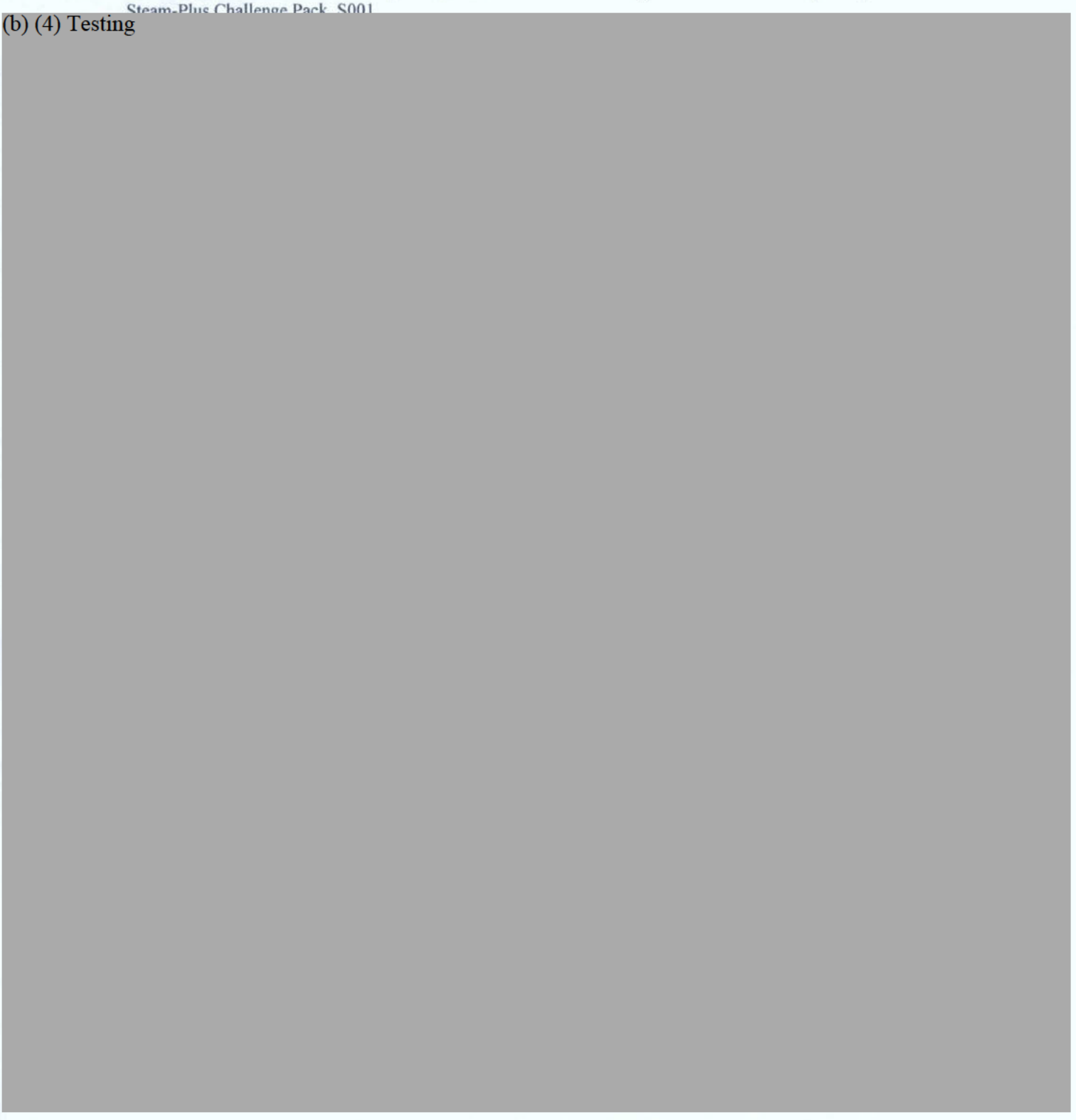

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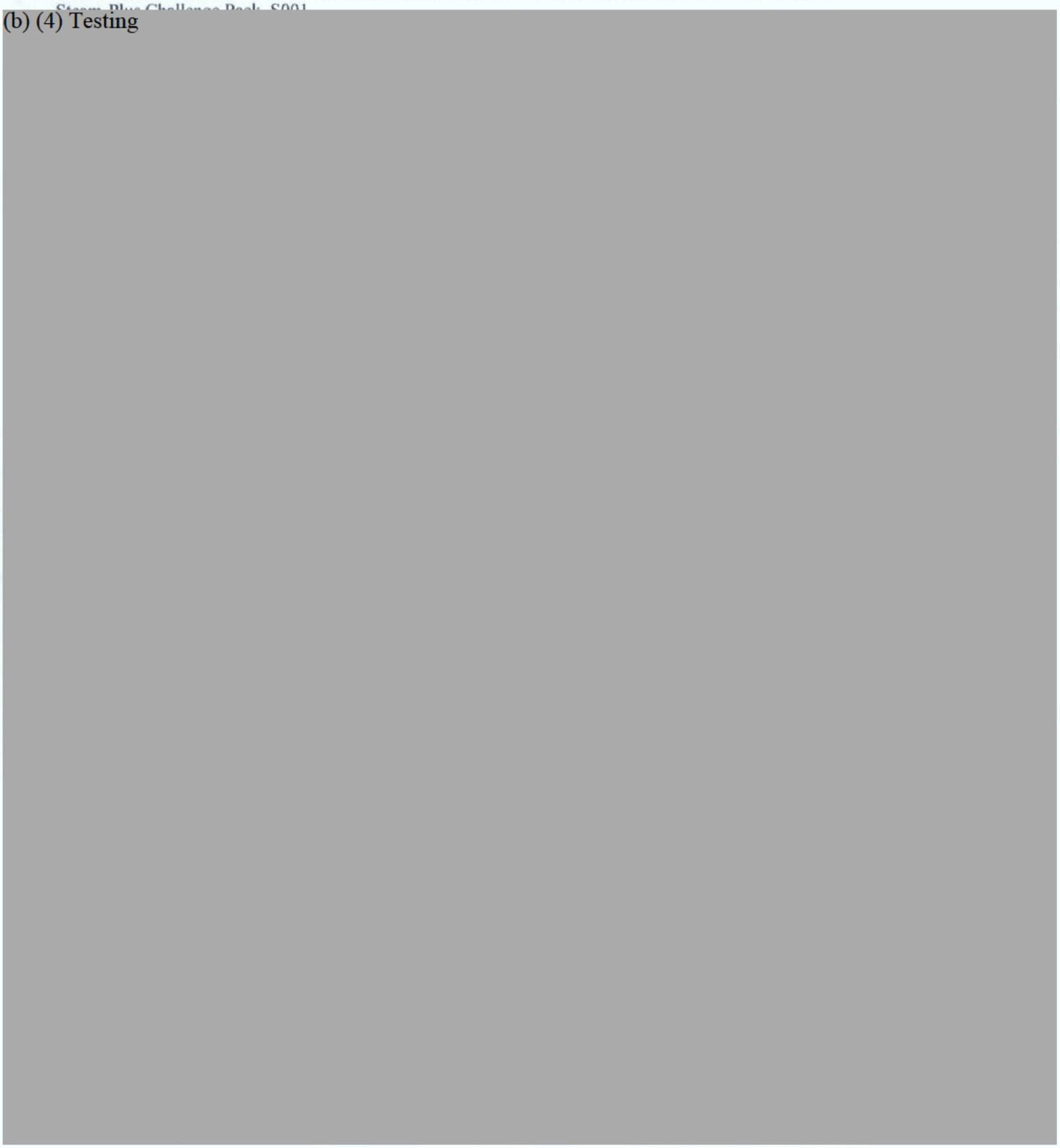

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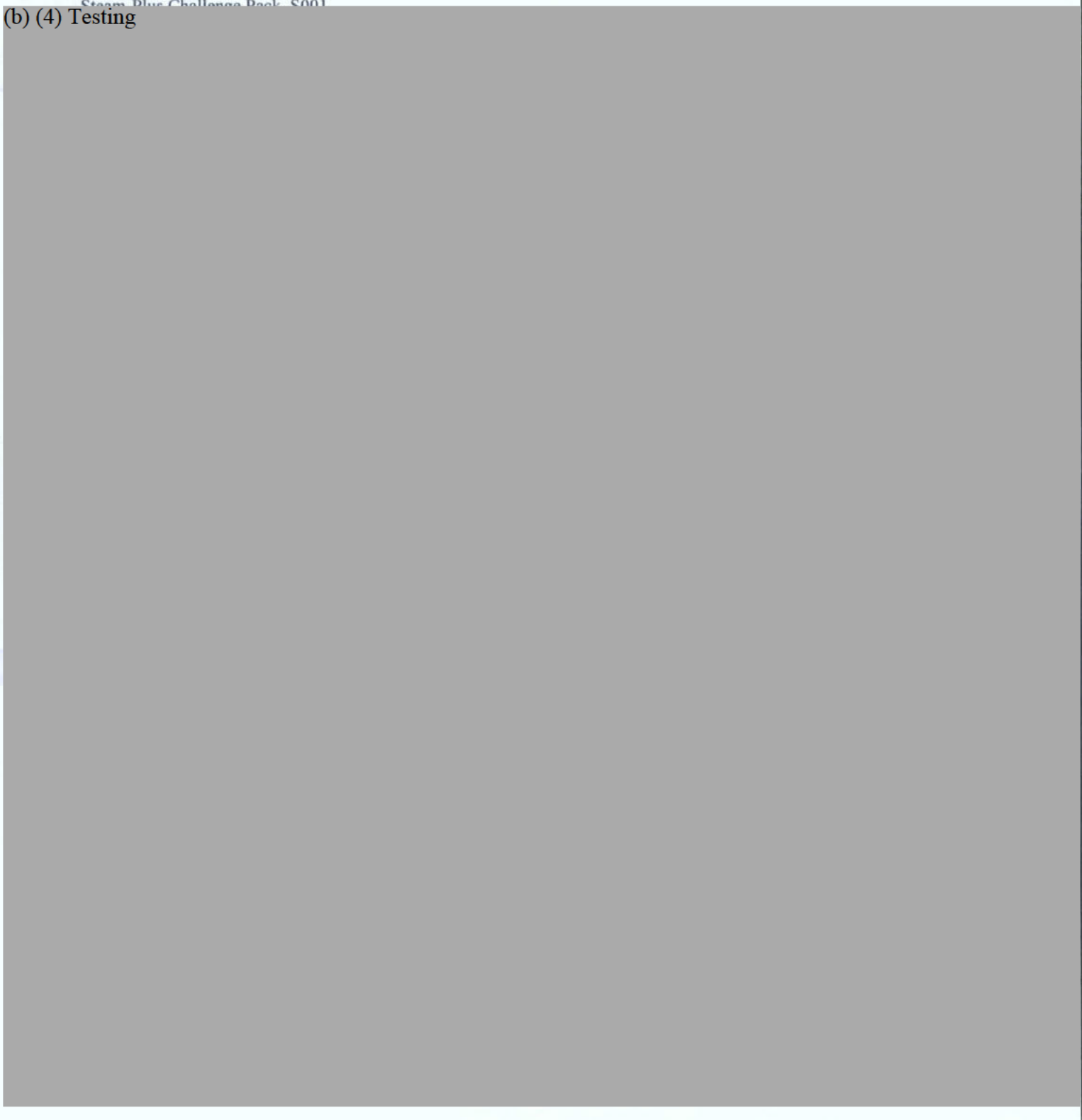

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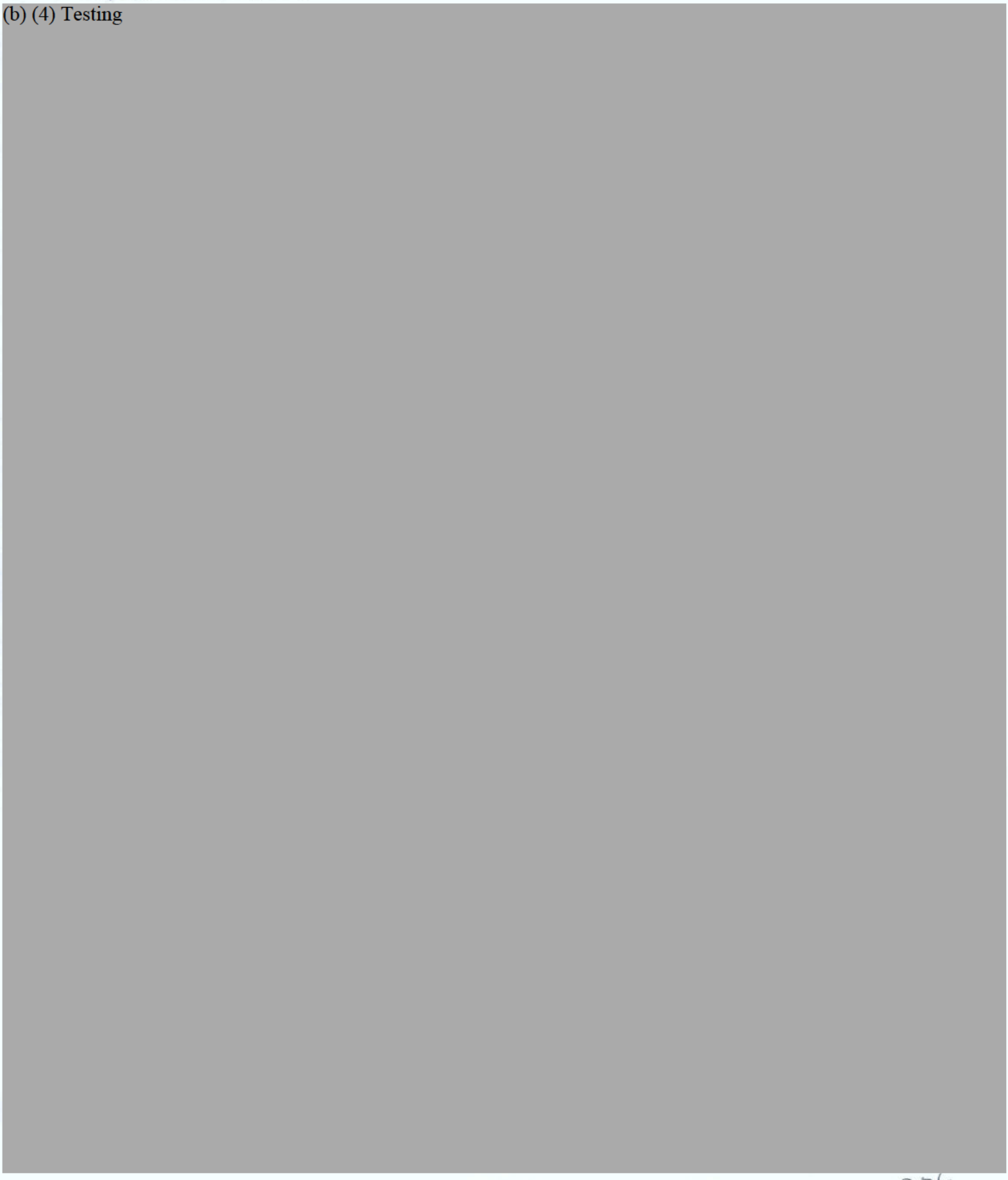

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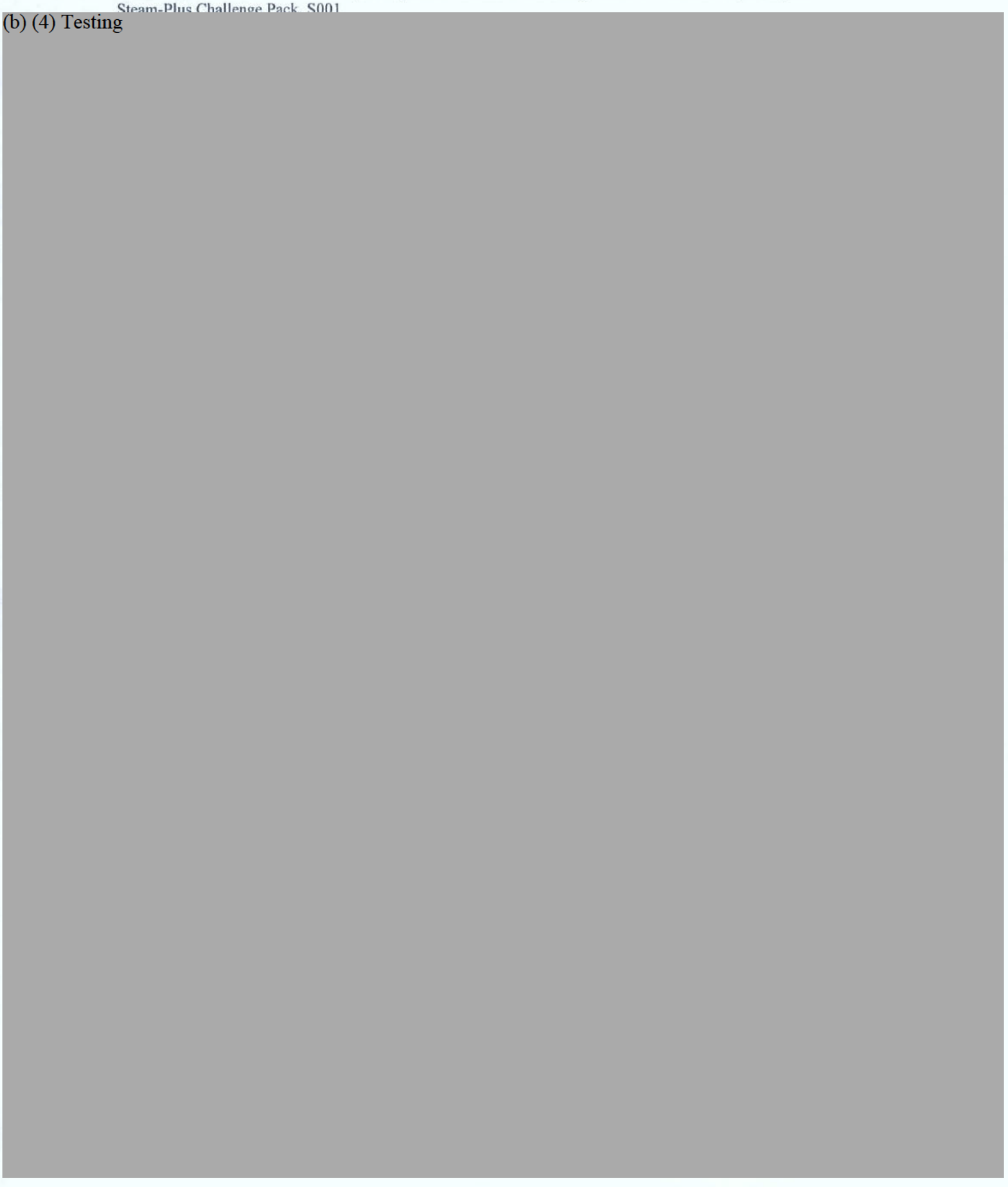

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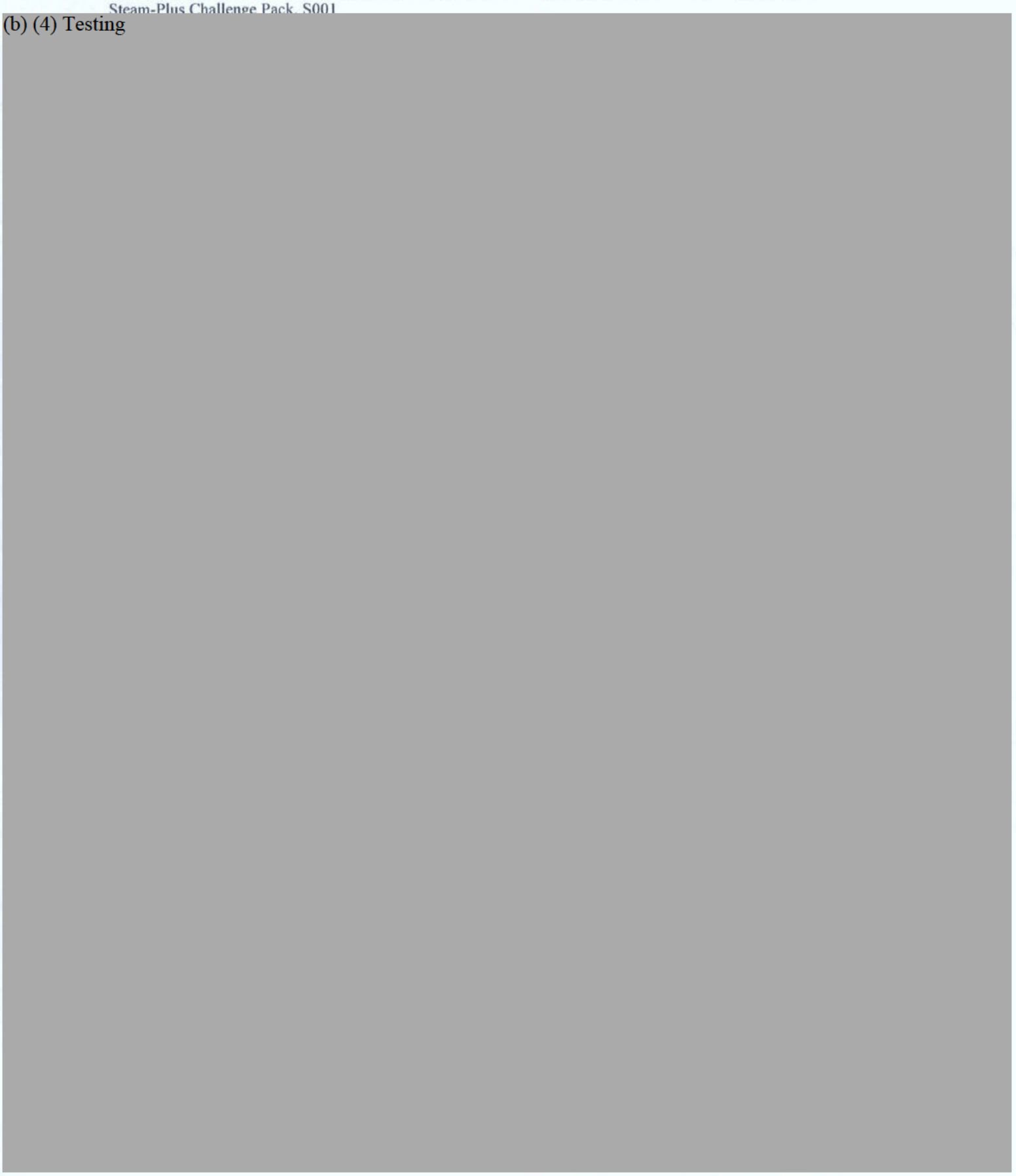

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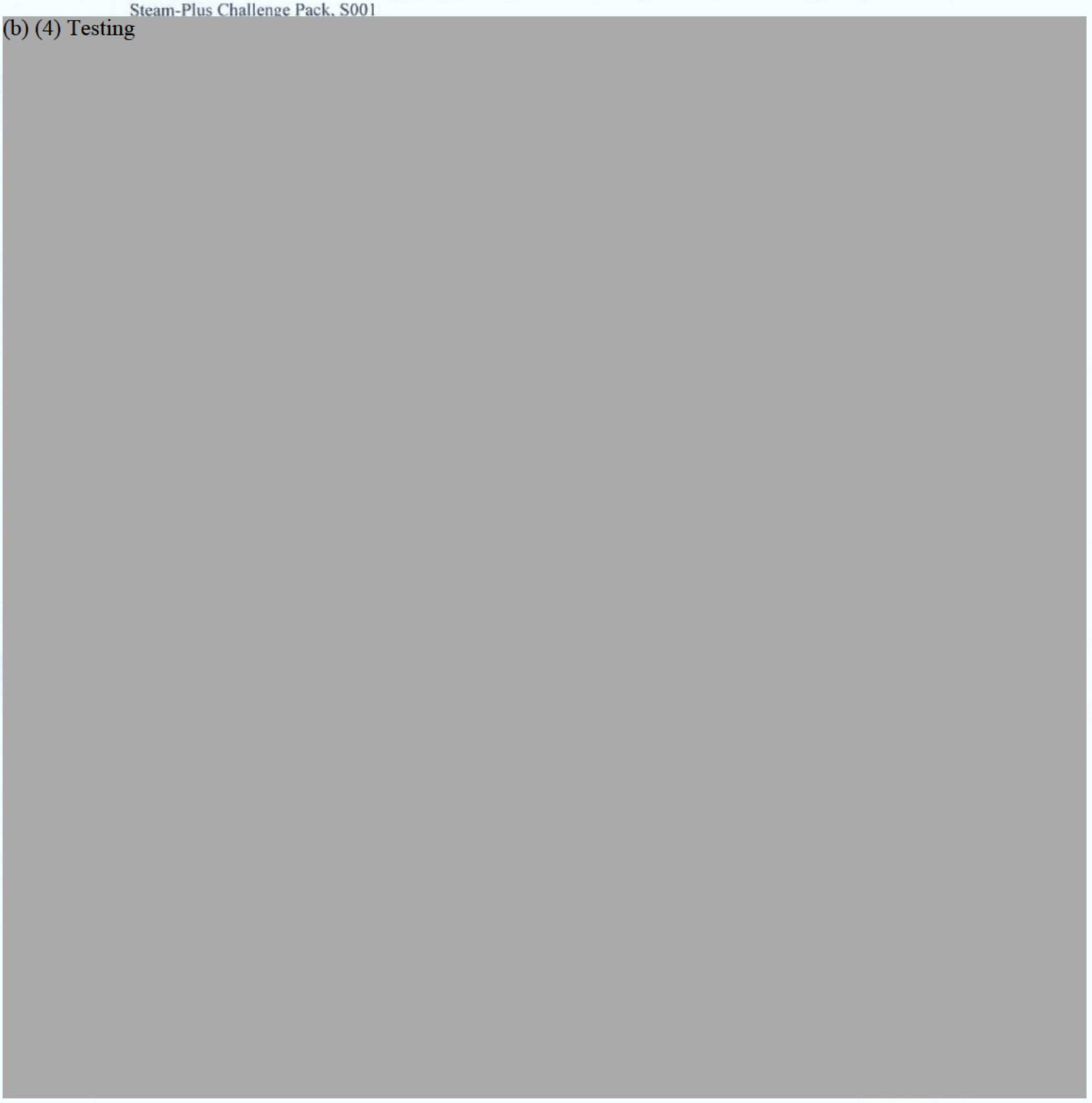

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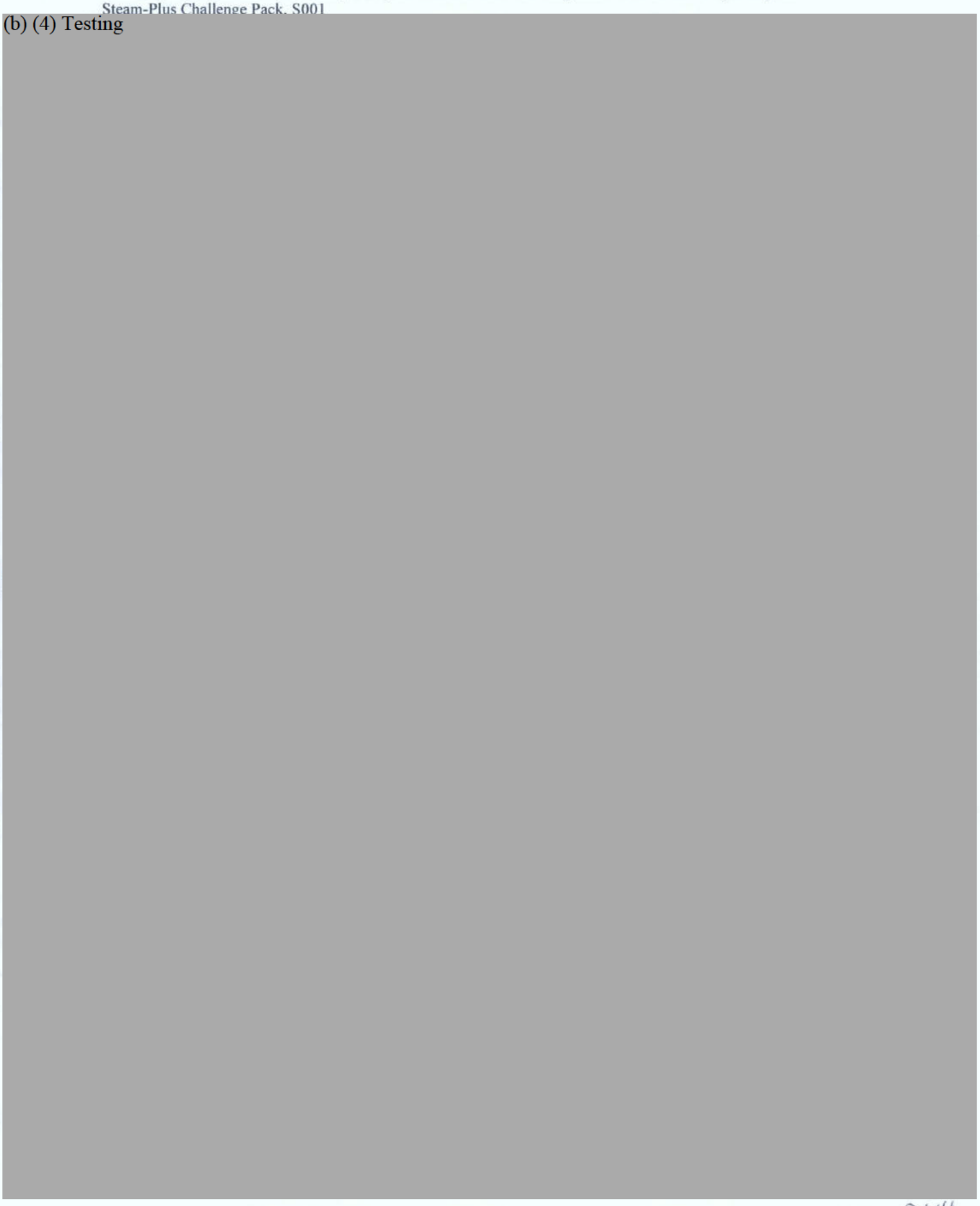

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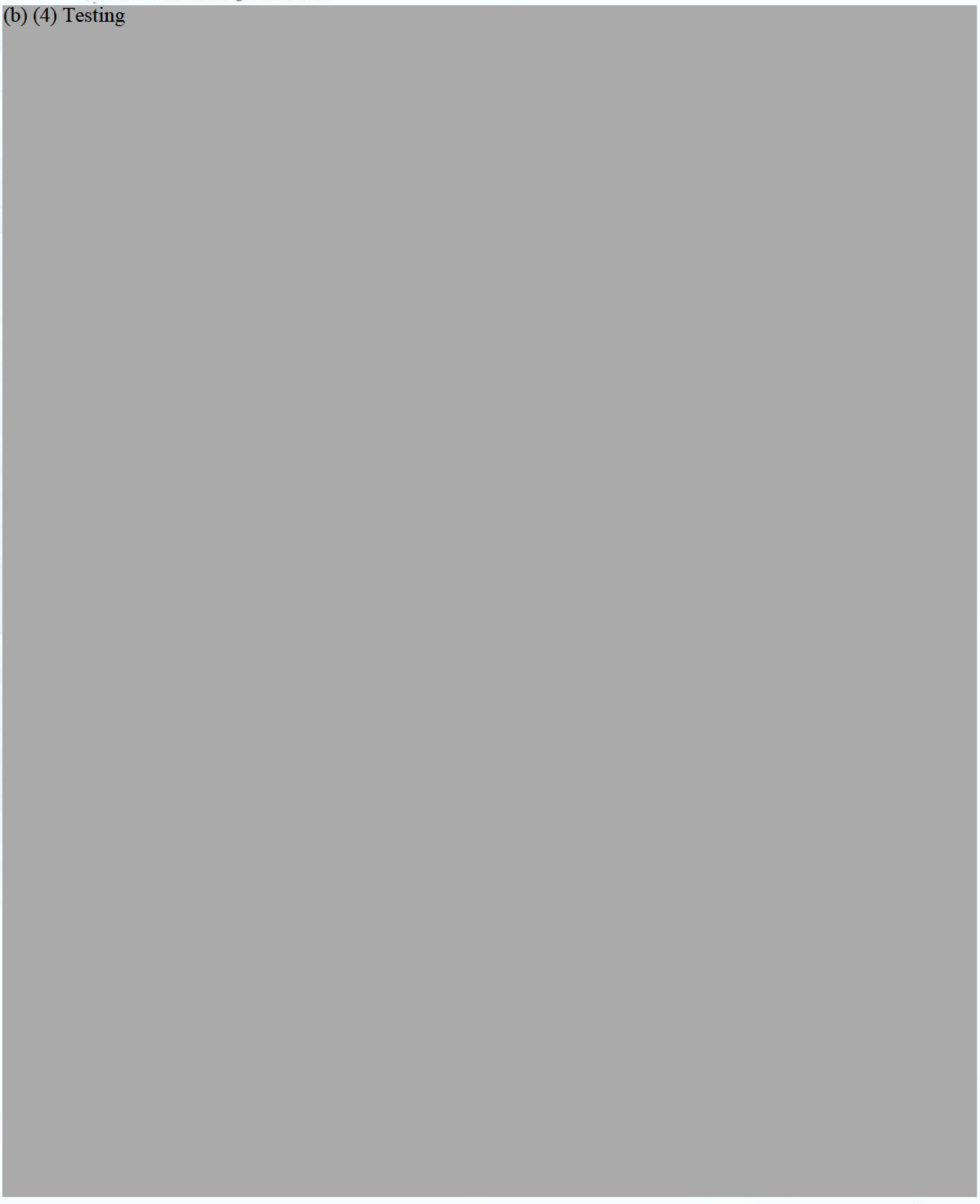

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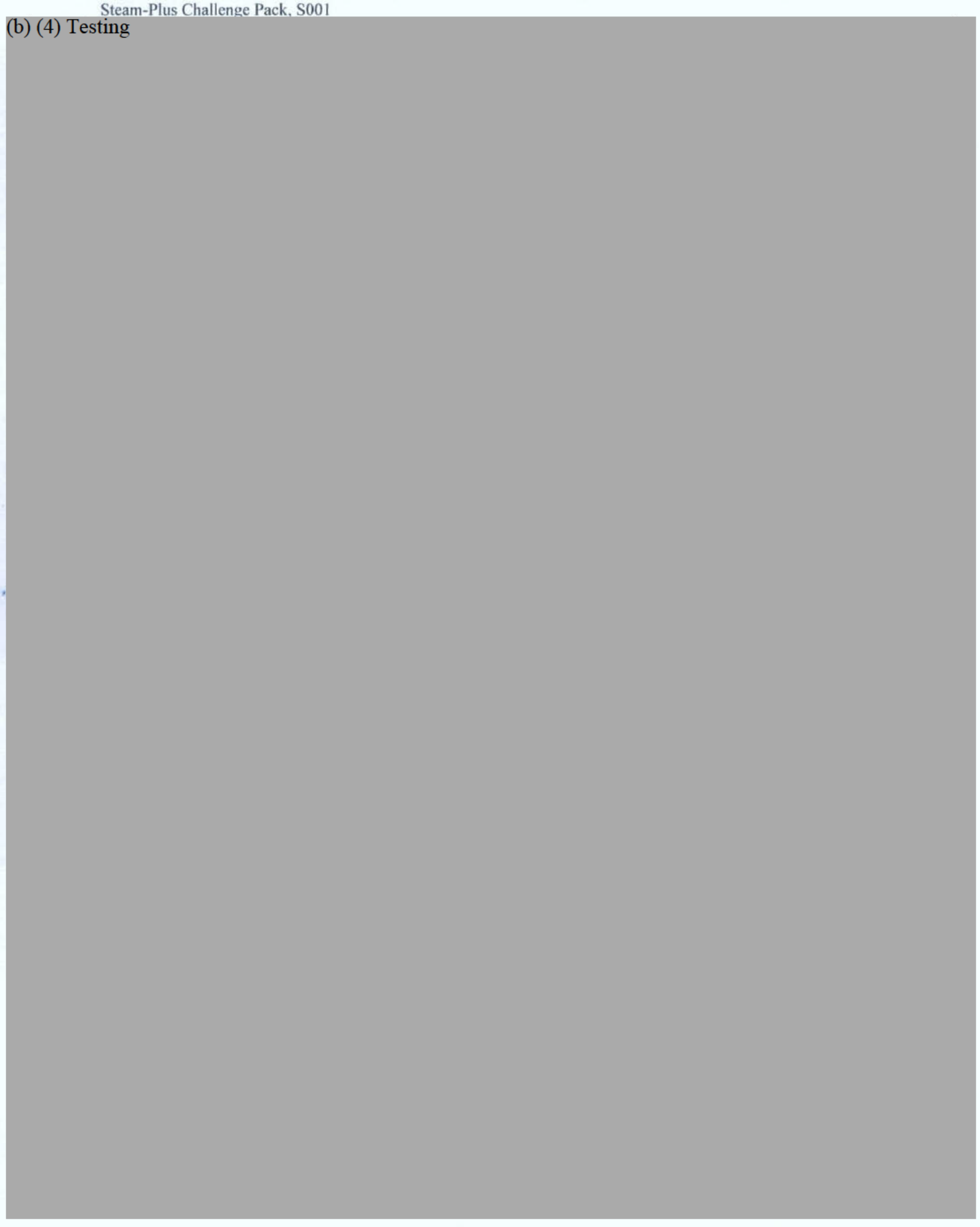

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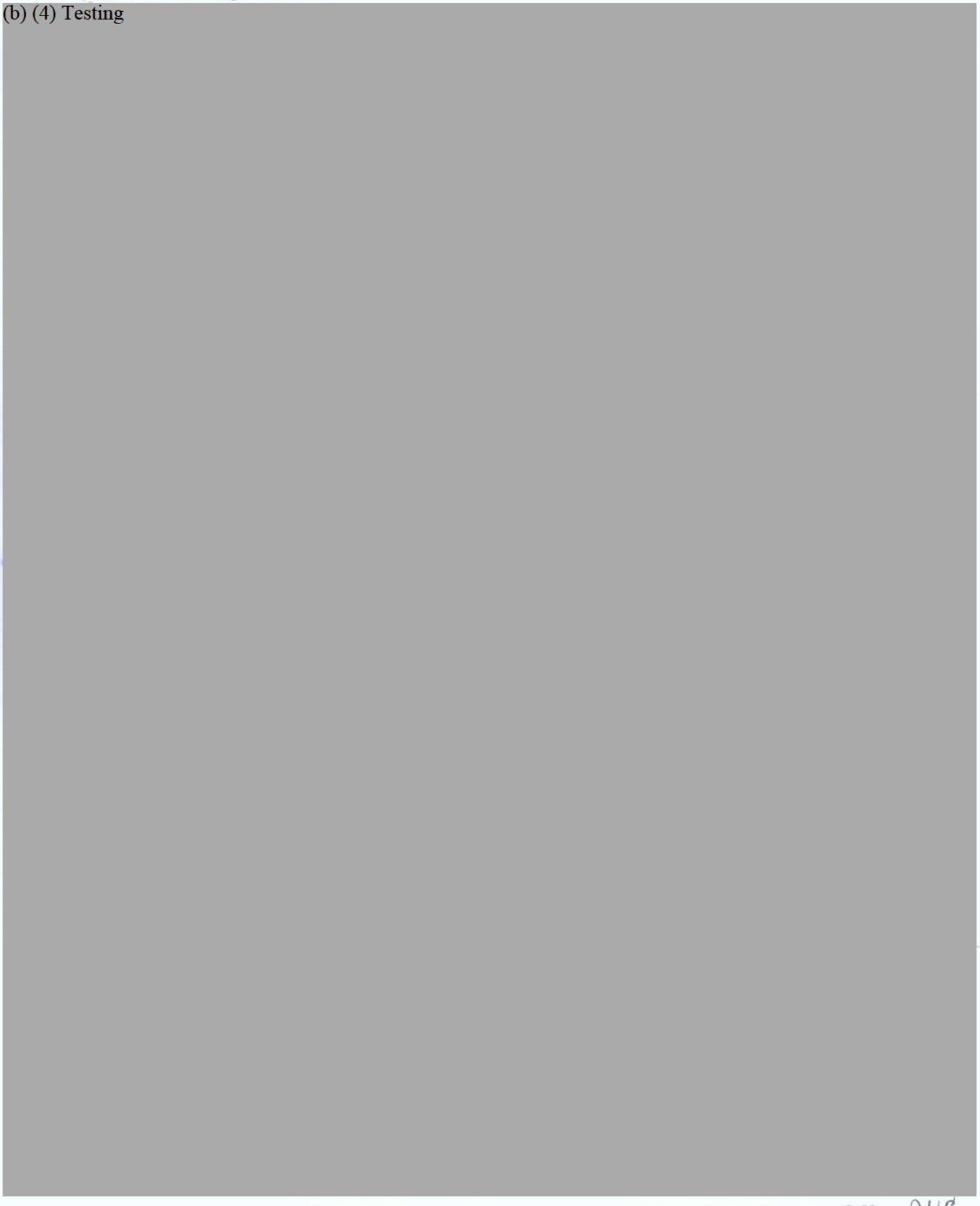


Attachment H: Study II - (b) (4)
(b) (4)
(Raw data sheets included)

The following pages contain Study II (in the original submission as Section 12.3.2), a comparison of the Challenge Packs with the AAMI Towel Pack (b) (4)
(b) (4)

12.3.2. Study II: (b) (4) Comparison of 1496V and 41482V Challenge Packs Compared to an AAMI Towel Pac(b) (4)

Objective:

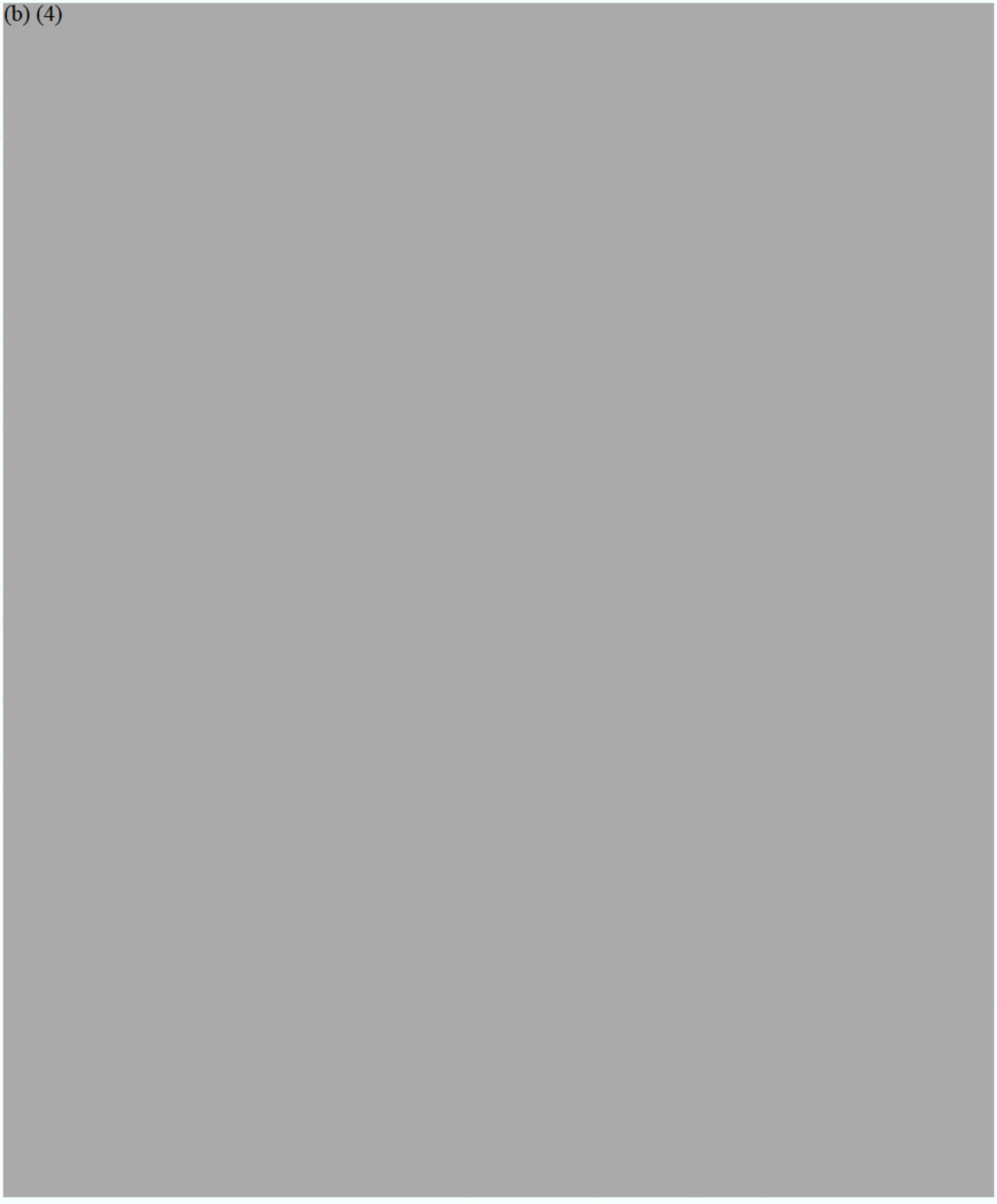
This study was designed to compare(b) (4) 1496V and 41482V Challenge Packs to an AAMI Towel Pack(b) (4)

Protocol:

(b) (4) Protocols

250

(b) (4)



(b) (4)

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Conclusion:

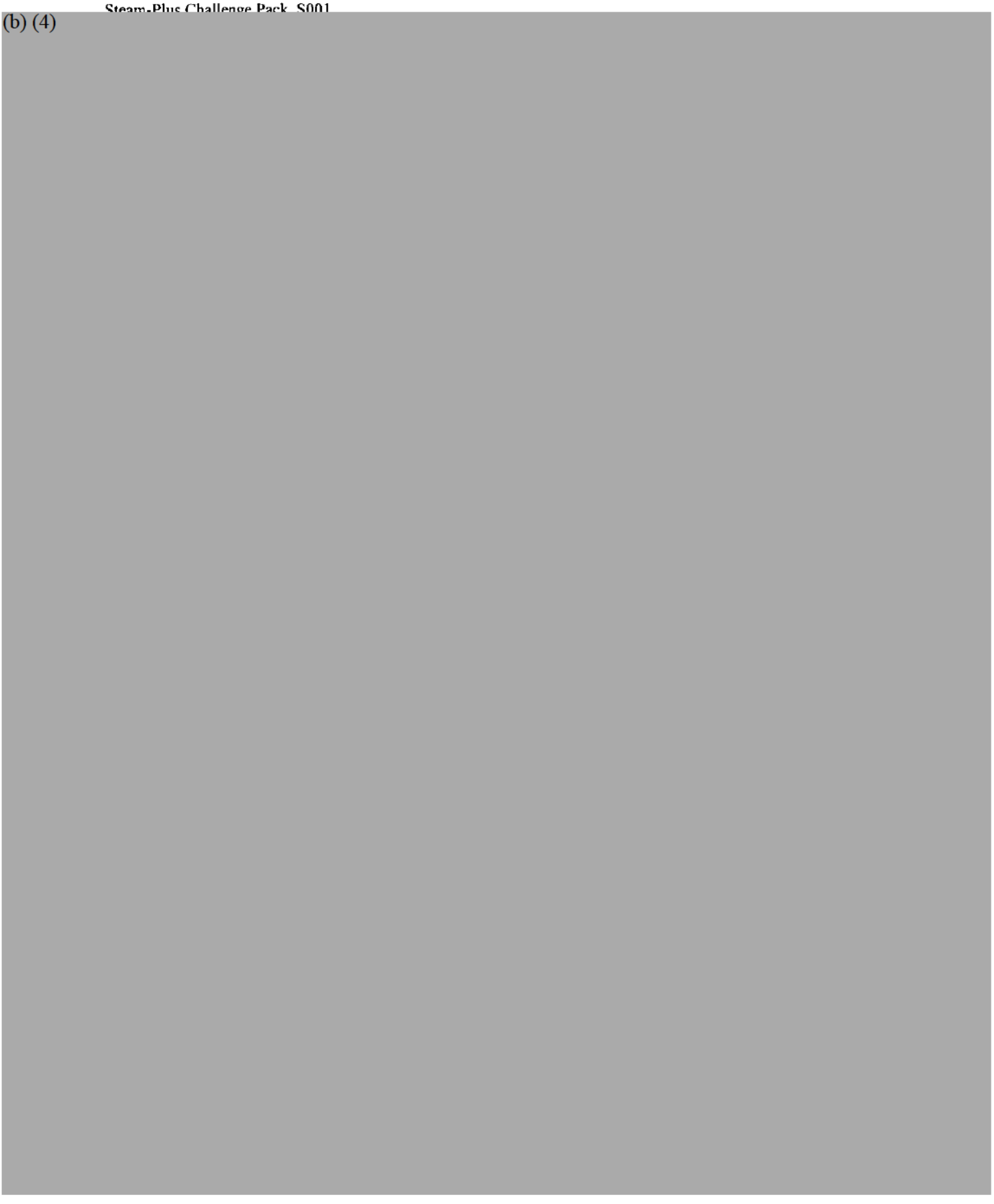
The data presented above demonstrates:

(b) (4)

(b) (4)

(b) (4)

(b) (4)



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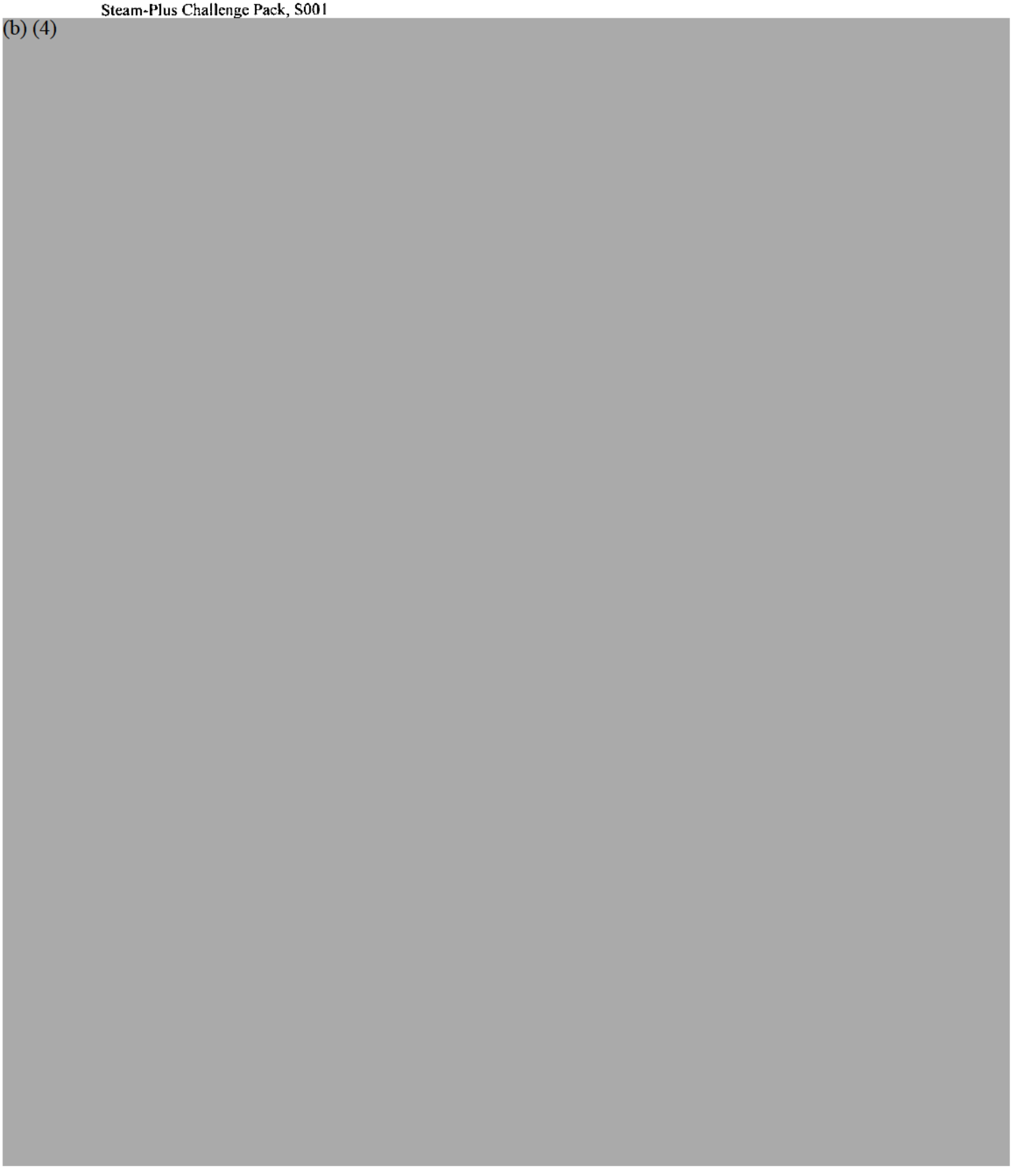

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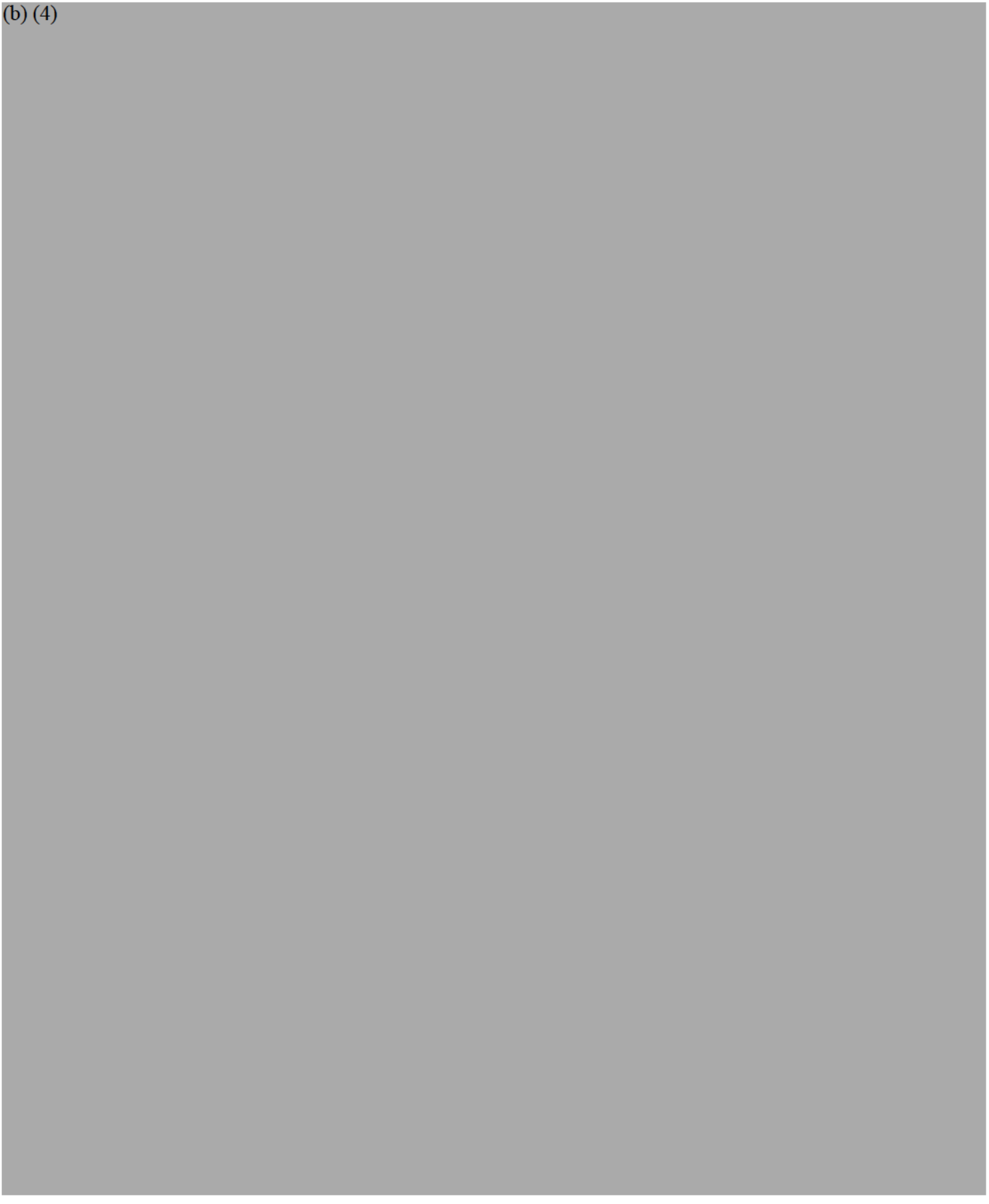

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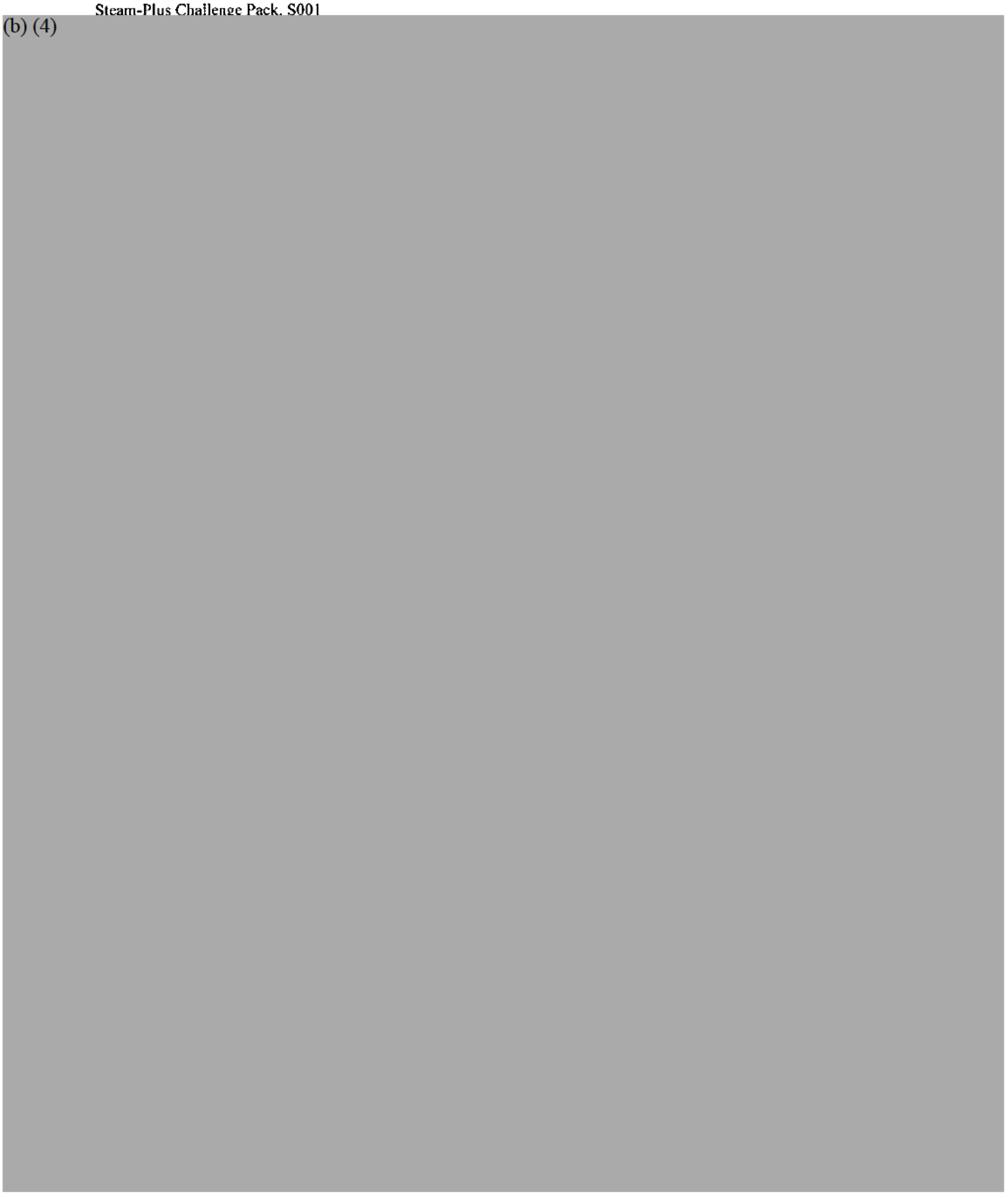

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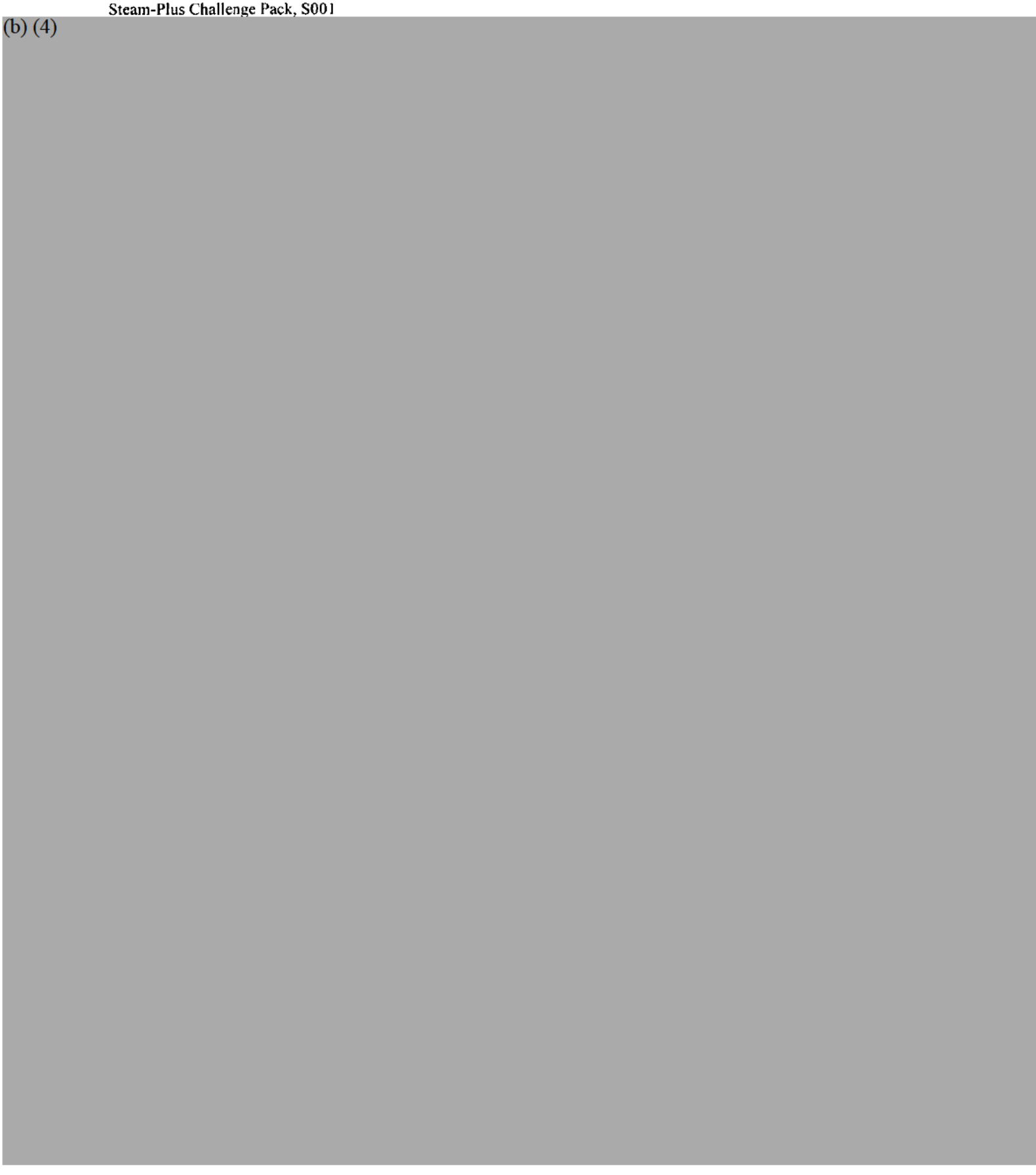

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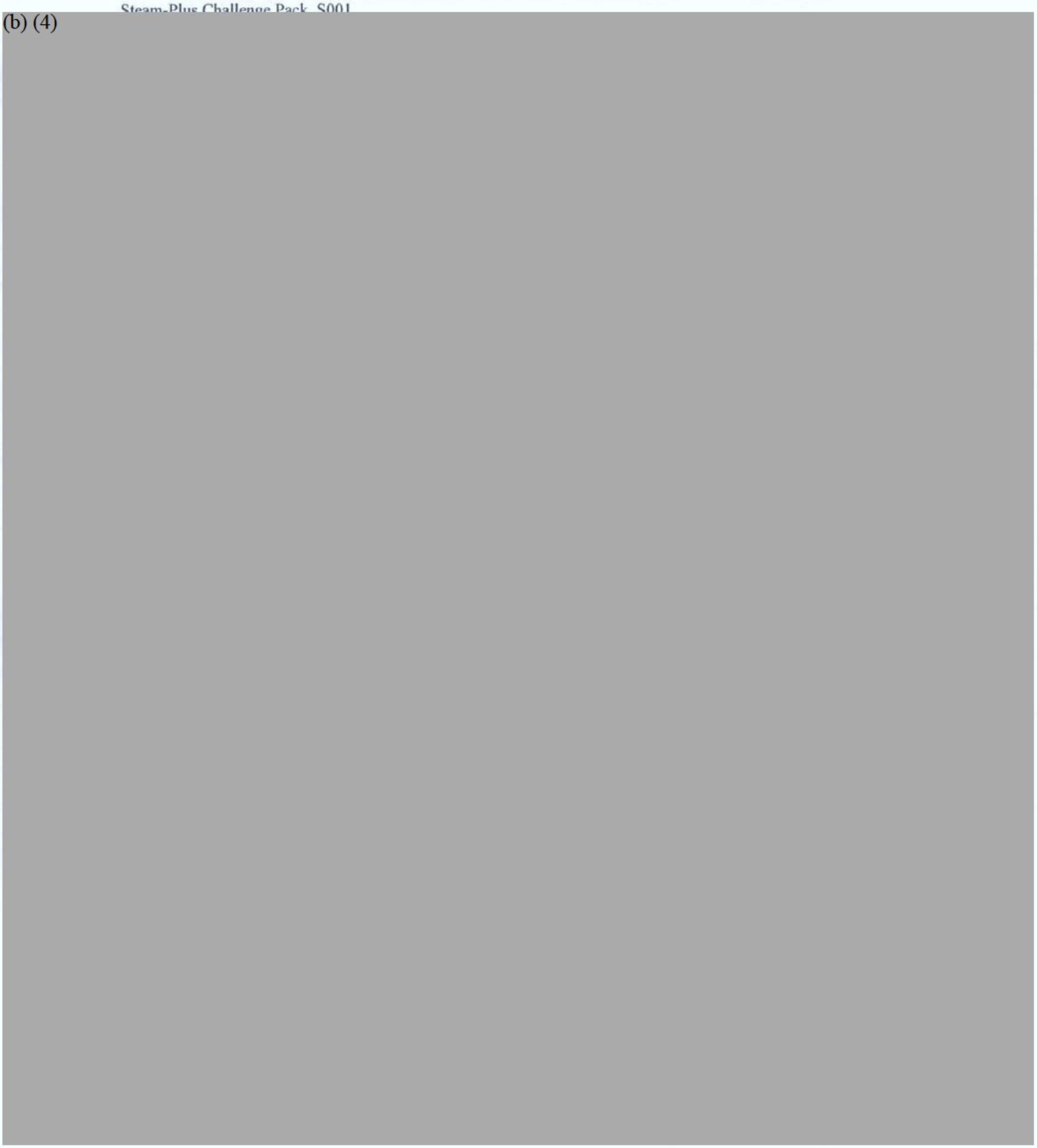

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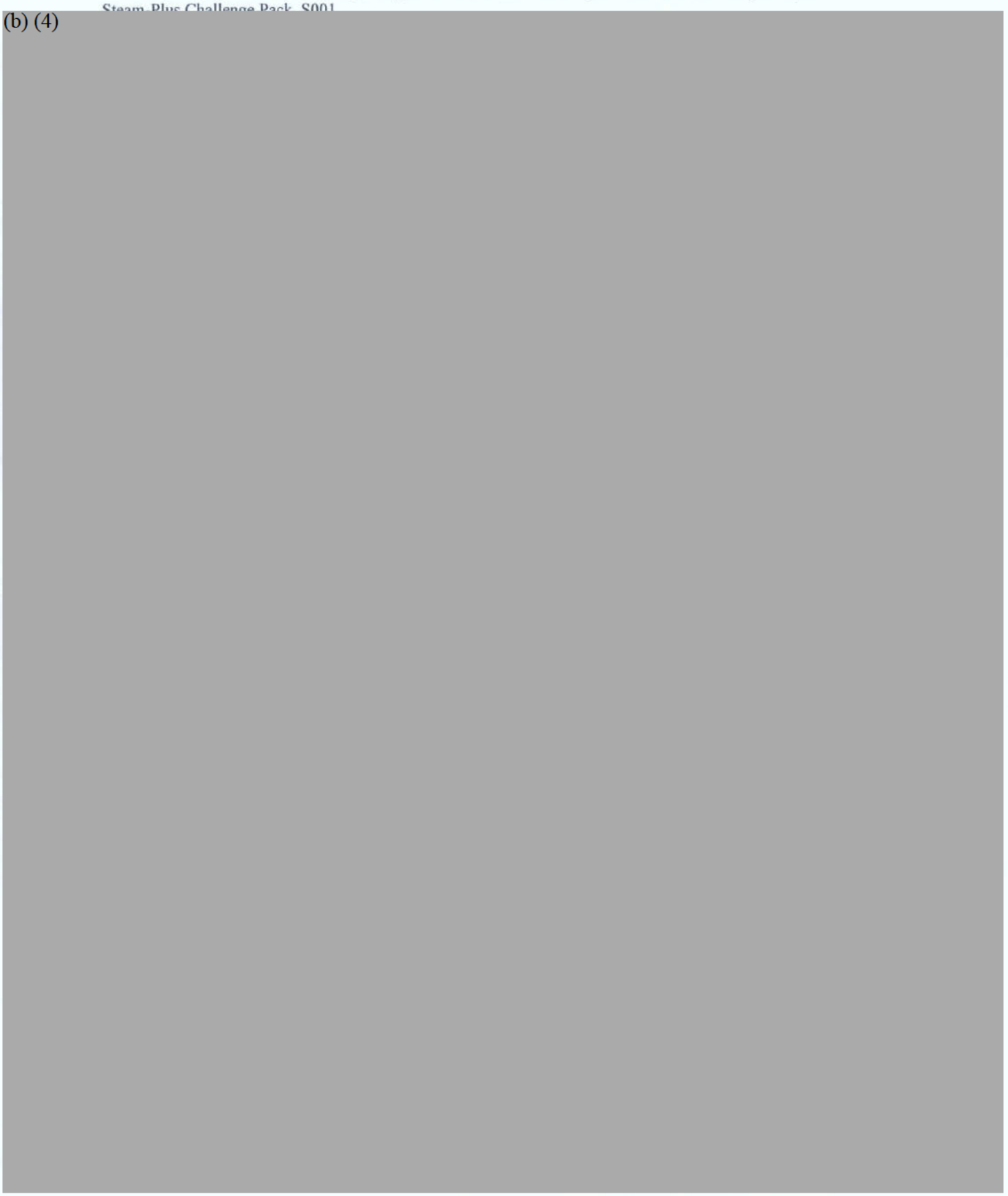

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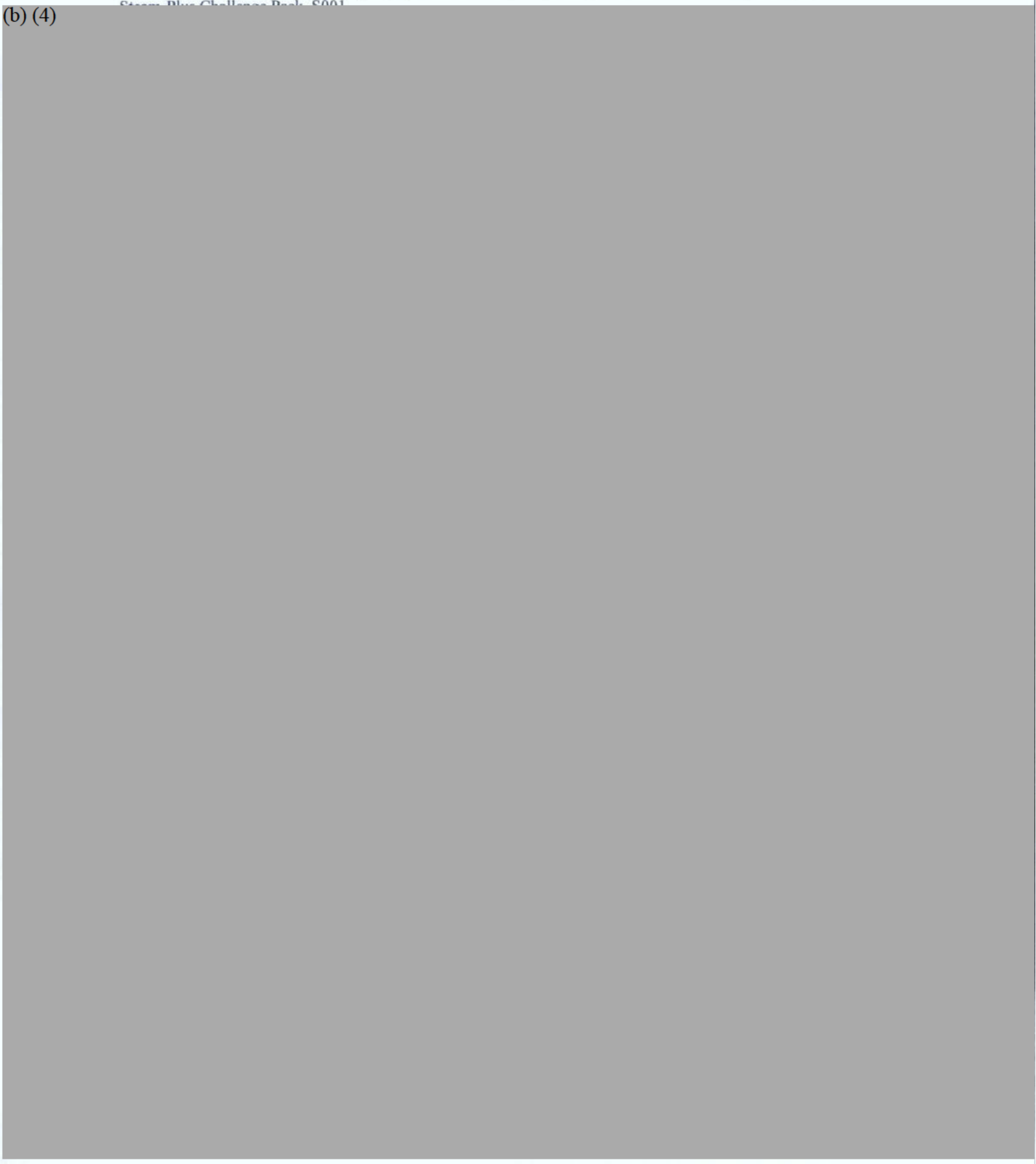

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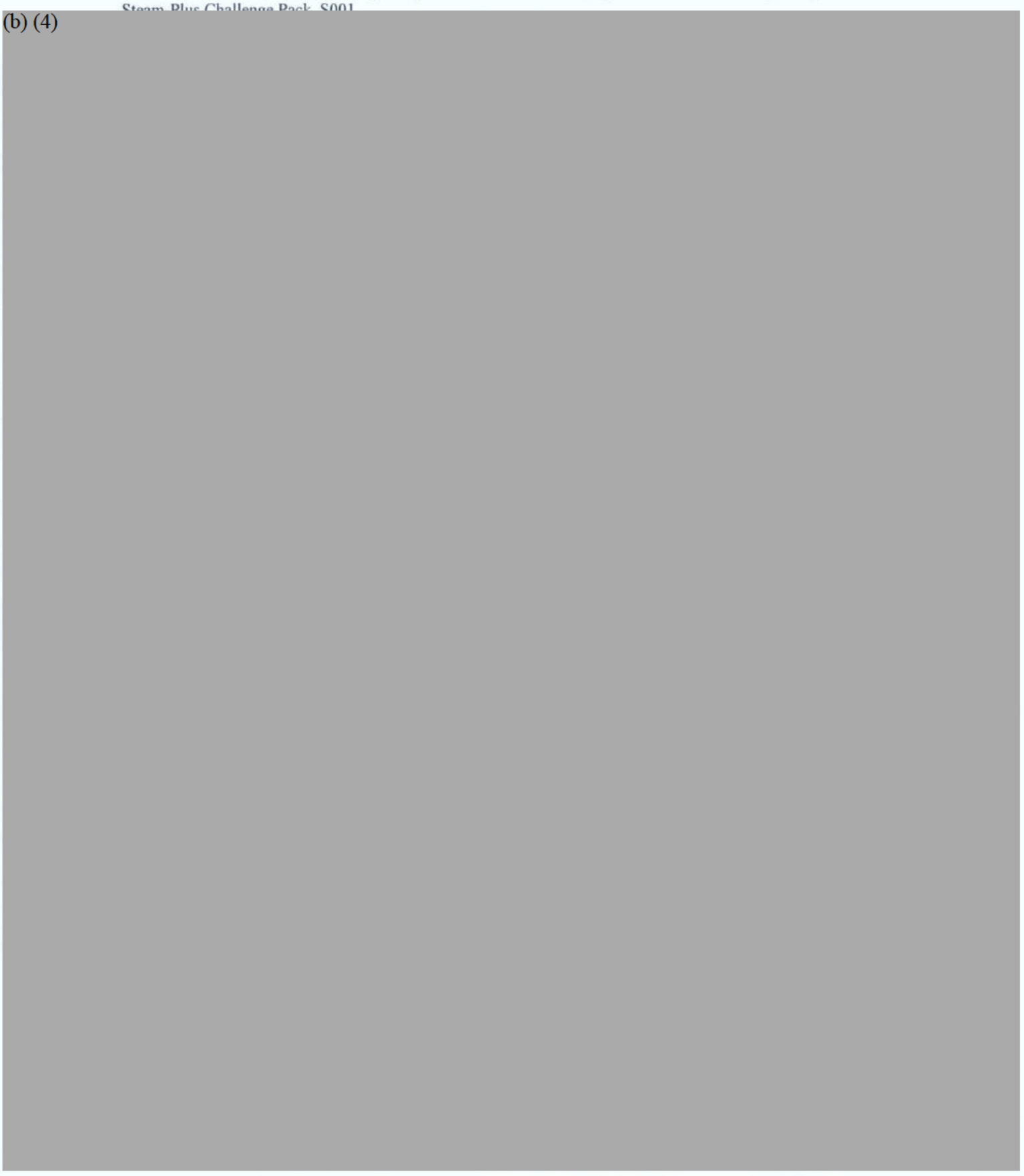

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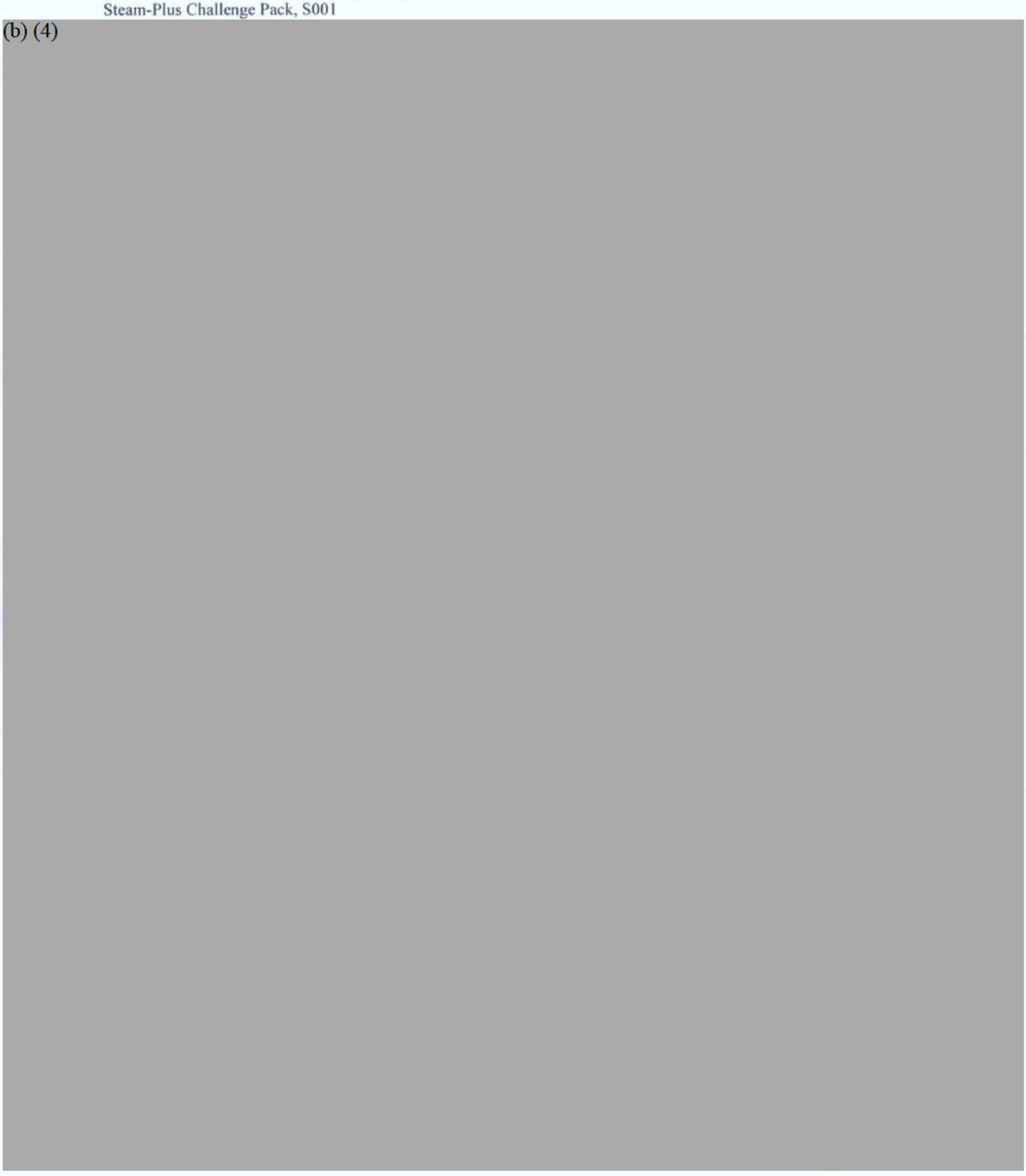

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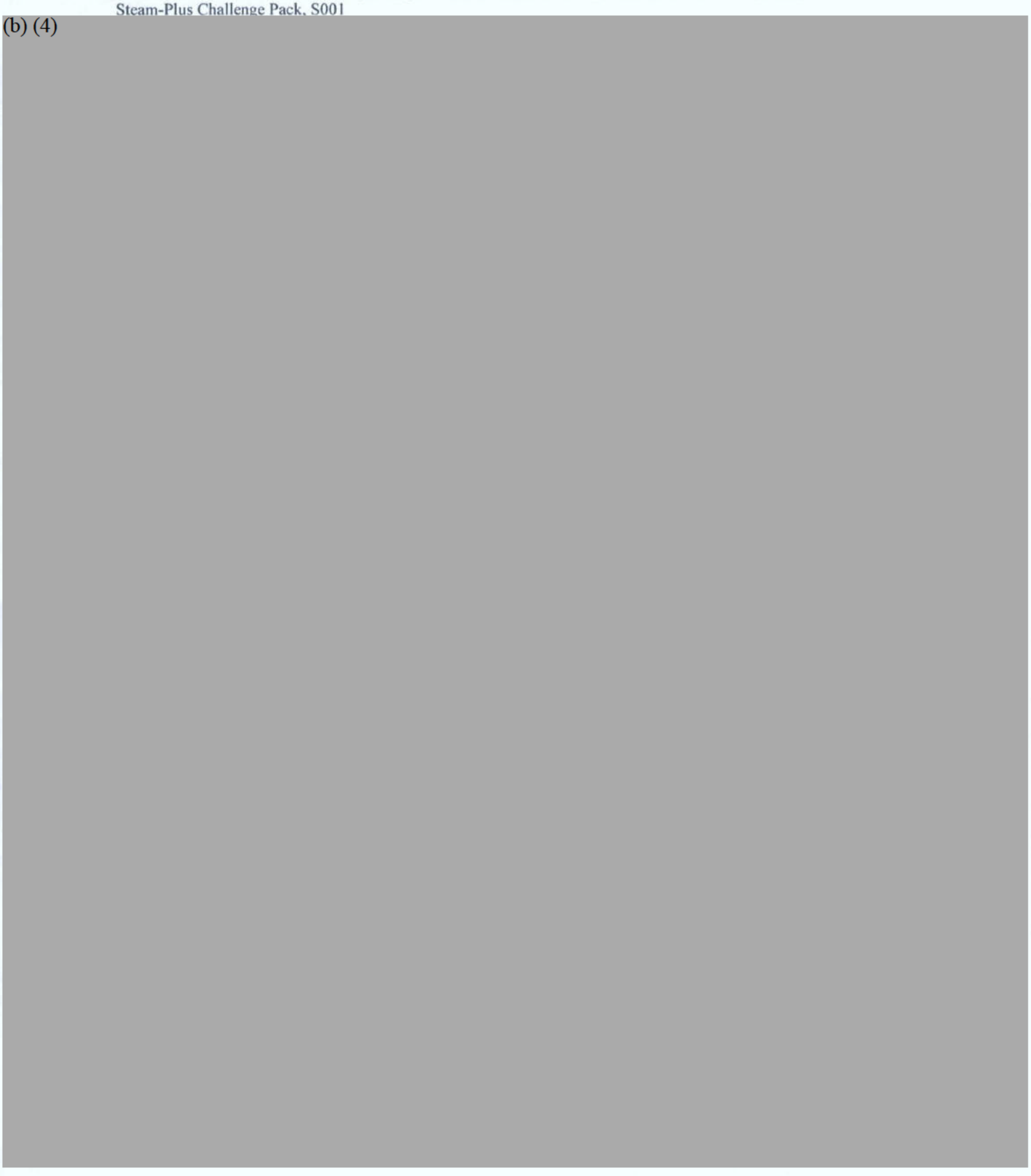

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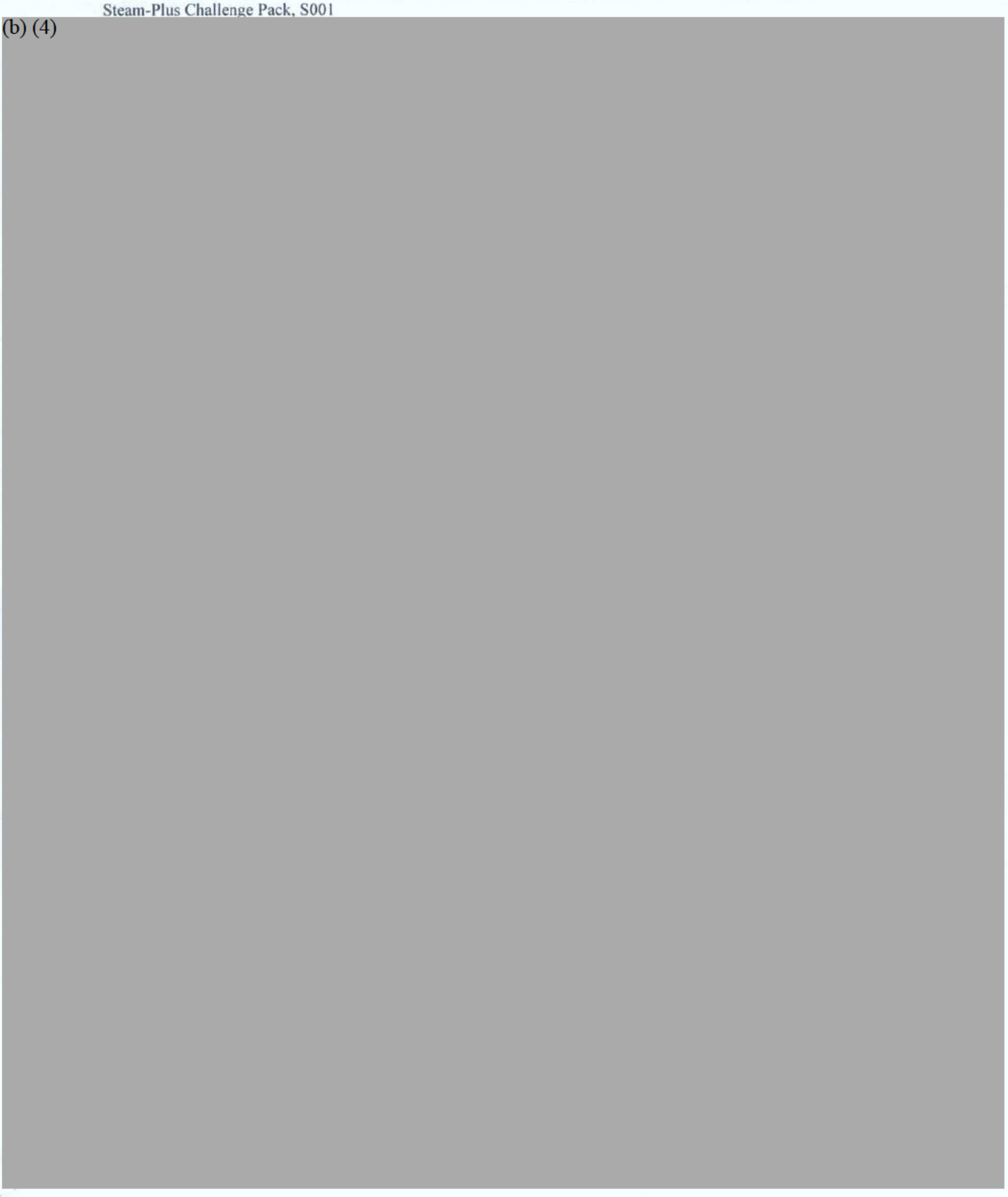

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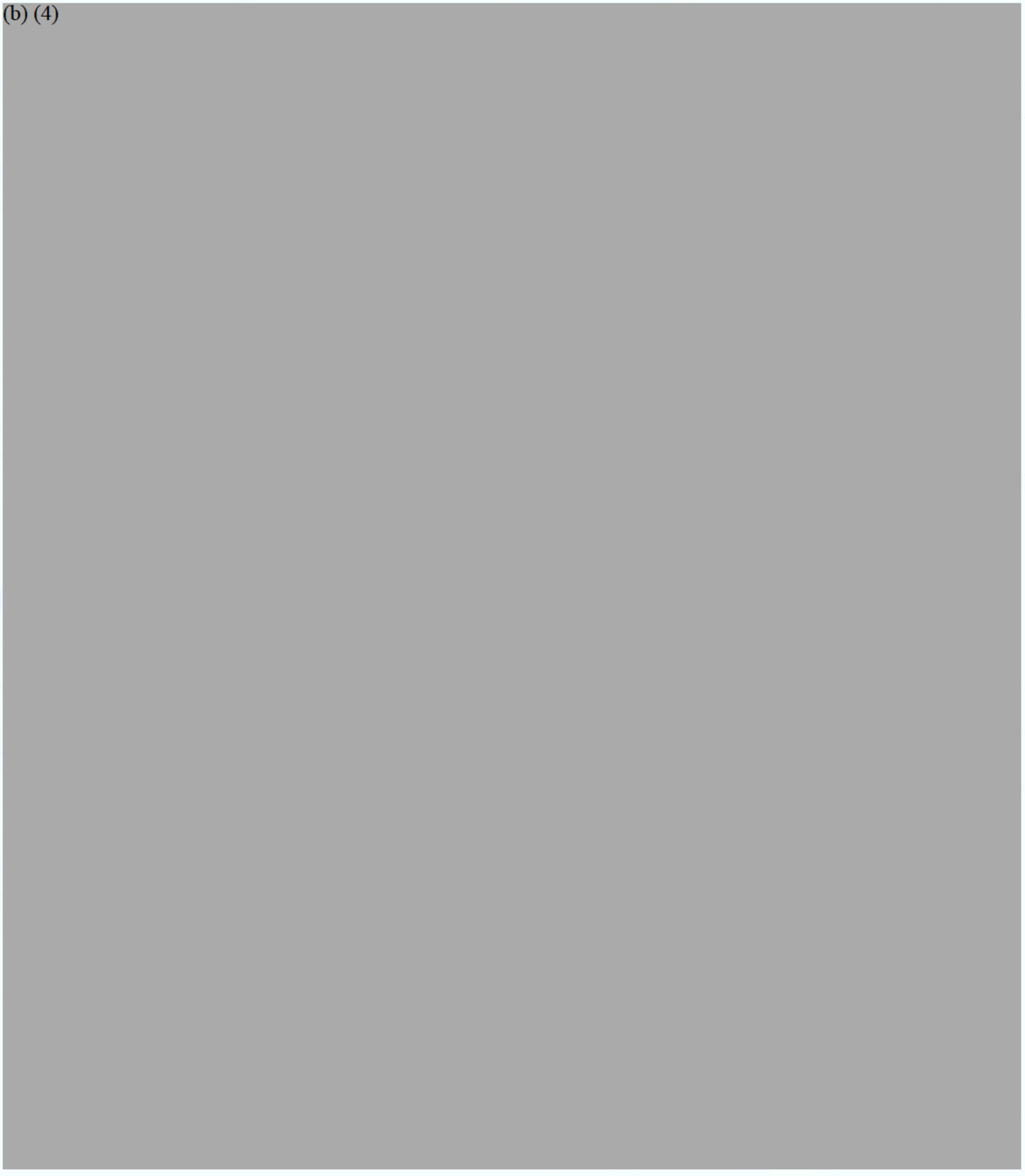

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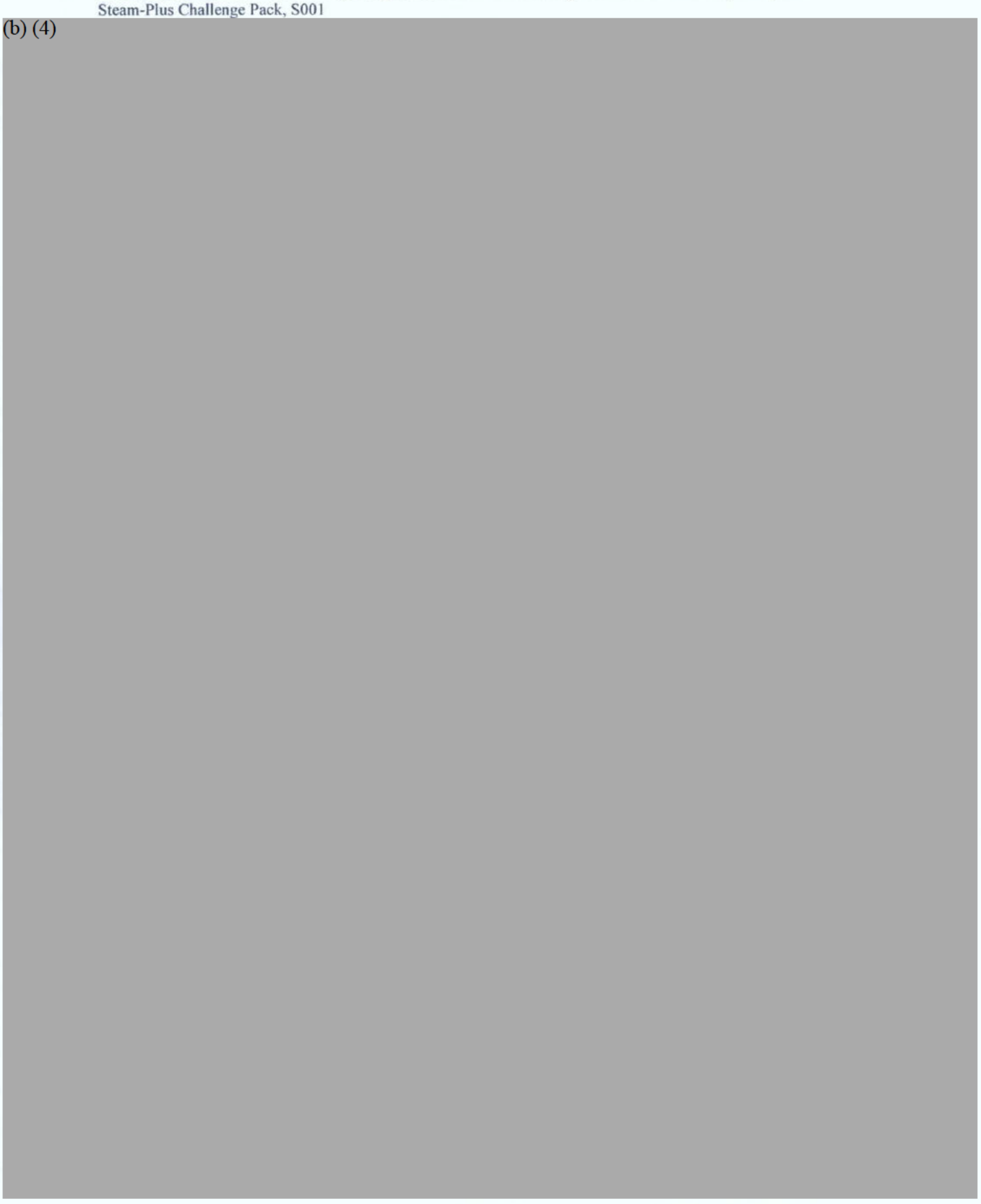

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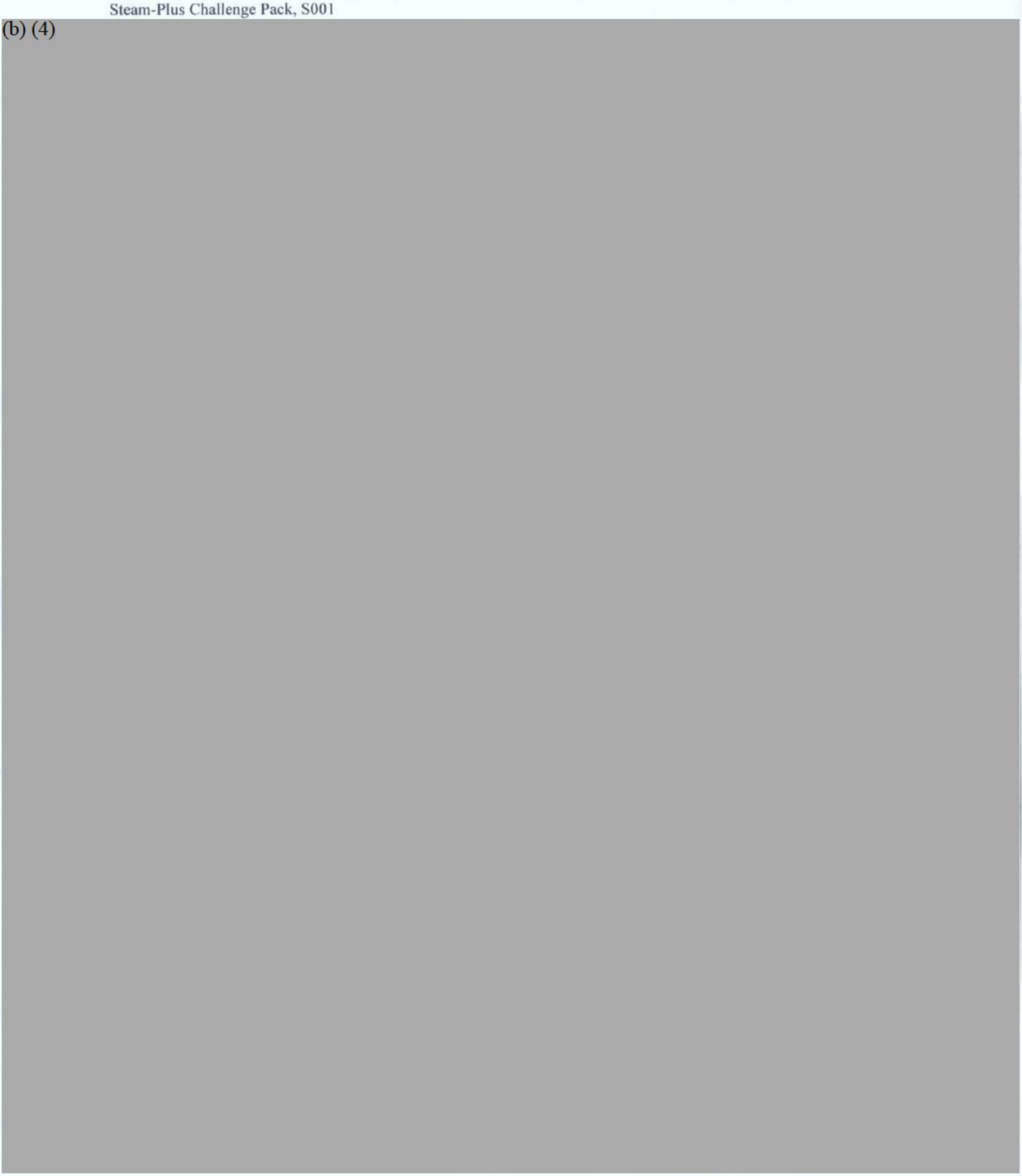

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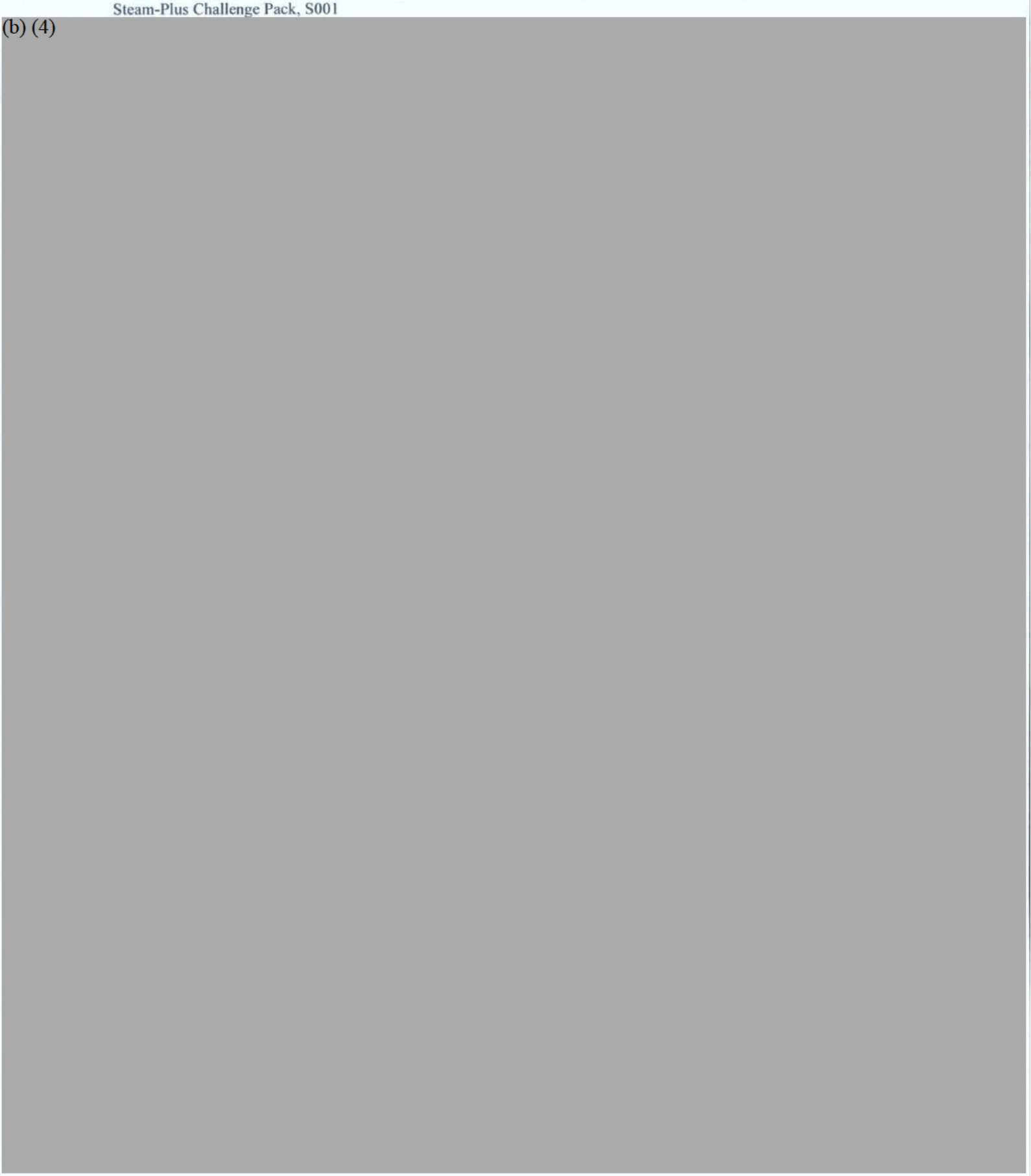

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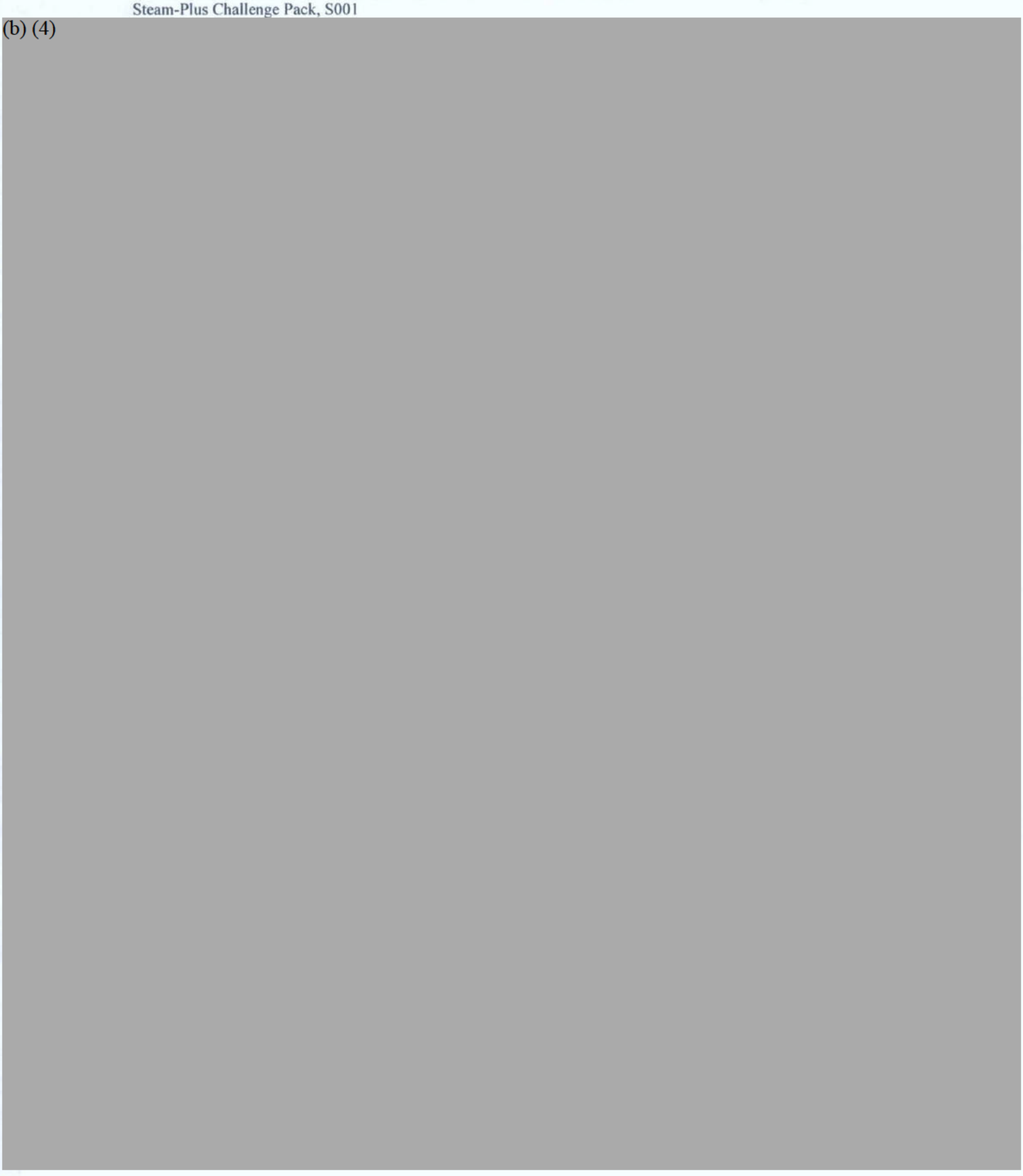

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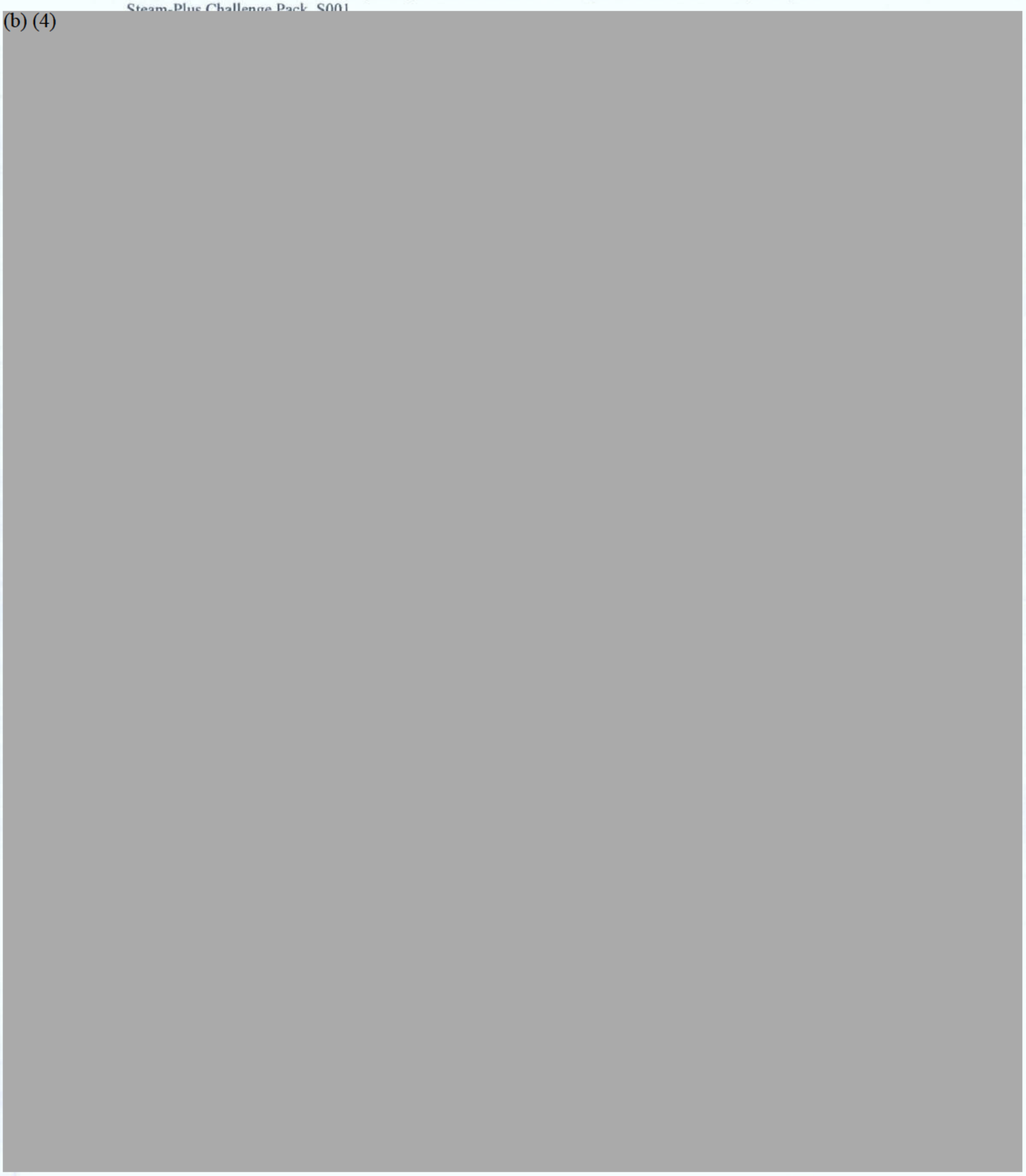

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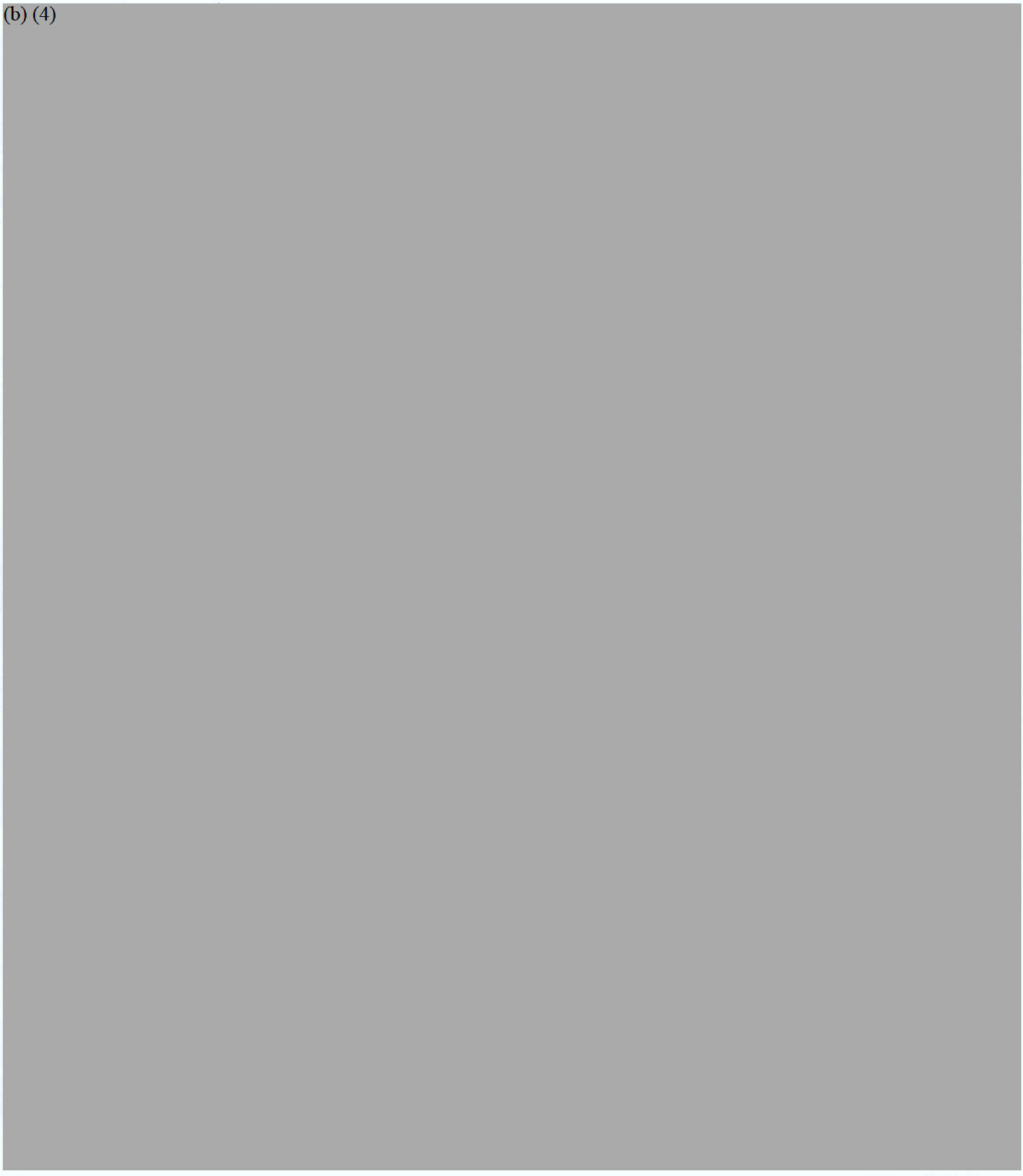

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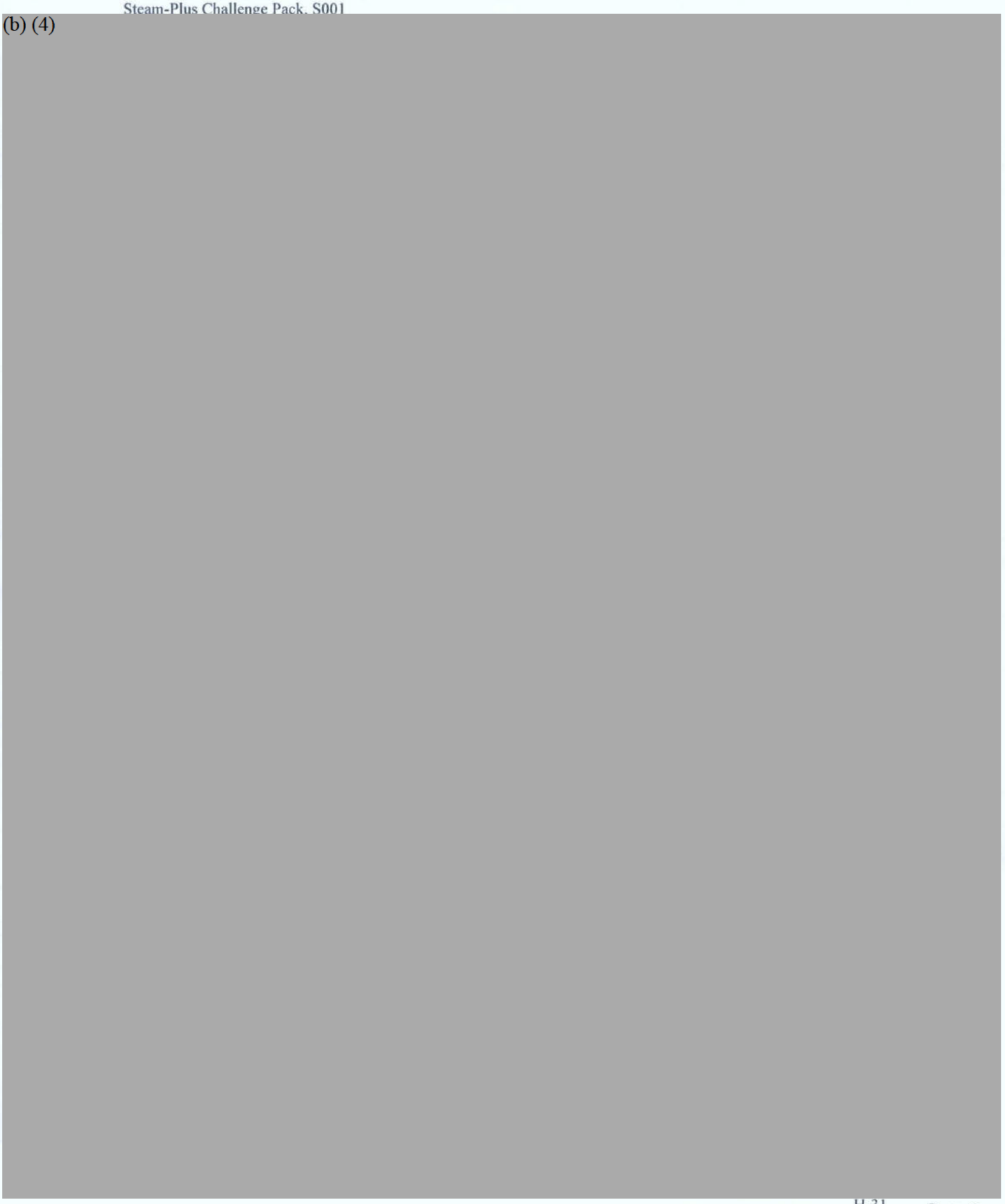

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