K171816

AliveCor®

June 16, 2017

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

RE: Traditional 510(k) Premarket Notification for the Kardia Band System, 21 CFR§870.2920, Transmitters and Receivers, Electrocardiograph, Telephone, Class II, Cardiovascular Devices

Dear Sir/Madam:

AliveCor, Inc. ("AliveCor") is seeking FDA clearance to market and commercially distribute a new device, the Kardia Band System, in the United States. In accordance with 21 CFR§807.90(e), enclosed are two copies (1 paper, 1 electronic) of a Traditional 510(k) Premarket Notification for the Kardia Band System.

AliveCor is submitting a new device to enable use of AliveCor's proprietary electrocardiogram (ECG) recording and analysis solutions with the Apple Watch. The Kardia Band System consists of the Kardia Band Hardware (watchband), Kardia watch app software (installed on the Apple Watch), and the Kardia phone app software (installed on the Apple iPhone). AliveCor's most recent cleared device, Kardia Mobile (K142743) is the predicate for the Kardia Band System as the devices have the same intended use and indications for use and similar technological characteristics including the same mechanism for recording and analyzing ECG. This submission contains performance testing to address technological differences between the proposed and predicate devices.

The Kardia Band System is a new device with no pending PMA submission. There were two prior submissions for the Kardia Band System, K160404 and an informational pre-submission meeting, Q170282. K160404 resulted in a not substantially equivalent (NSE) determination and this new Traditional 510(k) includes the responses to the NSE letter (Appendix 1- Prior Submission Information). The meeting minutes from the Pre-Submission Meeting (Q170282) are also provided for the reviewer's convenience in Appendix 1- Prior Submission Information.

AliveCor is enclosing an electronic copy of this submission on a CD in accordance with FDA's "Guidance for Industry and Food and Drug Administration Staff, eCopy Program for Medical Device Submissions", dated December 3, 2015. The electronic copy is an exact duplicate of the paper copy; however, minor formatting changes may have been introduced as a result of the PDF conversions. For the reviewer's convenience, the electronic PDF copy can be searched using standard Adobe Acrobat Document Reader programs and includes electronic bookmarks outlining the structure of the submission

including all appendices. Clicking on a specific bookmark title directs the reviewer to the appropriate section of the submission.

This premarket notification has been formatted in compliance with FDA's August 12, 2005 guidance document titled, "Guidance for Industry and Staff: Format for Traditional and Abbreviated 510(k)s". Additionally, the principal factors about the design and use of the Kardia Band System are outlined in the following table.

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

This submission contains technical, commercial and confidential trade secret information, and AliveCor, Inc. respectfully requests the maximum confidentiality protection provided by law, in accordance with 21 CFR§807.95.

Thank you in advance for your review of this submission. If you have any questions, please contact me by phone at 408-400-0856 (office), or 408-204-3370 (mobile), or by email at anna@experiengroup.com.

Sincerely,

Anna Libman
Regulatory Consultant to AliveCor, Inc.
Senior Manager, Regulatory Affairs, Experien Group, LLC

Enclosures,
Simon Prakash, VP Product and Design, AliveCor, Inc.

510(k) PREMARKET NOTIFICATION
FOR THE
KARDIA BAND SYSTEM

JUNE 16, 2017

ALIVECOR, INC.
444 CASTRO STREET, SUITE 600
MOUNTAIN VIEW, CA 94041

PREPARED BY:

EXPERIEN GROUP

SECTION 1
MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

The Medical Device User Fee Cover Sheet (Form FDA 3601) is provided in this section.

Form Approved OMB No. 0910-0511 Expiration Date August 31, 2019. 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 your check.

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
ALIVECOR INC Suit 600 Mountain View CA 94041 US	Arezou Azar
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1679	2.1 E-MAIL ADDRESS RA@alivecor.com 2.2 TELEPHONE NUMBER (include Area code) 650-8040285 2.3 FACSIMILE (FAX) NUMBER (Include 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center

[X] CDRH
[ ] CBER

3.2 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 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 your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)

[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm 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, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

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

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) 26-Apr-2017

"Close Window" Print Cover sheet

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/ CDRH 510(k) REFUSE TO ACCEPT CHECKLIST

In this section, please find the following:

- CDRH Premarket Review Submission Cover Sheet (FDA Form 3514, Expiration Date: December 31, 2013).
- Acceptance Checklist for Traditional 510(k)s taken from the FDA's August 4, 2015 guidance document entitled "Refuse to Accept Policy for 510(k)s". For the reviewer's convenience, the item's location in the submission is indicated.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/15/2017	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ 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	Establishment Registration Number *(if known)*		
AliveCor, Inc	3009715978		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	650-396-8553		
Street Address	**FAX Number *(including area code)***		
444 Castro Street, Suite 600	650-282-7932		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Mountain View	CA	94041	USA
Contact Name			
Arezou Azar			
Contact Title	**Contact E-mail Address**		
Director, Product Compliance Management, Regulatory Affairs, Quality Eng	RA@alivecor.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Experien Group, LLC			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	408-400-0856		
Street Address	**FAX Number *(including area code)***		
224 Airport Parkway, Suite 250	408-400-0865		
City	**State / Province**	**ZIP Code**	**Country**
San Jose	CA	95110	USA
Contact Name			
Anna Libman			
Contact Title	**Contact E-mail Address**		
Senior Manager, Regulatory Affairs	anna@experiengroup.com		

PSC Publishing Services (301) 443-6740 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	DXH	2	DPS	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*
1	K142743	1	Kardia Mobile	1	AliveCor, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Transmitters and Receivers, Electrocardiograph, Telephone

	Trade or Proprietary or Model Name for This Device		Model Number
1	Kardia Band System	1	AC-011
2		2	
3		3	
4		4	
5		5	

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

1	K160404 (NSE)	2	Q170282	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
DXH, DPS	870.2920	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Cardiovascular		

Indications *(from labeling)*

The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	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 Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number

(b) (4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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 Sterilizer ☐ Contract Manufacturer ☐ 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

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.					
1	Standards No. 60601-1	Standards Organization IEC	Standards Title Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	Version 2012	Date 12/05/2005
2	Standards No. 60601-1-2	Standards Organization IEC	Standards Title Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests	Version 2014	Date 02/25/2014
3	Standards No. 60601-2-47	Standards Organization IEC	Standards Title Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems	Version 2012	Date 02/16/2012
4	Standards No. 10993-1	Standards Organization ISO	Standards Title Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process	Version 2009	Date 10/15/2009
5	Standards No. 14971	Standards Organization ISO	Standards Title Medical Devices – Application of Risk Management to Medical Devices	Version 2012	Date 07/31/2012
6	Standards No. 15223-1	Standards Organization ISO	Standards Title Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	Version 2012	Date 07/01/2012
7	Standards No. 62304	Standards Organization IEC	Standards Title Medical device software – Software Lifecycle Processes	Version 2006	Date 05/09/2006

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
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.

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: K_____ Date Received by DCC: _____

Lead Reviewer Name: _____ Branch: ____ Division: ____ Center/Office: _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA review and that element will be assessed during substantive review.

Preliminary Questions Answers in the shaded blocks indicate consultation with Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. Provide a summary of the Jurisdictional Officer's/Liaison's determination. If the product does not appear to be a device or such a combination product, mark "No."	√		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide a summary of the Jurisdictional Officer's/Liaison's determination. If submission should not be reviewed by your Center mark "No."	√		
Comments:			

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/ CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

Preliminary Questions (cont.)			
Answers in the shaded blocks indicate consultation with Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	**Yes**	**No**	**N/A**
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			√
Comments:			
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	√		
Comments:			
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		√	
Comments:			
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at **http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.** If no clinical studies have been submitted, mark "N/A."		√	

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

Organizational Elements *Failure to include these items should not result in an RTA designation.*			
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	**Yes**	**No**	***Page #**
1. Submission contains a Table of Contents	☒	☐	33
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☒	☐	All
c. All pages of the submission are numbered. All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).	☒	☐	All
d. Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	5, 31
Comments:			

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/ CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
• Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			**Yes**	**No**	**N/A**	***Page #**
A.	Administrative					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).	☒	☐		All
		Comments:				
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):				
		a. Device trade/proprietary name	☒	☐		7, 35
		b. Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☒	☐		7, 35
		Comments:				
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).	☒	☐		38
		Comments:				
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*	☒	☐		40-43
		Comments:				
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). See recommended format (http://www fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707 htm).	☒	☐		45
		Comments:				

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/ CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
	6.		Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*	☐		☒	
		a.	Contains Class III Summary and Certification *See recommended content (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm).* *Select "N/A" only if submission is not a Class III 510(k).*	☐	☐	☒	
		Comments:					
	7.		Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.*	☒		☐	115-117 A10-1 to A10-114
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry- Financial Disclosures by Clinical Investigators.*	☒	☐	☐	49
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☒	☐	☐	120-121
		Comments:					
	8.		The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514).	☒	☐		7, 31

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

		This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).					
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☒	☐	☐	A1-1 to A1-97
		Comments:					
B.	**Device Description**						
	9.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☒	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☐	☐	☐	

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

			Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review				
		Comments:					
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☒	☐		54-73
		Comments:					
	11.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐		63-66
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐		54
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☐	☐	☒	
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). I*n lieu of engineering drawings, schematics, etc. of each device to be marketed," representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*	☒	☐		A2-1 to A2-7
		Comments:					
	12.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.*		☒		☐	55-73
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☒	☐		54

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/ CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

		b.	Submission includes a description (as detailed in item 11a., 11b., and 11d. above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☒	☐	☐	55-73
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	☒	☐		55-73
		Comments:					
C.	**Substantial Equivalence Discussion**						
	13.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	☒	☐		7, 74-82
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☒	☐		All
		Comments:					
	14.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☒	☐		77-78

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

		b.	Technology, including features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.*	☒	☐		75-82
		Comments:					
D.	**Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)**						
	15.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☒	☐		83, A3-1 to A3-47
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☒	☐		7, 38, A3-2, A3-7
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** o Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐		A3-2 to A3-3, A3-6 to A3-8
		Comments:					
	16.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)		☒	☐		A3-2, A3-31
		Comments:					
	17.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements"). *Select "N/A" if not indicated for prescription use.*		☐	☒	☐	
		Comments:					
	18.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☒	

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
	19.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. Select "N/A" if not an in vitro diagnostic device.		☐	☐	☒	
E.	**Sterilization** *If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*					☐	
	Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked) ☐ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☒ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				☐		84

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

	If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist. *If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."* *The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:* • *Supplied sterile and requires reprocessing prior to subsequent patient use* • *Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use* • *Reusable medical device (single-user) reprocessed between each use* • *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use* *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*						
		Comments:					
	20.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.					
		a.	Identification of device, and/or accessories, and/or components that are provided sterile. *Select "N/A" if no part of the device, accessories, or components is provided sterile.*	☐	☐	☒	
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected. *Select "N/A" if no part of the device, accessories, or components is end user sterilized or disinfected.*	☐	☐	☒	
		c.	Identification of device, and/or accessories, and/or components that are reusable. *Select "N/A" if no part of the device, accessories, or components is reusable.*	☒	☐	☐	54-73
		Comments:					
	21.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*			☒		
		a.	Sterilization method is stated for each component (including dose for radiation sterilization)	☐	☐		
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). *Note: the sterilization validation report is not required.*	☐	☐		
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	☐	☐	☐	

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

			Select "N/A" if not sterilized using chemical sterilants.					
		d.	Sterility Assurance Level (SAL) stated	☐	☐			
		e.	Submission includes description of packaging	☐	☐			
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*	☐	☐	☐		
		Comments:						
	22.	If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device, accessories, or components are reusable or end user sterilized or disinfected, otherwise complete a-d below.*				☐		
		a.	Cleaning method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization*	☒	☐	☐	A3-3, A3-11	
		b.	Disinfection method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use*	☐	☐	☒		
		c.	Sterilization method is provided in labeling for each device and/or accessory, and/or component. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use*	☐	☐	☒		
		d.	Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." *Device types identified in Appendix E of the reprocessing guidance represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*	☐		☒		
			i. If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*	☐	☐	☒		
		Comments:						
	23.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device		☐		☒		

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

		If "N/A" is selected, parts a and b below are omitted from the checklist.					
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
F.	**Shelf Life**						
	24.	Proposed shelf life/ expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐		84-85
		Comments:					
	25.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☐	☐	☒	
		Comments:					
	26.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR**	☒	☐		84-85

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

		Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.				
		Comments:				
G.		**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*			☐	
		Submission states that there: (one of the below must be checked) ☒ Are direct or indirect patient-contacting components ☐ Are no direct or indirect patient-contacting components ☐ Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Patient contact information not needed for this device (e.g., software-only device) ☐ Patient contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the patient-contact status is not provided, and contact information is needed or its contact status is unclear, select "No."* *An example of a direct patient-contacting device would be an implant that has direct contact with patient tissues during use. An example of an indirect patient-contacting device would be fluid entering the patient's body following passing through device/device components not in direct contact with the patient.*		☐		86
		Comments:				
	27.	Submission includes a list identifying each patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		86
		Comments:				
	28.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter).	☒	☐		86
		Comments:				
	29.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. OR A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		A5-1 to A5-58
		Comments:				

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

H.	**Software**					
	Submission states that the device: (one of the below must be checked) ☒ Does contain software/firmware ☐ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*		☐		
	Comments:					
	30.	Submission includes a statement of software level of concern and rationale for the software level of concern	☒	☐		87-100
		Comments:				
	31.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	☒	☐		A6-1 to A6-164
		Comments:				
I.	**EMC and Electrical Safety**					
	Electrical Safety: Submission states that the device: (one of the below must be checked) ☒ Does require electrical safety evaluation ☐ Does not require electrical safety evaluation ☐ Information on whether device requires electrical safety evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.			☐		101-107

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

	If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."					
	Comments:					
	32.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		A7-1 to A7-229
		Comments:				
	EMC: Submission states that the device: (one of the below must be checked) ☒ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."*			☐		101-107
	Comments:					
	33.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		A7-1 to A7-229
		Comments:				
J.	**Performance Data – General**				☐	

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

	If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐	☐	☐	
	Comments:						
	34.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*		☒	☐	☐	A8-1 toA8-190, A9-1 to A9-21
		a.	Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). *Select "N/A" if the submission does not include performance data.*	☒	☐	☐	108-113
		Comments:					
	35.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding performance data that is applicable to the subject device *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☒	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☐	☐	☐	

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

			Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.				
		Comments:					
	36.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A" is selected, parts a and b below are omitted from the checklist.* *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*				☒	
		a.	Legible reprints or a summary of each article.	☐	☐		
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☐		
		Comments:					
	37.	For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A" is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*				☒	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐	☐		
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☐		
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐	☐		
		Comments:					
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						
	Submission indicates that device: (one of the below must be checked) ☐ Is an in vitro diagnostic device ☒ Is not an in vitro diagnostic device						

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

	If "is not" is selected, the performance data-related criteria below are omitted from the checklist.						
	38.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
		a.	Precision/reproducibility	☐	☐	☐	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☐	☐	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐	
		d.	Analytical specificity	☐	☐	☐	
		Comments:					
	39.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulations regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐	☐	☐	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such*	☐	☐	☐	

SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET/
CDRH ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(k)s (CONT.)

			mitigation measures have been addressed should be assessed during the substantive review.				
		Comments:					

Decision: Accept ___ Refuse to Accept ___

If Accept, notify applicant

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

*Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

SECTION 3
510(K) COVER LETTER/TABLE OF CONTENTS
/GENERAL INFORMATION

AliveCor®

June 16, 2017

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

RE: Traditional 510(k) Premarket Notification for the Kardia Band System, 21 CFR§870.2920, Transmitters and Receivers, Electrocardiograph, Telephone, Class II, Cardiovascular Devices

Dear Sir/Madam:

AliveCor, Inc. ("AliveCor") is seeking FDA clearance to market and commercially distribute a new device, the Kardia Band System, in the United States. In accordance with 21 CFR§807.90(e), enclosed are two copies (1 paper, 1 electronic) of a Traditional 510(k) Premarket Notification for the Kardia Band System.

AliveCor is submitting a new device to enable use of AliveCor's proprietary electrocardiogram (ECG) recording and analysis solutions with the Apple Watch. The Kardia Band System consists of the Kardia Band Hardware (watchband), Kardia watch app software (installed on the Apple Watch), and the Kardia phone app software (installed on the Apple iPhone). AliveCor's most recent cleared device, Kardia Mobile (K142743) is the predicate for the Kardia Band System as the devices have the same intended use and indications for use and similar technological characteristics including the same mechanism for recording and analyzing ECG. This submission contains performance testing to address technological differences between the proposed and predicate devices.

(b) (4)

AliveCor is enclosing an electronic copy of this submission on a CD in accordance with FDA's "Guidance for Industry and Food and Drug Administration Staff, eCopy Program for Medical Device Submissions", dated December 3, 2015. The electronic copy is an exact duplicate of the paper copy; however, minor formatting changes may have been introduced as a result of the PDF conversions. For the reviewer's convenience, the electronic PDF copy can be searched using standard Adobe Acrobat Document Reader programs and includes electronic bookmarks outlining the structure of the submission

including all appendices. Clicking on a specific bookmark title directs the reviewer to the appropriate section of the submission.

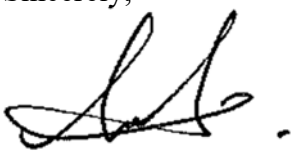
This premarket notification has been formatted in compliance with FDA's August 12, 2005 guidance document titled, "Guidance for Industry and Staff: Format for Traditional and Abbreviated 510(k)s". Additionally, the principal factors about the design and use of the Kardia Band System are outlined in the following table.

Question	**Yes**	**No**
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

This submission contains technical, commercial and confidential trade secret information, and AliveCor, Inc. respectfully requests the maximum confidentiality protection provided by law, in accordance with 21 CFR§807.95.

Thank you in advance for your review of this submission. If you have any questions, please contact me by phone at 408-400-0856 (office), or 408-204-3370 (mobile), or by email at anna@experiengroup.com.

Sincerely,



Anna Libman
Regulatory Consultant to AliveCor, Inc.
Senior Manager, Regulatory Affairs, Experien Group, LLC

Enclosures,
Simon Prakash, VP Product and Design, AliveCor, Inc.

SECTION 3
510(K) COVER LETTER / TABLE OF CONTENTS / GENERAL INFORMATION (CONT.)

TABLE OF CONTENTS

SECTION 3
510(K) COVER LETTER / TABLE OF CONTENTS / GENERAL INFORMATION (CONT.)

APPENDICES

SECTION 3
510(k) COVER LETTER / TABLE OF CONTENTS / GENERAL INFORMATION (CONT.)

Applicant:
AliveCor, Inc.
444 Castro Street, Suite 600
Mountain View, CA 94041
Phone: 650-396-8553
Fax: 650-282-7932

Applicant Contact Person:
Anna Libman
Regulatory Consultant to AliveCor, Inc.
Senior Manager, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110 USA
Phone: 408-400-0856
Fax: 408-400-0865
Email: anna@experiengroup.com

Trade Name:
Kardia Band System

Generic/Common Name:
Telephone electrocardiograph transmitter and receiver

Classification:
21 CFR§870.2920, Transmitters and Receivers, Electrocardiograph, Telephone, Class II

Product Code:
DXH, DPS

Establishment Registration:
3009715978

Manufacturing Facility:
(b) (4)

SECTION 3
510(k) COVER LETTER / TABLE OF CONTENTS / GENERAL INFORMATION (CONT.)

Reason for Premarket Notification:

The purpose of this premarket notification is to obtain clearance to market a new device, the Kardia Band System, that is substantially equivalent to a predicate device currently on the market.

Substantial Equivalence:

The indications for use for the Kardia Band System is substantially equivalent to the indications for use for the predicate device. Any differences in the technological characteristics between the devices do not raise any different questions of safety or efficacy. Thus, the Kardia Band System is substantially equivalent to the predicate device.

SECTION 4
INDICATIONS FOR USE STATEMENT (FORM FDA 3881)

The Indications for Use form (FDA Form 3881, Expiration Date: January 31, 2017) is provided in this section.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Kardia Band System

Indications for Use *(Describe)*

The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

SECTION 5
510(K) SUMMARY

This summary of the 510(k) premarket notification for the Kardia Band System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

510(k) Notification K_____

GENERAL INFORMATION

Applicant:

AliveCor, Inc.
444 Castro Street, Suite 600
Mountain View, CA 94041
Phone: 650-396-8553
Fax: 650-282-7932

Applicant Contact Person:

Anna Libman
Regulatory Consultant to AliveCor, Inc.
Senior Manager, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110 USA
Phone: 408-400-0856
Fax: 408-400-0865
Email: anna@experiengroup.com

Date Prepared:

June 16, 2017

DEVICE INFORMATION

Trade Name:

Kardia Band System

Generic/Common Name:

Telephone electrocardiograph transmitter and receiver

Classification:

21 CFR§870.2920, Transmitters and Receivers, Electrocardiograph, Telephone, Class II

Product Code:

DXH, DPS

PREDICATE DEVICE(S)

- K142743 – AliveCor Heart Monitor (also known as Kardia Mobile)

INDICATIONS FOR USE

The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.

DEVICE DESCRIPTION

The Kardia Band System is a trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorder that records, stores and transfers single-channel electrocardiogram rhythms. The device utilizes the computing power of the Apple, Inc. Apple Watch to obtain and analyze single-channel ECG. The Kardia Band System consists of the Kardia Band Hardware (watchband), the Kardia watch app software (installed on the Apple Watch), and the Kardia phone app software (installed on the Apple iPhone). The Kardia Band System transmits the ECG signal from its electrode to the Kardia watch app on the Apple Watch to be analyzed and presented to the user. All ECGs are synced with the user's account.

Physical and Technological Characteristics of the Kardia Band System

Feature	Kardia Band System	Kardia Mobile K142743
Product Code	DXH, DPS	Same
Mechanism of Action	(b) (4)	Same
Where used (intended use)		Same
Anatomical sites		Left hand fingers to right hand fingers
Data Acquisition: Frequency Response		Same
ECG channels		
Resolution		
Sample Rate		
Memory Capacity:		Same

510(k) SUMMARY

Feature	Kardia Band System	Kardia Mobile K142743
Number of ECG Leads	(b) (4)	Same
Power Supply: Battery Battery Life (typical)	(b) (4)	Same
User Interface: Primary Lead Data acquisition Hardware Software interface	(b) (4)	Same Same iPhone Case and Universal Module Apple iOS based software
Physical Specs: Dimensions Weight	(b) (4)	118 x 62 x 16.5 mm 40 grams
Prescribed:	(b) (4)	Same
Environmental: Operating Temp Storage Temp	(b) (4)	Same
Communications	(b) (4)	Ultrasonic Acoustics acquired by phone

SUBSTANTIAL EQUIVALENCE

The Kardia Band System is substantially equivalent to the previously cleared Kardia Mobile product (AliveCor Heart Monitor hardware and software (K142743), also known as Kardia Mobile). The new Kardia Band System has been redesigned to fit on an Apple Watch band and has the same intended use and similar technological characteristics as those of the predicate device. Differences in technological characteristics have been evaluated through performance testing, and therefore the proposed device is substantially equivalent to the predicate device.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the Kardia Band System to support a determination of substantial equivalence to the predicate device. This testing included testing to the following standards: IEC 60601-1:2012 *Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance*, IEC 60601-1-2:2014 *Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests*, and IEC 60601-2-47:2012 *Medical Electrical Equipment* --

Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems. The collective results of the non-clinical testing demonstrate that the Kardia Band System meets the established specifications and complies with the aforementioned standards.

CLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Clinical performance testing was conducted to demonstrate that the AliveCor Kardia Band System generates rhythm strip data that meets the clinical quality requirements for accurate cardiac rhythm diagnosis.

The presented data shows very strong mathematical correlation and qualitative clinical equivalence. The study is sufficient to draw a conclusion of substantial equivalence based on meeting qualitative and quantitative acceptance criteria.

CONCLUSION

The results of both clinical and nonclinical testing demonstrate that the Kardia Band System is substantially equivalent to the predicate device.

SECTION 6
TRUTHFUL AND ACCURATE STATEMENT/CONFIDENTIALITY STATEMENT

6.1 TRUTHFUL AND ACCURATE STATEMENT

6.2 CONFIDENTIALITY STATEMENT

SECTION 6.1
TRUTHFUL AND ACCURATE STATEMENT

510(k) PREMARKET NOTIFICATION
FOR THE
ALIVECOR, INC.
KARDIA BAND SYSTEM
PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(AS REQUIRED BY 21 CFR 807.87(K))

I certify that, in my capacity as Chief Executive Officer of AliveCor Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

DocuSigned by:
Vic Gundotra
9F7F7902D98D40C...

6/13/2017

Vic Gundotra
Chief Executive Officer
AliveCor, Inc.

Date

K_____
Premarket Notification [510(k) Number]

510(k) PREMARKET NOTIFICATION
FOR THE
ALIVECOR, INC.
KARDIA BAND SYSTEM
CONFIDENTIALITY STATEMENT

AliveCor, Inc. considers the information in this submission to be confidential commercial information, and we have taken precautions to protect the confidentiality of this information under 21 CFR§807.95, Confidentiality of Information. We respectfully request that this notification and proprietary information herein be treated as confidential in accordance with the Freedom of Information Act.

SECTION 7
CLASS III PRODUCT SUMMARY AND CERTIFICATION

Because the Kardia Band System is not a Class III device, and is not substantially equivalent to a Class III device, the Literature Search and Certification requirement of the Safe Medical Devices Amendments (SMDA) of 1990 is not applicable.

SECTION 8
FINANCIAL CERTIFICATION/DISCLOSURE STATEMENT

The Disclosure Forms of Financial Interests and Arrangements of Clinical Investigators are shown on the following pages.

We include FDA Form 3454 for investigators and staff who have not entered into financial arrangements with AliveCor, Inc. None of the investigators involved have entered into financial arrangements with AliveCor, Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: March 31, 2019

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	D. Albert M.D.	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Vic Gundotra	Chief Executive Officer
FIRM/ORGANIZATION: AliveCor, Inc.	
SIGNATURE: DocuSigned by: Vic Gundotra 9F7F7902D98D40C...	DATE *(mm/dd/yyyy)*: 6/13/2017

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

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

Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Operations
PRAStaff@fda.hhs.gov

"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 number."

SECTION 9
DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

Not applicable, as this application is not being submitted as an Abbreviated 510(k). Standards Data Report forms (FDA Form 3654) are provided in Appendix 11.

SECTION 10
EXECUTIVE SUMMARY

10.1 DEVICE DESCRIPTION

The Kardia Band System is a trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorder that records, stores and transfers single-channel electrocardiogram rhythms. The device utilizes the computing power of the Apple, Inc. Apple Watch to obtain and analyze single-channel ECG. The Kardia Band System consists of the Kardia Band Hardware (watchband), the Kardia watch app (installed on the Apple Watch), and the Kardia phone app (installed on the Apple iPhone). The Kardia Band System uses a proprietary method of data transmission using acoustic waves in the inaudible ultrasonic wavelength. The Kardia Band System transmits the ECG signal from its electrode to the Kardia watch app on the Apple Watch to be analyzed and presented to the user. All ECGs are synced with the user's account.

10.2 INDICATIONS FOR USE

The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.

10.3 SUBSTANTIAL EQUIVALENCE

Legally marketed predicate device: AliveCor, Inc. Kardia Mobile K142743.

The Kardia Band System and the Kardia Mobile predicate device have the same intended use and indications for use and similar technological characteristics including the same mechanism for measuring ECG. Both devices collect single lead ECG, analyze, display, and store the data in the same intended user. Performance testing was conducted to validate the performance of the Kardia Band System and usability testing was performed to ensure that a representative user can use the device as intended. The results of the testing show that the device performs as intended and the differences in design including data acquisition and display do not raise different questions of safety or effectiveness as compared with the predicate device. Therefore, the Kardia Band System and predicate Kardia Mobile (K142743) are substantially equivalent. Please refer to Section 12: "Substantial Equivalence Discussion" for more details.

SECTION 10
EXECUTIVE SUMMARY (CONT.)

Table 10.1: Comparison Between Subject and Predicate Device

Feature	Predicate: AliveCor Mobile (K142743)	Subject: Kardia Band System
General		(b) (4)
Indications for Use	The AliveCor Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band ECG also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band ECG is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals.	
Anatomical sites	Left hand fingers to right hand fingers	
Technical Specifications		
User Interface: Primary Lead Data acquisition Hardware Software interface	 Lead I, Left to Right Ultrasonic acoustics iPhone Case and Universal Module Apple iOS based software	
Physical Specs: Dimensions Weight	 118 x 62 x 16.5 mm 40 grams	
Electrodes: Skin Contact Material Surface Area	Integrated into device Any part of hand (left to right) 304 Stainless Steel Coated > 3 cm^2	
Communications	Ultrasonic Acoustics acquired by phone	

10.4 PERFORMANCE TESTING

(b) (4)

SECTION 10
EXECUTIVE SUMMARY (CONT.)

(b) (4)

[redacted]

10.5 CONCLUSION

The Kardia Band System and the Kardia Mobile predicate device have the same intended use and indications for use, and similar technological characteristics. Performance testing provided in this submission verified and validated that the differences between the devices do not raise different questions of safety or effectiveness. Therefore, the Kardia Band System is substantially equivalent to the predicate device.

SECTION 11
DEVICE DESCRIPTION

11.1 INTRODUCTION

The Kardia Band System is a trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorder that records, stores and transfers single-channel electrocardiogram rhythms (See **Figure 11.1**). The device utilizes the computing power of the Apple, Inc. Apple Watch to obtain and analyze single-channel ECG. The Kardia Band System consists of the Kardia Band Hardware (watchband), the Kardia watch app (installed on the Apple Watch), and the Kardia phone app (installed on the Apple iPhone). The Kardia Band System uses a proprietary method of data transmission using acoustic waves in the inaudible ultrasonic wavelength. The Kardia Band System transmits the ECG signal from its electrode (in the Kardia Band Hardware) to the Kardia watch app on the Apple Watch to be analyzed and presented to the user.

The Kardia Band System is used with accessory secondary display devices known as Kardia Pro and the Consumer Portal. Kardia Pro provides clinician web access to data shared by the user (patient). The Consumer Portal provides user web access to his or her ECG data recorded with the Kardia Band System for convenience should the user prefer a computer screen display. The functionalities of Kardia Pro and the Consumer Portal meet the category of enforcement discretion (not regulated medical devices) per the FDA Guidance Document entitled, "Medical Device Data Systems and Mobile Medical Apps Guidance Document", issued on February 9, 2015. These two products are therefore referred to as "MDDS" or "Enforcement Discretion" products. These specific functions are presented further in this section.

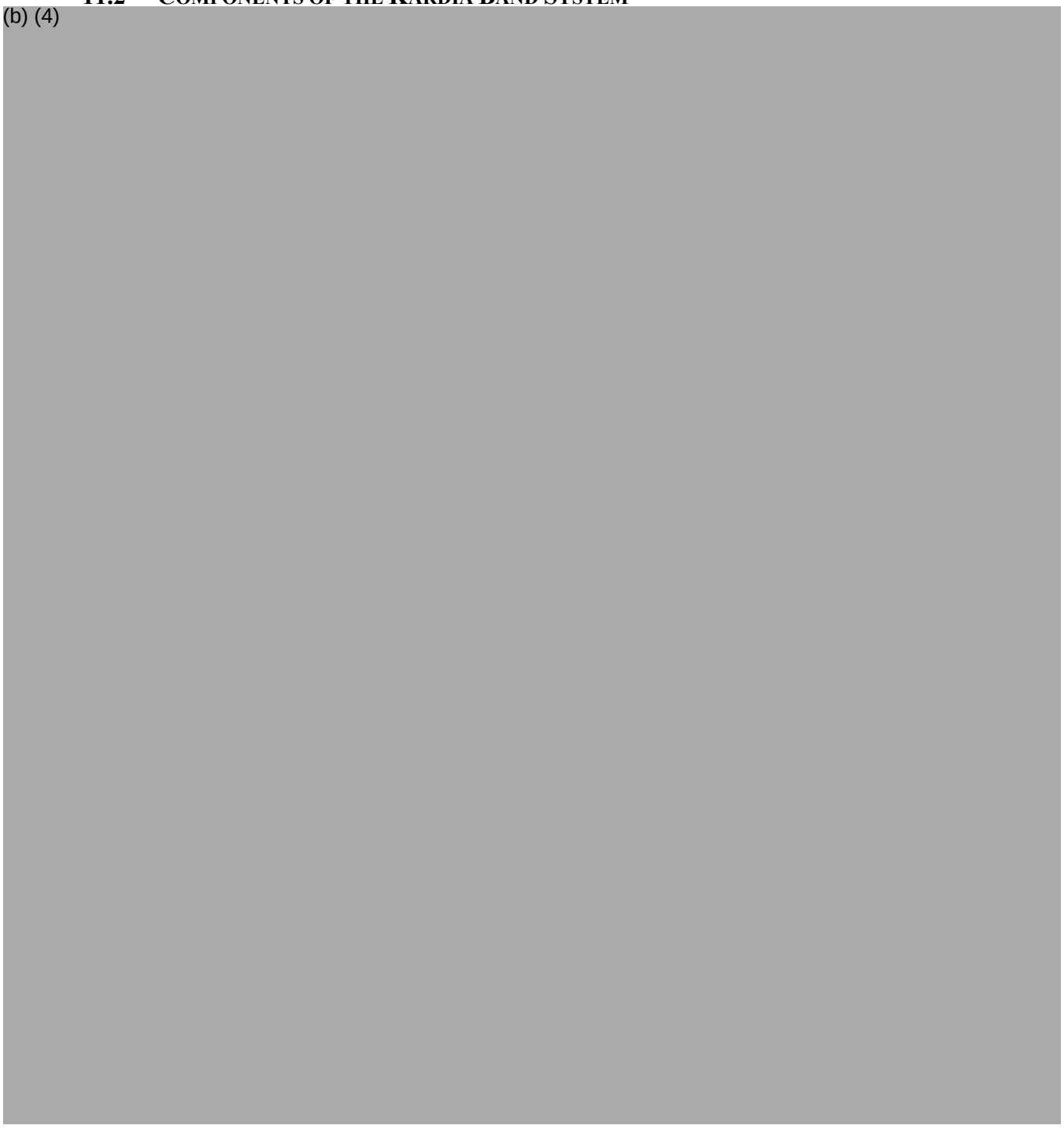
(b) (4)

Figure 11.1. Kardia Band System (left hand side) and Secondary Displays (right hand side)

SECTION 11
DEVICE DESCRIPTION (CONT.)

11.2 COMPONENTS OF THE KARDIA BAND SYSTEM

(b) (4)



SECTION 11
DEVICE DESCRIPTION (CONT.)

Figure 11.4. Kardia watch app

The Kardia Band Hardware is attached to the Apple Watch strap and worn on the wrist as are standard Apple Watch compatible watchbands. To record an ECG, the user opens the Kardia watch app on the Apple Watch, taps the button to begin a recording, and then places his or her opposing thumb on the exposed Sensor of the Kardia Band electrode to record a Lead 1 ECG (**Figure 11.5**). The Kardia Band uses the same proprietary acoustic waves method of data transmission that is used by all the models in the AliveCor Mobile ECG family (including latest clearance under K142743).

Figure 11.5. Recording an ECG with the Kardia Band System

SECTION 11
DEVICE DESCRIPTION (CONT.)

11.2.1. KARDIA BAND HARDWARE (HARDWARE)

(b) (4)

SECTION 11
DEVICE DESCRIPTION (CONT.)

(b) (4)

SECTION 11
DEVICE DESCRIPTION (CONT.)

(b) (4)

11.3 KARDIA WATCH APP – ECG RECORDING, DISPLAY AND ANALYSIS

The Kardia Band System is primarily used to record ECG and receive an analysis of the recording. The device's key functionalities are listed below:

- Acquisition of the ECG data wirelessly (audio) from the Kardia Band Hardware
- Display of ECG data on the MCPs screen for users under the care of a physician
- De-noising of ECG signal (Enhanced Filter)
- Detection of Atrial Fibrillation (AF Algorithm)
- Detection of Normal ECGs (Normal Algorithm)
- Detection of Interference (Interference Algorithm)

Tapping the Kardia app logo on the Apple Watch screen launches the Kardia watch app (**Figure 11.8)**.

SECTION 11
DEVICE DESCRIPTION (CONT.)

Figure 11.8. Kardia watch app Home Screen

Tapping the "Record EKG" button allows the user to record an ECG. To take an ECG recording, the user is presented with a step by step guidance on the Kardia watch app, as presented in **Figure 11.9**. The user takes a 35 second recording by using a finger from the opposite hand and pressing on the Kardia Band.

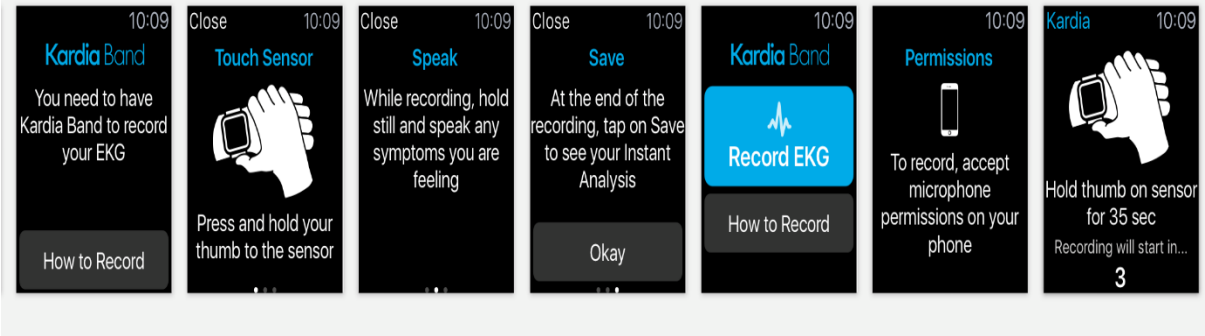


Figure 11.9. Take an ECG recording for new Kardia Band users

After saving the recording, the ECG is analyzed by the Kardia watch app on the Apple Watch to determine if 1) it is at least 30 seconds long, 2) it is Normal, 3) it is Unclassified, 4) Atrial Fibrillation is present, or 5) it is too noisy to interpret (**Figure 11.10**).

SECTION 11
DEVICE DESCRIPTION (CONT.)

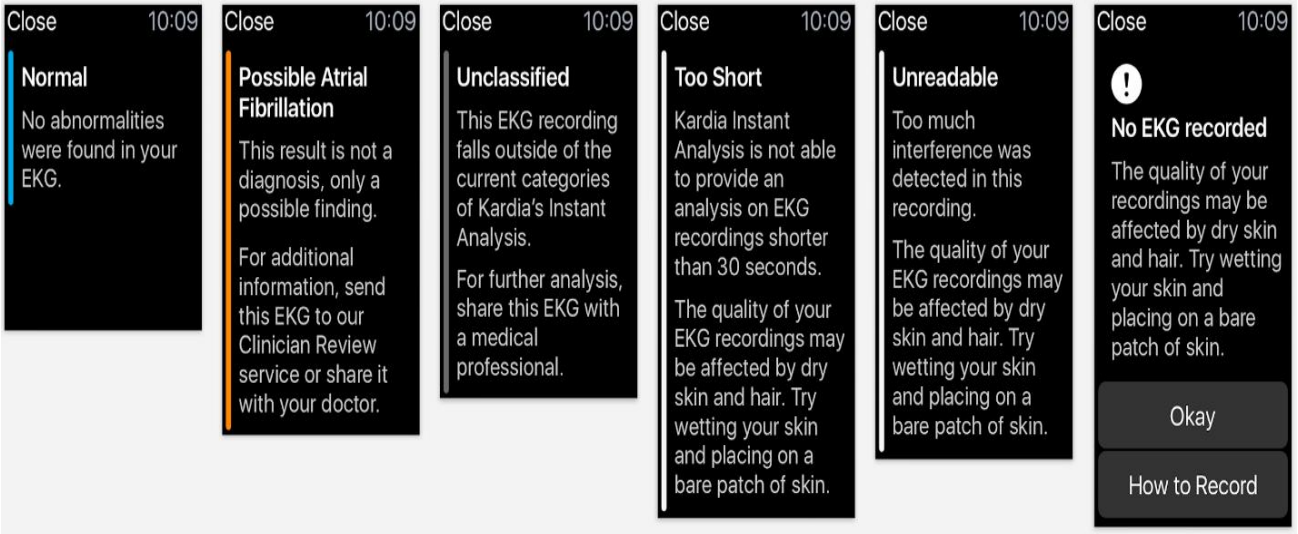


Figure 11.10. Different type of sceens that the user could see as result of their ECG analysis

Only one of the possible results listed in **Figure 11.10** will be shown to the user on the Apple Watch as result of each ECG analysis. Users may scroll through the length of their ECG recording (**Figure 11.11**), once the analysis has been presented to them.

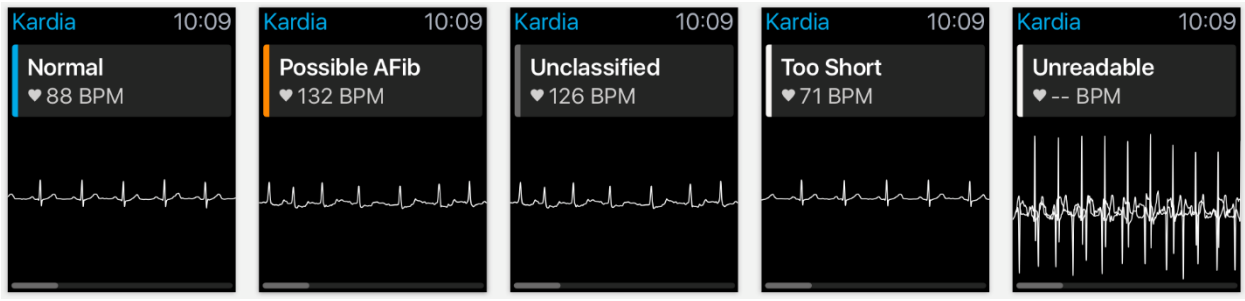


Figure 11.11. ECG Review Screen and Analysis results Kardia Band Hardware

Also, the recorded ECG and the results of the analysis are stored on the watch. These data are sent to the Kardia phone app via Bluetooth connectivity and additionally synced to the Kardia User account to be displayed on the Kardia Pro clinician web portal and Consumer Portal user web portal.

SECTION 11
DEVICE DESCRIPTION (CONT.)

11.4 KARDIA PHONE APP – ACCOUNT SETUP

The Kardia phone app is installed on the Apple iPhone and supports the onboarding process during set-up of the Kardia Band System for recording ECG. It also functions as a secondary display and data transmission source. Due to limitations in the display size of the Apple Watch, AliveCor uses the Kardia phone app on the phone for account creation purposes. When a user launches their Kardia watch app on the watch, the Kardia watch app checks for an account upon launch. If the user does not have an AliveCor account, the user is directed to their Kardia phone app on the iPhone to setup their account (**Figure 11.12**).

Figure 11.12. New Account Screen

(b) (4)

SECTION 11
DEVICE DESCRIPTION (CONT.)

(b) (4)

(b) (4)

11.5 OPERATING PRINCIPLE AND DETAILED DESIGN DESCRIPTION

The Kardia Band Hardware communicates to the Apple Watch with an ultrasonic audio signal. It has high resolution analog-to-digital conversion processed by the

SECTION 11
DEVICE DESCRIPTION (CONT.)

Kardia watch app. The Apple Watch provides the computing power for the app to digitally filter the audio data and process it to then create a high-resolution human readable ECG strip.

Mobile Computing Platform (MCP)

The frequency modulated ultrasonic ECG signal is acquired by the built-in microphone on the Apple Watch (the MCP for Kardia Band System). The storage on the MCP is used for storing the ECG recordings, analysis and other data.

Software Design of the Kardia watch app

(b) (4)

Software Design of the Enhanced Filter

(b) (4)

Software Design of the AF Algorithm

(b) (4)

SECTION 11
DEVICE DESCRIPTION (CONT.)

(b) (4)

SECTION 11
DEVICE DESCRIPTION (CONT.)

(b) (4)

Software Design of the Noise Algorithm

(b) (4)

Software Design of the NSR Algorithm

(b) (4)

11.6 MEDICAL DEVICE AND MDDS/ENFORCEMENT DISCRETION FUNCTIONALITIES

The Kardia Band System's Kardia phone app has several features that are recognized under enforcement discretion based on FDA's Guidance Document titled "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Device" issued on February 9, 2015 and "Mobile Medical Apps" issued on February 9, 2015. Additionally, the Kardia Band System is used with other AliveCor products including AliveCor cloud servers, Consumer Portal and Kardia Pro, whose functionalities are defined as MDDS and Enforcement Discretion categories based on the FDA Guidance Documents, titled "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Device" issued on February 9, 2015 and "Mobile Medical Apps" issued on February 9, 2015. The functionalities for the Kardia Band System are listed below in Tables 11.1 and 11.2:

SECTION 11
DEVICE DESCRIPTION (CONT.)

Table 11.1 – Summary of Kardia Band Medical Device Features

(b) (4)

SECTION 11
DEVICE DESCRIPTION (CONT.)

Table 11.2: Summary of Enforcement Discretion/ MDDS Functionalities Kardia

(b) (4)

SECTION 11
DEVICE DESCRIPTION (CONT.)

11.7 OTC AND PRESCRIPTION USES

Like AliveCor's previously cleared devices K142743, K142672, and K140933, the Kardia Band System is indicated for Over-The-Counter and for Prescription use. The use of the device with both options is described below:

11.7.1. GENERAL USE SCENARIO – OVER-THE-COUNTER (OTC) MODE

(b) (4)

11.7.2. GENERAL USE SCENARIO – CONNECTED MODE

The Kardia Band System can be used in the Connected Mode. In this mode, the Kardia Band System is prescribed to the user by their physician. The user receives a "connection code" from their physician via email. This "connection code" is used during the onboarding process to connect to the physician facing app called Kardia Pro. Apart from entering the "connection code" during onboarding, the use scenario is the same as the Over-the-Counter Mode explained above. The benefit of this mode is that when connected, the ECG recordings can be viewed by the user's physician using the Kardia Pro web app.

11.8 INTERACTIONS WITH OTHER DEVICES ON A WIRELESS NETWORK

The Kardia phone app can be used to view data from third-party medical devices such as the Omron Blood Pressure cuff devices to serve as a secondary display of that device's data. The blood pressure data from the Omron device is transferred to the Kardia phone app via Bluetooth. The blood pressure data is only used for re-display purposes on the Kardia phone app. As a secondary display, it falls under MDDS as per FDA's Guidance Documents titled "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications

SECTION 11
DEVICE DESCRIPTION (CONT.)

Device" issued on February 9, 2015 and "Mobile Medical Apps" issued on February 9, 2015.

AliveCor ECG recordings are independent of the data transfer from Omron devices and both functions cannot be performed at the same time. AliveCor has performed testing to ensure that the ECG recording functionality is not affected by the data transfer functionality of Omron devices. Please see Section 18 for this wireless coexistence testing performed by AliveCor.

11.9 SPECIFICATIONS

(b) (4)

11.9.2. MCP COMPATIBILITY

The Kardia Band System is compatible with the Apple Watch running WatchOS 3.1.3. The Apple Watch comes in two sizes 38mm and 42mm, enabling fit to a variety of wrist sizes. As such, the Kardia Band System will be offered in 38mm and 42mm sizes.

All iPhones currently validated as compatible with AliveCor's proprietary audio signal are as follows:

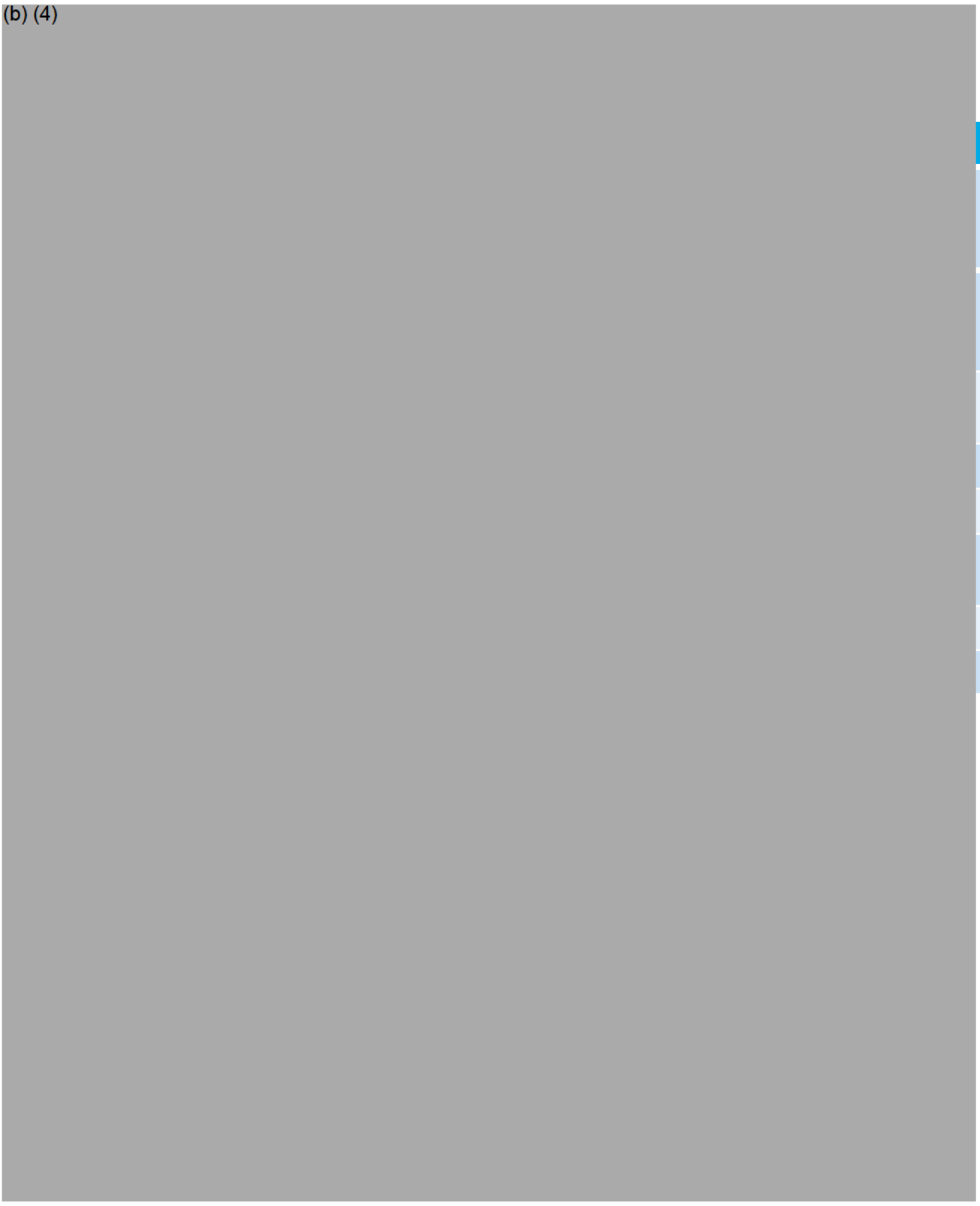
The Kardia phone app is compatible with (iOS versions).

- iPhone 4s (iOS 9.3.5), 5/5s/5c (iOS 10.0.2), 6/6 Plus (iOS 10.0.2), 6s/6s Plus (iOS 10.0.2), 7/7 Plus (iOS 10.0.2)
- iPad Air / Air 2 (iOS 9.3.5)
- iPad Mini (iOS 9.3.5), Mini 2 / 3 (iOS 10.0.2)
- iPod Touch 5G (iOS 9.3.5)

SECTION 11
DEVICE DESCRIPTION (CONT.)

11.9.3. COMMUNICATION PROTOCOL

(b) (4)



SECTION 11
DEVICE DESCRIPTION (CONT.)

(b) (4)

11.9.4. PERFORMANCE SPECIFICATIONS

The performance specifications for the Kardia Band System are presented below and engineering drawings for the Kardia Band are provided in Appendix 2- Engineering Drawings.

Performance Characteristics

ECG Channel ..... Single Channel

Input Dynamic Range ..... 10mV Peak-to-Peak

Memory length ..... Practically Unlimited

Recording Format ..... Continuous

Shelf Life ..... Estimated 2 years

SECTION 11
DEVICE DESCRIPTION (CONT.)

Circuitry

Frequency Response ..... 0.5 Hz to 40 Hz

CMRR 76dB

Input Impedance ..... > 100 MOhm

Differential Range ..... +/- 5 mV

A/D Sampling Rate ..... 300 samples/second

Resolution ..... 16 bit

DC Offset Correction ..... +/- 300 mV

Output

Modulation ..... Frequency Modulated Ultrasonic Audio Tone

Center Frequency ..... 19 kHz

Frequency Deviation ..... 200 Hz/mV

Power Requirements

Battery Type ..... Lithium Manganese-Dioxide 3V Coin Cell

Battery life ..... 100 Hours Operational Time, 12-months typical use

Physical Characteristics

Sensor ..... 9 grams 24.5 x 24.5 x 6.5 mm 3cm2 electrode area

Environmental Specifications

Operational Temperature ..... +10 to +45 degrees C

Operational Humidity ..... 10% to 95% (non-condensing)

Operational Altitude ... Based on mobile computing platform specifications

Storage Temperature ..... -20 to +60 degrees C

Storage Humidity ..... 10% to 95% (non-condensing)

SECTION 12
SUBSTANTIAL EQUIVALENCE DISCUSSION

The Kardia Band System is a trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorder that records, stores and transfers single-channel electrocardiogram rhythms. The device utilizes the computing power of the Apple, Inc. Apple Watch to obtain and analyze single-channel ECG. The Kardia Band System consists of the Kardia Band Hardware (watchband), the Kardia watch app (installed on the Apple Watch), and the Kardia phone app (installed on the Apple iPhone). The Kardia Band System uses a proprietary method of data transmission using acoustic waves in the inaudible ultrasonic wavelength. The Kardia Band Hardware transmits the ECG signal to the Kardia watch app on the Apple Watch to be analyzed and presented to the user.

The Kardia Band System has the same intended use and indications for use as well as similar technological characteristics as AliveCor's previously cleared Kardia Mobile (K142743) predicate device. This section presents the detailed substantial equivalence rationale including analysis of differences between the devices as well as a discussion of how the testing presented with this submission supports substantial equivalence between the subject device and the predicate device.

Comparison Table of Subject to Predicate Device

The subject and predicate device have the same intended use and indications for use. Both the Kardia Band System and the predicate, Kardia Mobile, are single-lead electrocardiograms (ECGs) that activate when a user makes skin contact on both stainless-steel electrodes in order to record and analyze. The Kardia Band ECG's Sensor has a different geometric shape than the predicate's hardware so that it can fit on a watch band and make contact with the wrist. With the predicate device, the skin contact is made with the fingertips of both hands, whereas in the case of the subject device, the skin contact is made with the right wrist and the left thumb (or left wrist and right thumb). However, the data recording and transmission mechanism is the same for both devices. Pressing of the electrodes in both devices closes the open circuit and causes the piezo oscillator to emit an ultrasonic frequency centered at ~19kHz for a mobile computing platform (MCP) to interpret and demodulate the audio signal into an ECG waveform. Table 12.1 provides a summary comparison of the subject and the predicate device and a detailed discussion of the comparison follows Table 12.1.

SECTION 12
SUBSTANTIAL EQUIVALENCE DISCUSSION (CONT.)

Table 12.1– Predicate and Subject Device Substantial Equivalence Comparison Table

Feature	Predicate: Kardia Mobile (K142743)	Subject: Kardia Band System	Analysis of Differences
General			
Indications for Use	The Kardia Mobile is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Mobile also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Mobile is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals.		
Product Code	DXH, DPS		
Mechanism of Action	User completes circuit with skin contact and hardware transmits audio signal to Mobile Computing Platform (MCP) to convert and display ECG waveform		
Use Environment	Mobile/active users at rest (ambulatory)		
Anatomical sites	Left hand fingers to right hand fingers		

SECTION 12
SUBSTANTIAL EQUIVALENCE DISCUSSION (CONT.)

Feature	Predicate: Kardia Mobile (K142743)	Subject: Kardia Band System	Analysis of Differences
Where used:	Ambulatory outpatient use		
Indicated use method	Prescription and OTC		
Technical Specifications			
Standards: Essential Performance AECG Safety General Safety EMC Safety	 IEC 60601-2-47 IEC 60601-2-47 IEC 60601-1 IEC 60601-1-2		
Data Acquisition: Frequency Response ECG channels Resolution Sample Rate	 0.5 Hz – 40 Hz Single Channel 16 bit 300 Samples/Second		
Memory Capacity:	MCP memory		
Number of ECG Leads	Single lead, 2 electrodes		
Power Supply: Battery Battery Life (typical)	 1 Lithium Manganese Dioxide Coin Cells 100 hours operational		
User Interface: Primary Lead Data acquisition Hardware Software interface	 Lead I, Left to Right Ultrasonic acoustics Kardia Mobile ECG Apple iOS based software Kardia phone app		

(b) (4)

SECTION 12
SUBSTANTIAL EQUIVALENCE DISCUSSION (CONT.)

Feature	Predicate: Kardia Mobile (K142743)	Subject: Kardia Band System	Analysis of Differences
Analysis Algorithms	Atrial Fibrillation Noise Algorithm Normal Sign Rhythm		
Physical Specs: Dimensions Weight	 118 x 62 x 16.5 mm 40 grams		
Electrodes: Skin Contact Material Surface Area	Integrated into device Any part of hand (left to right) 304 Stainless Steel > 3 cm^2		
Lead Wires:	None		
Communications for measurement:	Ultrasonic Acoustics		
Environmental: Operating Temp Storage Temp	 10 to 40 degrees C -20 to 60 degrees C		

(b) (4)

SECTION 12
SUBSTANTIAL EQUIVALENCE DISCUSSION (CONT.)

Intended Use and Indications for Use

The Kardia Band System and the Kardia Mobile predicate device have the same intended use of recording, analyzing, displaying, storing and transferring single-channel electrocardiogram (ECG) rhythms. Both devices analyze the recorded ECG and detect the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). Lastly, both devices are available as OTC and prescription devices intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The indications for use language for both devices is identical with the exception that the Kardia Band System's indications for use are specific to adult use only. As such, the two devices are substantially equivalent with respect to intended use and indications for use. Please refer to Table 12.1 for a comparison of the proposed device and the predicate device.

Product Labeling

Both devices have a User Manual, which is shared for the two products, and in-app step by step instructions of how to set up the device and take an ECG measurement. The joint User Manual showing labeling for both devices is provided in Appendix 3. The user manual contains device description, use instruction, warnings, precautions, and other safety information in similar fashion. The Kardia Band System also has an Instructions For Use document which provides an abbreviated and quick access instructions to the user. Please refer to both the User Manual and Instructions For Use that are provided in Appendix 3.

Patient Population

Both devices are used in adult patients. As such, the two devices are substantially equivalent with respect to patient population.

Anatomical Sites

The Kardia Band System records ECG from the patient's wrist and finger whereas the predicate device's hardware is a hand-held card that records ECG from fingers of both right and left hand. The proposed device contains noise filtering and a noise algorithm that assesses whether an ECG recorded signal is adequate for processing to mitigate risk related to potential noise. AliveCor also performed bench, usability, and clinical testing that validated the ECG recording from the wrist and thumb configuration of the Kardia Band System. Please see Sections 18 and 20 for testing. As such, this difference does not result in different questions of safety or effectiveness.

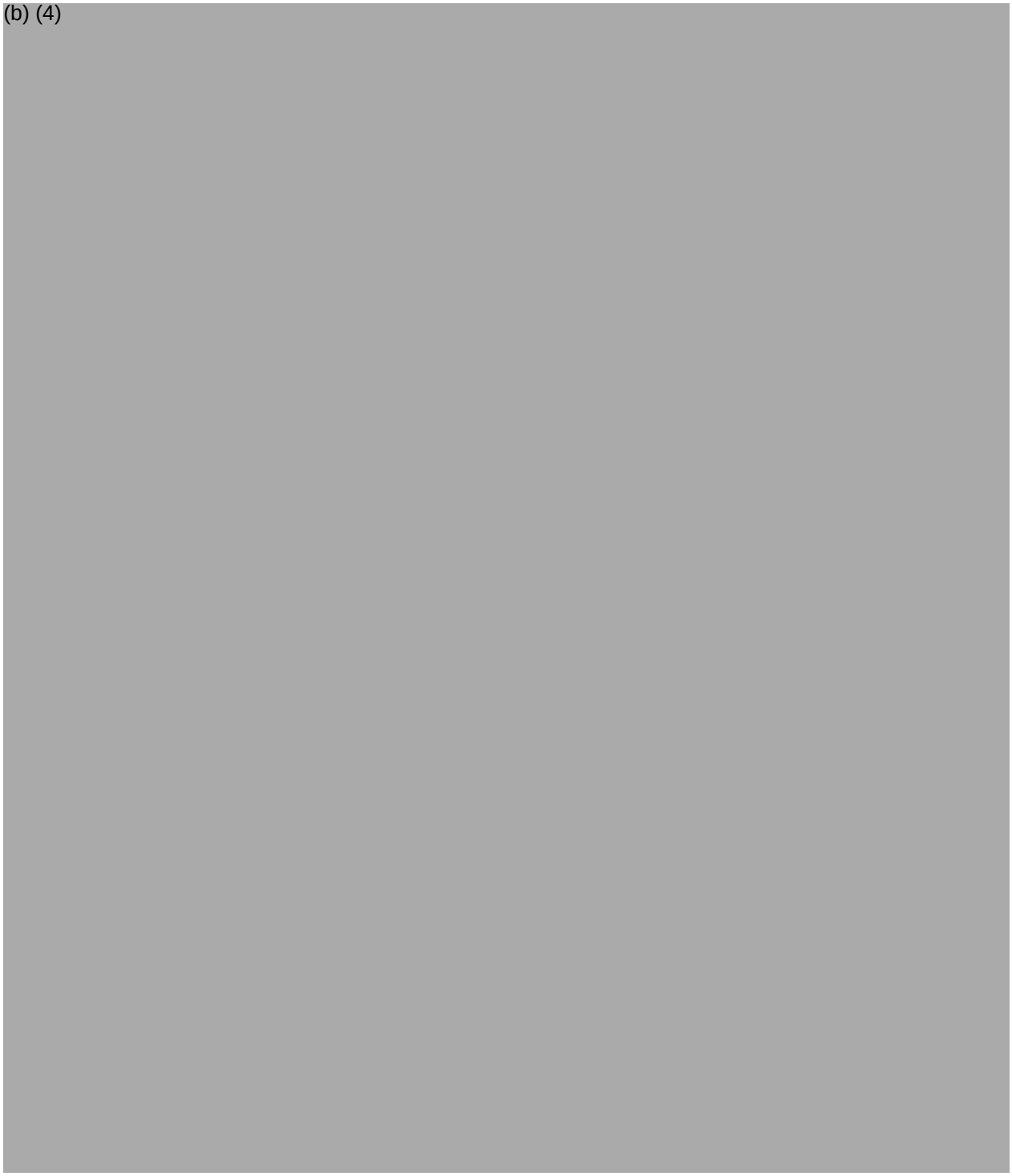
Safety Characteristics and Technological Characteristics

The Kardia Band System and the Kardia Mobile predicate device have similar technological characteristics and the same mechanism for measuring and analyzing ECGs. Both devices have a single channel ECG sensor that upon manual press with the user's fingers send an acoustic signal to the mobile computing platform that listens for the signature acoustic signal. Once received, the mobile computing platform on which the AliveCor software application is installed analyzes the signal using Atrial Fibrillation (AF) and Normal Sinus Rhythm (NSR) algorithms to present the user with the same

SECTION 12
SUBSTANTIAL EQUIVALENCE DISCUSSION (CONT.)

information. Both products provide the user with an ECG waveform tracing and algorithm results to indicate whether AF or NSR is detected. The comparison between the two devices with respect to the hardware electrode sensor, communication between the hardware and the processing software, the processing algorithms, and the user interface is presented below.

(b) (4)



SECTION 12
SUBSTANTIAL EQUIVALENCE DISCUSSION (CONT.)

(b) (4)

- **ALGORITHMS**

(b) (4)

- **USER INTERFACE**

  The Kardia Band System records and analyzes the EGC signal from the hardware device on the Apple Watch platform whereas the predicate performs these functions on the iPhone app interface. Due to limitations of the platform, the Kardia watch app in the Kardia Band System does not display a real-time ECG

SECTION 12
SUBSTANTIAL EQUIVALENCE DISCUSSION (CONT.)

waveform while recording, unlike with the predicate device. Both devices allow the user to capture ECG and view the analyzed results. During measurement, the Kardia watch app displays the count down time remaining for pressing on the Kardia Band sensor until the measurement recording is complete. The difference in lack of real-time wave form display does not impact the safety or effectiveness of the device as compared with the predicate device as it is an aesthetic feature for the user on the Kardia Mobile device. Human factors and usability testing validated that representative users can use the Kardia Band System as intended, including using the Kardia watch app interface for measuring and viewing results. As such, the difference in where the data is displayed and in the lack of real-time wave display during measurement do not result in different questions of safety or effectiveness.

Performance Testing

(b) (4)

CONCLUSION

The Kardia Band System and the Kardia Mobile predicate device have the same intended use and indications for use and similar technological characteristics. Both devices collect single lead ECG, analyze, display, and store the data for the same intended user. Performance testing was conducted to validate the performance of the Kardia Band System and usability testing was performed to ensure that a representative user can use the device as intended. The results of the testing show that the device performs as intended and the differences in design including data acquisition and display do not raise different questions of safety or effectiveness as compared with the predicate device.

SECTION 12
SUBSTANTIAL EQUIVALENCE DISCUSSION (CONT.)

Therefore, the Kardia Band System and predicate Kardia Mobile (K142743) are substantially equivalent.

SECTION 13
PROPOSED DEVICE LABELING

The Kardia Band System labeling materials are listed below and provided in Appendix 3.

USER MANUAL (08LB12.5 – KARDIA USER MANUAL ENGLISH)

Kardia Band System User Manual is provided in Appendix 3- Labeling. This User Manual is shared among the Kardia Band System and AliveCor's Kardia Mobile product as a single point of reference for AliveCor customers.

INSTRUCTIONS FOR USE (15LB1.4 – KARDIA BAND IFU)

The Instructions for Use document is supplied with the Kardia Band System provides essential setup steps, important user instruction, information about Kardia Band System's clinical study, and reference to the more detailed User Manual. The IFU is provided in Appendix 3- Labeling

PACKAGING (14LB10.2 – KARDIA BAND ECG GLOBAL PACKAGING)

The packaging labels are illustrated in 14LB10.2, which is provided in Appendix 3-Labeling.

SECTION 14
STERILIZATION, SHELF LIFE AND PACKAGING

14.1 Sterilization

The Kardia Band System is provided and used non-sterile, therefore, this section does not apply.

14.2 Shelf Life and Packaging

The life time limiting factor of the Kardia Band System is the battery in the Kardia Band Hardware. The battery is a non-rechargeable lithium coin cell that is commonly used in wrist watches and other miniature electronic equipment. The battery in the device is replaceable, and is readily available at retail/grocery stores that carry batteries.

Battery Shelf Life Analysis

(b) (4)

SECTION 14
STERILIZATION, SHELF LIFE AND PACKAGING (CONT.)

(b) (4)

[redacted]

PACKAGING

The Kardia Band Hardware is packaged in a pressboard carton (14LB10) identical to the AliveCor's FDA cleared Mobile ECG (02PK08) device (K142743). The only differences are in the graphics applied and in the usage of a retention feature in the Mobile ECG package. All materials and dimension are otherwise the same. Please refer to package labeling document 14LB10 for an illustration of the packing configuration for the Kardia Band Hardware.

(b) (4)

[redacted]

SECTION 15
BIOCOMPATIBILITY

The Kardia Band System's patient contacting component is the Kardia Band Hardware (wristband). Per ISO 10993-1:2009, *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management*, the Kardia Band Hardware is a surface device (intact skin contacting) with permanent contact duration (>30 d). While it is anticipated that the product will be removed from the wrist on a daily basis (for Apple Watch charging), the permanent duration of contact has been classified based on the cumulative possible exposure. The materials that comprise the patient contacting portions of the AliveCor Kardia Band are as presented in Table 15.1.

Table 15.1: Contacting Materials

(b) (4)

[redacted]

TESTING SUMMARY

(b) (4)

[redacted]

SECTION 16
SOFTWARE

16.1 INTRODUCTION

The Kardia Band System is a trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorder that records, stores and transfers single-channel electrocardiogram rhythms. The device utilizes the computing power of the Apple, Inc. Apple Watch to obtain and analyze single-channel ECG. The Kardia Band System consists of the Kardia Band Hardware (watchband), the Kardia watch app (installed on the Apple Watch), and the Kardia phone app (installed on the Apple iPhone). The Kardia Band System uses a proprietary method of data transmission using acoustic waves in the inaudible ultrasonic wavelength. The Kardia Band ECG transmits the ECG signal from its electrode to the Kardia watch app on the Apple Watch to be analyzed and presented to the user.

Software documentation for the Kardia Band System was developed in consideration of FDA's guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2015) and “Content of Premarket Submissions for the Management of Cybersecurity in Medical Devices” (October 2, 2014). Per the aforementioned FDA guidance, this section identifies the Software Level of Concern (LOC) and provides documentation required per the LOC.

16.2 SOFTWARE – LEVEL OF CONCERN

Using methods described in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued by FDA on May 11, 2005, AliveCor, Inc. (AliveCor) has made the determination, from the decision tree and tables, that the Level of Concern is Moderate because a malfunction or latent design flaws could lead to erroneous diagnosis or delay in delivery of appropriate medical care that could lead to minor injury of the patient.

The Moderate Level of Concern determination is consistent with our understanding of most if not all other ambulatory ECG Event Recorders on the market.

SECTION 16
SOFTWARE (CONT.)

Table 16.1: FDA Guidance Table 1: Major Level of Concern

If the answer to any one question below is a Yes, the Level of Concern for the Software Device is likely to be Major	Yes/No
Does the Software Device qualify as Blood Establishment Computer Software? (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)	No
Is the Software Device intended to be used in combination with a drug or biologic?	No
Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No
Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:	No
Does the Software Device control a life supporting or life sustaining function?	No
Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	No
Does the Software Device control the delivery of treatment of therapy such that an error or malfunction could result in death or serious injury?	No
Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	No
Does the Software Device provide vital signs monitoring and alarms for potentially life-threatening situations in which medical intervention is necessary?	No

Conclusion: The Kardia Band System software is not Major Level of Concern software. Proceed to Table 16.2 for Moderate Level of Concern:

Table 16.2: LOC Questions Moderate

If the Software Device is not a Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate	Yes/No
Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	No
Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	Yes
Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of Appropriate medical care that would likely lead to Minor Injury?	Yes

Conclusion: Kardia Band System software is Moderate Level of Concern software.

SECTION 16
SOFTWARE (CONT.)

Per the Moderate Level of Concern, Table 16.3 presents the software documentation developed per the FDA Guidance documents for the Kardia Band System and their location in this submission.

Table 16.3: Moderate Level of Concern Documentation

Software Documentation	Kardia app
(b) (4)	

16.3 SOFTWARE DESCRIPTION

The Kardia Band System consists of the Kardia Band Hardware (watchband), the Kardia watch app (installed on the Apple Watch), and the Kardia phone app

SECTION 16
SOFTWARE (CONT.)

(installed on the Apple iPhone) (Left side of Figure 16.1). The Kardia Band System transmits the ECG signal from its electrode to the Kardia watch app on the Apple Watch to be analyzed and presented to the user. The Kardia Band Hardware acquires an ECG signal from the body through metal electrodes integrated into an Apple Watch band. The Kardia Band Hardware converts the ECG into a frequency modulated (FM) audio signal, which provides audio input to the Kardia watch app running on the Apple WatchOS. The Kardia watch app analyzes the ECG and stores the ECG and the analysis results on the local watch storage. The patient also views the recorded ECG and the analysis results on the watch screen. The data is then sent to the user iPhone for additional storage and is transferred to the AliveCor cloud server from the Kardia phone app. As presented in Section 11, the Kardia Band Hardware does not contain software or firmware and leverages a mechanical mechanism of recording and sending acoustic signal when it's sensor is physically pressed by the user.

The software units (modules) of the Kardia Band System are the Kardia watch app and the Kardia phone app and are described below:

(b) (4)

SECTION 16
SOFTWARE (CONT.)

(b) (4)

16.4 SOFTWARE ARCHITECTURE DIAGRAM

(b) (4)

SECTION 16
SOFTWARE (CONT.)

(b) (4)

[redacted]

16.5 HAZARD ANALYSIS

(b) (4)

[redacted]

SECTION 16
SOFTWARE (CONT.)

16.6 TRACEABILITY ANALYSIS

(b) (4)

16.7 SOFTWARE DEVELOPMENT ENVIRONMENT

(b) (4)

(b) (4)

(b) (4)

16.9 REVISION LEVEL HISTORY

The current revisions and compatibility requirements for the Kardia watch app and Kardia phone app are listed below followed by the respective software revision history reflecting major changes in the software and the testing that was conducted:

(b) (4)

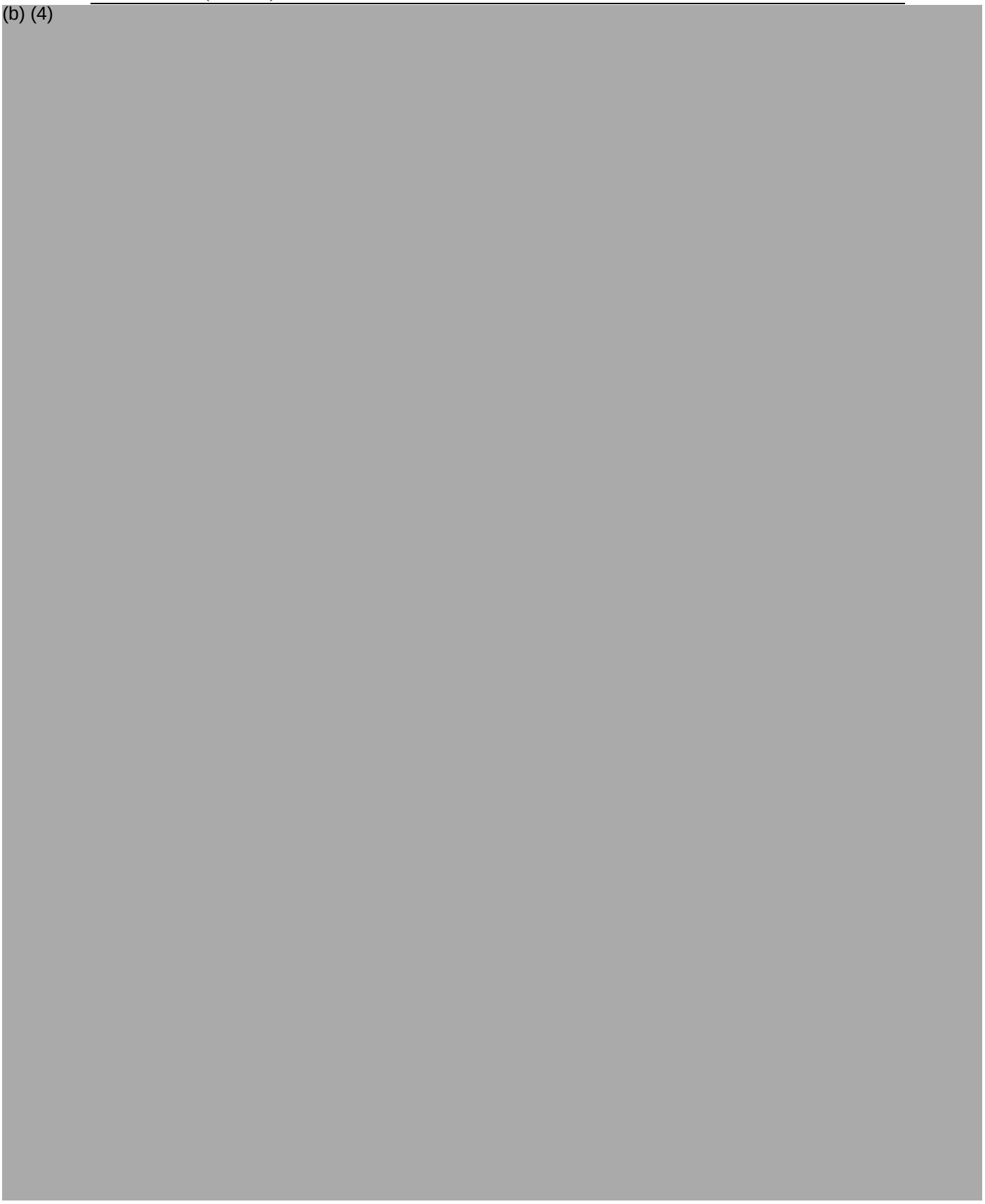
SECTION 16
SOFTWARE (CONT.)

(b) (4)

[redacted]

SECTION 16
SOFTWARE (CONT.)

(b) (4)



SECTION 16
SOFTWARE (CONT.)

(b) (4)

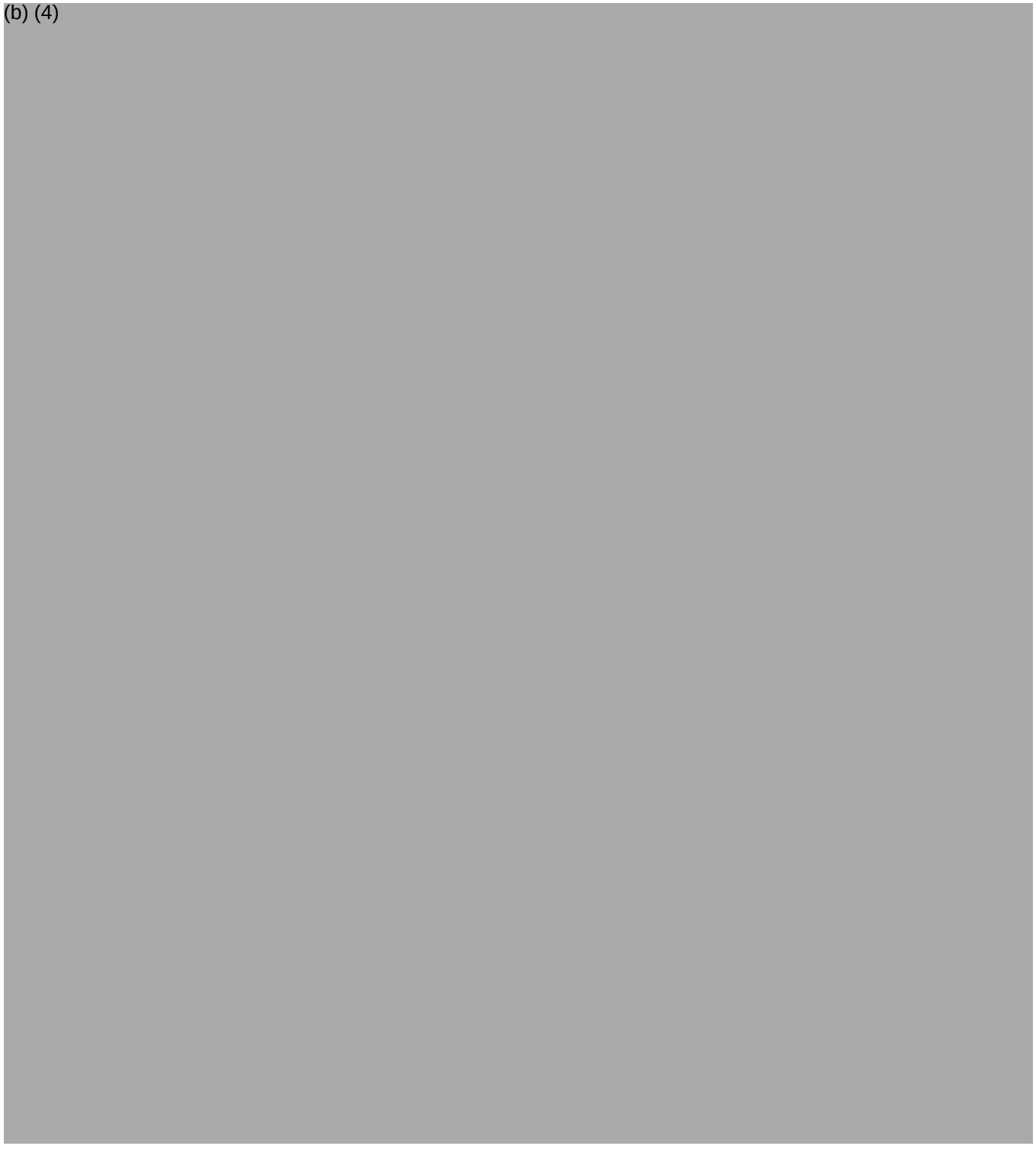
SECTION 16
SOFTWARE (CONT.)

(b) (4)

[redacted]

SECTION 16
SOFTWARE (CONT.)

(b) (4)



SECTION 16
SOFTWARE (CONT.)

(b) (4)

16.10 UNRESOLVED ANOMALIES

(b) (4)

16.11 CYBERSECURITY

(b) (4)

SECTION 17
ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

17.1 ELECTRICAL SAFETY

The AliveCor Kardia Band System has been evaluated for general safety in accordance with the following standards:

- IEC 60601-1:2005 Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-47:2012, Medical Electrical Equipment – Part 2-47: Particular Requirements for the Basic Safety and Essential performance of Ambulatory Electrocardiographic Systems

Testing was performed by ITC Engineering Services, Inc. (Sunol, CA) with passing results. Please refer to the test reports that are provided in Appendix 7- Electrical Safety and EMC for further details on the testing and results.

17.2 ELECTROMAGNETIC COMPATIBILITY

The Kardia Band System has been subject to EMC testing per IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Disturbances – Requirements and tests. Testing was completed with passing results. Please refer to the test report provided in Appendix 7- Electrical Safety and EMC for further details on the testing.

Additionally, the FDA Guidance Document titled, “Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-powered Medical Devices” issued on July 11, 2016, was considered and the required elements from the guidance are provided below:

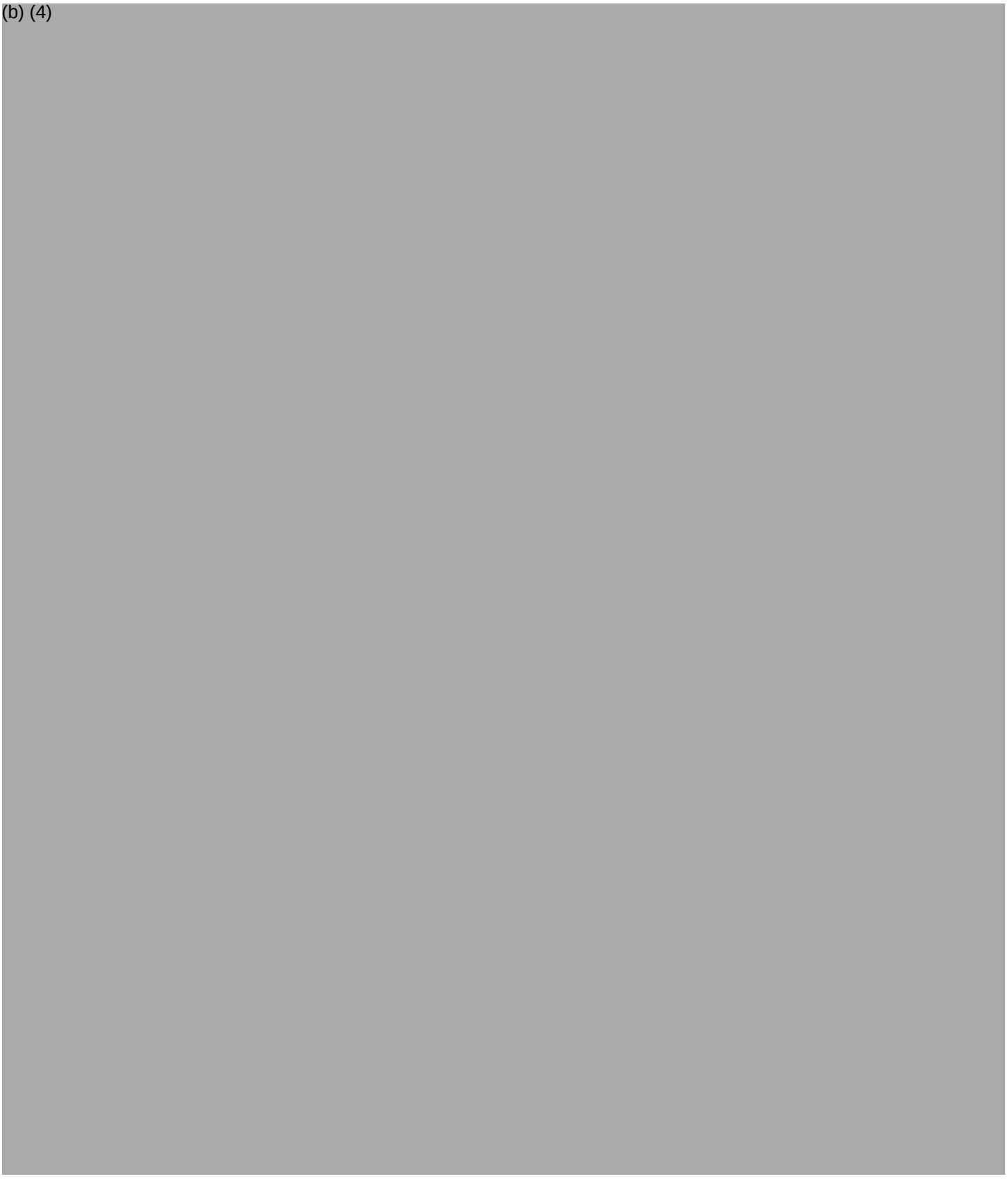
(b) (4)

SECTION 17
ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY (CONT.)

(b) (4)

SECTION 17
ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY (CONT.)

(b) (4)



SECTION 17
ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY (CONT.)

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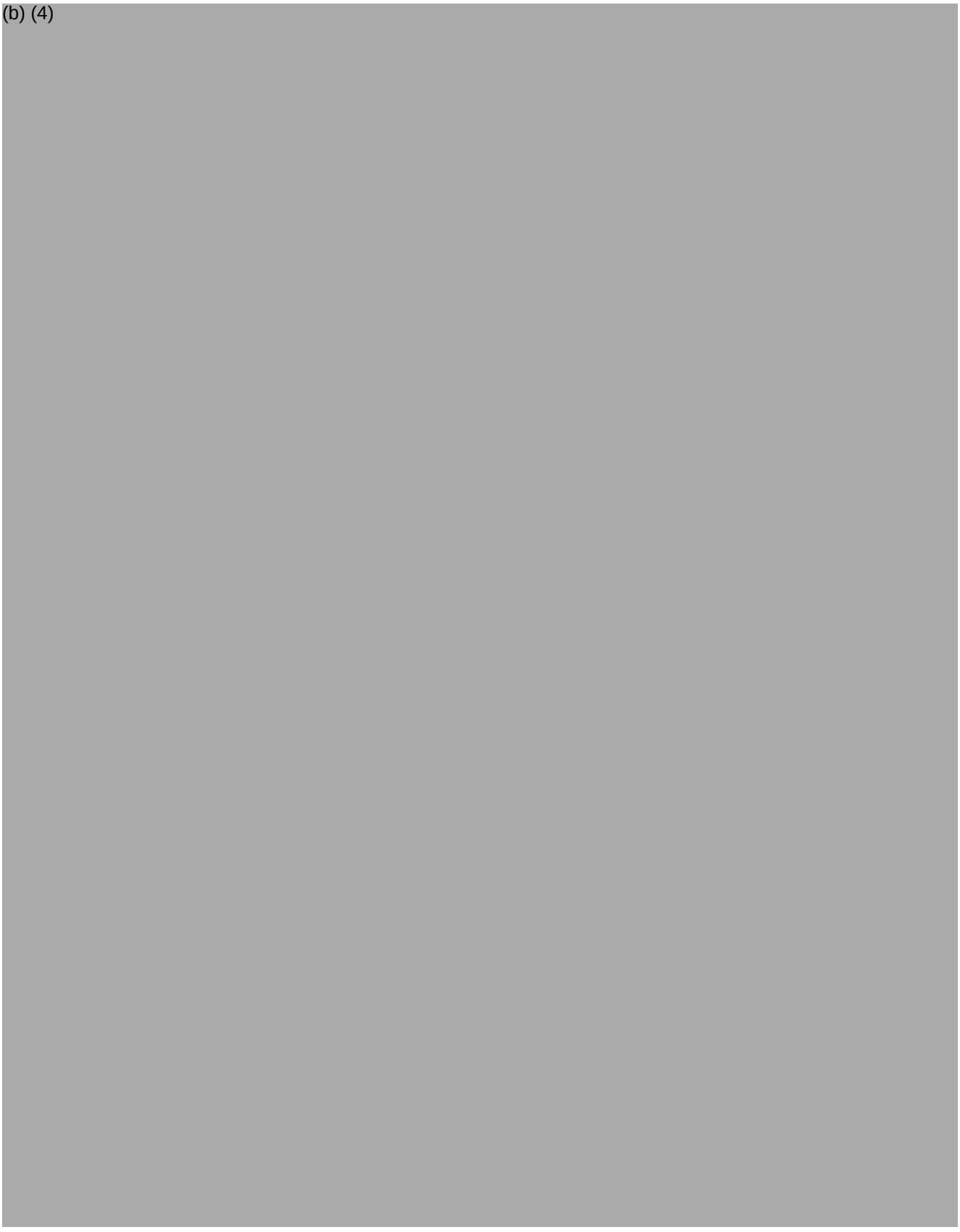


SECTION 17
ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY (CONT.)

(b) (4)

EMISSION TESTS: RADIATED EMISSIONS PER CISPR11: 2009/A1:2010 CLASS B

(b) (4)

SECTION 17
ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY (CONT.)

Test result

(b) (4)

Test result

The EUT met the requirements of the Essential Performance Criteria.

SECTION 18
PERFORMANCE TESTING – BENCH

(b) (4)

18.1 Bench Performance Testing

(b) (4)

SECTION 18
PERFORMANCE TESTING – BENCH (CONT.)

18.1.2 Design Verification Testing

(b) (4)

Table 18.1: Performance Testing for the Kardia Band System

Test	Objectives	Result	Report/ Protocol
Hardware Testing			

(b) (4)

SECTION 18
PERFORMANCE TESTING – BENCH (CONT.)

Table 18.1: Performance Testing for the Kardia Band System (Cont.)

Test	Objectives	Result	Report/ Protocol
Software Testing			
(b) (4)			

SECTION 18
PERFORMANCE TESTING – BENCH (CONT.)

Deviations

(b) (4)

18.2 Usability Study

(b) (4)

SECTION 18
PERFORMANCE TESTING – BENCH (CONT.)

(b) (4)

SECTION 18
PERFORMANCE TESTING – BENCH (CONT.)

(b) (4)

18.3 Summary

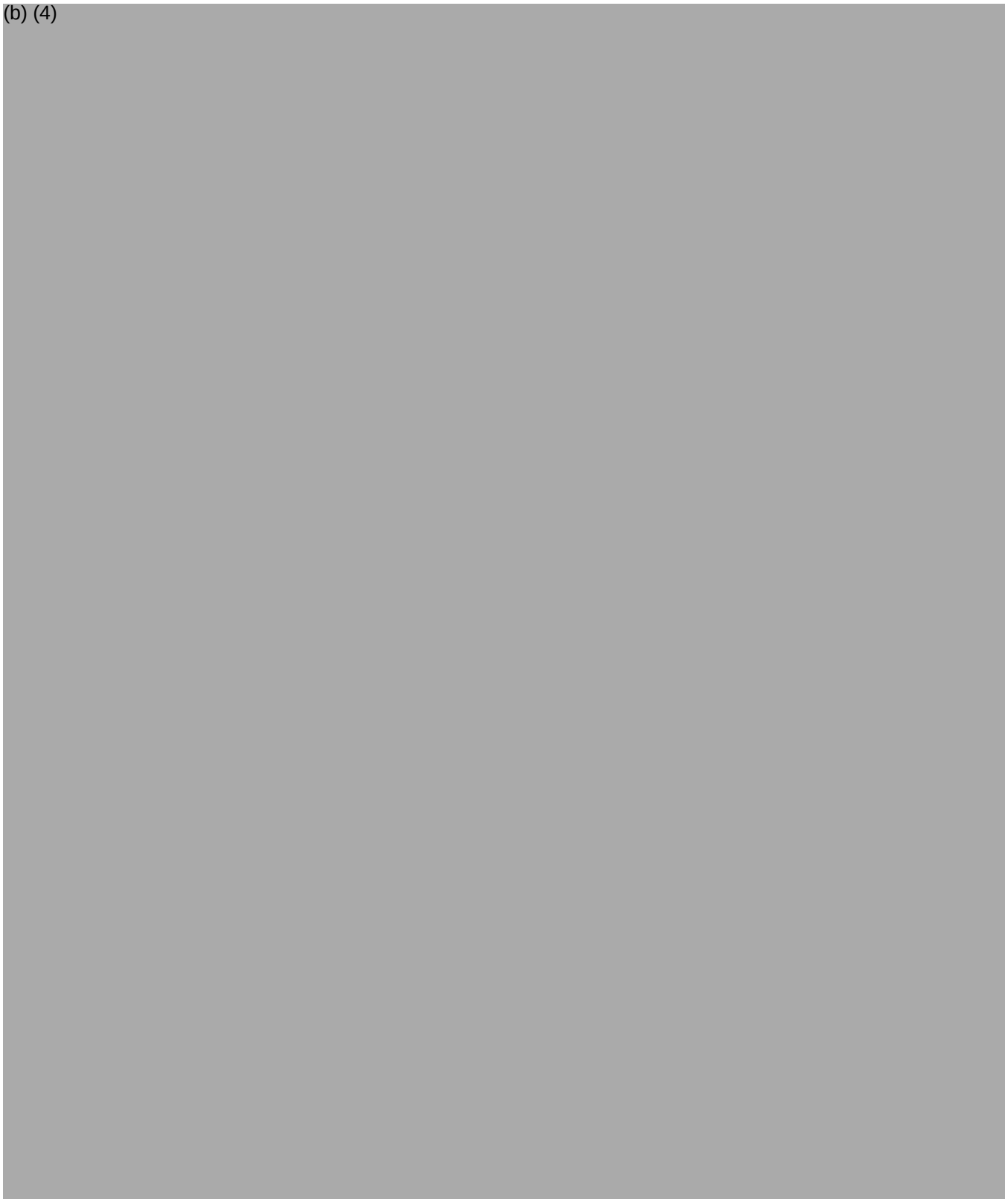
(b) (4)

SECTION 19
PERFORMANCE TESTING – ANIMAL

This section is not applicable, as no animal testing is being submitted in support of this premarket notification.

SECTION 20
PERFORMANCE TESTING – CLINICAL

(b) (4)



SECTION 20
PERFORMANCE TESTING – CLINICAL (CONT.)

(b) (4)

SECTION 20
PERFORMANCE TESTING – CLINICAL (CONT.)

(b) (4)

SECTION 21
STANDARDS DATA REPORT FOR 510(K)S (FORM FDA 3654)

The Standards Data Reports (Form FDA 3654) for each standard are provided in the following order in Appendix 11:

- IEC 60601-1:2012, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-2-47:2012, Medical Electrical Equipment – Part 2-47: Particular Requirements for the Basic Safety and Essential performance of Ambulatory Electrocardiographic Systems
- ISO 10993-1:2009, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 14971:2012, Medical Devices – Application of Risk Management to Medical Devices
- ISO 15223-1:2012, Medical Devices – Symbols to be used with Medical Device Labels, Labelling, and Information to be Supplied – Part 1: General Requirements
- IEC 62304:2006, Medical Device Software – Software Lifecycle Processes

SECTION 22
CERTIFICATE OF COMPLIANCE WITH CLINICAL TRIALS COVER SHEET

In this section please find the complete form FDA 3674 – Certification of Compliance, under 42 U.S.C. §282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. §282(j)).

Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2018. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
AliveCor, Inc.

2. Date of the Application/Submission Which This Certification Accompanies
06/12/2017

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
444 Castro Street

Address 2 *(Apartment, suite, unit, building, floor, etc.)*
Suite 600

City
Mountain View

State/Province/Region
CA

Country
USA

ZIP or Postal Code
94041

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 650-396-8553

(Fax): 650-282-7932

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Transmitters and Receivers, Electrocardiograph, Telephone; Class II; Kardia Band System; AC-011

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Anna Libman	Senior Manager, Regulatory Affairs

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	
224 Airport Parkwat	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
Suite 250	
City: San Jose	State/Province/Region: CA
Country: USA	ZIP or Postal Code: 95110

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 408-400-0856

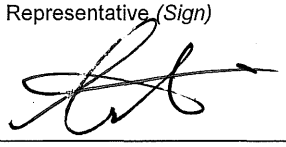
(Fax): 408-400-0865

14. Date of Certification

June 8, 2017

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign



This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

APPENDIX 1
PRIOR SUBMISSION

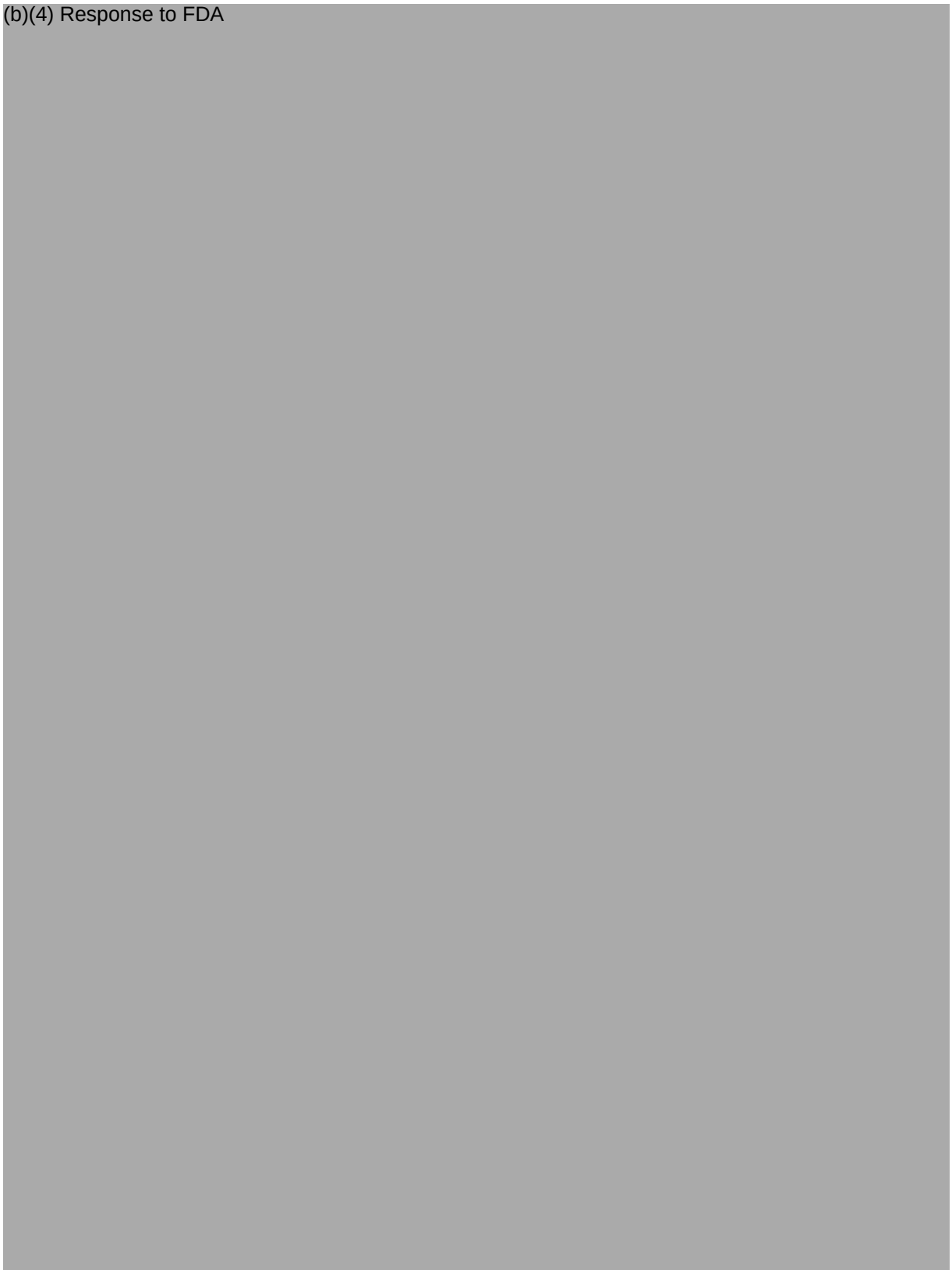
Provided in this appendix are the following documents:

- AliveCor's Response to FDA's NSE letter dated February 3, 2017
- AliveCor's Submission Issue Meeting Notes (b) (4)

AliveCor®

Response to FDA's NSE letter dated February 3, 2017

(b)(4) Response to FDA



(b)(4) Response to FDA

(b)(4) Response to FDA

(b)(4) Response to FDA

[redacted]

[1] http://chchearing.org/noise/common-environmental-noise-levels/

(b)(4) Response to FDA

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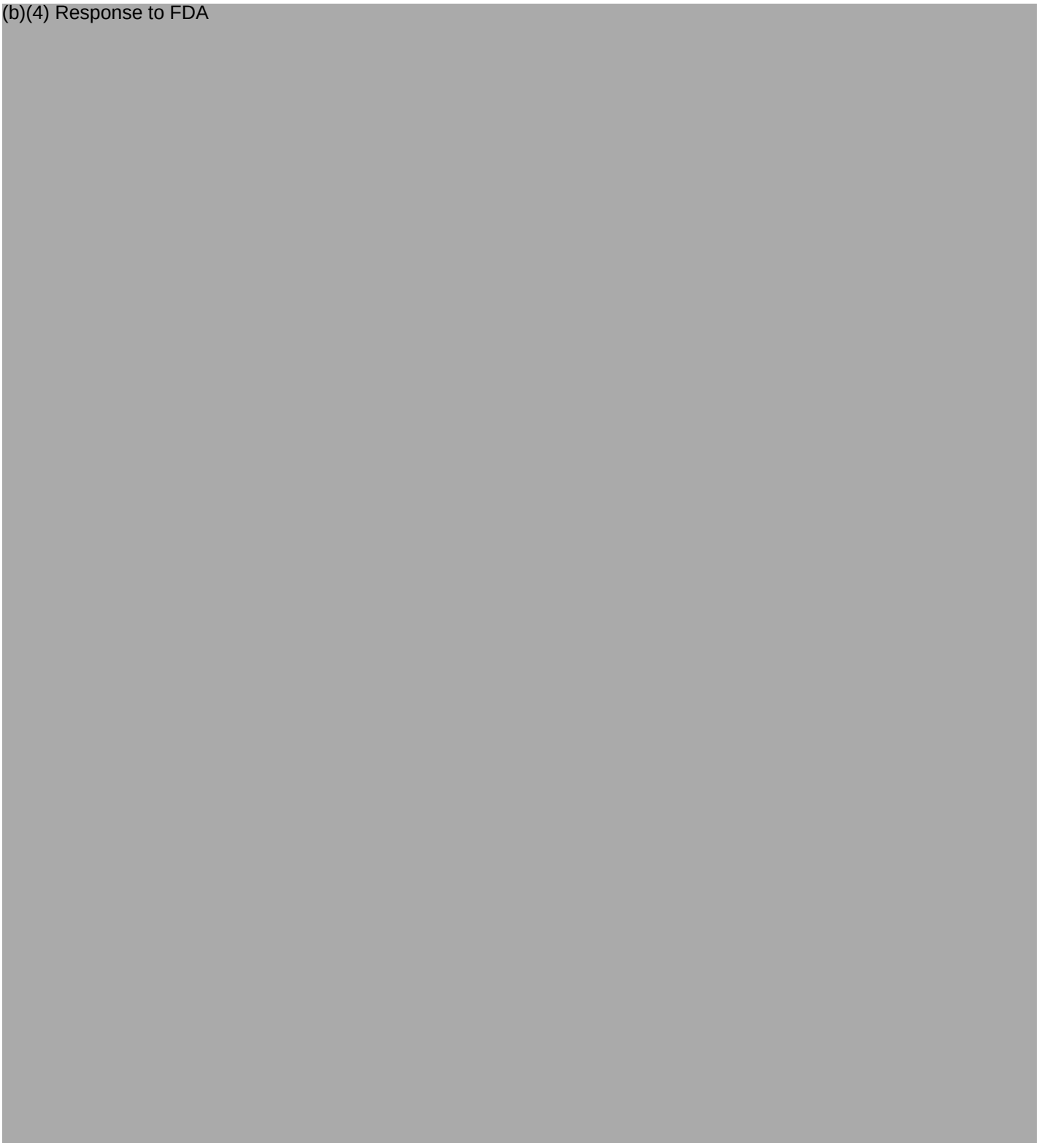

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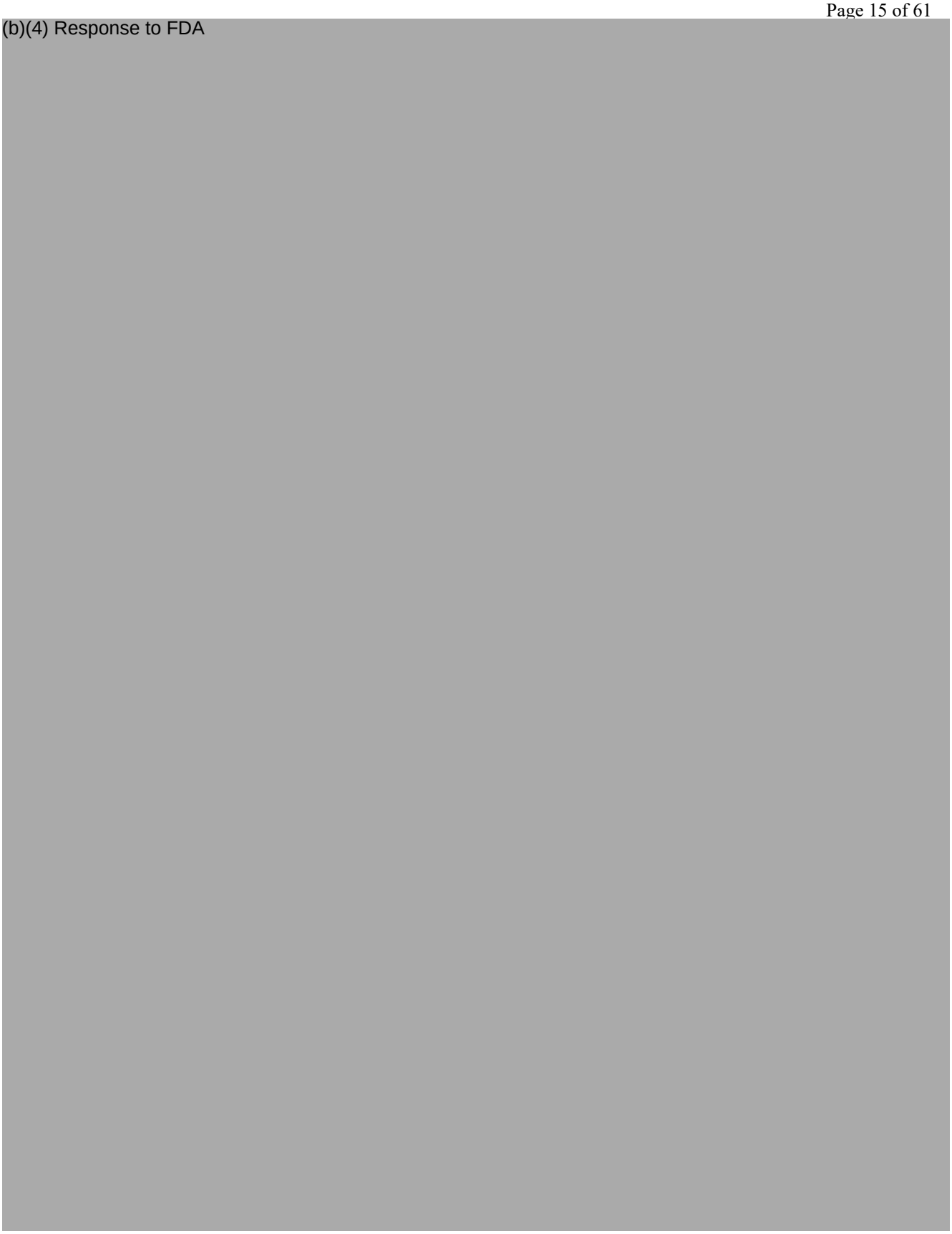

(b)(4) Response to FDA

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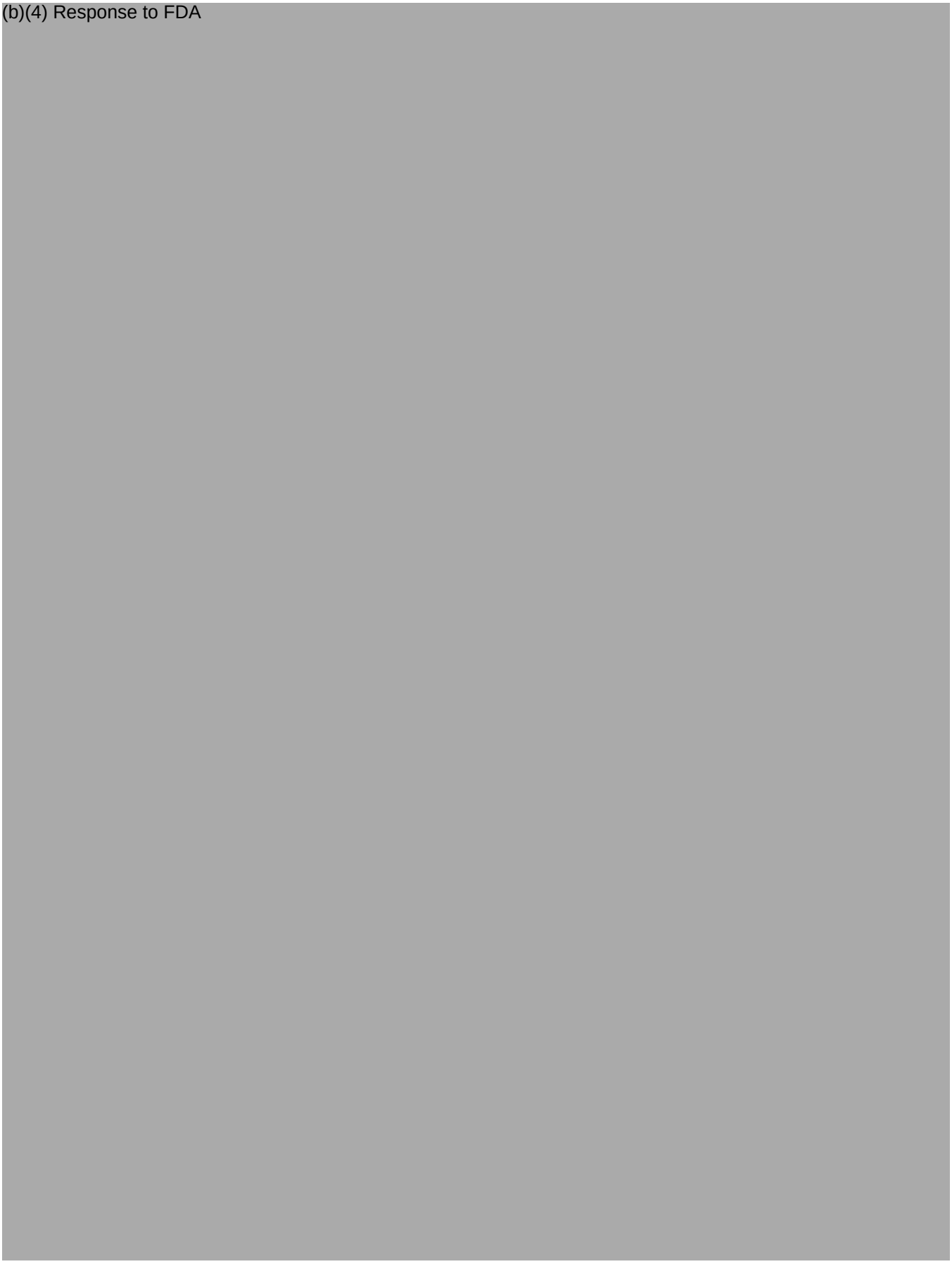

(b)(4) Response to FDA

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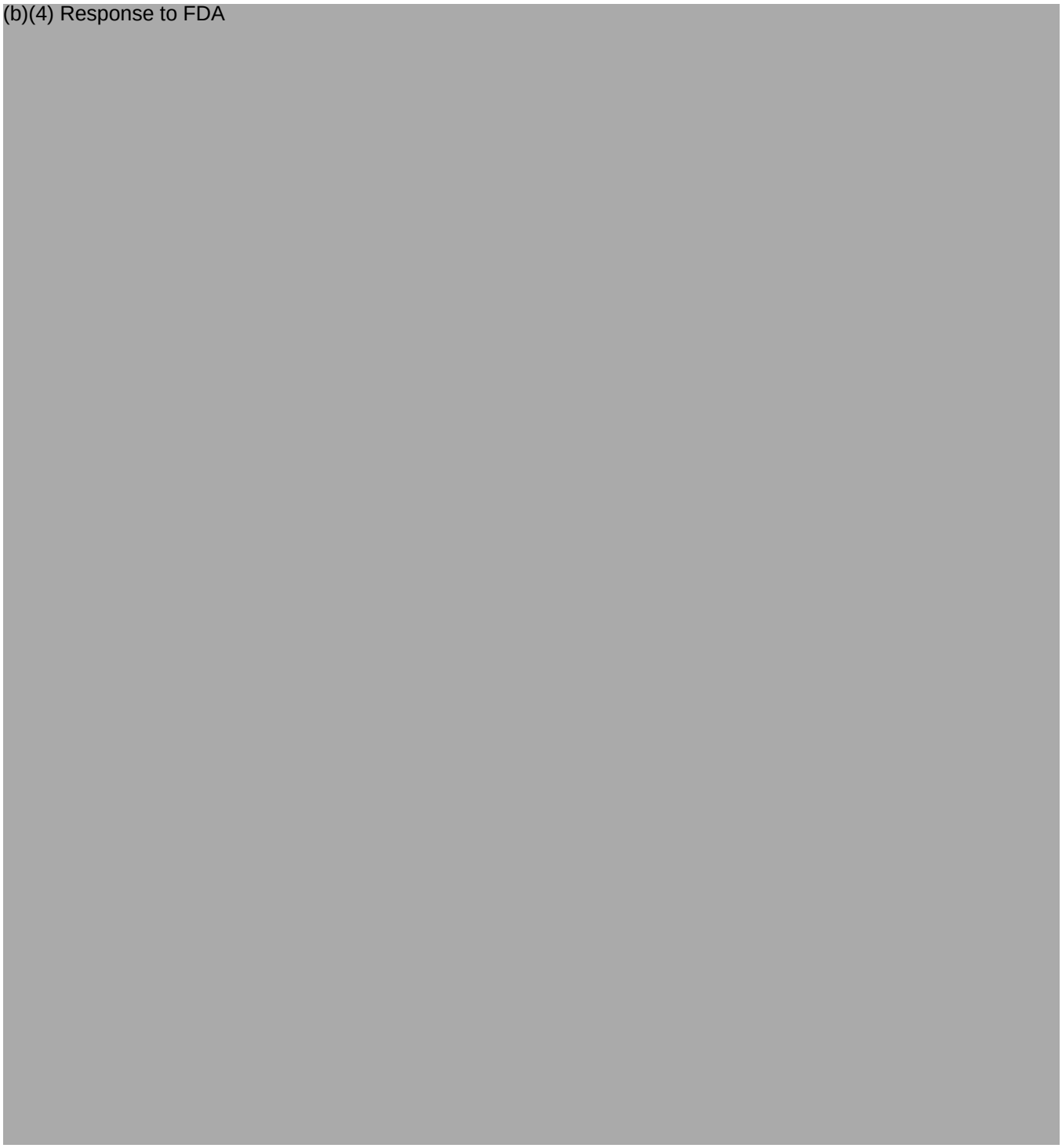

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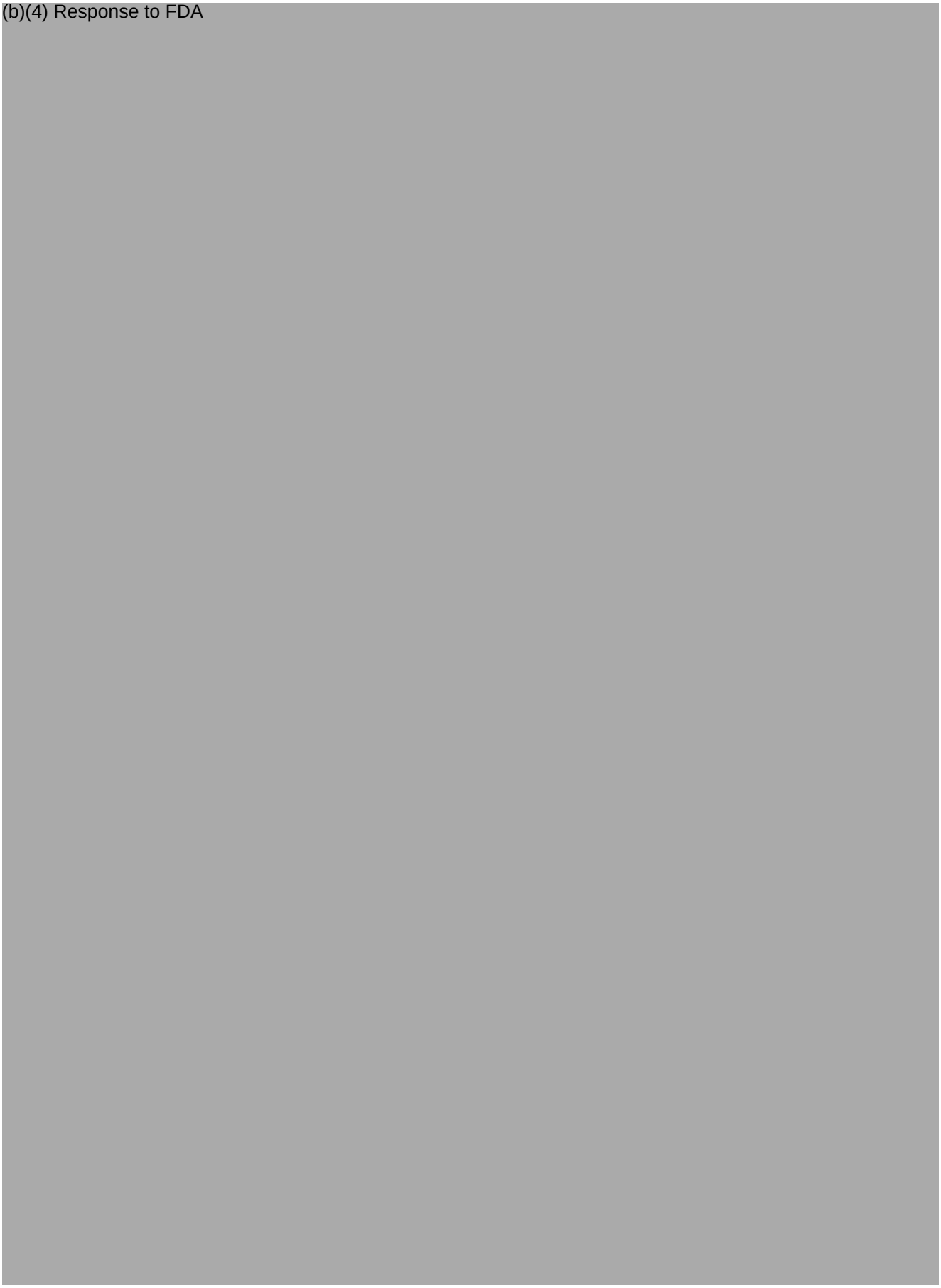

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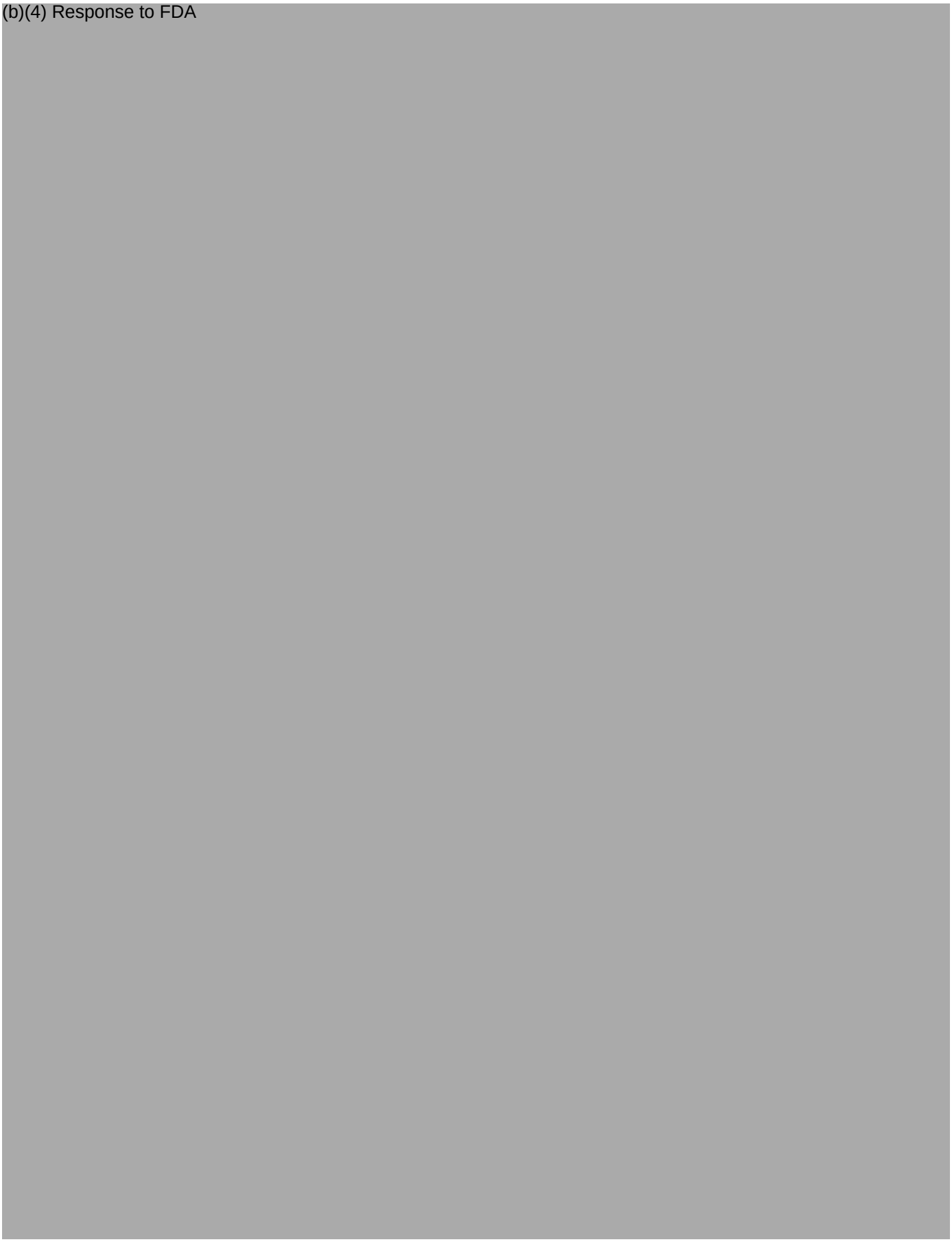

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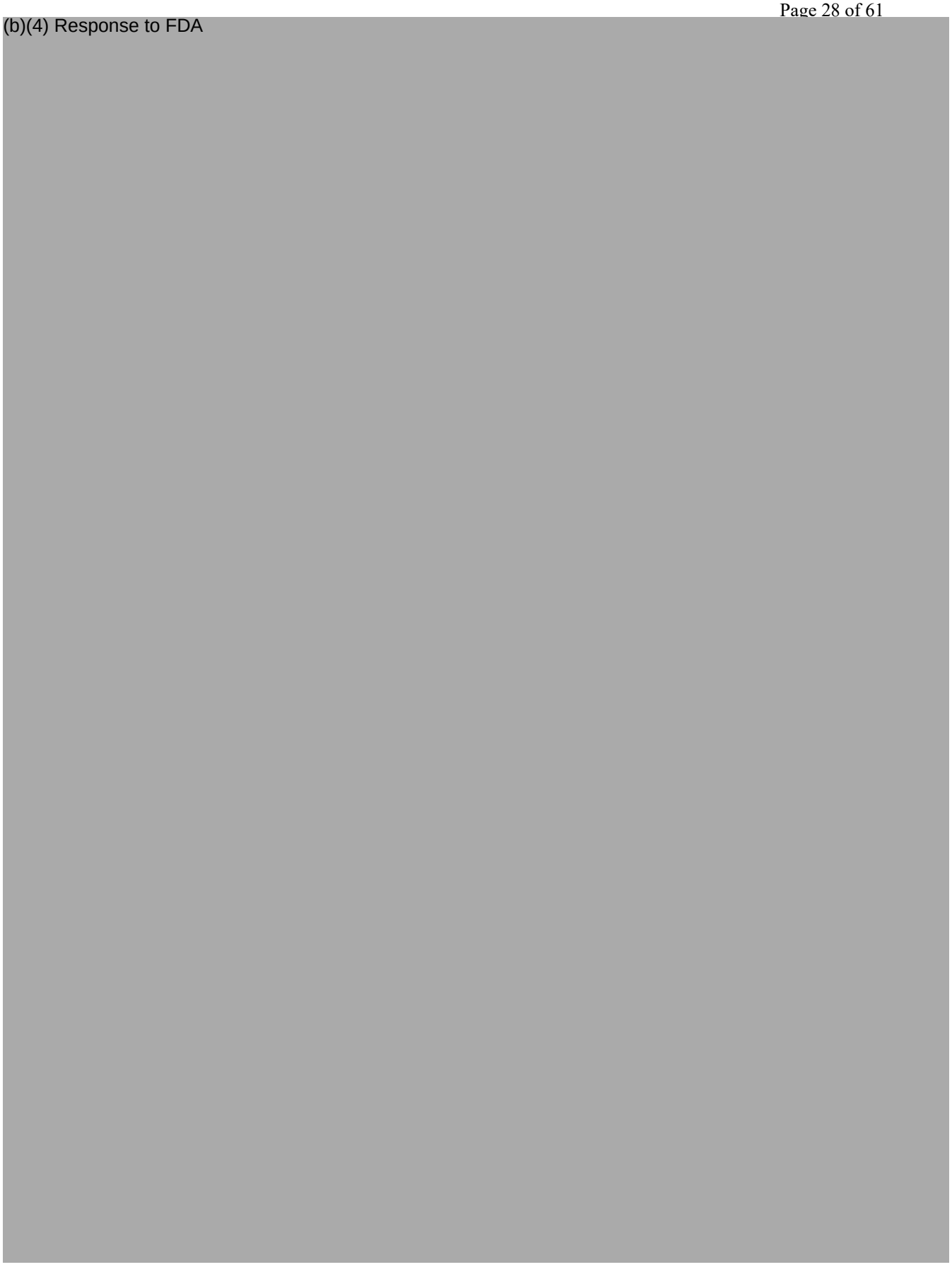

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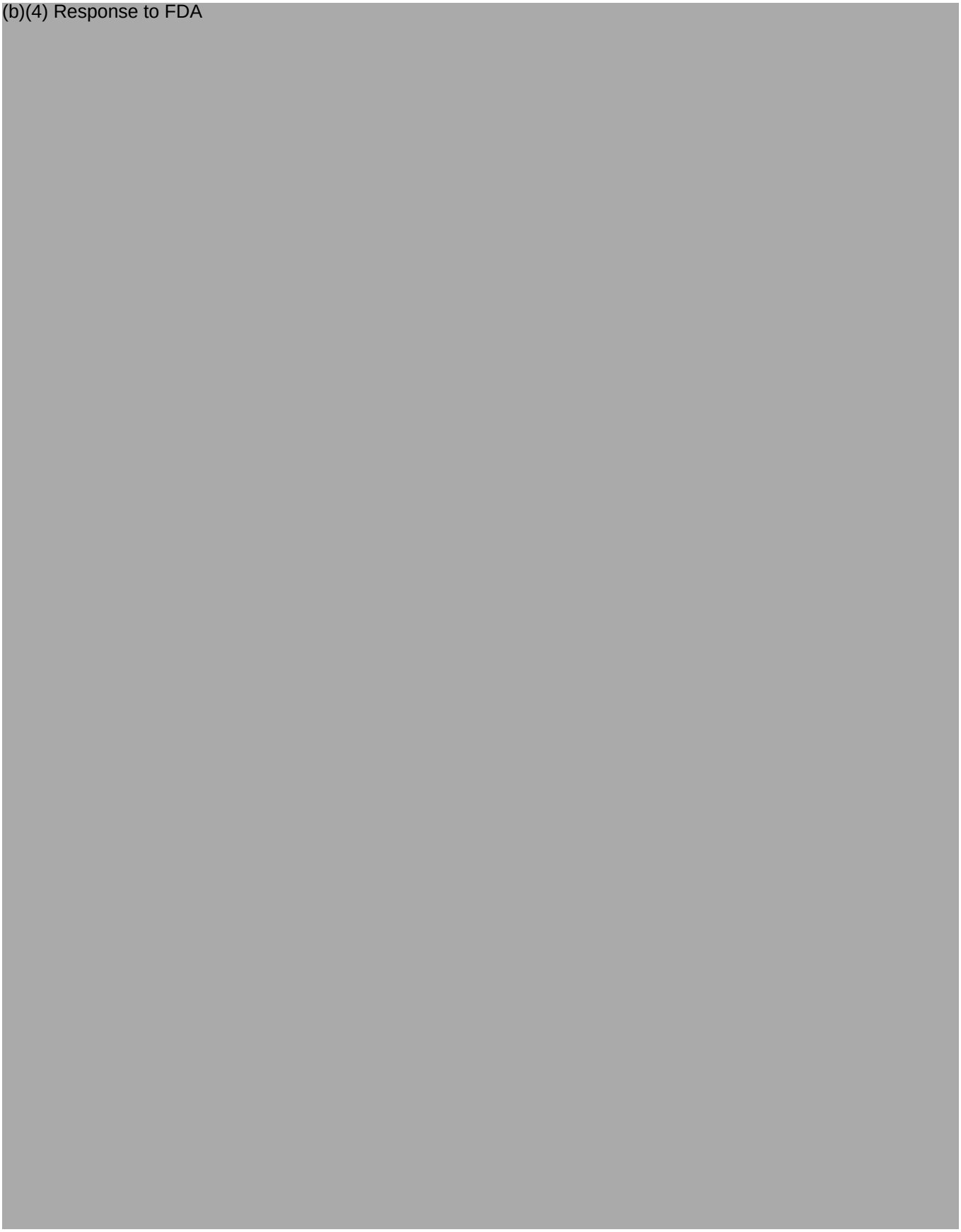

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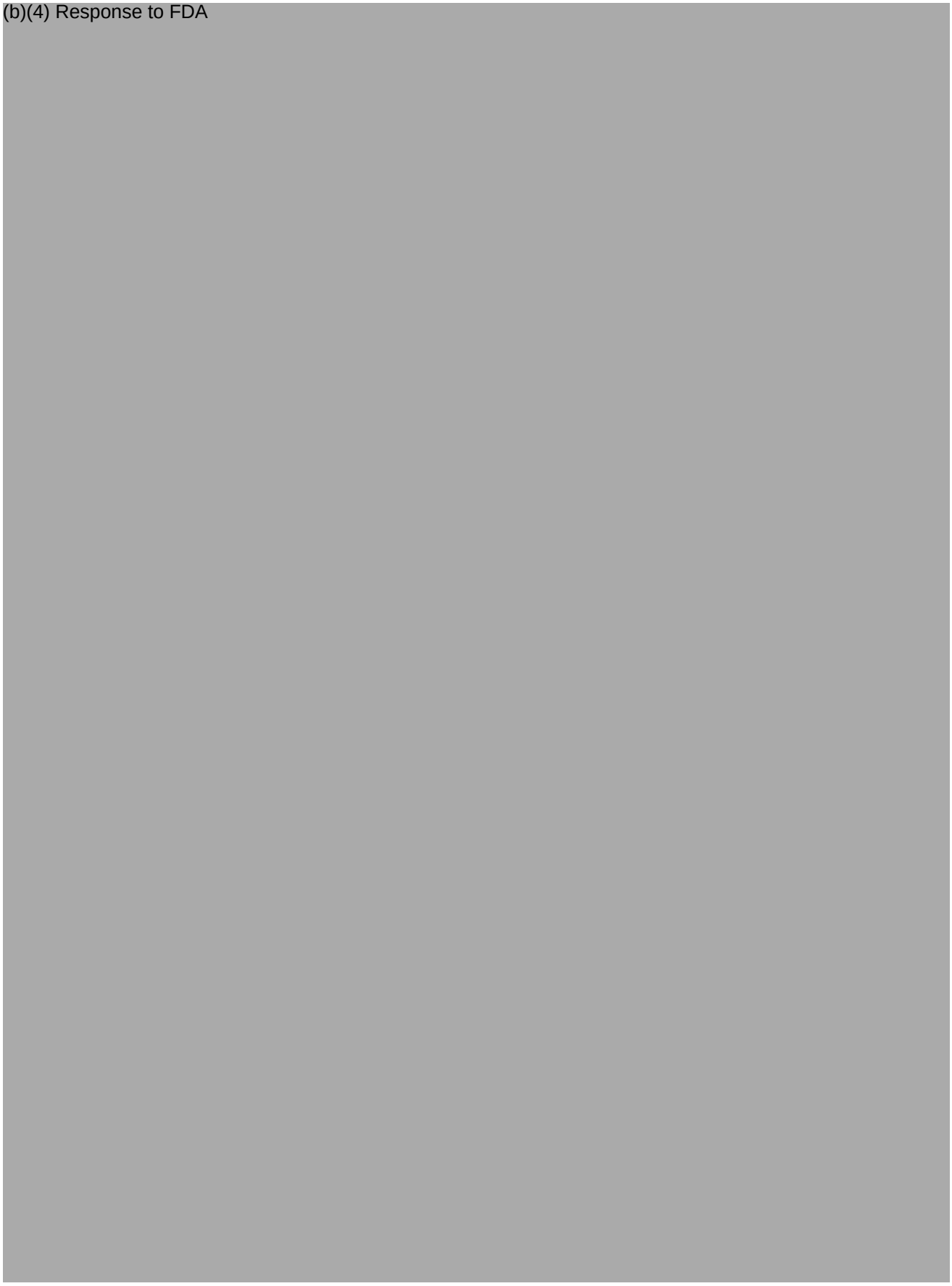

(b)(4) Response to FDA

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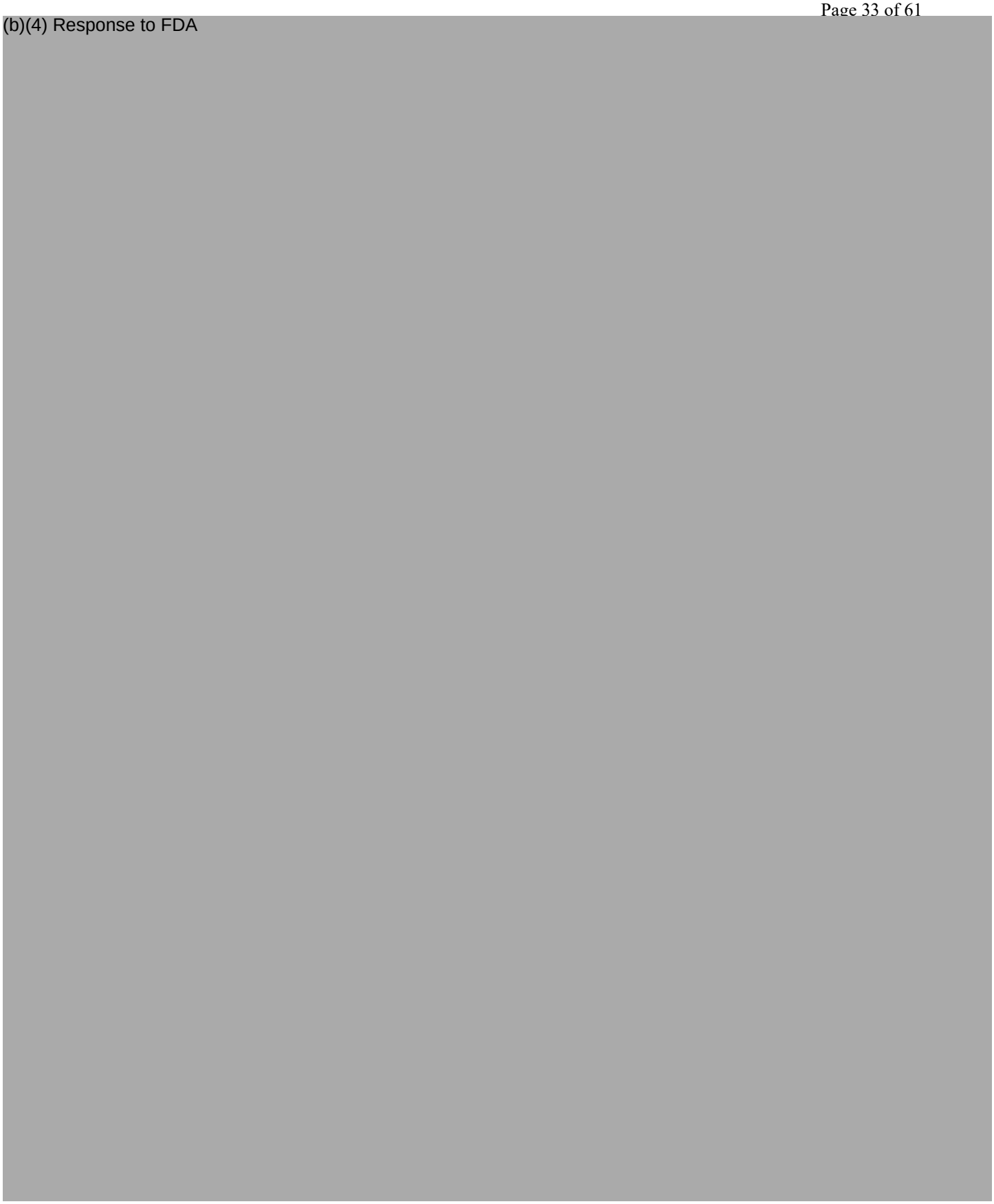

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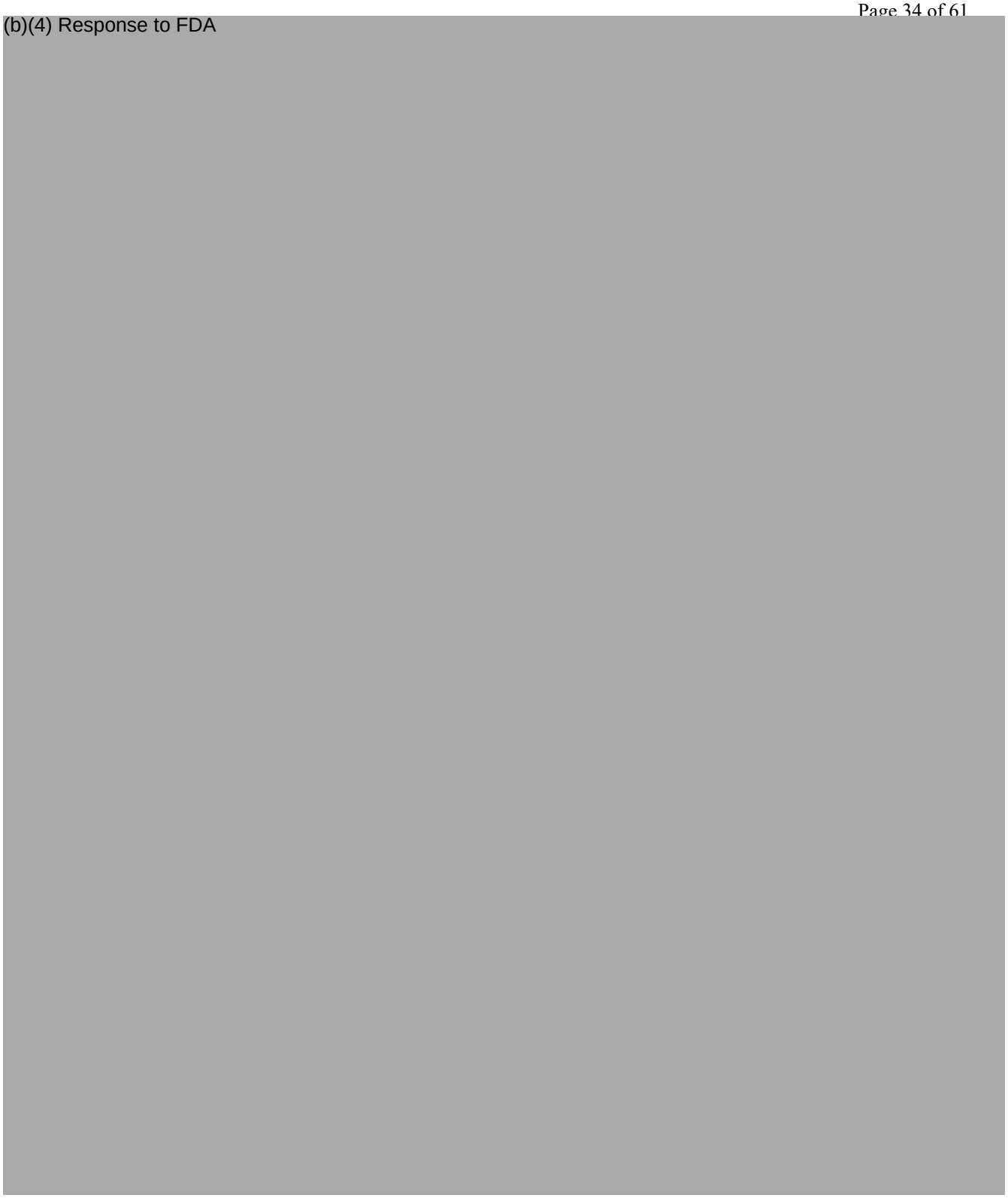
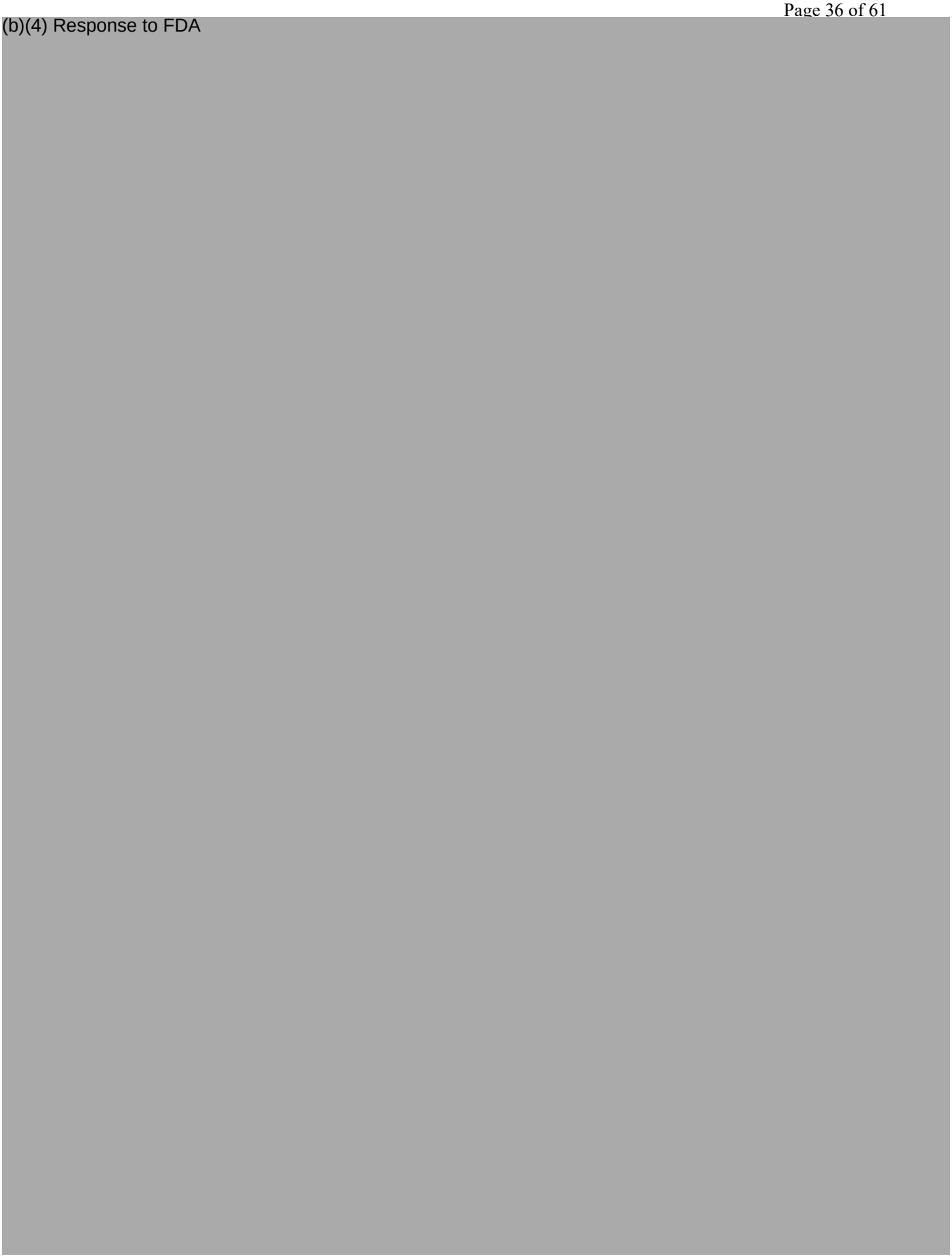


(b)(4) Response to FDA

(b)(4) Response to FDA



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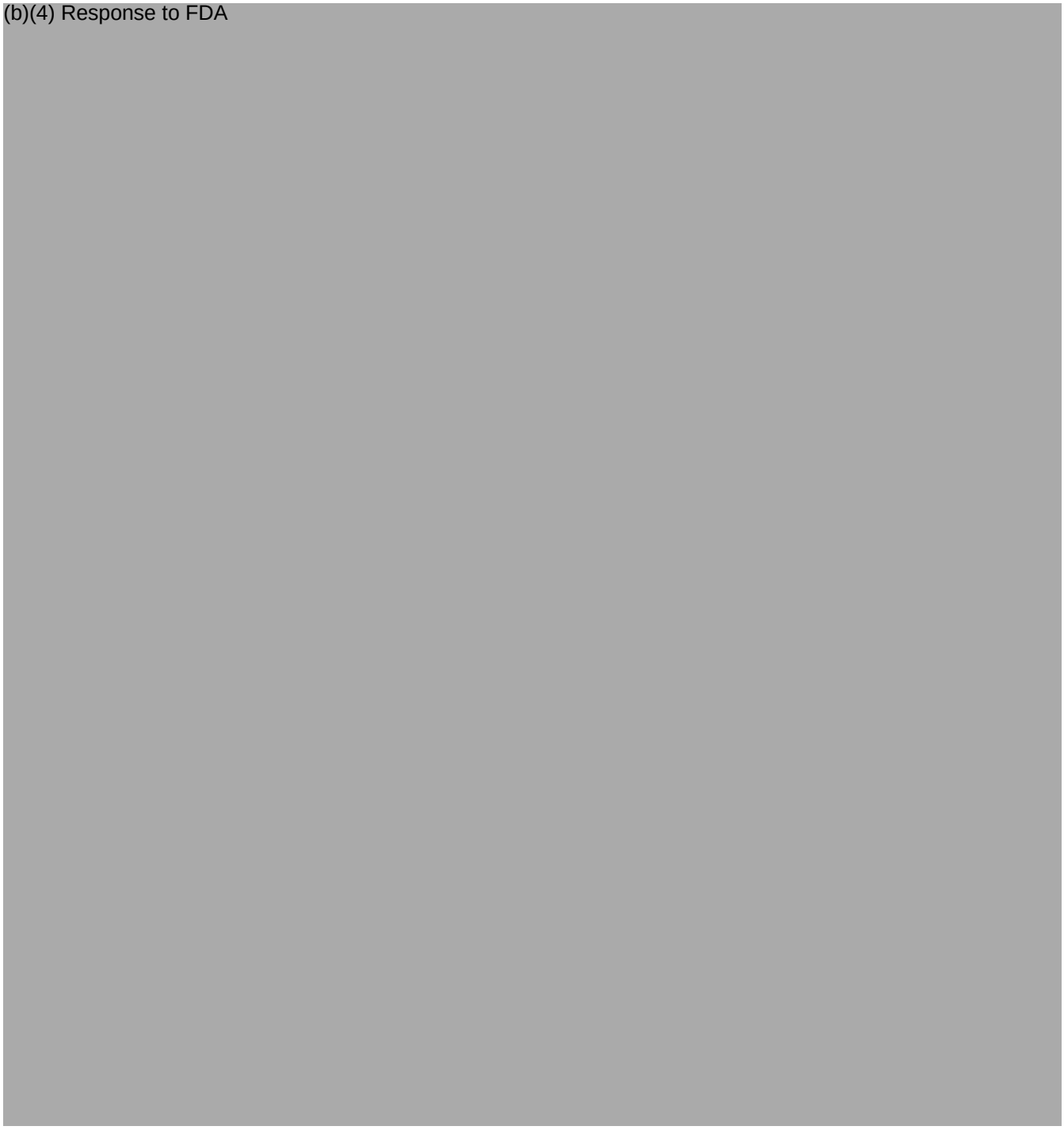

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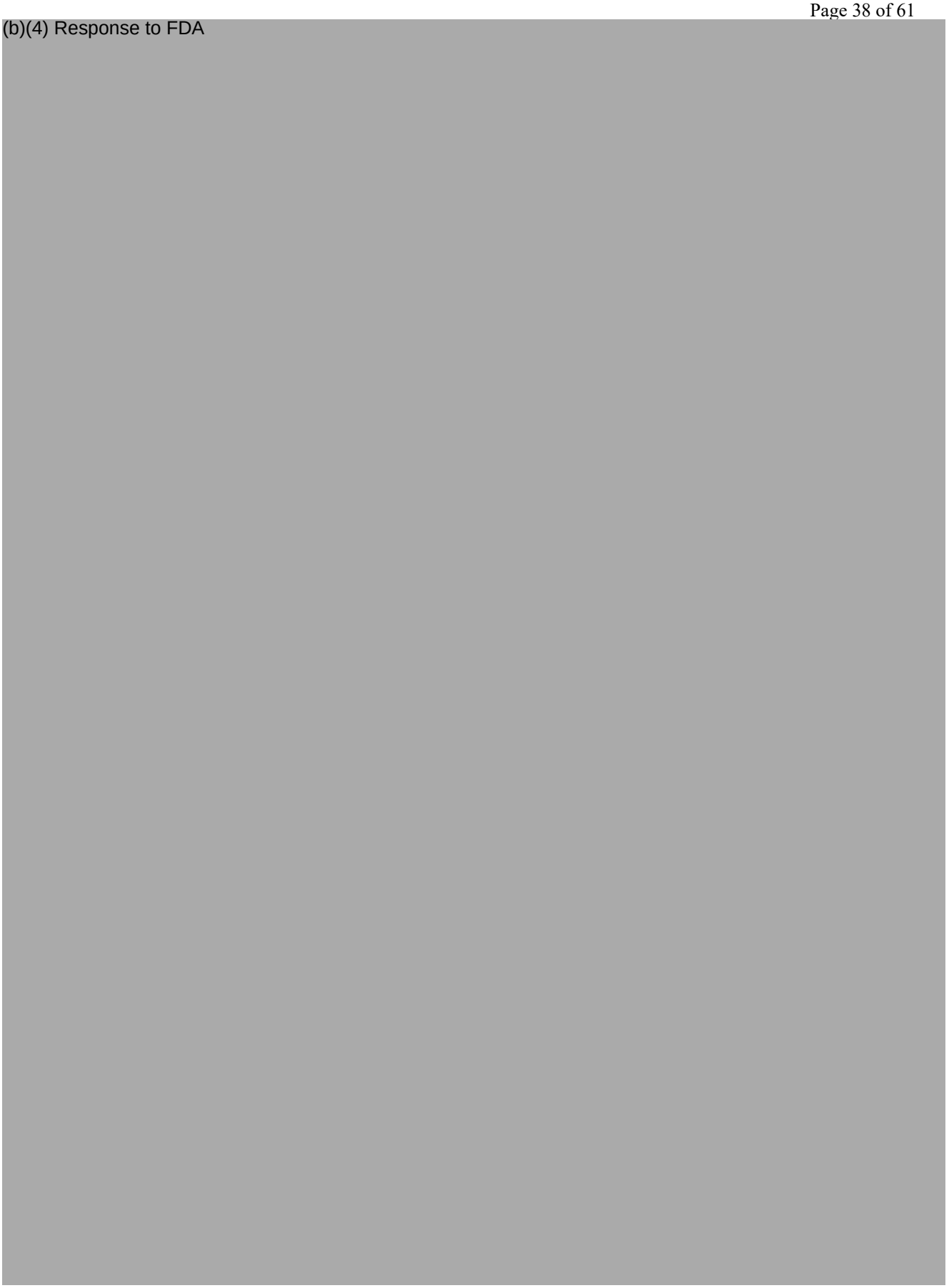

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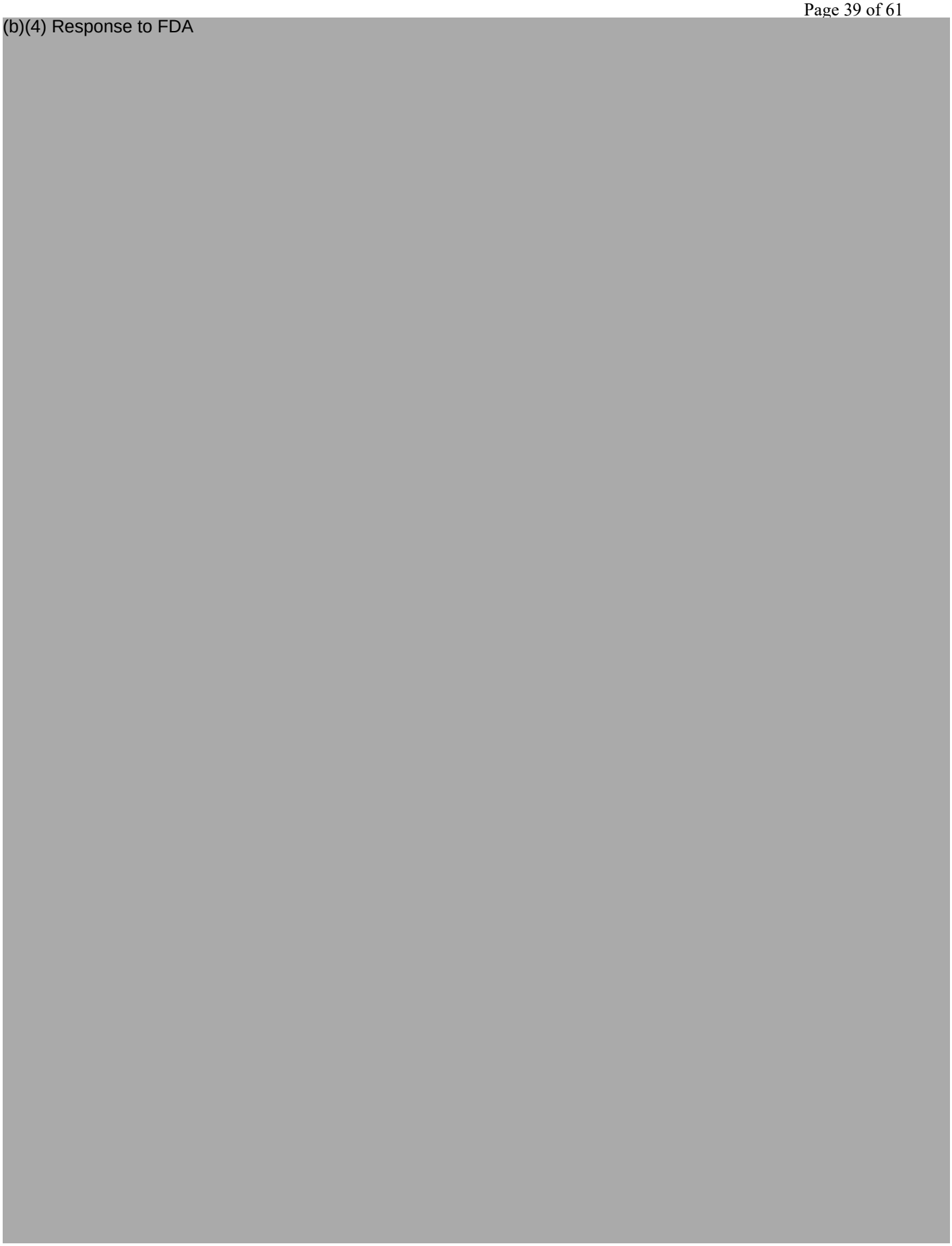

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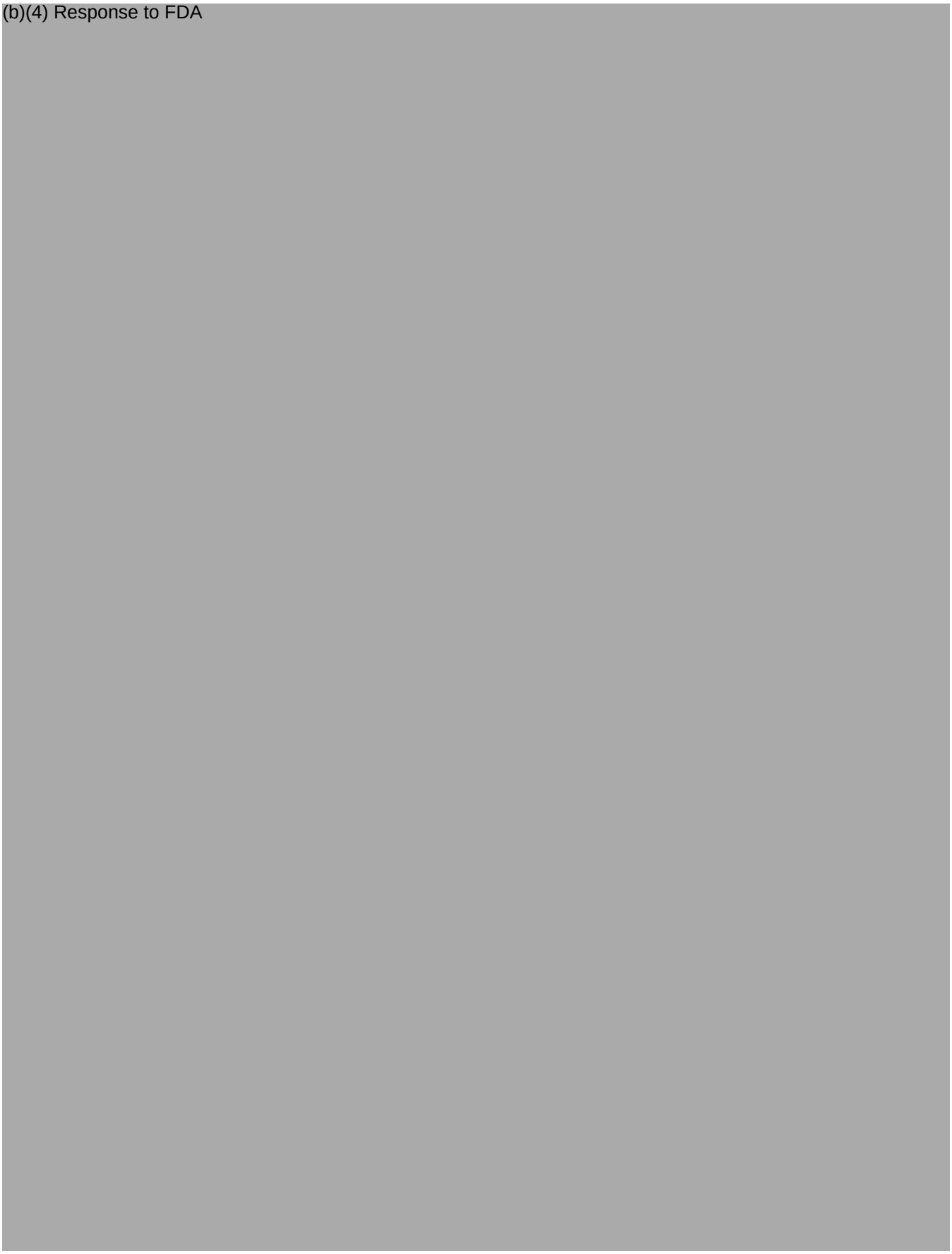

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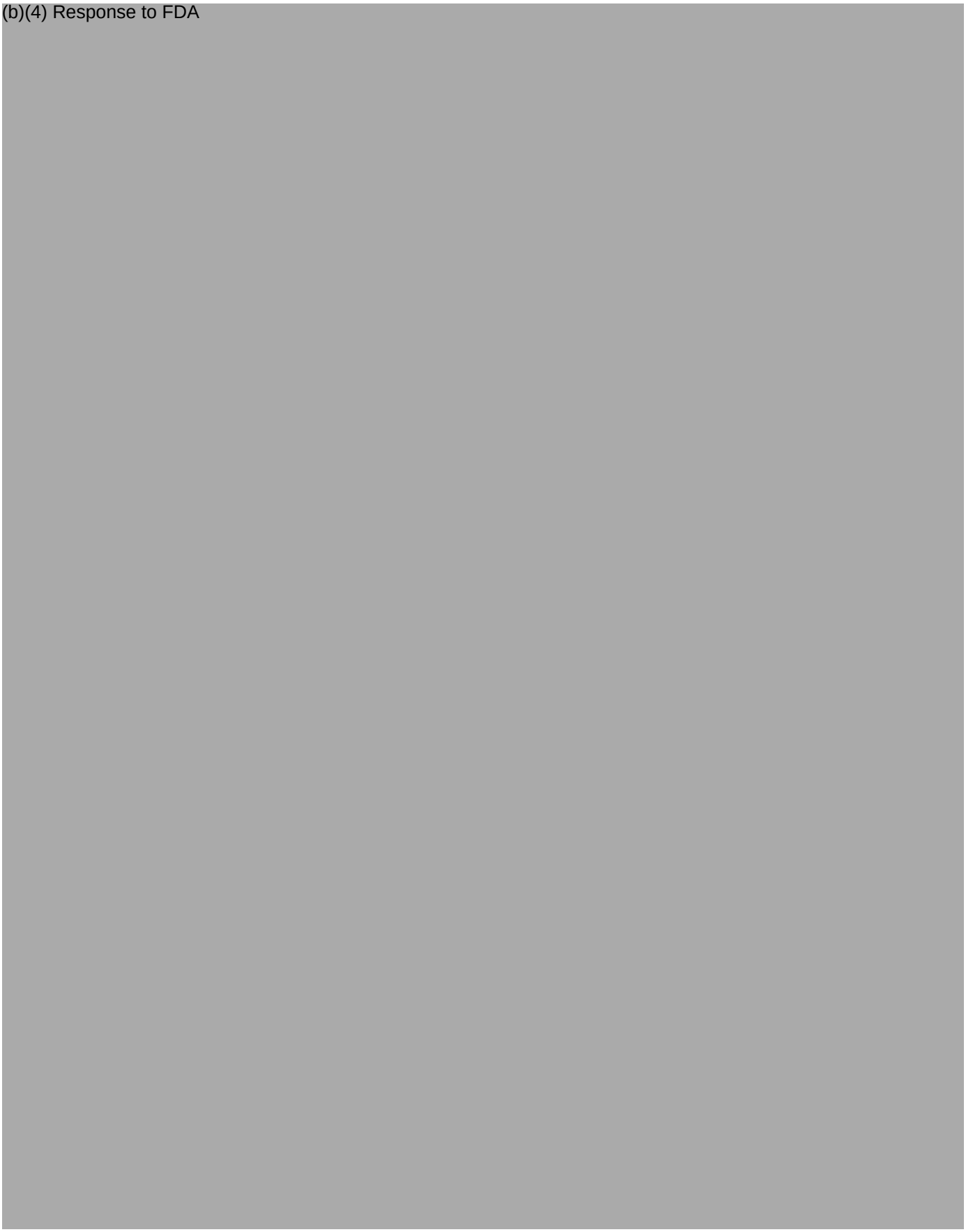
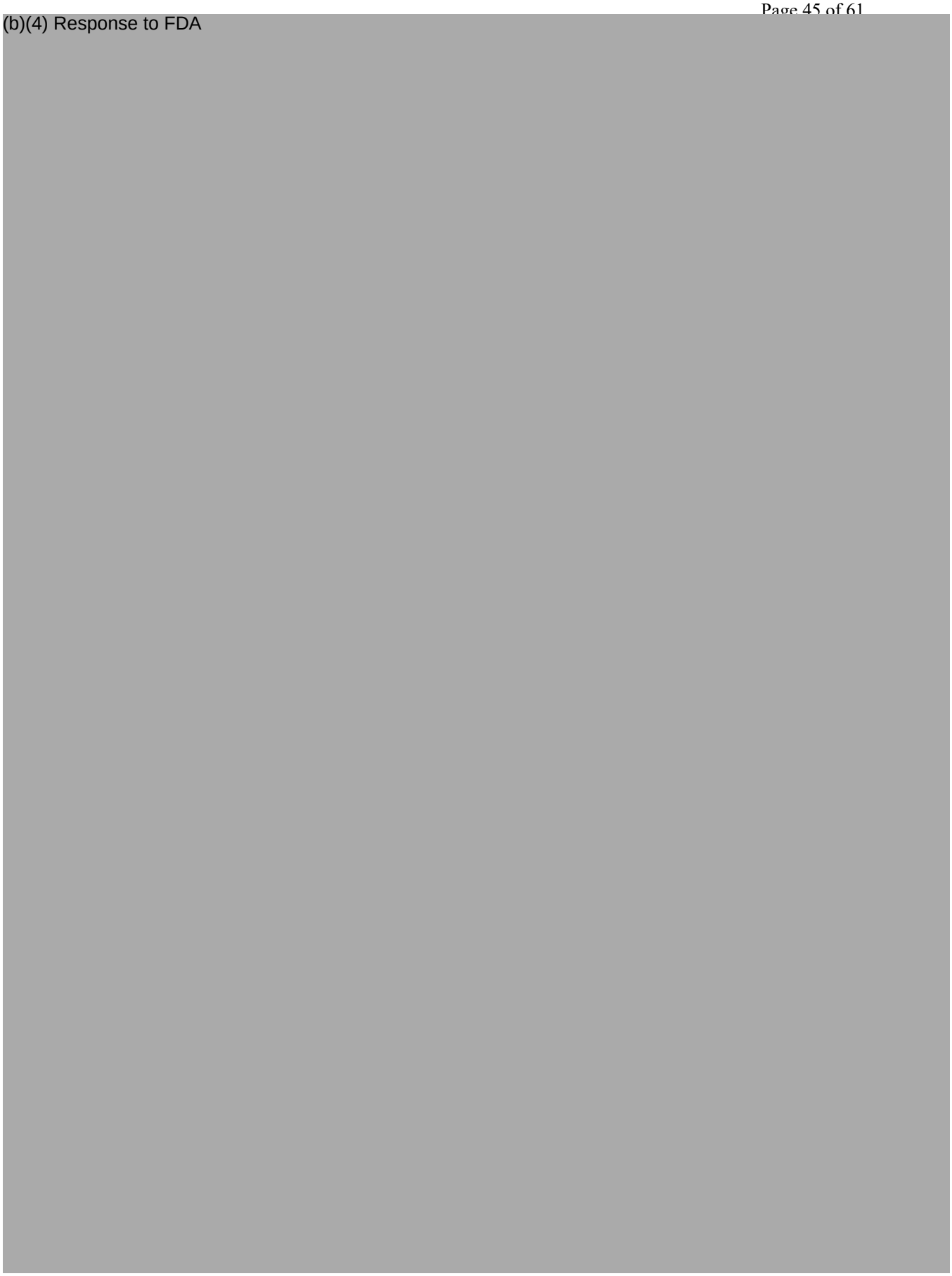


(b)(4) Response to FDA

(b)(4) Response to FDA



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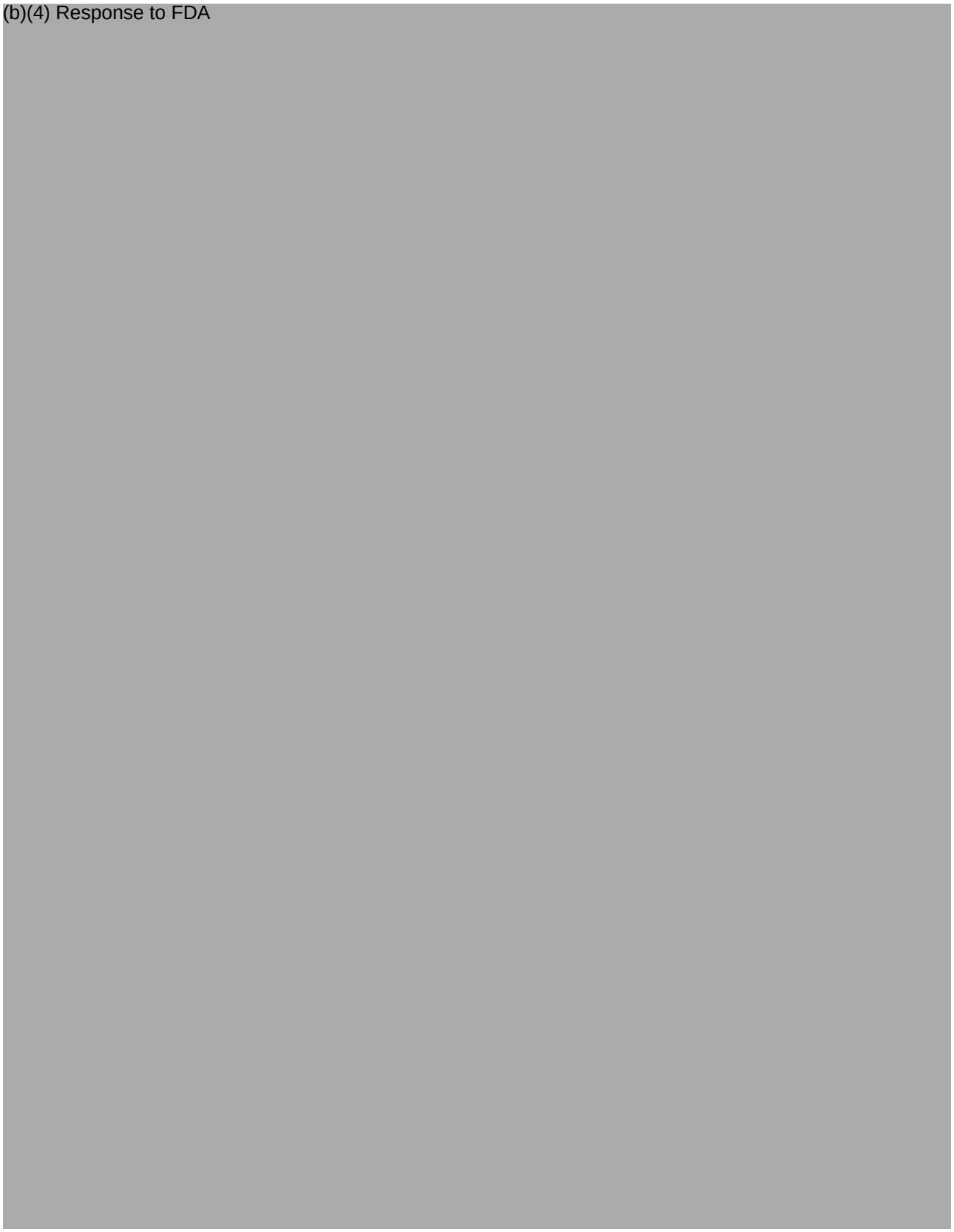

(b)(4) Response to FDA

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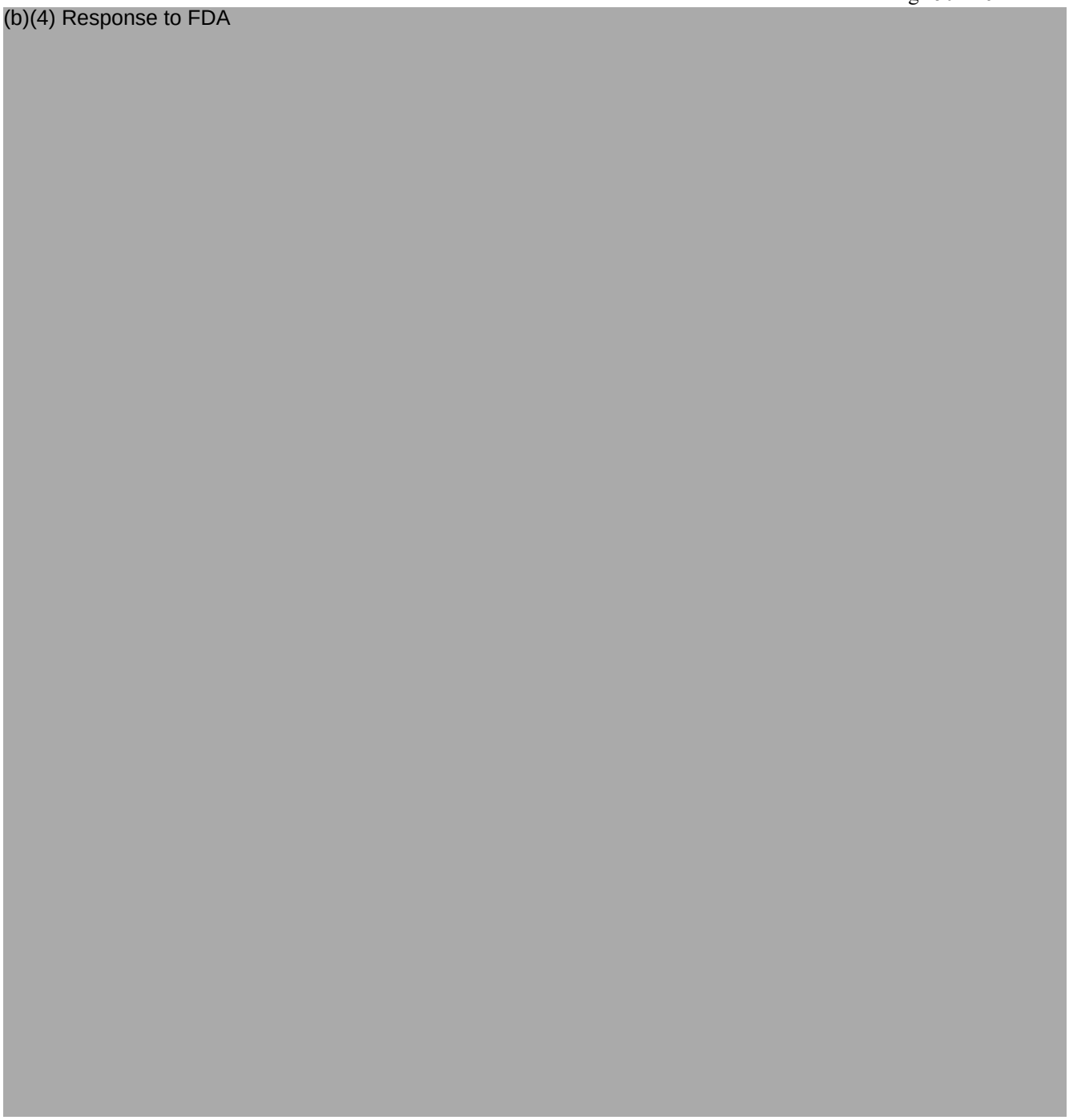
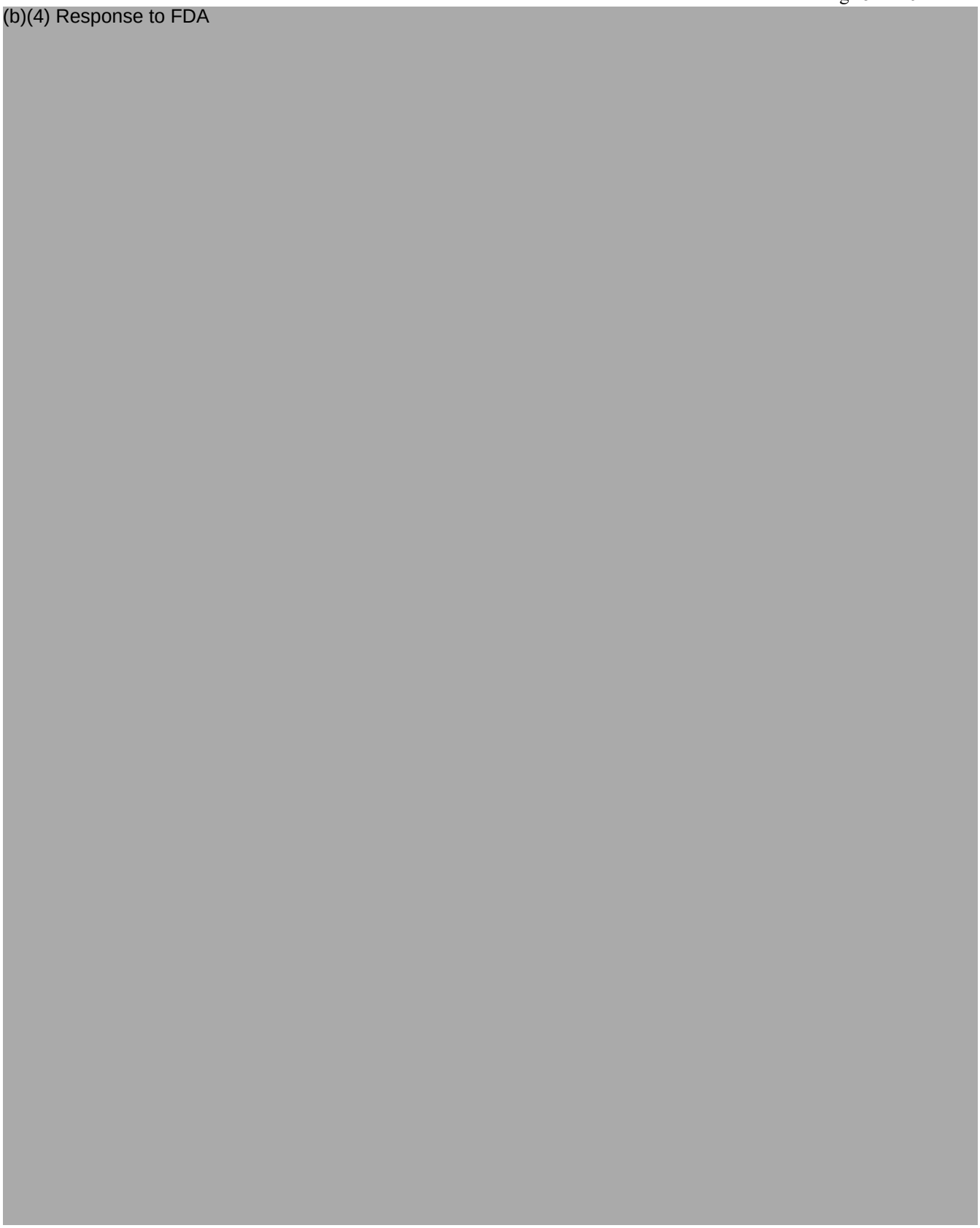


(b)(4) Response to FDA



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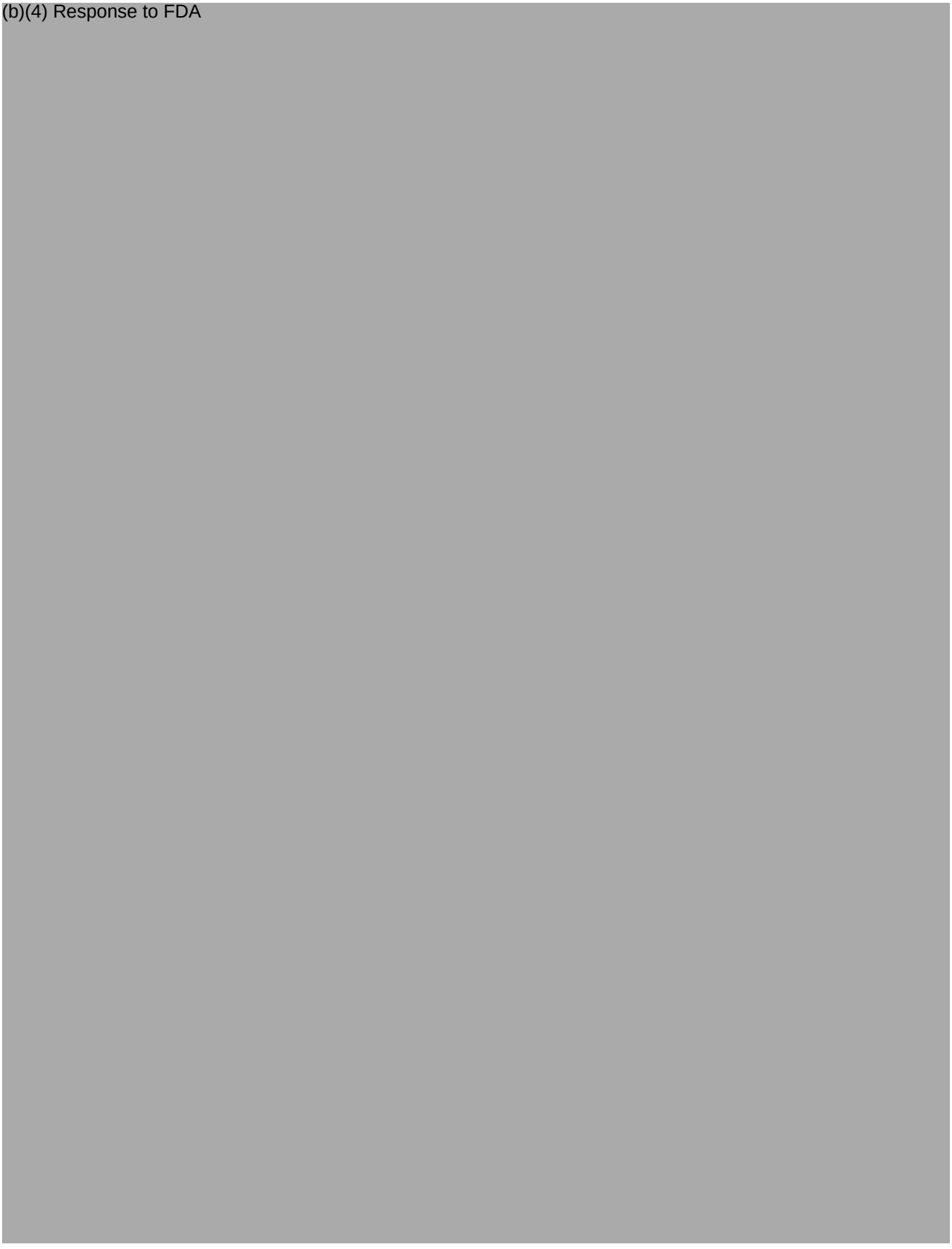

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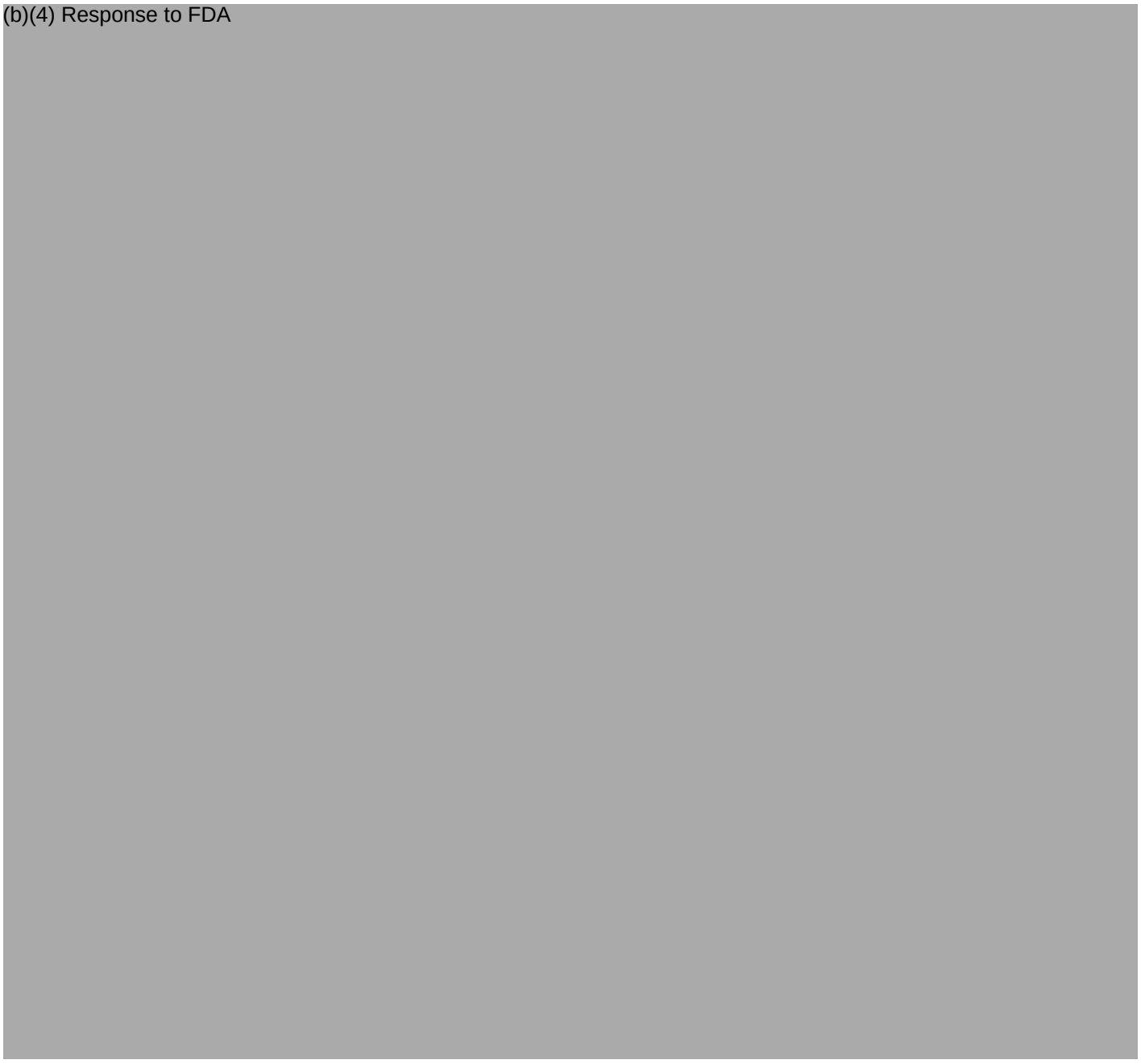

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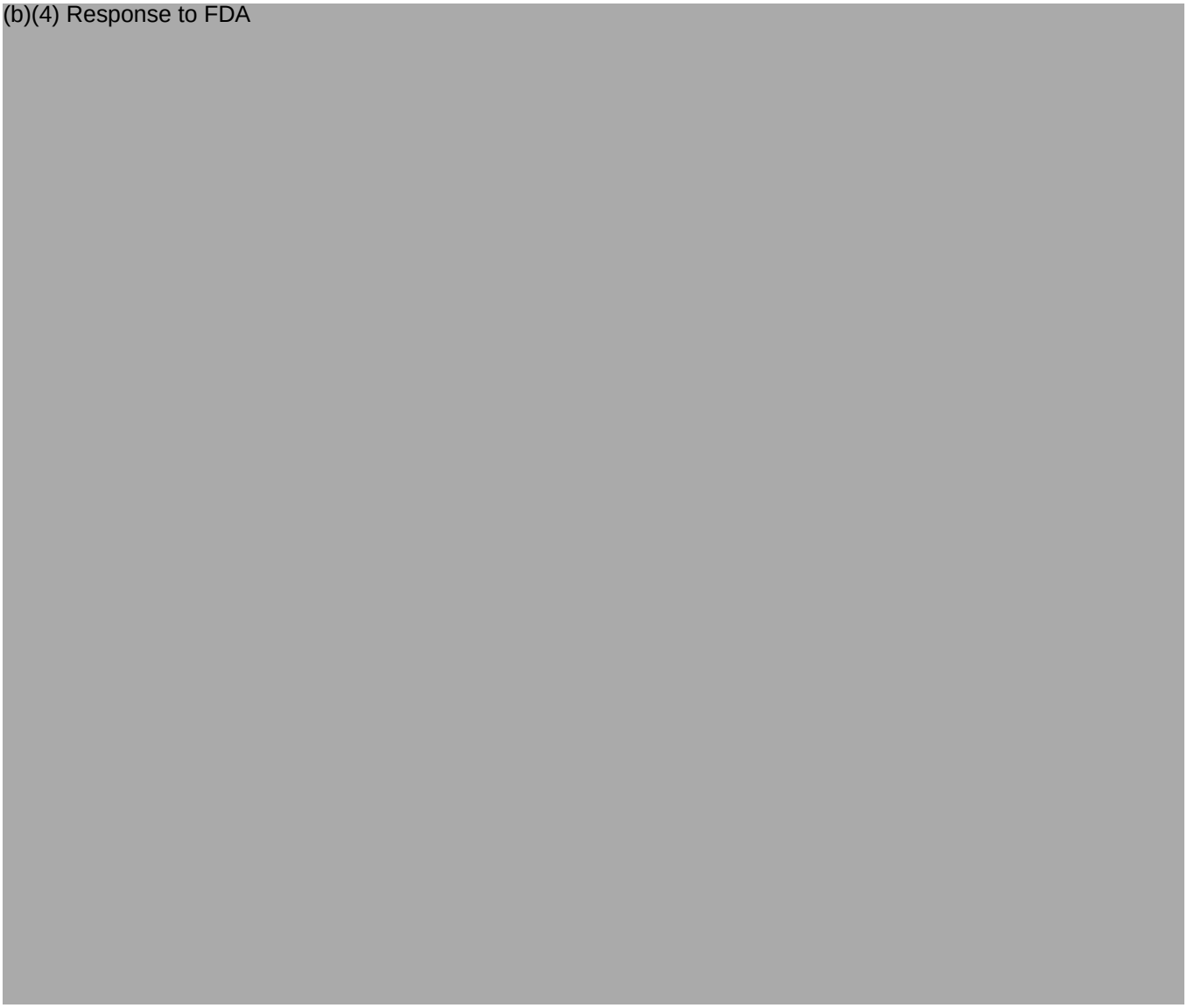

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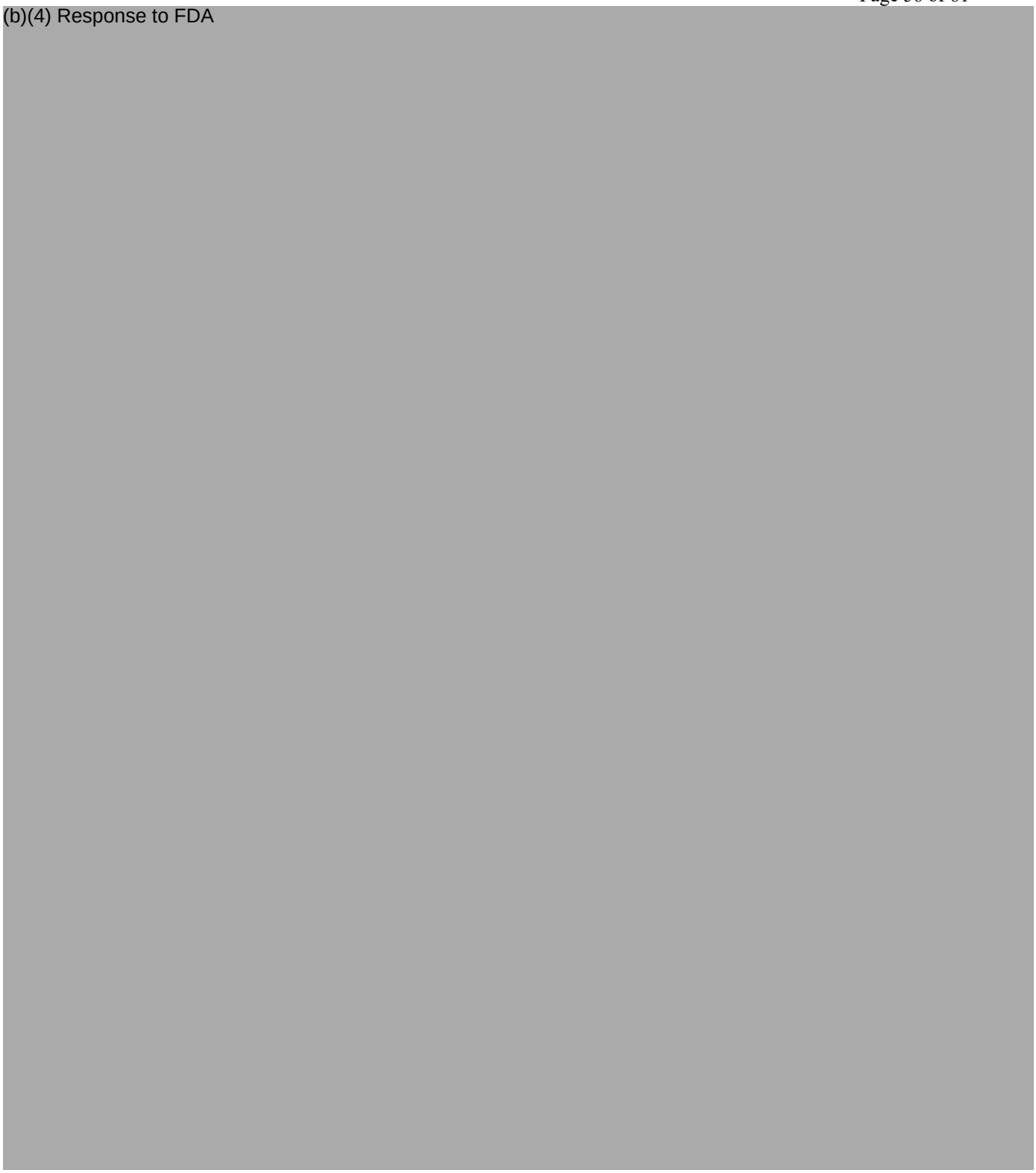

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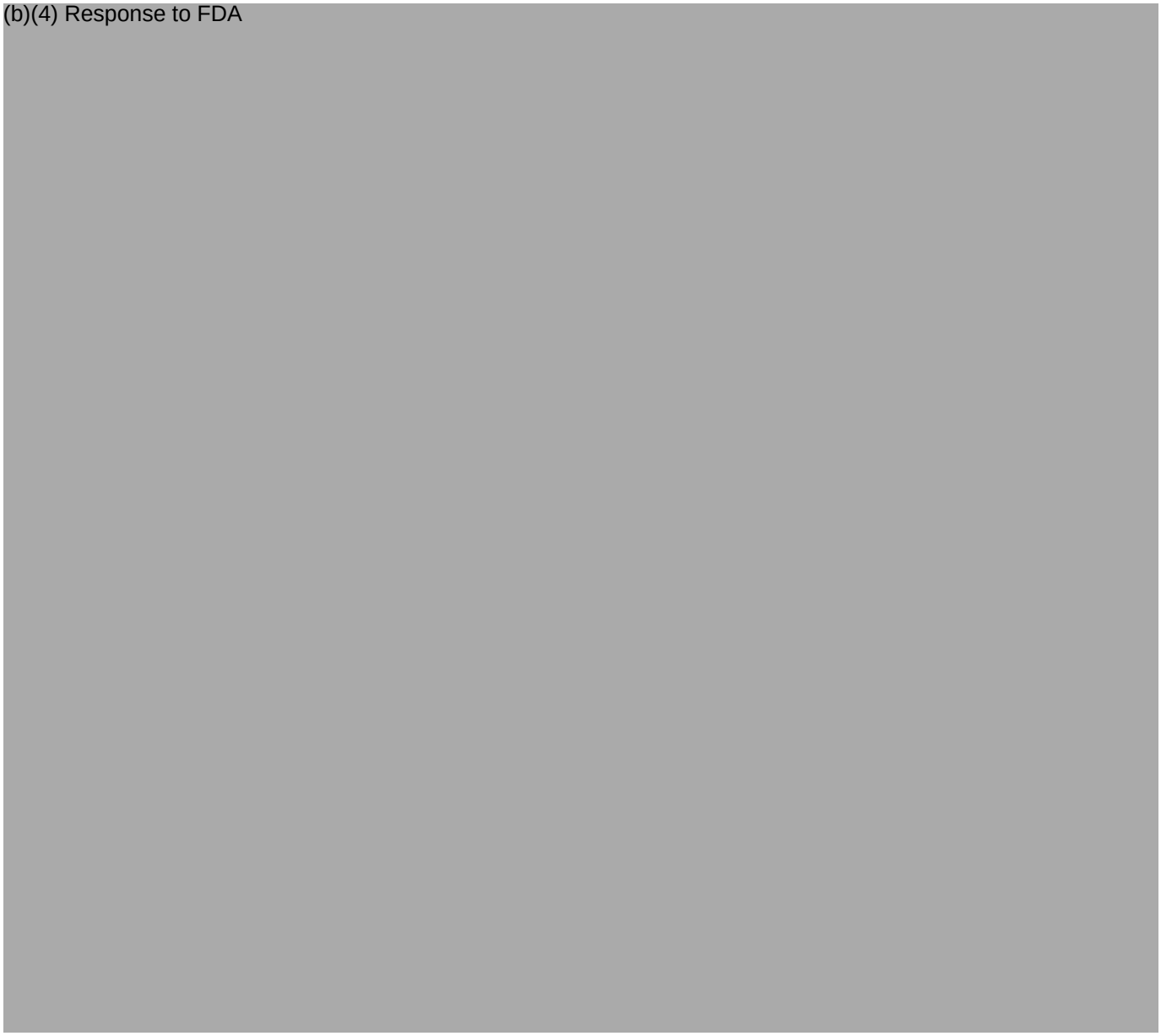

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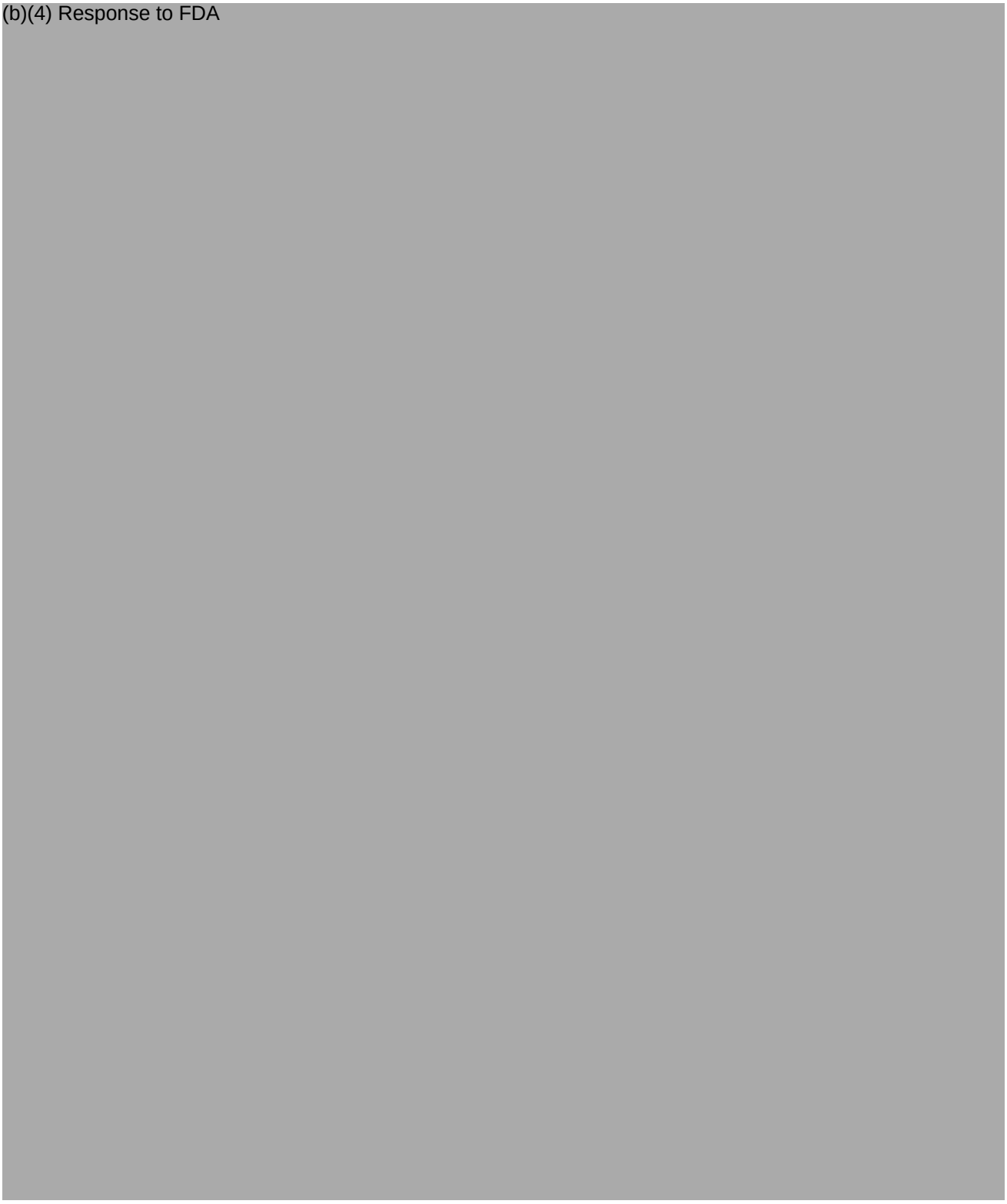

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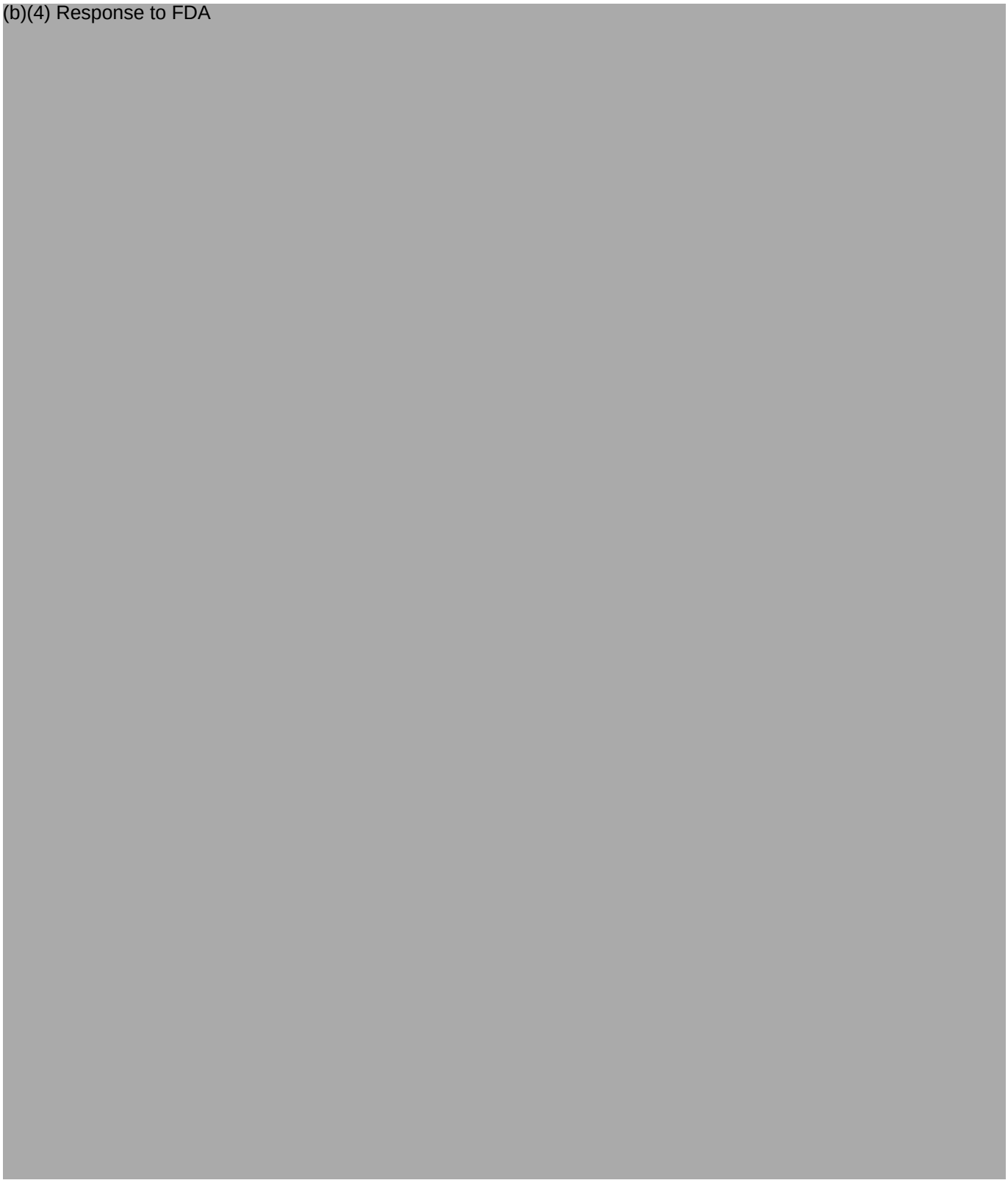

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www.alivecor.com

AliveCor®

SUBMISSION ISSUE MEETING REQUEST NOTES

April 24, 2017

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

RE: Submission Issue Meeting Notes (b) (4)

Dear Erdit,

Attached please see the meeting minutes for AliveCor and FDA meeting on April 13th 2017. Please let me know if there are any additional notes from FDA side. Please consider these meeting notes as an amendment to (b) (4)

We included a paper copy and an eCopy of this meeting minutes. The eCopy is an exact duplicate of the paper copy. Please let me know if there are any questions.

Sincerely,

Arezou Azar

Director, Regulatory Affairs, Product Compliance Management,

Quality Engineering

(b) (4) Kardia Band Submission Issues Meeting Notes: April 13, 2017

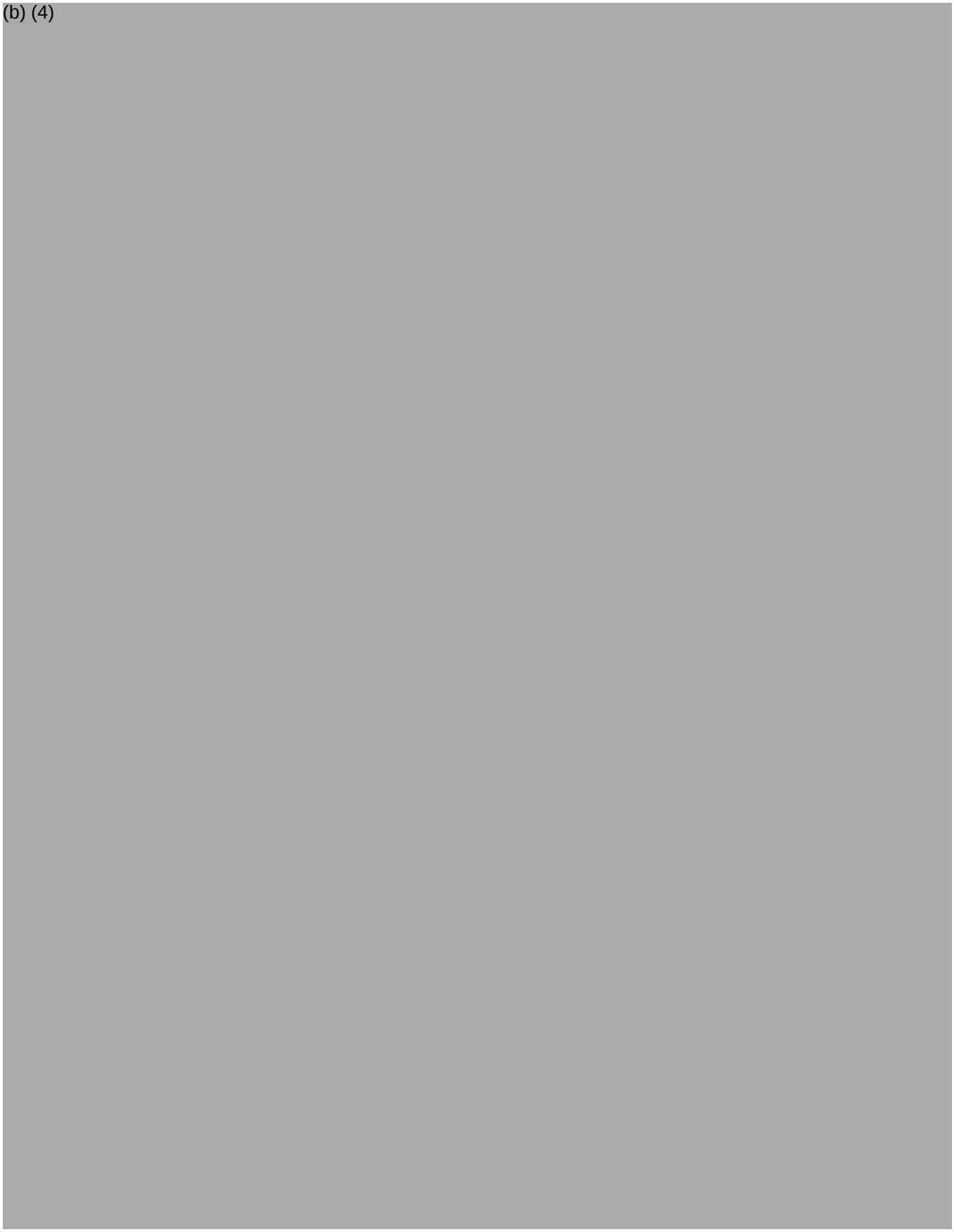
Attendees:

FDA:
Aneesh Deoras, Bradley Quinn, Hetal Patel, Linda Ricci, Loriano Galeotti, Matthew Hillebrenner, Mohua Choudhury, Erdit Gremi

AliveCor:
Arezou Azar, Director of Regulatory, Quality and Product Compliance
Dave Albert, Founder, Chief Medical Officer
Simon Prakash, VP, Hardware Engineering

(b) (4)

(b) (4)



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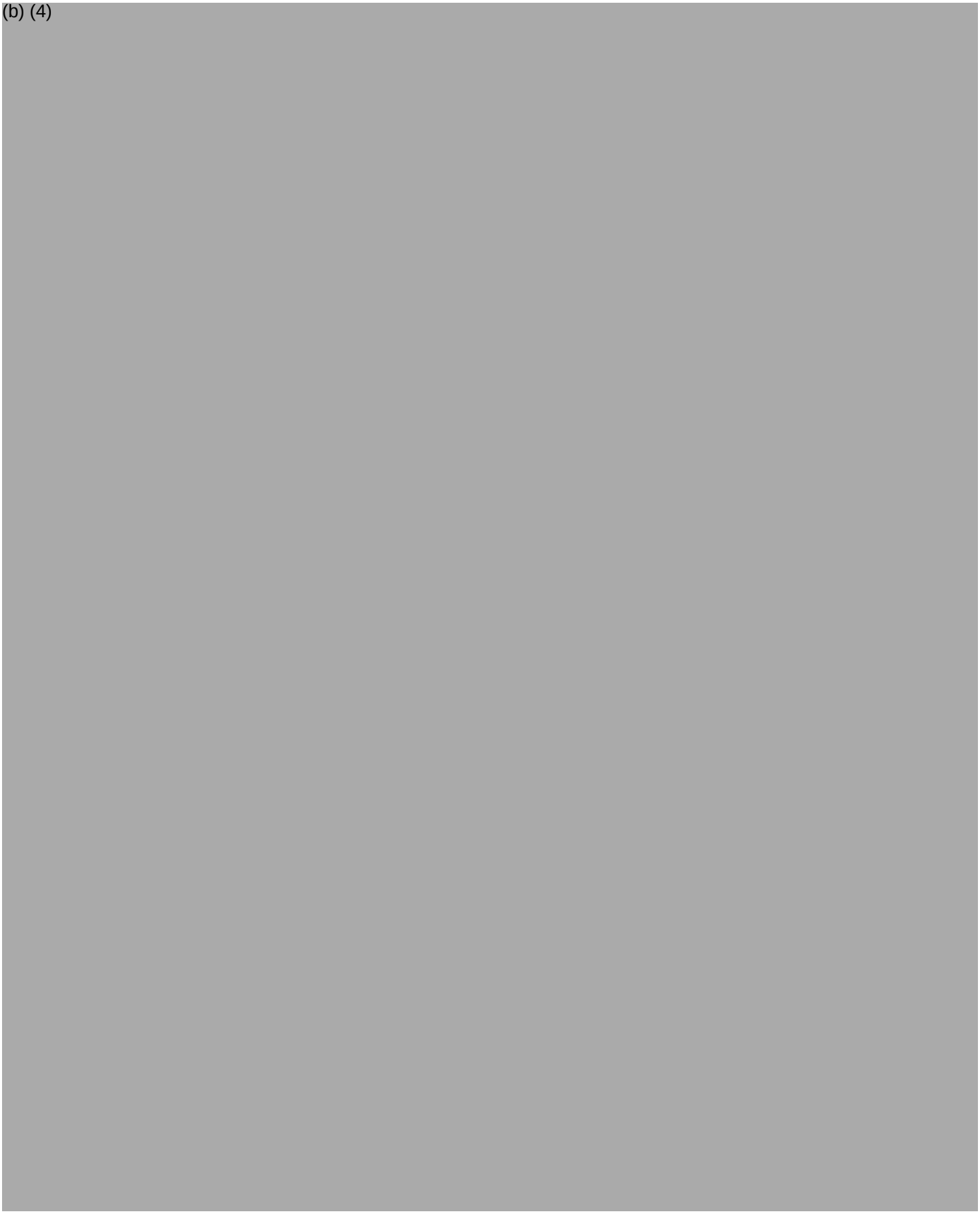

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AliveCor

(b) (4)

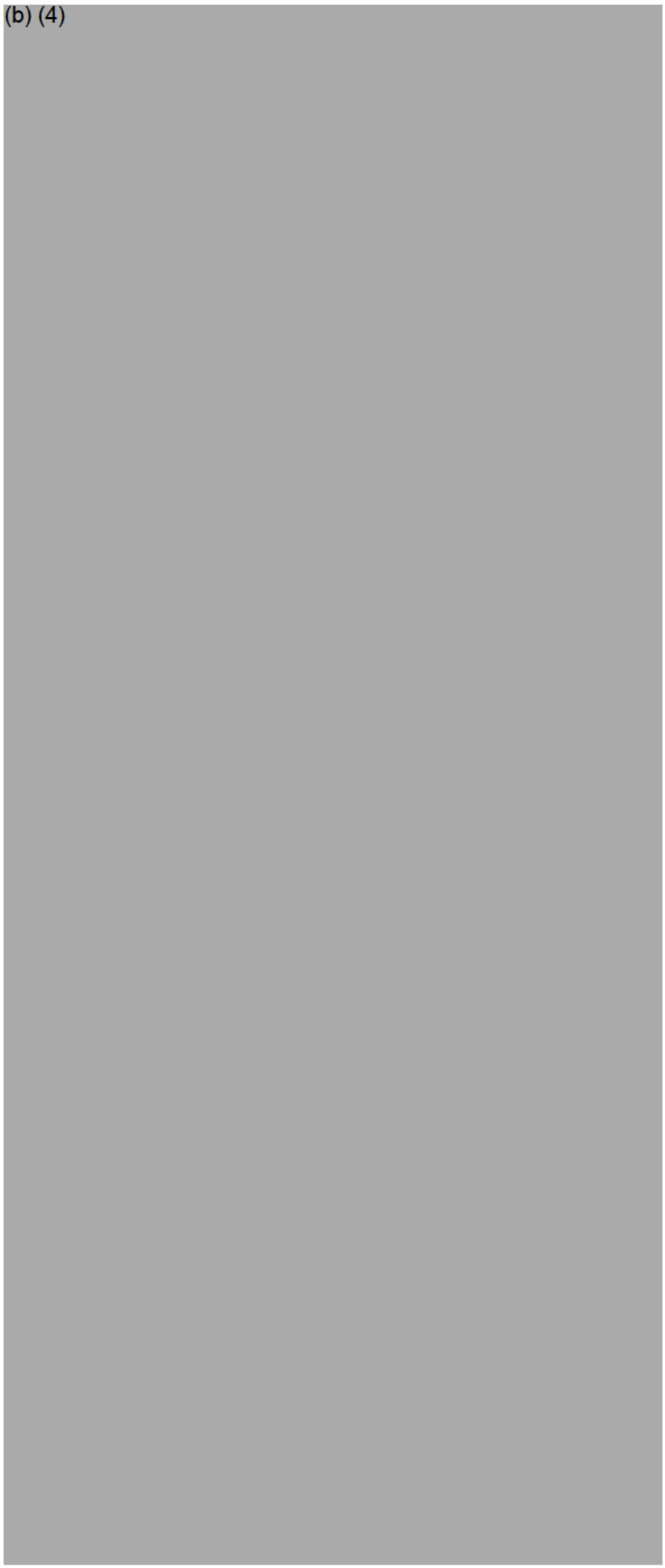
Submission Issue Meeting for **Kardia Band**

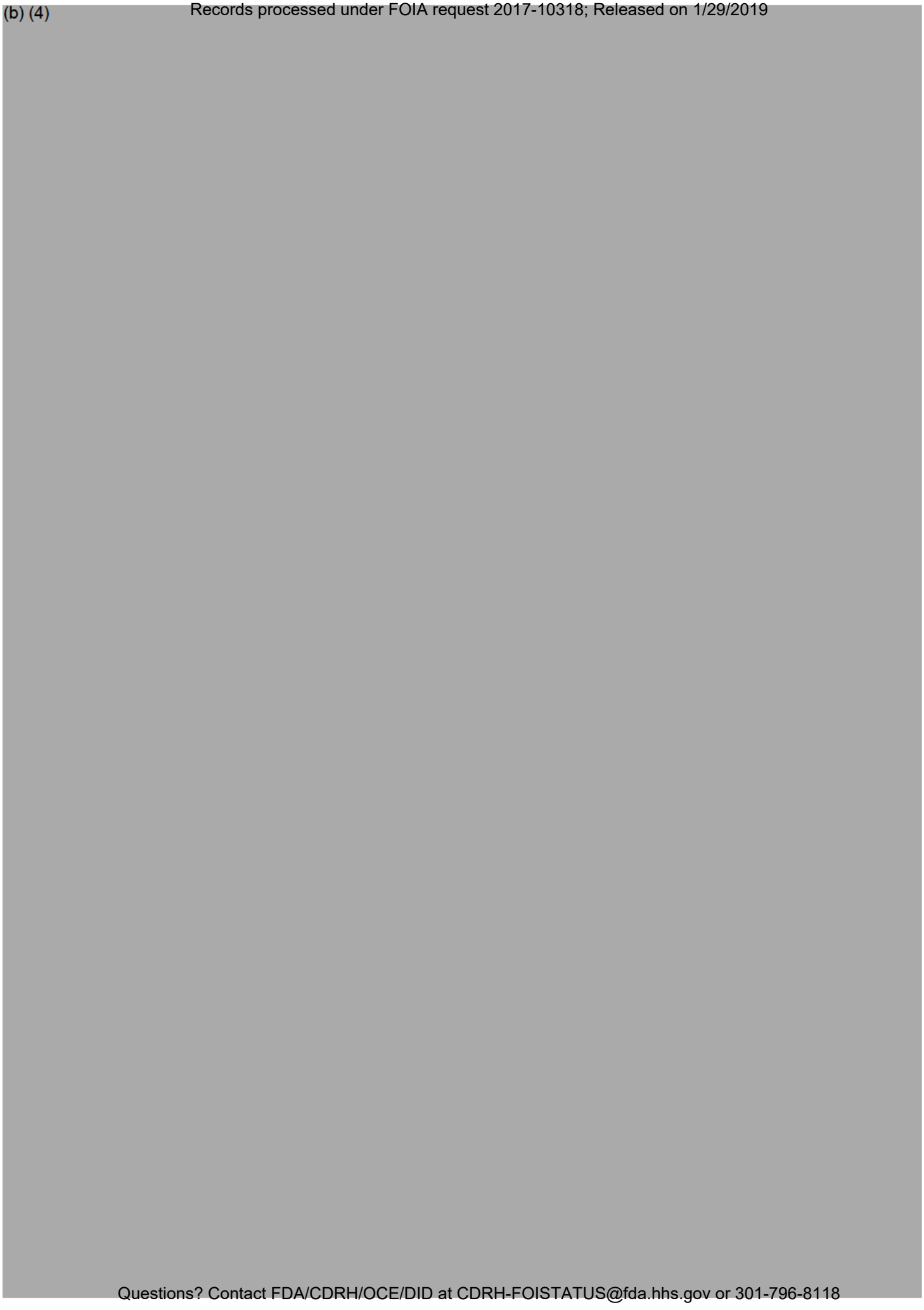
Arezou Azar, Director of Regulatory, Quality and Product Compliance

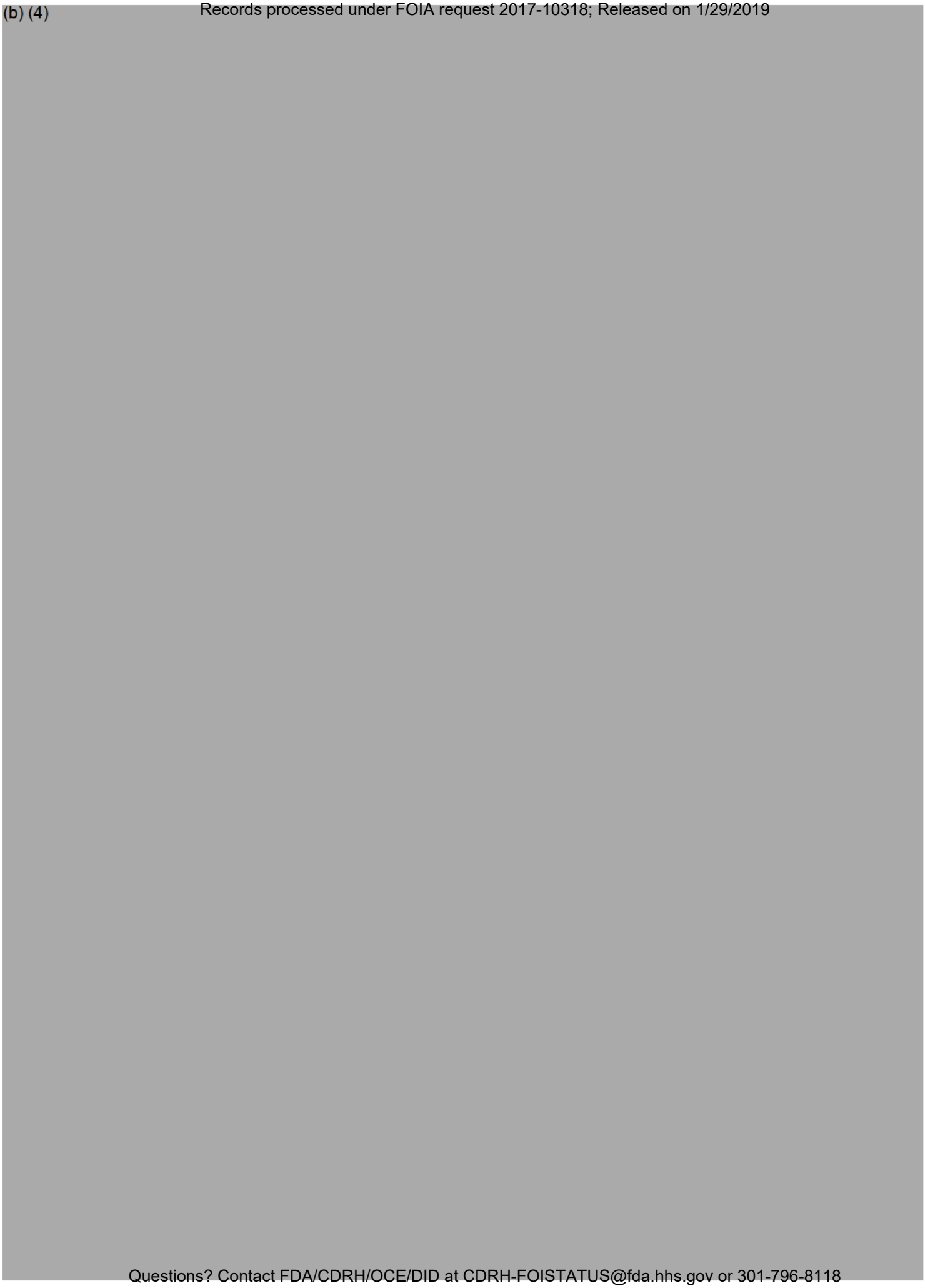
April 13, 2017

Dave Albert, Founder , Chief Medical Officer

Simon Prakash, VP, Hardware Engineering







AliveCor Questions

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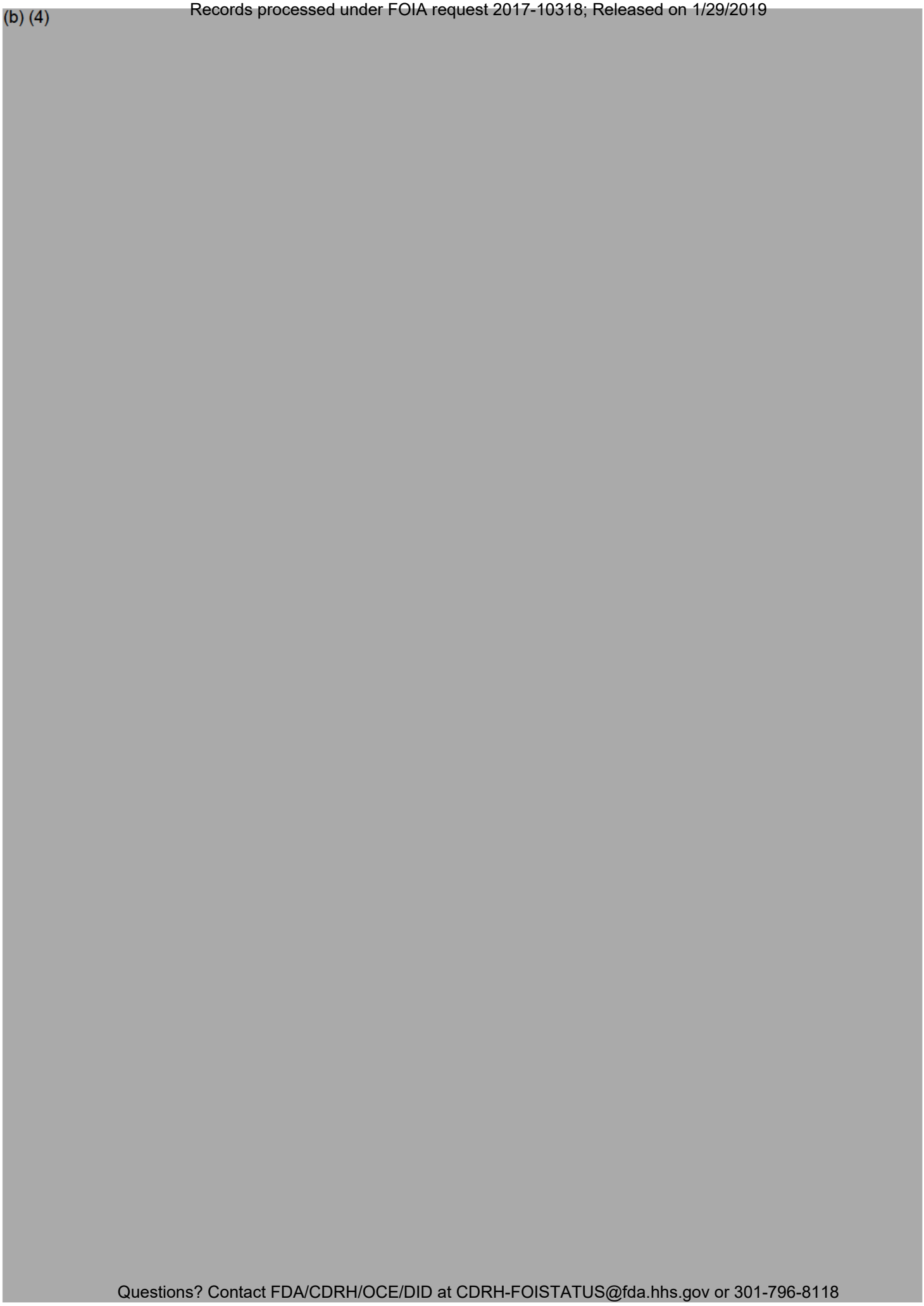

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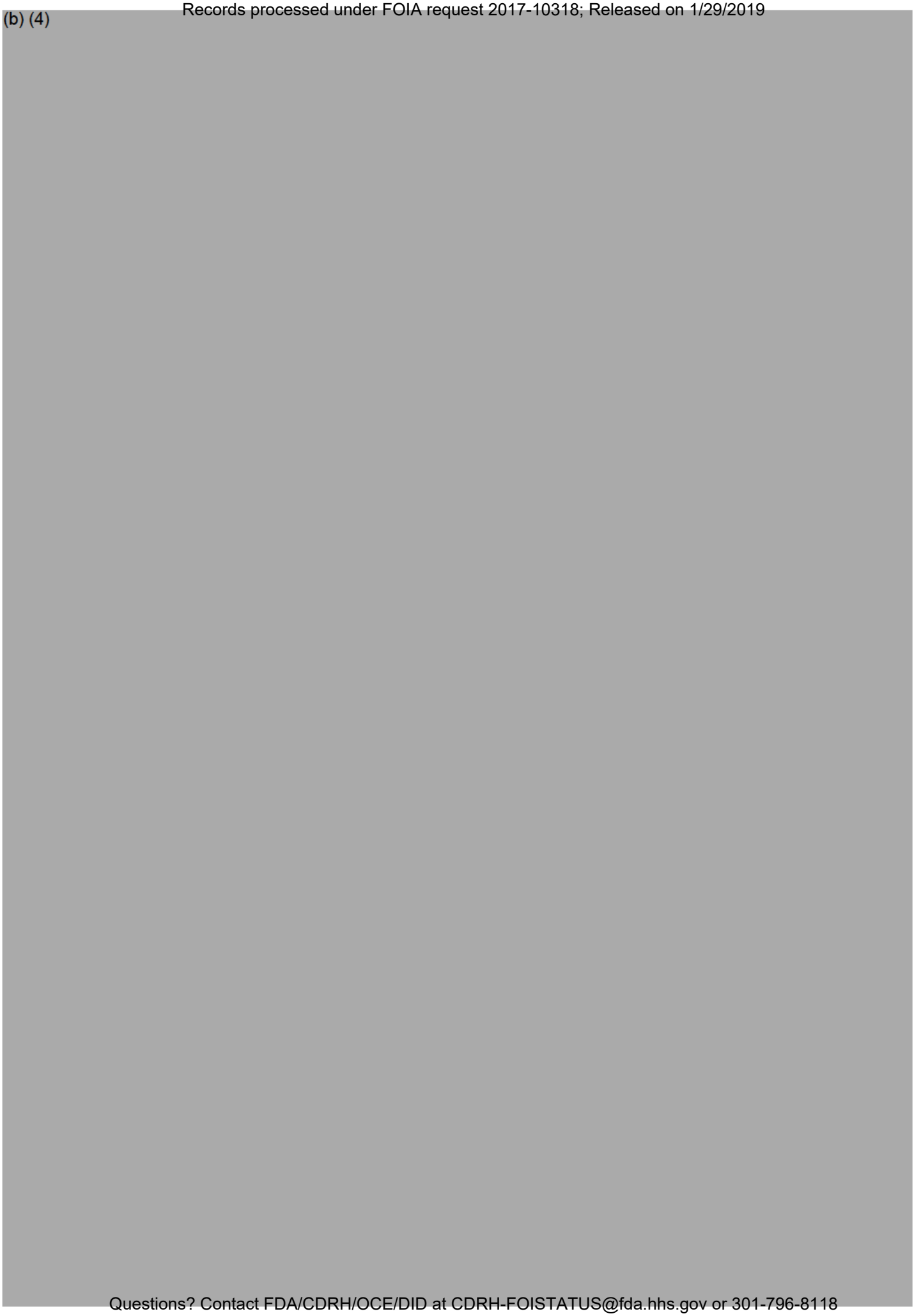

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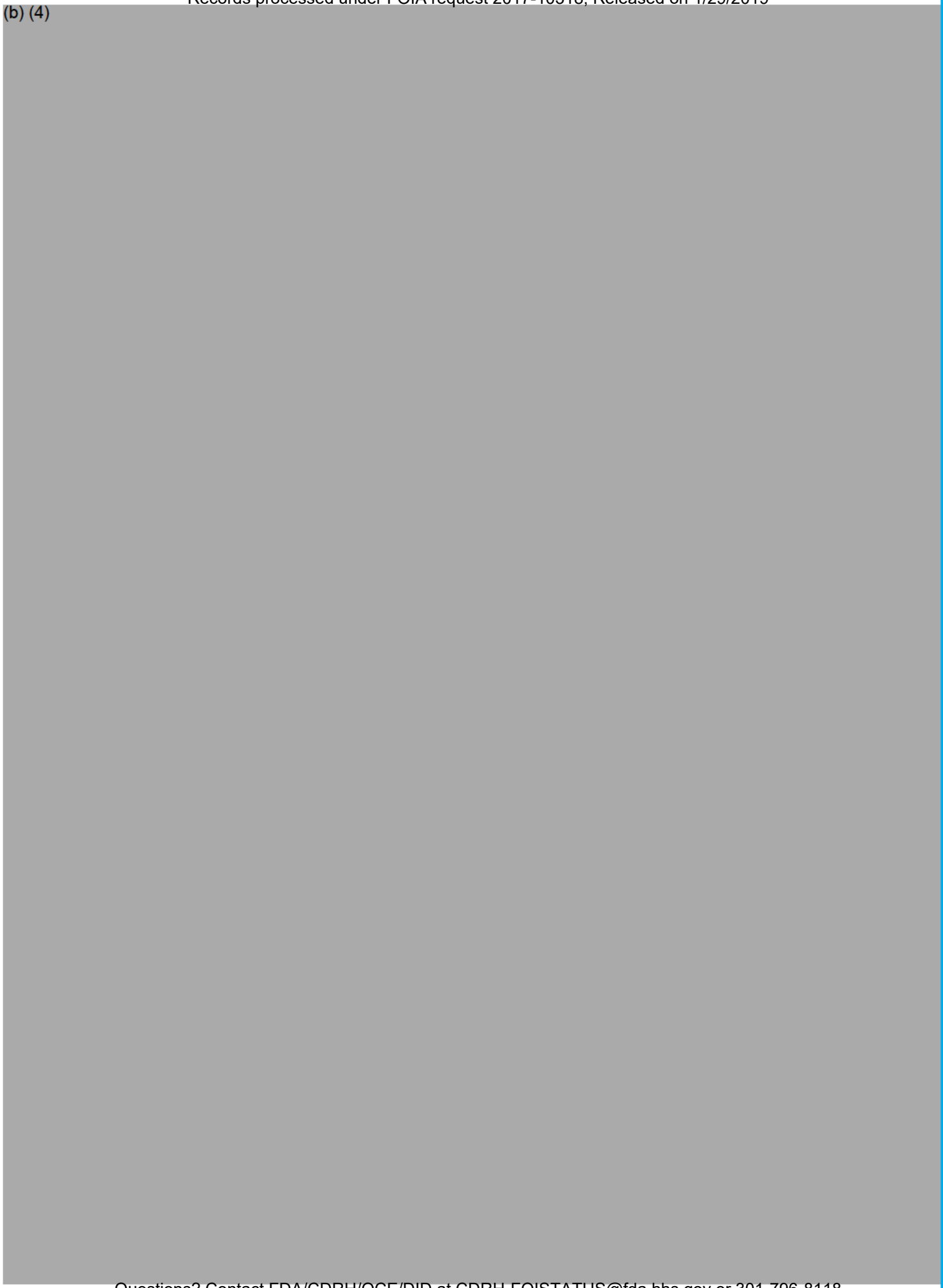

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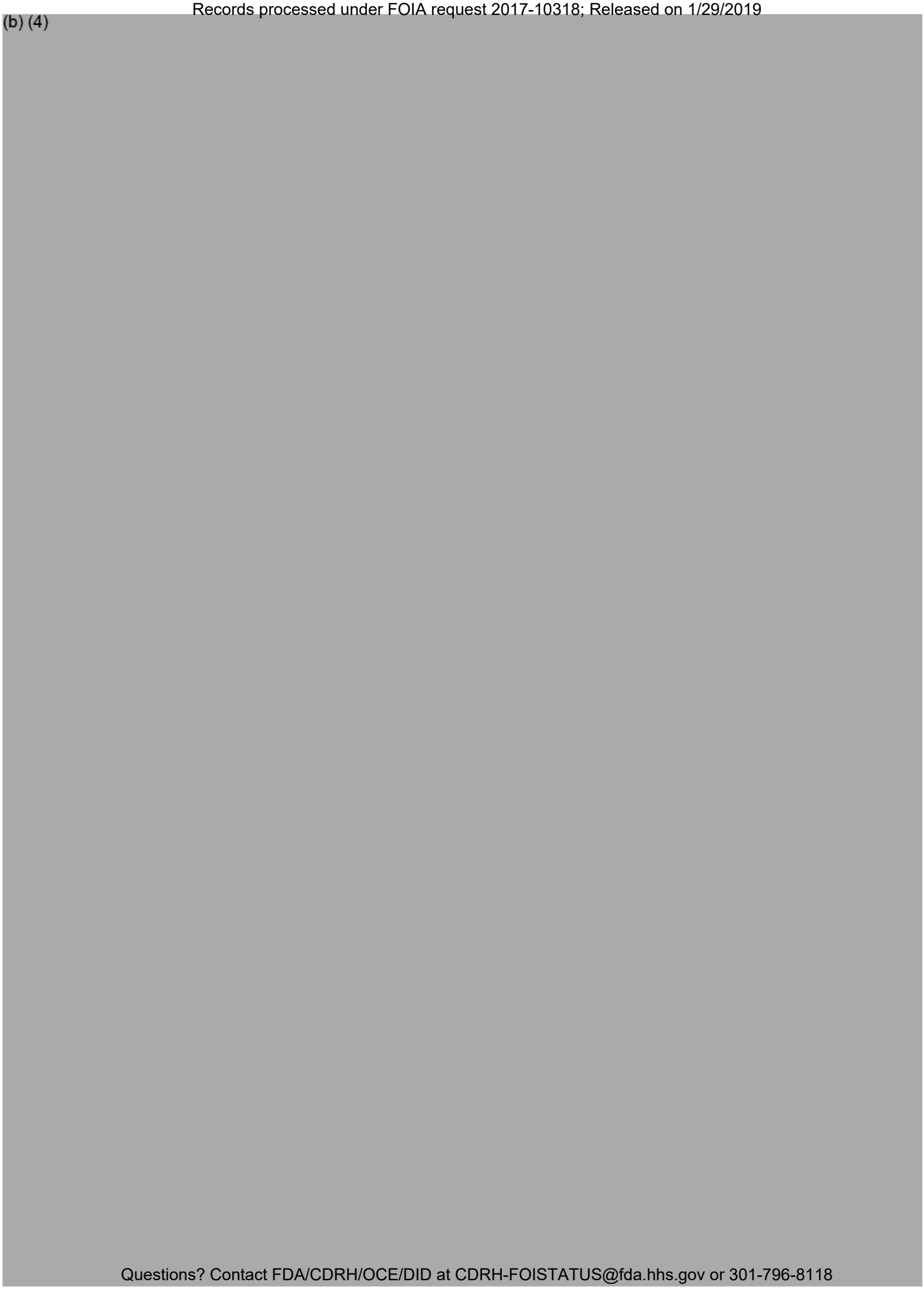

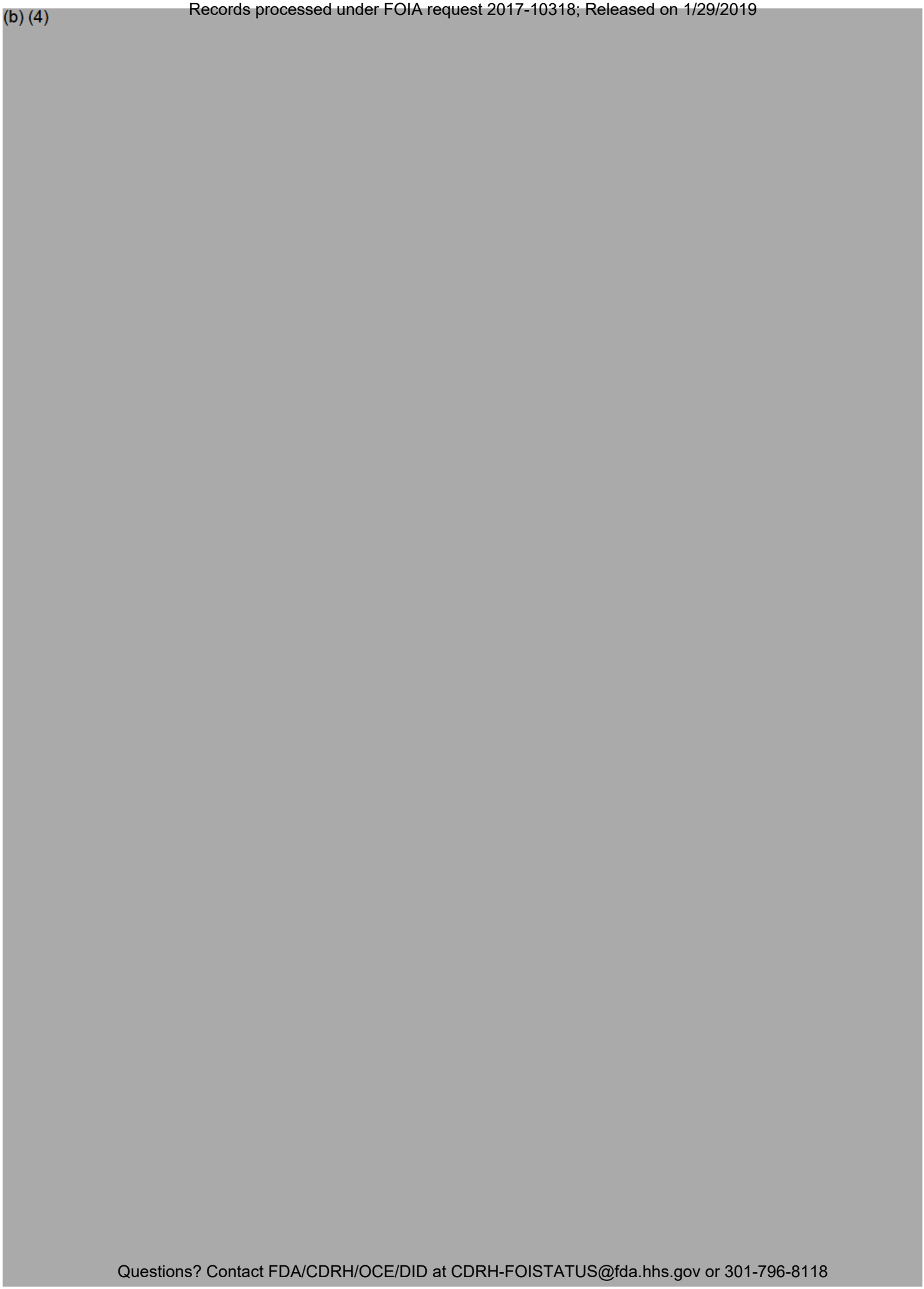

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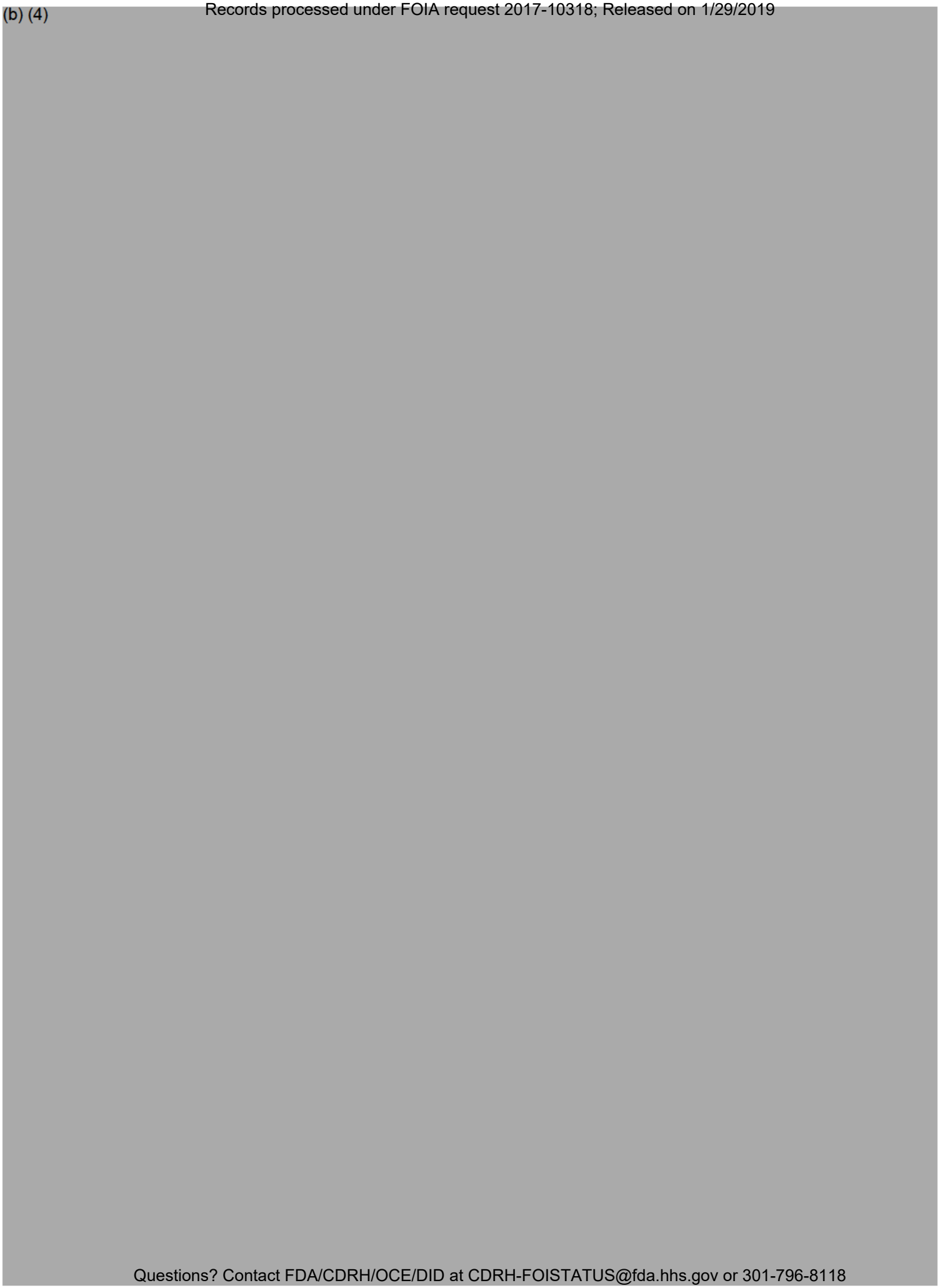

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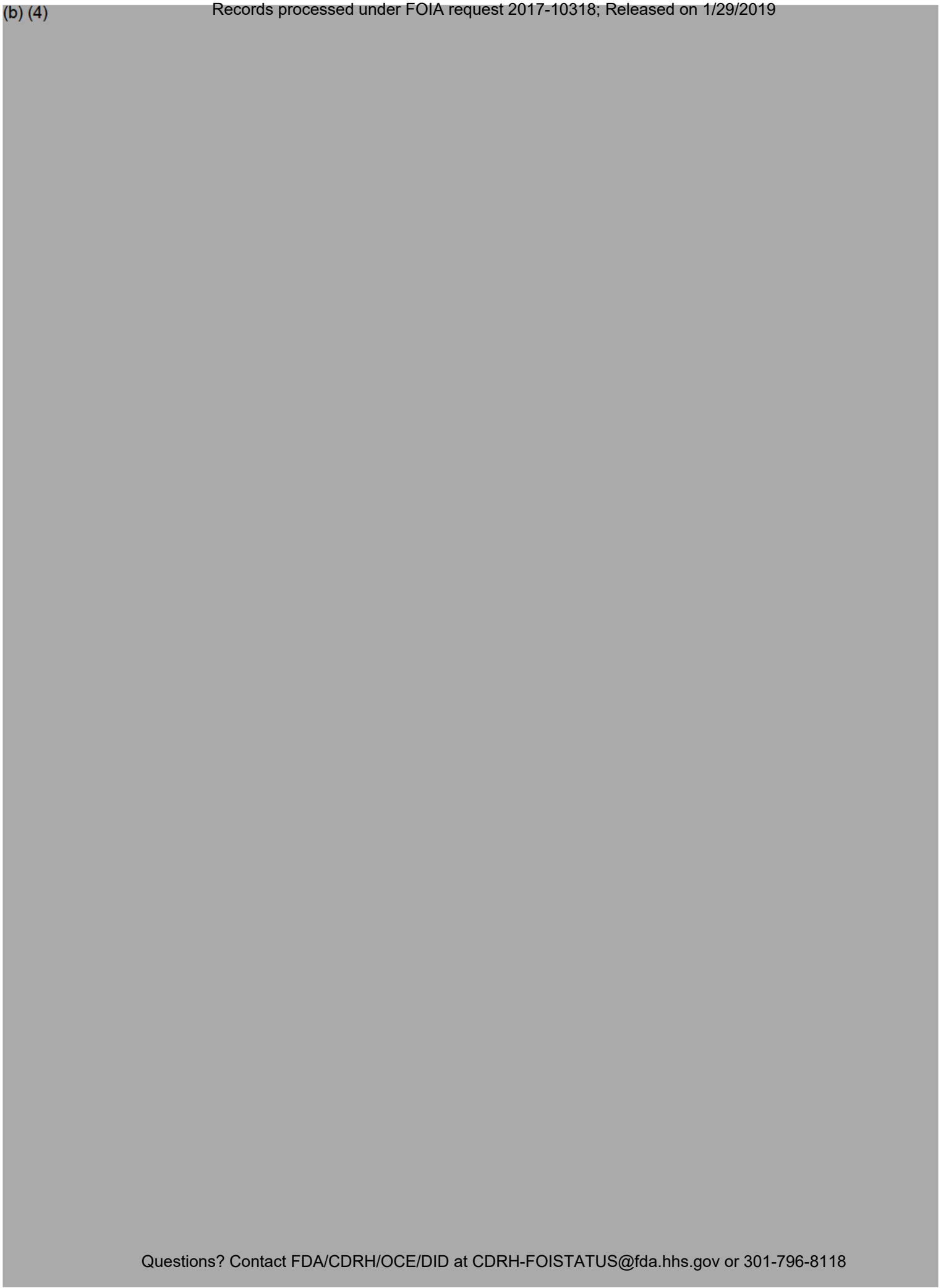

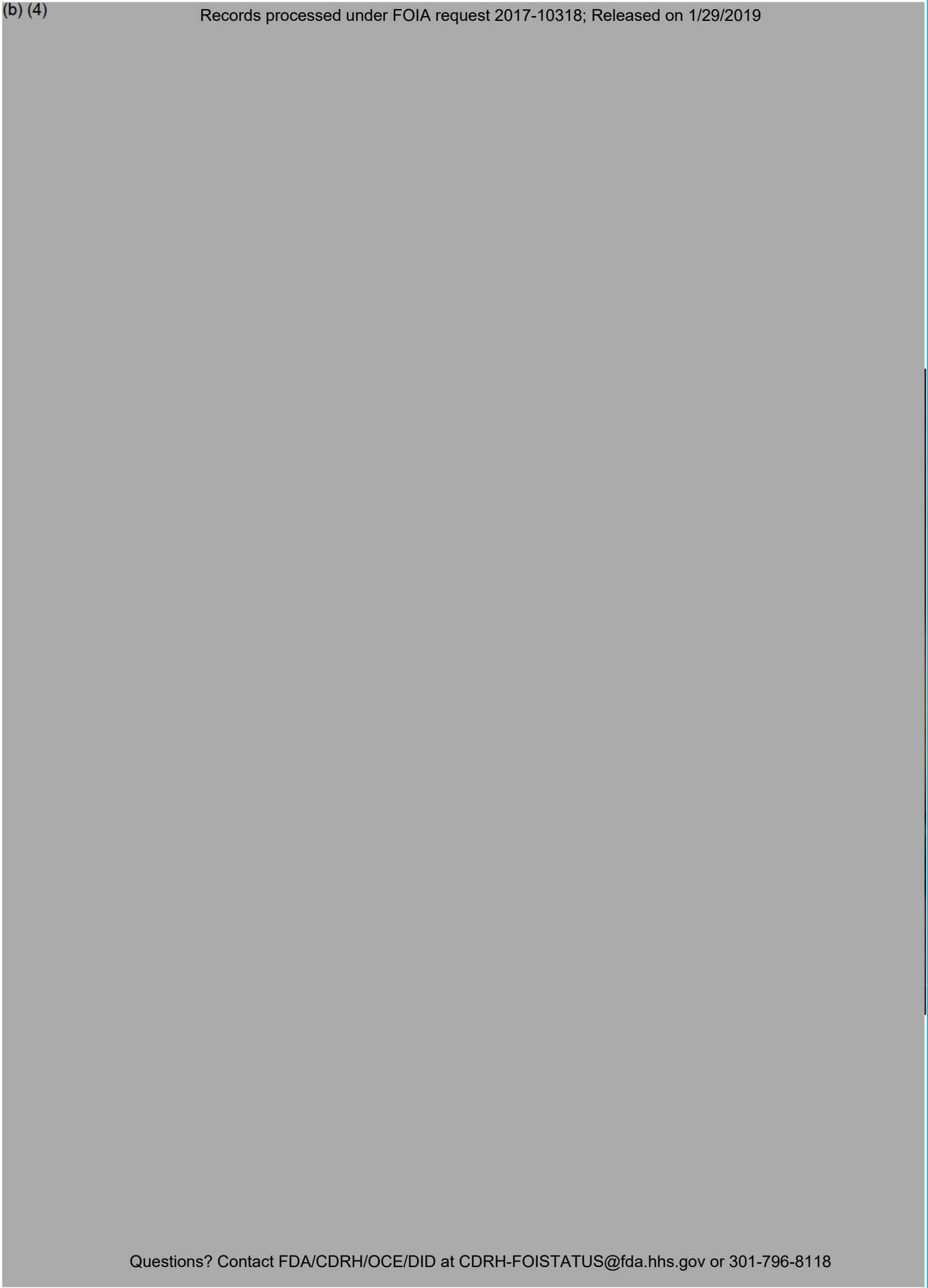

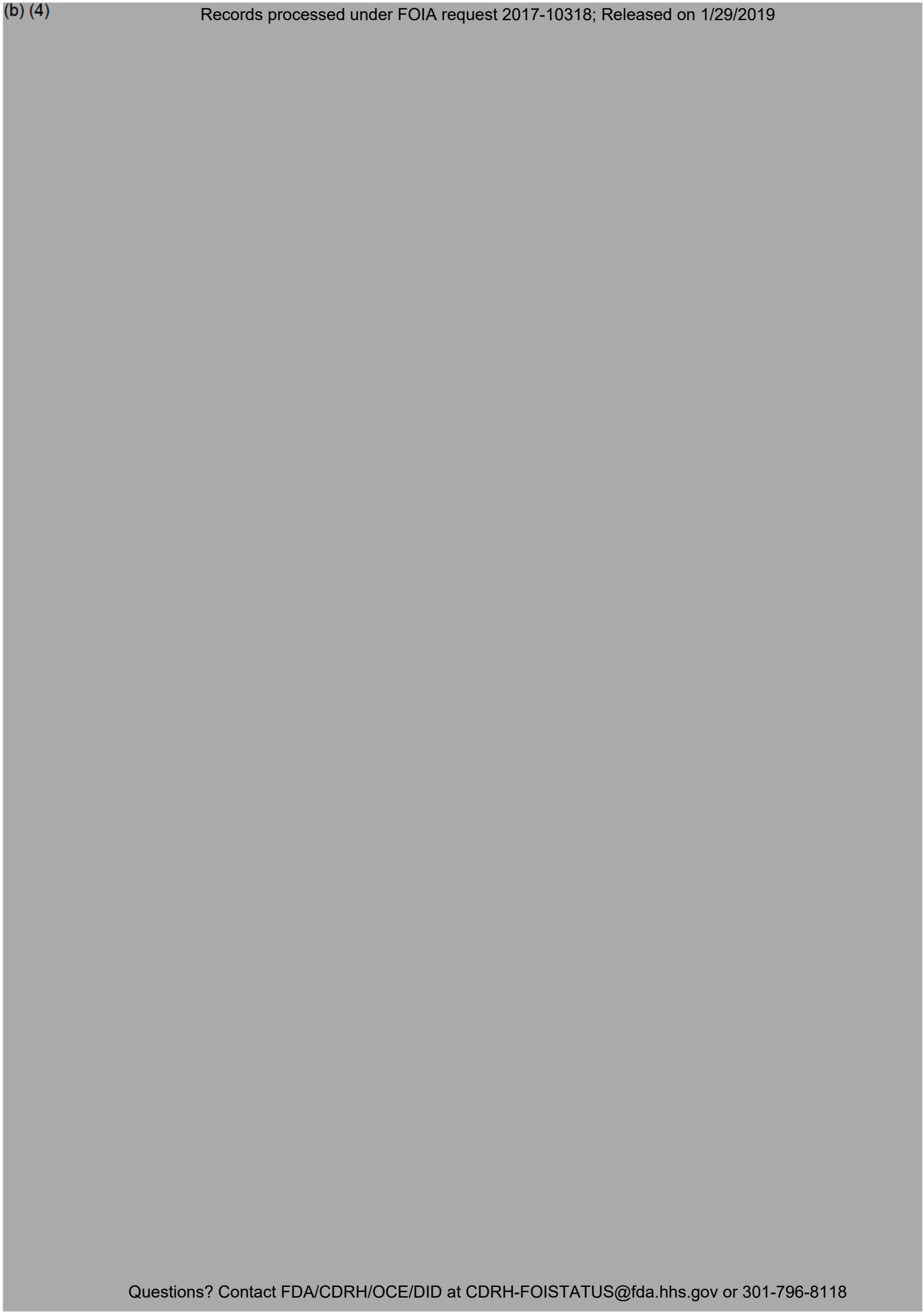

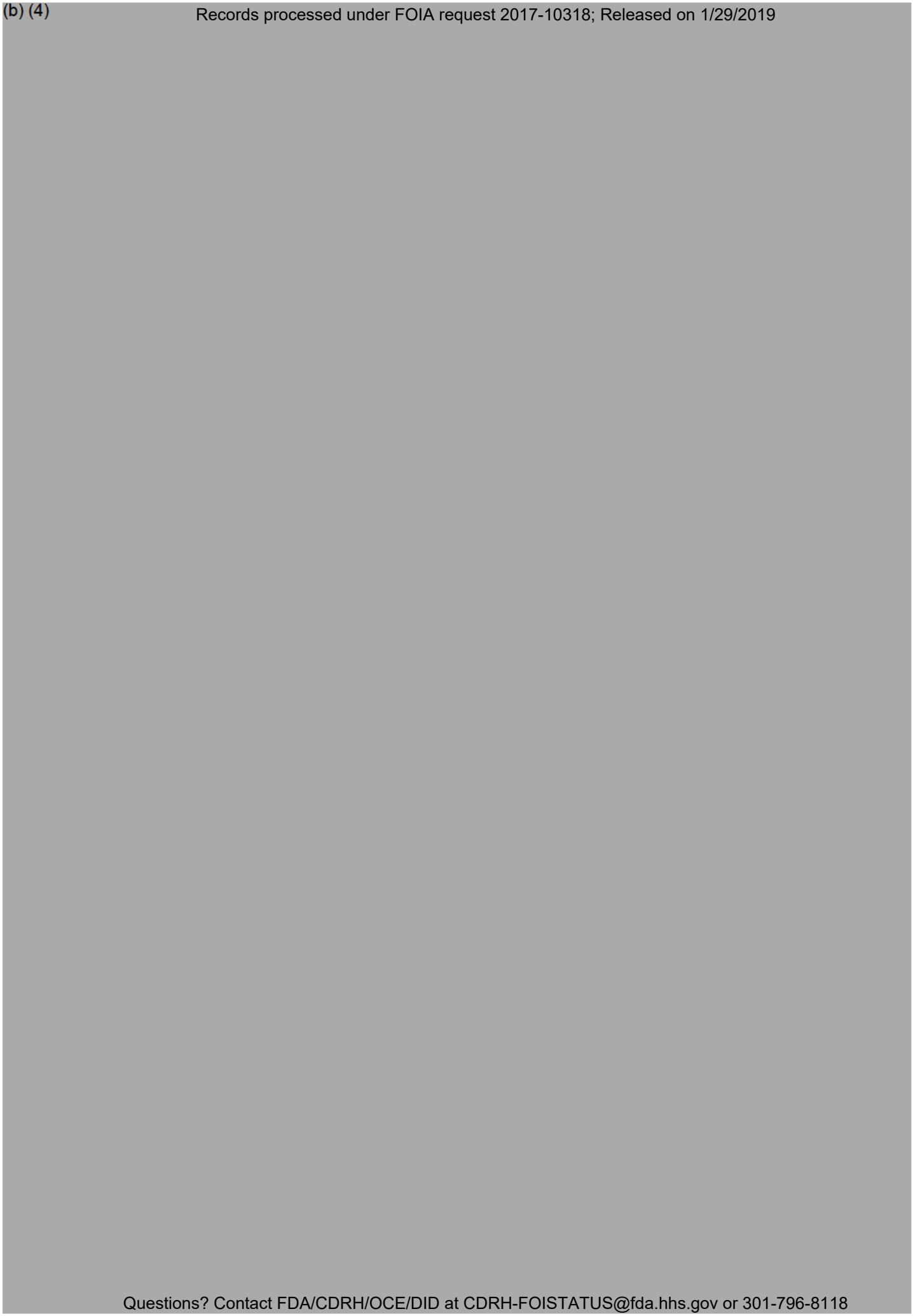

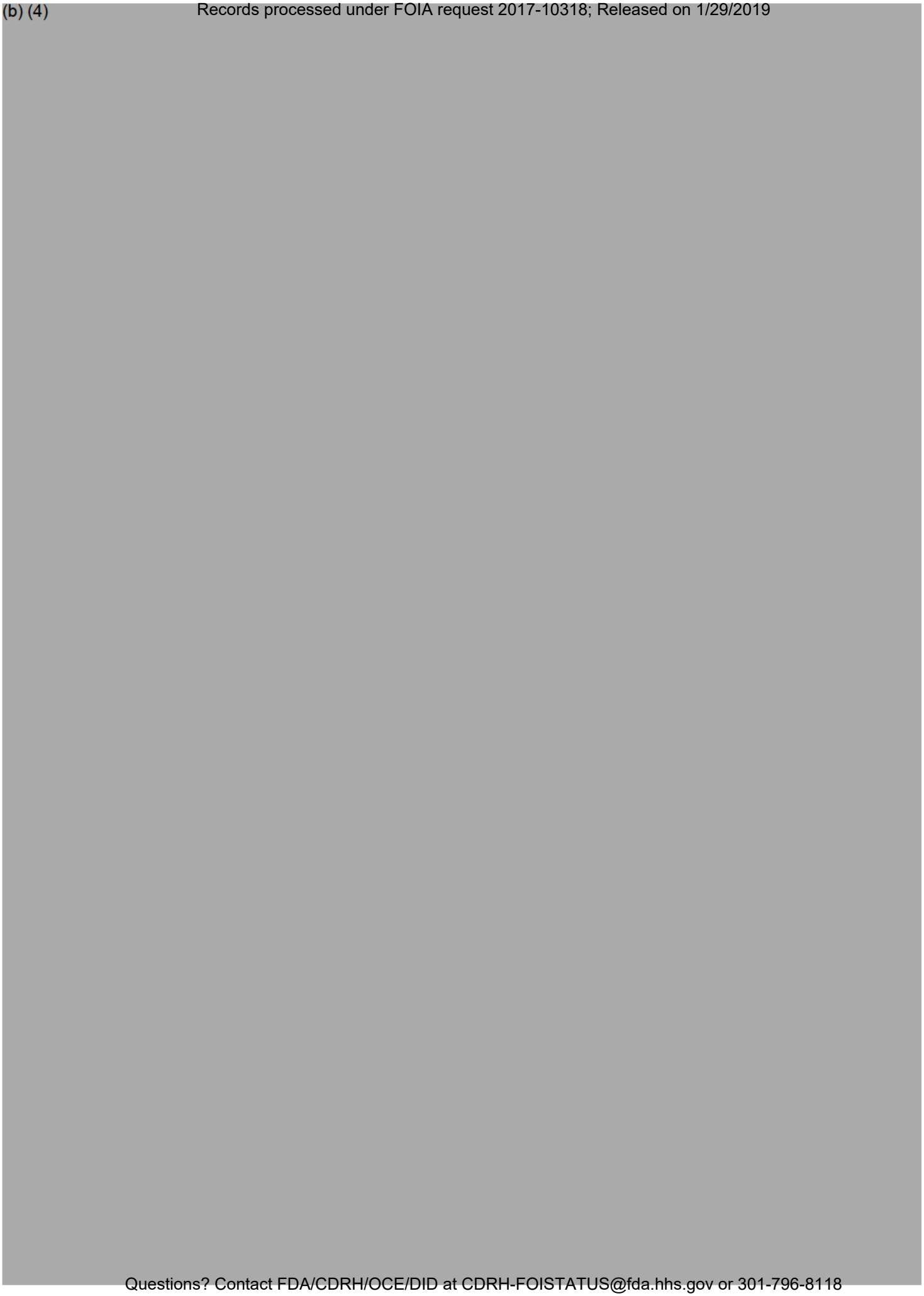

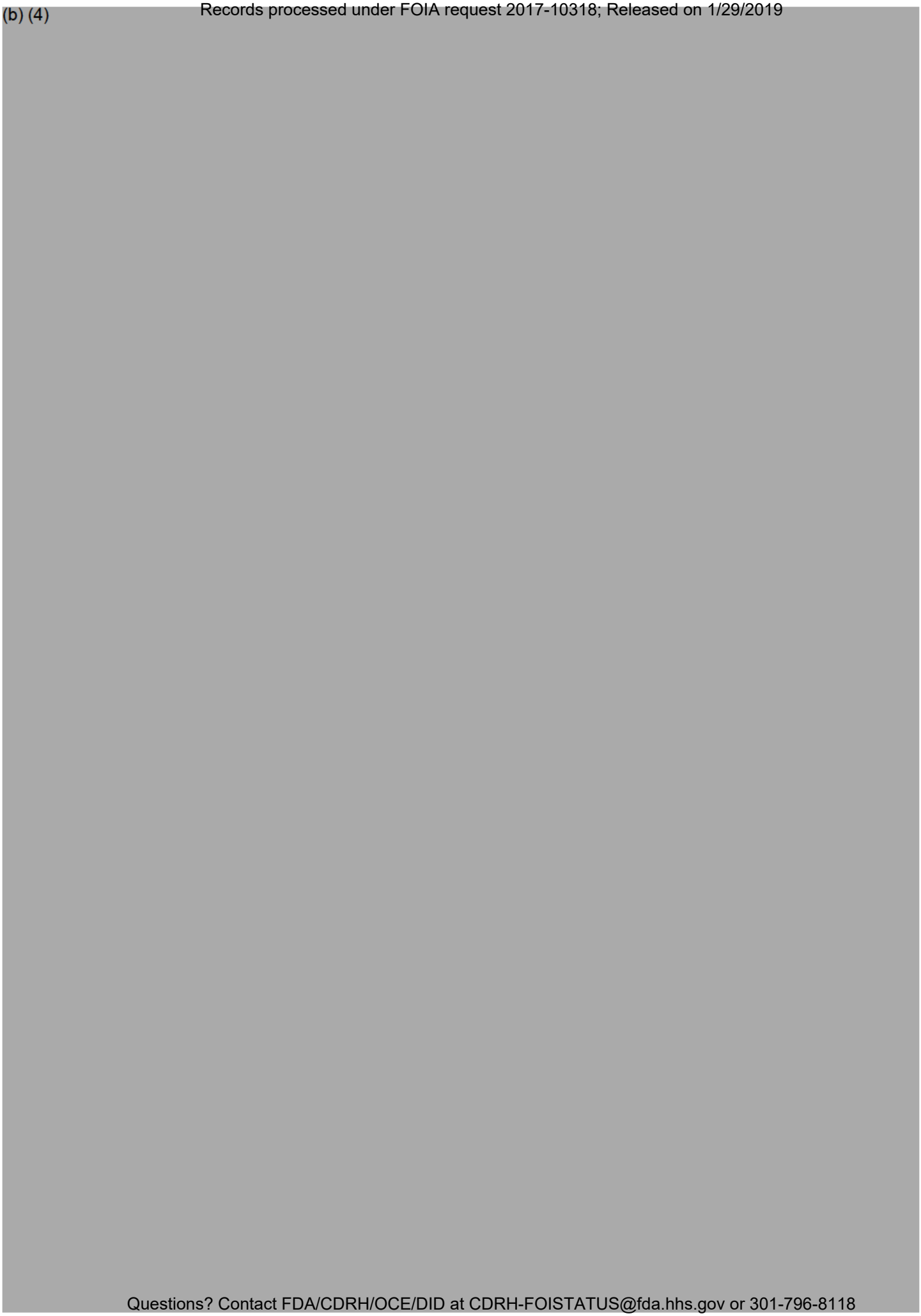

Thank You

APPENDIX 2
ENGINEERING DRAWINGS

Provided in this appendix are the following engineering drawings for the Kardia Band System:

(b) (4)

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

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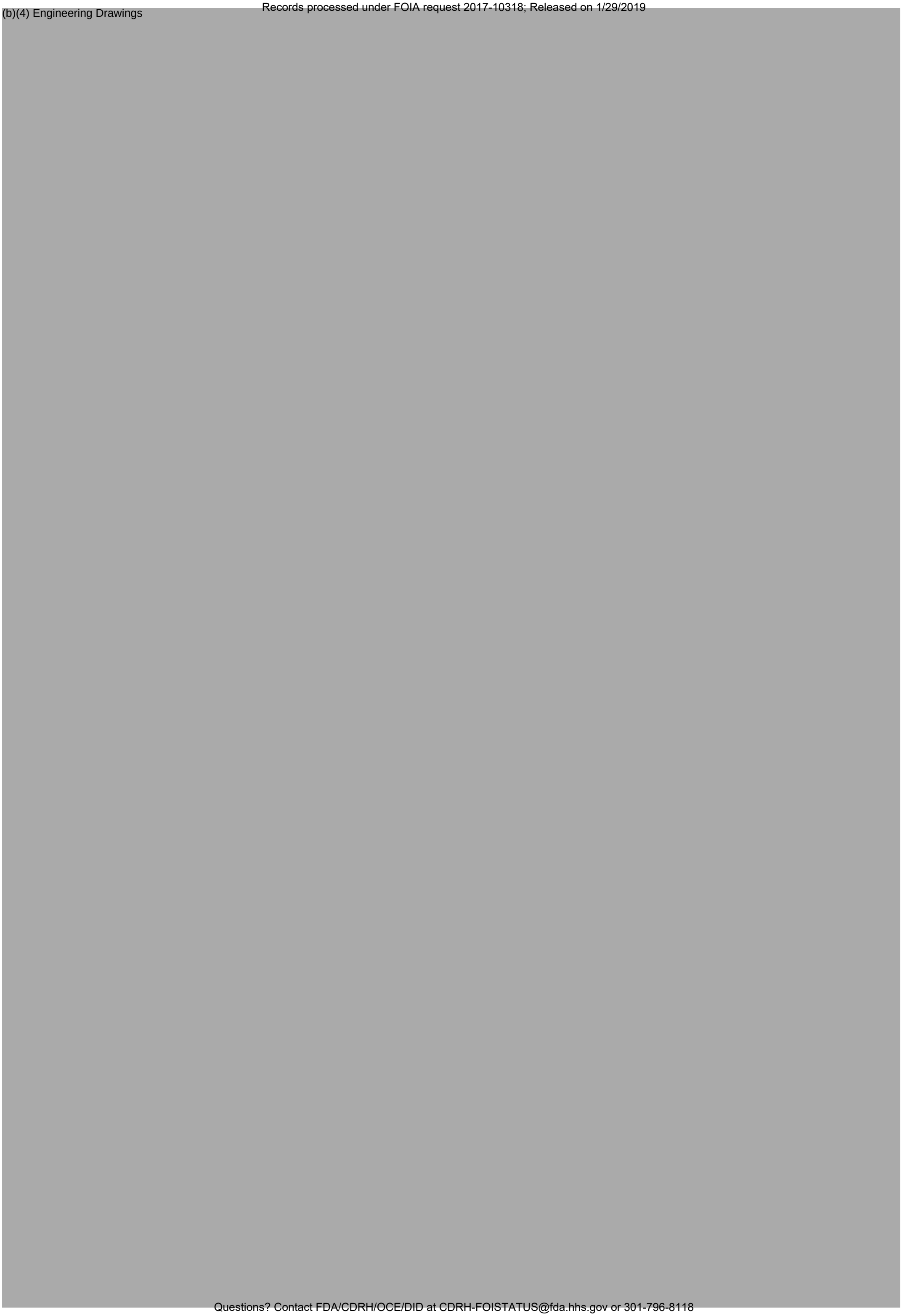


APPENDIX 3
LABELING

The following pieces of proposed labeling for the Kardia Band System are provided in this appendix:

- Kardia Band System Instructions for Use (15LB1.4)
- User Manual for Kardia by AliveCor (08LB12.5)
- Kardia Band ECG Global Packaging (14LB10.2)

Kardia™ Band System
by AliveCor®

Instructions For Use

AliveCor, Inc.
444 Castro Street, 6th Floor
Mountain View, CA 94041
United States

www.alivecor.com
Tell: 650-396-8650

EC REP Obelis SA
BD General Wahis 53
1030, Brussels
Belgium

CE 0123

Made in China

15LB1 Revision 4 |
JUNE 2017

A3-2

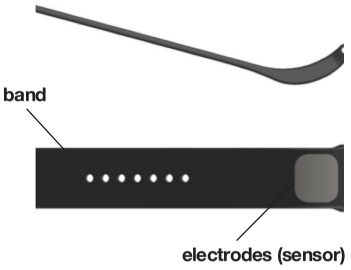
INDICATIONS FOR USE

The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.

USING KARDIA BAND

1. Assembly

- Remove Kardia Band from the box.
- Remove existing watchband from your Apple Watch.
- Attach both Kardia Band pieces to the watch – the electrode piece attaches to the 6 o'clock side of the watch body. Choose the band that ensures a tight fit so that the sensor contacts the skin.



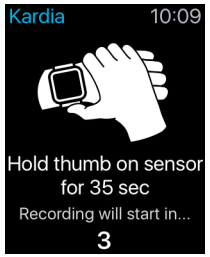
2. App set up

- On your iPhone, download the Kardia app from the App Store.
- Open the Apple Watch app on your iPhone and tap the My Watch tab.
- Scroll to find the Kardia watch app and tap it.
- Tap the "Show app on Apple Watch" toggle to turn on each feature.
- On your iPhone, tap the Kardia app and follow the on-screen instructions.

3. Recording an ECG

NOTE: These instructions are specific for those who wear their Apple Watch on their left wrist. If you wear your watch on your right wrist, follow the instructions by swapping left and right.

- Tap the Kardia watch app on the Apple Watch to open the application.
- In the in-app tutorial, swipe the screen right to left to view the instructions.
- With your right hand, grasp your left hand. Rest your right thumb on the outer electrode on the Kardia Band. Push your right thumb with enough force to ensure that the inner electrode is in contact with the skin of your left wrist for the entire duration of the recording. Remain still while recording – your watch, forearm, and hands should not move while recording.



- Do not use Kardia Band while charging your watch.
- Do not take a recording while driving or physical activity.
- Do not take a recording if the electrodes are dirty. Clean them first.
- Wrist hair may affect the performance of the device. We recommend removing excess hair from your wrist.
- Tap the "Record" button. Ensure that your hands and fingers are in the proper position.
- The recording takes 35 sec.
- After 35 sec, you have the option to Save or Cancel the recording.

Free medical interpretation of your first ECG reading in the United States only.

A U.S. board-certified cardiologist will automatically review your first recording for free and will provide a medical interpretation of your ECG within 24 hours. Due to FDA regulations, the heart rhythm for your first recording will not be visible on your mobile device screen and you will not be able to record any additional ECGs while the cardiologist is preparing your report. After you receive your report notification email, you will be able to record and view as many ECGs as you like.

4. ECG Analysis

Subsequent recordings:

- After an ECG recording is complete, the ECG is analyzed to determine if it is at least 30 seconds long, if it is Normal, Unclassified, if Atrial Fibrillation is present, or if it is too noisy to interpret.
- Tapping the analysis result displays a description of the result.
- To view the ECG, use the digital crown or swipe the screen right to left.
- Presence of Atrial Fibrillation (AF) in your ECG results may present only potential findings. If you are experiencing any symptoms or have concerns, contact your physician.
- Normal results mean your heart rate is between 50 and 100 beats per minute, and shape, timing and duration of each beat is considered normal.

  CAUTION: AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions when labeling an ECG as normal. You should notify your physician for possible changes in your health.
- Unreadable ECG results determines that you didn't have proper ECG recording for analysis. You might try to re-record your ECG.
- ECG reports viewed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.
- All ECGs are synced to the Kardia phone app. You may use the phone app to send your ECGs for physician analysis.

CLINICAL TESTING

Kardia Band was extensively tested in clinical studies. Overall, 41 volunteers over 18 years old participated in the Kardia Band studies, where Lead I recordings were compared between Kardia Band and an FDA-cleared 12-lead device. Clinical equivalence of the recordings from the two devices was verified by two Board Certified Cardiac Electrophysiologists.

TROUBLE SHOOTING

If you experience difficulties in operating your AliveCor products, refer to the troubleshooting guide below or contact technical support at support@alivecor.com.

Problem:	Solution:
My Kardia Band is not working.	**Option 1:** Ensure that the Kardia watch app has access to the watch's microphone. On the iPhone, go to Settings and tap the Kardia app. Tap the microphone toggle. **Option 2:** Ensure that the watch microphone is unobstructed. Consult the watch user manual if it is obstructed. **Option 3:** Check and change the battery. Use a Torx T3 screwdriver for the sensor battery door.
I have a lot of artifact, noise, or interference in my recording, or "No EKG recorded" message displays.	**Option 1:** Ensure that your watch, arms, and hands remain still during recordings. **Option 2:** Clean the electrodes on the Kardia Band with an alcohol-based sanitizer. **Option 3:** If your hands are very dry, use a water-based lotion before recording. **Option 4:** When recording, relax your arms and hands to reduce muscle noise. Rest the forearms and hands on a flat surface.
The ECG rhythms appear upside down.	**Option 1:** The watch orientation may be set to the wrong wrist. On your iPhone, go to the Watch app. Tap My Watch > General > Watch Orientation. **Option 2:** The Kardia Band pieces may be attached to the watch in the wrong orientation. Review "Assembly" instructions.

CAUTIONS

General:
DO NOT store in extremely hot, cold, humid, wet, or bright conditions.

DO NOT expose to strong electromagnetic fields.

DO NOT take recordings in close vicinity to other equipment emitting ultrasonic acoustics.

DO keep components out of reach of children.

DO use this device to record heart rate and heart rhythm only.

DO NOT use the sensor on portion of the body with too much body fat, body hair or very dry skin, a successful recording may not be possible.

AliveCor makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed. Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional for clinical decision-making.

Kardia Band:
DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.

DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the sensor or band.

DO NOT drop or bump with excessive force.

DO NOT use to diagnose heart-related conditions.

DO NOT expose the device to a magnetic resonance (MR) environment.

DO NOT wear during cautery and external defibrillation procedures.

After ECG analysis, the app may incorrectly identify ventricular flutter, ventricular bigeminy, and ventricular trigeminy heart conditions as unreadable. Please consult with your physician.

CAUTION: AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions when labeling an ECG as normal. You should notify your physician for possible changes in your health.

KARDIA BAND SPECIFICATIONS

Battery: CR1620 Coin Cell

Storage Conditions: Original package under normal room temperature and humidity

The Kardia Band sensor may be removed and inserted a maximum of 50 times without performance degradation.

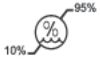
ELECTROMAGNETIC & OTHER INTERFERENCES

The Kardia Band has been tested and deemed in conformance with the relevant requirements in IEC60601-1-2:2014 Class BF for Electromagnetic Compatibility (EMC).

INGRESS PROTECTION MARKING

Kardia Band is IP22 rated. Kardia Band is protected against insertion of fingers and is not affected by vertically dripping water. Kardia Band has been tested with relevant requirement standard IEC60601-1-11:2015.

EQUIPMENT SYMBOLS

SN	Serial number
REF	Model number
EC REP	European Authorized Representative
	Manufacturer
	Read instructions before use
	Type BF applied part
	Temperature range
	Humidity range
	Do not dispose with household waste

ADDITIONAL INFORMATION

For more detailed troubleshooting and technical information, please visit: https://www.alivecor.com/support/#user-manual

User Manual for Kardia™ by AliveCor®

08LB12 Revision 5 | 08June2017

Contents

1. PRODUCT DESCRIPTION

Kardia™ by AliveCor® is a family of mobile, clinical-quality electrocardiogram (EKG or ECG) recorders. Users may record EKGs using Kardia™ Mobile with their smartphone or tablet, or the Kardia™ Band System with their Apple Watch.

The duration of the recording is established by the Kardia phone and Kardia watch apps with a default setting of 30 seconds. The Kardia phone app may extend recordings to a maximum time of 5 minutes. The software application can store thousands of recordings on your smartphone or tablet and these recordings are also accessible to authorized users on AliveCor servers (www.alivecor.com).

Patients with known or suspected heart conditions and health conscious individuals can use Kardia Mobile or Kardia Band to record an EKG daily or whenever they are feeling symptoms and share their recordings with their physician. Medical professionals can quickly assess rate and rhythm, screen for arrhythmias, and remotely monitor and manage patients who use Kardia Mobile or Kardia Band.

The Kardia Mobile product is used with a user-supplied compatible smartphone or tablet. The Kardia Mobile product consists of:

1. Kardia Mobile attaches to your compatible smartphone or tablet and has electrodes to transmit EKG rhythms to the smartphone or tablet.
2. The Kardia phone app is used to collect, view, save, and wirelessly transmit recordings to the AliveCor server.

The Kardia Band System product is used with user-supplied compatible iOS smartphone or tablet and a user-supplied compatible Apple Watch. The Kardia Band System consists of:

1. Kardia Band – Apple Watch watchband with electrodes embedded into the watchband that transmit EKG rhythms to the Apple Watch.
2. Kardia watch app (a companion to the Kardia phone app)- used to collect, view, save, and wirelessly transmit recordings to the AliveCor server.
3. Kardia phone app

NOTE: The Kardia Mobile and Kardia Band System products have the ability for users to connect to their physicians (Kardia Pro), by using a connection code. When connected, the user's ECG recordings are available to be viewed by their physicians.

The Kardia Mobile and Kardia Band System products enable users to:

- Collect and store single-channel EKG recordings.
- Record voice memos that are automatically transcribed to notes.
- Edit user information data associated with the recording.
- Wirelessly transmit EKG recordings to the AliveCor server.
- Access EKG recordings stored on the AliveCor server.
- Print or save the recording in PDF format.
- Request professional clinical interpretation and analysis of your EKG recordings.
- Track events that may impact your heart health, such as symptoms, activities, diet, etc.

After a user has created an account on the Kardia phone app and received an EKG analysis, the Kardia Mobile and Kardia Band products enable a user to:

- View EKG recordings in real-time and after the recording.
- View the output of the Atrial Fibrillation, Normal, and Unreadable Detectors.

1.1. Indications for Use – U.S.

Kardia Mobile:

The Kardia Mobile product is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Mobile product also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Mobile product is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The product has not been tested and it is not intended for pediatric use.

Kardia Band System:

The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.

1.2. Clinical Testing

Kardia Band System was extensively tested in clinical studies. Overall, 41 volunteers over 18 years of age participated in the Kardia Band System study, where Lead I recordings were compared between the Kardia Band System and a standard FDA-cleared 12-lead device. Clinical equivalence of the recordings from the two devices was validated by two Board Certified Cardiac Electrophysiologists.

1.3. Contraindications

There are no known contraindications for the Kardia Mobile or Kardia Band System products, although care should be taken when considering using the device according to the warnings and precautions below.

2. CAUTIONS

General:

- DO NOT store in extremely hot, cold, humid, wet, or bright conditions.
- DO NOT expose to strong electromagnetic fields.
- DO NOT take recordings in close vicinity to other equipment emitting ultrasonic acoustics.
- DO NOT take a recording while driving or during physical activity.

- DO NOT use Kardia Mobile while charging your phone. DO NOT use Kardia Band while charging your watch.
- DO NOT take a recording if the electrodes are dirty. Clean them first.
- DO keep components out of reach of children.
- DO use this device to record heart rate and heart rhythm only.
- DO NOT use the sensor on a portion of the body with too much body fat, body hair or very dry skin, a successful recording may not be possible.
- DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the sensor or band.
- AliveCor makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed. Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional for clinical decision-making.

Kardia Band System

- DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.
- DO NOT drop or bump with excessive force.
- DO NOT use to diagnose heart related conditions.
- DO NOT expose the device to a magnetic resonance (MR) environment.
- DO NOT wear during cautery and external defibrillation procedures.
- DO NOT use in the presence of flammable anesthetics, drugs or pressurized oxygen.
- After ECG analysis, the app may incorrectly identify ventricular flutter, ventricular bigeminy, and ventricular trigeminy heart conditions as unreadable. Please consult with your physician.
- AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions when labeling an EKG as normal. You should notify your physician for possible changes in your health.

Kardia Mobile

- DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.
- DO NOT drop or bump with excessive force.
- DO NOT use to diagnose heart related conditions.
- DO NOT use during magnetic resonance imaging (MRI), cautery and external defibrillation procedures.
- After ECG analysis, the app may incorrectly identify ventricular flutter, ventricular bigeminy, and ventricular trigeminy heart conditions as unreadable. Please consult with your physician.
- AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions when labeling an EKG as normal. You should notify your physician for possible changes in your health.

3. SET UP KARDIA MOBILE OR KARDIA BAND SYSTEM AND TAKE THE FIRST EKG RECORDING

3.1. Decide which smartphone, smartwatch, or tablet to use

Your Kardia Mobile or Kardia Band is compatible with all of the smartphones, smartwatches, and tablets (smart devices) listed on AliveCor's website: https://store.alivecor.com/#compatibility, including:

- iPhone 4s, 5/5s, 5c, 6/6 Plus, 6s/6s Plus, 7/7 Plus, and SE
- iPad Air and Air 2
- iPad Mini, Mini 2, and Mini 3
- iPad Pro 9.7-inch
- iPod Touch 5G
- Apple Watch, Series 1 and Series 2, 38mm and 42mm (Kardia Band System use only)

The Kardia phone app is compatible with iOS versions 5.1 – 10.0.2 and WatchOS 3.0.

- Samsung Note 3 and Note 5
- Samsung Galaxy S3, S4, S5, S6, and S7
- Samsung Galaxy J1
- LG Nexus 5
- HTC One and HTC 10
- Jitterbug Touch 2 and Touch 3

The Kardia phone app is compatible with the Android operating system versions 4.0 – 6.0.1.

Kardia Mobile for iPhone 5/5s and iPhone 6/6s can also be used on all compatible smartphones or tablets by removing Kardia Mobile from its case:

1. If Kardia Mobile is currently attached to an iPhone 5/5s/6/6s, remove it and its case from your iPhone 5/5s/6/6s (press gently on the phone camera through the case cutout and peel back from that corner of Kardia Mobile).
2. Face the electrodes of Kardia Mobile away from you.
3. AC-007: Gently push the left side of Kardia Mobile toward you while at the same time gently pulling the left edge of the case away from the device itself.
4. Kardia Mobile should then "pop out" of its case.

3.2. Unpack Kardia Mobile (Kardia Mobile Users)

1. Remove Kardia Mobile from the box.
2. Choose Kardia Mobile placement.
   a) For Kardia Mobile cases, place Kardia Mobile on your phone as you would any standard phone case.
   b) The Kardia Mobile can be attached directly to the smartphone or tablet or to the case of your choosing (the surface should be smooth and flat).
      a. AC-001 - AC-007: With the AliveCor logo right side up, the top of the smartphone or tablet should be on the right.
      b. AC-009: With the 'K' of the Kardia logo closest to the top of the smartphone or tablet.

c) For use with an iPad, AliveCor does not recommend attaching Kardia Mobile to your iPad. Instead, rest Kardia Mobile in both hands or place it on a flat surface less than one foot away from the iPad to record EKGs.

Note: The Kardia Mobile must be less than 1 foot from the smartphone or tablet to ensure communication between devices.

3.3. Unpack Kardia Band (Kardia Band Users)

1. Remove Kardia Band from the box, which consists of 2 pieces – one band that attaches to the 12 o'clock side of the watch body and the other band that attaches to the 6 o'clock side of the watch body. The band that attaches 6 o'clock side the watch body contains the electrodes.
2. Remove existing watchband from the Apple Watch – consult the watch user manual, if necessary.
3. Attach the Kardia Band EKG to the Apple Watch – consult the watch user manual, if necessary. Ensure that the band with electrode attaches to the 6 o'clock side of the watch body.

NOTE: A second (shorter) band that attaches to the 6 o'clock side of the watch body is included in the box to make sure you have the right band for your wrist size. Use the band that ensures a tight fit of the watch so that the sensor contacts the skin. For more information on how to attach the bands to the watch, refer to a video at https://www.youtube.com/watch?v=p7ZnT_ubEFY.

NOTE: Wrist hair may affect the performance of the device. We recommend removing excess hair from your wrist.

3.4. Download the Kardia phone app

1. Using your smartphone or tablet, search for *Kardia* in the App Store or Google Play store.
2. Download and install the Kardia phone app.

NOTE: The Apple Watch only works with the Apple iPhone – consult the watch user manual, if necessary.

3.5. Add Kardia watch app to Apple Watch (Kardia Band System Users)

1. Open the Apple Watch app on your iPhone and tap the My Watch tab.
2. Scroll to find the Kardia watch app and tap it.
3. Tap the "Show App on Apple Watch" and "Show in Glances" toggles to turn on each feature.

NOTE: The toggle will turn to green if turned to the 'on' position.

3.6. Set up an AliveCor Account

You will use your AliveCor account to access, print, and save your EKG recordings stored on the Kardia phone app and the AliveCor server. Follow the instructions presented when you open the Kardia phone app for the first time. You can go back later and change your information if necessary.

Add a passcode (personal identification number [PIN]), or Touch ID (fingerprint) to your smart device to add a layer of security. It is important to secure the smart device since you will be storing personal health information. Review the manual of the smart device for information on how to add a layer of security.

NOTE: Kardia Band customers will be directed to the Kardia phone app to setup their account and go through onboarding.

3.7. Free Trial for Premium Features

Once an account has been created, you have access to premium features for a period of time. At the end of the free trial, your access to those features ends. If you wish to continue to access the premium features, follow the onscreen instructions for purchasing a subscription.

4. RECORD EKG RHYTHMS

NOTE: You will not be able to view your recordings or utilize any of Kardia's detectors until your over-read analysis is received. To gain access to these features, you must create an account on the Kardia phone app. Follow instructions on the Kardia phone app to take a first recording as part of setting up the device. Your first recording will then be automatically sent for a free analysis by a cardiologist (US customers only). Once you have received the EKG analysis, you will have access to view that recording and subsequent recordings.

4.1. To take an EKG recording with Kardia Mobile, follow the instructions below.

Before taking each recording:

- Disconnect headphones, charger cables, or any other connected devices.
- Clean the two electrodes with alcohol-based sanitizer.
- Using your smartphone or tablet, launch the Kardia phone app.

1. Select an EKG option – Standard EKG, Resting Heart Rate, or Guest EKG. All options will record an EKG. "Standard EKG" is recommended for taking an EKG at any time, e.g. when you are feeling symptomatic. "Resting Heart Rate EKG" is recommended to establish your resting heart rate baseline. We recommend taking that EKG when you first rise in the morning; the time of day when the body is most rested. "Guest EKG" is the recommended option when a family member or friend needs to record an EKG.

2. Rest two or more fingers (it doesn't matter which fingers) on Kardia Mobile; your right hand should contact the electrode closest to the bottom of the smartphone or tablet, and your left hand should contact the electrode closest to the top of the smartphone or tablet. This is a Lead I EKG.
3. While recording your EKG, speak your symptoms (e.g. "I'm feeling palpitations. Maybe due to anxiety") into the smartphone. Any voice memo recorded will be transcribed to text and added to the Notes section for that EKG recording.

You may also choose from two other placements:

- For a Lead II ECG, the left knee should contact the electrode closer to the top of the smartphone or tablet and the right hand should contact the electrode closer to the bottom of the smartphone or tablet.
- For an Anterior Precordial Lead, the device can be placed on the lower left side of the chest, just below the pectoral muscle. The bottom of the smartphone or tablet should be pointing towards the center of the body.

4.2. To take an EKG recording with the Kardia Band System, follow the instructions below.

NOTE: For the sake of clarity, the instructions below are specific for those who wear their Apple Watch on their left wrist. If you wear your watch on your right wrist, follow the instructions by swapping left and right.

1. Tap the Kardia watch app on the Apple Watch to open the application.
2. In the in-app tutorial, swipe right to left to view the instructions.
3. With your right hand, grasp your left hand. Rest your right thumb on the outer electrode on the Kardia Band EKG. Push your right thumb with enough force to ensure that the inner electrode is in contact with the skin of your left wrist for the entire duration of the recording. This is a Lead I EKG.
4. Tap the "Record EKG" button. A 3-second countdown will appear; ensure that your hands and fingers are in the proper position (described above).
5. While recording your EKG, speak your symptoms (e.g. "I'm feeling palpitations.") into the smartwatch. Any voice recording taken will be transcribed to text, which will be found in the Notes section for that EKG recording in the Kardia phone app.
6. The recording takes 35 seconds.

Additionally, you may add notes or tags to the recording in the Kardia phone app. Tags include symptoms, activities, diet, etc. that are relevant to heart health:

- When your recording is complete, you will arrive at the Data Entry screen where you may add notes or tags such as symptoms, activities, diet, etc.
- Alternatively, you may go to the Journal screen, and tap the dropdown arrow to the right of the EKG recording, then tap Edit. This will also take you to the Data Entry screen where you may add or edit notes and tags.

NOTES:

- The Kardia Mobile and Kardia Band System do not require a Wi-Fi or mobile connection to record an EKG and save it to the device's local memory; however, they do require a connection to sync automatically with the AliveCor server, email, or print directly from the Kardia phone app. If you do not have a Wi-Fi or mobile connection at the time of the EKG recording, you may email or print the data later when you have such a connection and the sync will happen automatically at that time.
- Kardia Mobile may be used up to a distance of 30 cm (1 ft.) from the smartphone or tablet. Using Kardia Mobile at a distance greater than 30 cm (1 ft.) may lead to communication issues between the devices and your recording may not be successful.
- Kardia Band must be attached to the Apple Watch. Using Kardia Band at a greater distance may lead to communication issues between the devices and our recording may not be successful.
- On the paired iPhone, Bluetooth must be turned on to transfer data from the Apple Watch.
- To reduce muscle noise, rest your arms on a flat surface to increase stability while you are recording.
- You must maintain contact with the electrodes for at least 10 seconds for the recording to be saved. If you remove contact after 10 seconds, but before the selected recording duration is complete, the EKG will be saved and you will be able to review it.
- The recording must be at least 30 seconds long for the detectors to work.
- If you are in a noisy area (e.g. train station, coffee shop, etc.), the voice recording with the Kardia Band may pick up other conversations and will be found in the Notes for that EKG. You may edit the Notes to remove any unwanted text in the Kardia phone app.

5. ONCE THE RECORDING IS FINISHED

5.1. For Kardia phone app:

- Immediately after recording, you will be shown an analysis of your EKG if it is available.
- After a recording, you are also prompted to add tags such as symptoms, activities, diet, etc. to the Data Entry screen. You may also enter personalized tags or notes, and you may also edit the transcribed voice memo. After making your choices, tap "Save" to continue.
- You may review the EKG in the Journal screen, or go to Insights and view the trending of your EKGs, heart rate, symptoms, activities, etc. You may also tap the EKG on the Journal screen for a larger view of the EKG on the EKG Review screen. EKGs can be starred, emailed, shared, or sent for analysis from the Journal screen, or on the EKG Review screen.

5.2. For Kardia watch app:

- Immediately after recording, you have the option to save the recording by tapping "Save" or delete the recording by tapping "Cancel."
- If an EKG was successfully recorded, an analysis result for your EKG appears, if one is available. Dismiss the result by tapping "Close."

- To view the ECG, use the digital crown or swipe right to left.
- Force touch the EKG tracing to replay the audio, invert the EKG, or delete the recording.
- On the Home screen in the Kardia watch app, tap the "Record EKG" button to take another EKG recording or view the last EKG recorded.
- Force touch the Home screen to view a tutorial and how to contact customer support.

NOTE: The EKG recordings marked with a circular arrow have not been synced to the iPhone. Those EKG recordings that have not been synced will sync once the Apple Watch has connected to the Kardia phone app on the iPhone. Note, the Kardia watch app will store all unsynced recordings until the sync has completed with the Kardia phone app.

NOTE: Due to the limited size of the Apple Watch screen, view the EKG on your phone, tablet, or computer for interpretation or analysis.

6. ENTER AN EVENT WITHOUT AN EKG (KARDIA PHONE APP ONLY)

You may enter a tag or note without an EKG at anytime. This may help you track your symptoms, activities, diet, etc. either before or after an EKG:

- Tap Journal, then tap the blue "Plus" icon at the top left.
- In the Data Entry screen, you may enter notes, or select tags such as symptoms, activities, diet, etc., or create personalized tags.
- In the Data Entry screen, you may also select a different date/time for the event you are logging, for example alcohol from the previous evening, or a meal from a couple days ago.
- All of your events will appear in the Journal screen in chronological order, and may be edited anytime by selecting the dropdown arrow to the right of the event on the Journal screen.

7. SETTINGS AND ADJUSTMENTS (KARDIA PHONE APP ONLY)

7.1. Recording Adjustments

- **Enhanced Filter.** The Enhanced Filter suppresses noise in the EKG. The filter may be toggled on a particular EKG from the EKG Review screen. To enable or disable the Enhanced Filter, tap "MORE" at the bottom of the EKG Review screen, and then tap the "ENHANCED" switch to toggle the filter ON or OFF.
- **Invert the EKG Recording.** In the event that Kardia Mobile was oriented improperly when the EKG was recorded, it may appear inverted. The orientation may be toggled on a particular EKG from the EKG Review screen. Tap "MORE" at the bottom of the EKG Review screen, and then tap the "INVERT" switch to toggle it ON or OFF.

7.2. Adjustable Settings

To access the Settings, tap the "More" icon at the upper right and then tap "Settings".

- **Duration**. Recording Duration is the maximum length of time the Kardia phone app will record a single EKG recording. For example, if the recording duration is set to 30 seconds, the Kardia phone app will automatically stop recording after 30 seconds of data has been collected.
- **Mains Filter**. The Mains Filter removes any mains interference from the EKG; it should be set to match the frequency of the alternating current (AC) used in your location. For the United States, Canada and Mexico, this is 60 Hz; in most other countries, it is 50 Hz.
- **Paper Size**. Paper Size of the PDF report can be changed to accommodate Letter and A4 paper sizes.
- **Reminders**. Reminders allow the EKG analysis reminder to be turned on or off. It also allows you to turn on or off the EKG reminder, set the frequency, and time for the reminder. You can also turn the AF Detector on or off, and modify your medication reminders.
- **Mode**. Tap to modify device transmission settings. Normal mode is recommended for most users. If your facility or location limits wireless communication, the Airplane/ICU setting may be selected.

8. EMAIL, PRINT, OR DELETE RECORDINGS

You may email/print recordings from either the Kardia phone app or your account on the server (www.alivecor.com).

To email a recording from the Kardia phone app, you must have an email account set up on your smartphone or tablet. If you need assistance setting up an email account or troubleshooting your email account, contact your smartphone or tablet provider for assistance.

1. Tap the envelope icon next to the EKG you would like to email/print on the Journal screen. Alternatively, you may tap the EKG, then tap the envelope icon on the EKG Review screen.
2. Tap Email. The PDF version of the EKG recording will then be attached to a new email in whatever email account you have set up on your smartphone or tablet.

To print a recording from the Kardia phone app, you must have an AirPrint compatible printer set up on your smartphone or tablet (iOS only). If you need assistance setting up an AirPrint compatible printer or troubleshooting your AirPrint compatible printer, contact your smartphone or tablet provider for assistance.

1. Tap the envelope icon next to the EKG that you would like to email/print on the Journal screen. Alternatively, you may tap the EKG, then tap the envelope icon on the EKG Review screen
2. Tap Print.

To print a recording from the website:

1. Go to www.alivecor.com.
2. Click the “SIGN IN” and enter your email address and password.
3. Select the desired recording by clicking the appropriate “View EKG” button on the right.
4. Click the “View PDF” link.
5. Print from your computer as you would any PDF.

To delete a recording:

1. Go to the Journal screen.
2. Tap the dropdown icon to the right of the EKG that you want to delete.
3. Tap “Delete”.

To delete or invert a recording in the Kardia watch app:

1. Go to the Home screen in the Kardia watch app.
2. Tap the EKG recording that you wish to delete.
3. Firmly press (force touch) the recording. A new screen will appear providing options to delete or invert the recording.
4. Tap the appropriate option – “Delete” or “Invert”. Tap anywhere else on the screen to cancel. “Cancel” if you do not wish to delete or invert the recording.

9. JOURNAL (KARDIA PHONE APP ONLY)

Journal is a premium feature where your previously recorded EKG recordings are displayed. To access it, tap the “Journal” icon.

- Launch the Kardia phone app.
- Tap Journal at the top of the screen to see a list of all EKG recordings on your smartphone or tablet (excluding any previously deleted).
- Tap the EKG recording you wish to view.

NOTE: You may listen to the voice memo associated with the EKG by tapping the Play button.

10. SEARCH OR FILTER RECORDINGS (KARDIA PHONE APP ONLY)

You may search or filter the events in the Journal screen by using the search icon on the top right of the screen.

To filter:

1. Tap the search icon on the top right.
2. Select one of the existing filters. The filters allow you to choose one of the following: Custom Search…, Starred, Atrial Fibrillation, Analysis Reports, My EKGs, and Guest EKGs.
3. Your Journal screen will show you EKGs that meet the filter criteria until you disable the filter.
4. You may disable the filter by tapping the “x” icon next to the filter name at the upper right of the Journal screen.

To search:

1. Tap the search icon at the top right.
2. Tap “Custom Search” at the top of the search menu.
3. Type in the term you are searching for in your events using the keyboard. For example, you may be looking for “Caffeine” or “Walked the dog” in your tags and notes.
4. Tap outside of the keyboard area if you would like to remove the keyboard for better scrolling through your records.
5. You may disable the search view by tapping “Cancel” on the top right of the screen or edit your search term by tapping in the search bar and entering another term.

11. VIEW AN EKG RECORDING ON THE ALIVECOR WEBSITE

To view an EKG recording on the AliveCor website, follow the instructions below:

- On your web browser, go to www.alivecor.com and click “SIGN IN”
- Enter your email address and the password you created when you set up your AliveCor account. Click “Sign In”.
- The EKG recordings you collected were automatically synced to the AliveCor server and will appear in list form, and each transmission is stored as an Adobe Acrobat PDF file and can also be viewed in HTML. Click the “View EKG” button.
- Click the back button in your browser to return to your AliveCor account homepage.

12. CLINICIAN REVIEW (KARDIA PHONE APP ONLY)

The Kardia phone app includes the ability to request professional clinical interpretation and analysis of your EKG recordings. Due to telemedicine restrictions, your location may restrict your ability to use this service. AliveCor does not know your location; it is your responsibility to ensure this service is legal according to your local telemedicine laws. This service is not intended to replace medical advice, please seek professional medical assistance if you are suffering from any medical problem.

To request a Clinician Review:

1. Tap Journal and find the EKG you would like to send for analysis. Tap the envelope icon to the right of the recording, then “Clinician Review”. Alternatively, you may tap the EKG, and then tap the envelope icon at the top right of the EKG Review screen.
2. Select one of the listed options.
3. If you haven’t already entered your name, date of birth and gender, you will be prompted to enter these details. Enter the required details and tap “Next”.
4. Select or enter your credit card information. Enter your card details and tap “Next”.
5. Confirm that the purchase order is correct and tap "PURCHASE" to place the order.

Your order is then processed and you will be sent an email confirmation. Another email will be sent when the report is available.

NOTE: The “Clinician Review” option is only visible if the analysis service is available in your country.

To view an EKG Analysis Report:

1. Tap “Journal”.
2. Tap the desired report below the EKG.

Alternatively, you may access EKG Analysis Reports from the EKG Review screen by tapping “Analysis”.

NOTE: To view PDF reports on your smartphone or tablet you must have a PDF reader, such as Adobe Reader, built-in or installed on your Android smartphone or tablet. Support for printing depends on the built-in printing options on your Android smartphone or tablet, or you may need to install a printer app from the Google Play Store.

13. DETECTORS (ATRIAL FIBRILLATION, NORMAL, UNREADABLE)

NOTE: Your EKG must be at least 30 seconds long to use the Atrial Fibrillation and Normal detectors. If an EKG is recorded that is less than 30 seconds, neither the Atrial Fibrillation nor the Normal detector will display a result.

Atrial Fibrillation Detector

The Atrial Fibrillation (AF) detector detects atrial fibrillation in an EKG tracing. After you take an EKG, if atrial fibrillation is detected you will be notified within the app. This finding is not a diagnosis, it is only a potential finding. You should contact your physician to review any EKG recording in which atrial fibrillation was detected, or send it to EKG Analysis. If you are experiencing any symptoms or concerns contact a medical professional.

The AF detector monitors for atrial fibrillation (AF) only. It will not detect other potentially life threatening arrhythmias, and it is possible that other cardiac arrhythmias may be present.

The AF detector only monitors for AF while you are taking a recording. It does not continuously monitor your heart and therefore cannot alert you if AF happens at any other time.

Normal Detector

The Normal detector notifies you when a recording is “normal”. This means that the heart rate is between 50 and 100 beats per minute, there are no or very few abnormal beats, and the shape, timing and duration of each beat is considered normal. It is important to remember that there is a wide range of normal variability among different individuals. Changes in the shape or timing of an EKG might be normal for a single individual, but since the apps are used by a large and diverse population, the Normal detector has been designed to be conservative with what it detects as normal.

If you have been diagnosed with a condition that affects the shape of your EKG (e.g., intraventricular conduction delay, left or right bundle branch block, Wolff-Parkinson-White Syndrome, etc.), experience a large number of premature ventricular or atrial contractions (PVC and PAC), are experiencing an arrhythmia, or took a poor quality recording it is unlikely that you will be notified that your EKG is normal.

It is also important to note that the Normal detector looks at the entire signal before determining if it can be declared to be normal. If you experience a small number of PACs or PVCs in a recording of otherwise normal beats in normal rhythm, the Normal detector will likely declare this recording to be normal.

CAUTION: AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions when labeling an EKG as normal. You should notify your physician for possible changes in your health.

Unreadable Detector

The Unreadable detector determines whether a recording can be accurately interpreted or not. After you take an EKG, if interference is detected you will be notified within the app that your recording is "Unreadable" and given some suggestions for acquiring the best quality EKG recording. You subsequently have the option to Save the recording, or Try Again. If the recording can be analyzed, the AF and Normal detectors will run on the EKG and inform you as described above.

CAUTION: After EKG analysis, the app may incorrectly identify ventricular flutter, ventricular bigeminy, and ventricular trigeminy heart conditions as unreadable. Please consult with your physician.

13.1. What is Atrial Fibrillation?

The most common type of non-sinus tachyarrhythmia is atrial fibrillation. In this case, disorganized electrical impulses that originate in the atria and pulmonary veins initiate the electrical activity in the conduction system of the heart. This causes what are commonly termed as "irregularly irregular" heart beats.

When a heart is in atrial fibrillation, its two upper chambers, the right and left atria essentially quiver, instead of beating efficiently. This does not allow for complete emptying of the atria and thus, blood may become stagnant and create blood clots. This can lead to major problems, namely, strokes, transient ischemic attacks (TIAs), and pulmonary emboli (PEs); depending which chamber of the heart has the blood clot in it.

Approximately 15 percent of strokes occur in people with atrial fibrillation. As age increases in a population, so too does the incidence of atrial fibrillation, which peaks at about 3-5% in people over the age of 65.

The most common presenting symptoms of atrial fibrillation are palpitations, dizziness, fast pulse rate, irregularly irregular rhythm, an abnormal heart sound (S1), chest pain, chronic shortness of breath, abnormal jugular venous pressure, fatigue, and impaired exercise tolerance. Other symptoms related to TIAs and strokes may be the initial symptoms of atrial fibrillation.

Some of the most common causes of atrial fibrillation are long-standing hypertension, congestive heart disease, cardiac valvular lesions, myocardial infarctions, history of coronary artery bypass grafts, hyperthyroidism, alcohol abuse, smoking, diabetes mellitus, and electrolyte imbalances.

13.2. AF, Normal, Unreadable, and Unclassified Recordings in EKG review screen and Journal

All tracings analyzed as positive for atrial fibrillation, normal, or unreadable will have a tag for future review. The Kardia phone app and Kardia watch app may display the "Unclassified" message for a tracing that is not Normal and not AF, and interference was not detected. An example of an unclassified tracing is one where tachycardia is observed. These tags will be visible in the Journal screen, Data Entry screen, and the EKG review screen.

13.3. Activation of the Detectors

The Unreadable and Unclassified detectors can be turned on or off in the settings of the Kardia phone app only.

13.4. Detector Usage

Note that the detectors have been trained and tested on Lead I recordings only. Due to the difference in the waveform from Lead II or Anterior Precordial Lead recordings, reliance on the analysis messages (e.g. “Normal”, “Unreadable”, etc.) of these recordings is not recommended.

14. MEDICATIONS (KARDIA PHONE APP – IOS ONLY)

You may track your medications with the Kardia phone app. To access and edit the medications:

- Tap “Insights” in the Menu at the bottom of the screen. Scroll to the bottom of the Insights screen and tap “Log Medications”. You may edit your medications or select those taken that day.
- Alternatively, tap the medication push notification that is sent to you by default at 9:00am every day. You may then edit your medications or select those taken that day.
- You may also edit your medications by accessing your Profile. Tap “. . . ”, “Profile”, “Medications”.
- You may view medications selected on the Insights screen.
- You may select a medication more than once per day by tapping “Medications Logged” at the bottom of the Insights screen, and tapping the specific medication again. The number to the right of the medication will update.

15. INSIGHTS (KARDIA PHONE APP ONLY)

Insights is a premium feature where your data will be graphed over time. To access it, tap the “Insights” icon. The following items are graphed in Insights over a 7-day period, and over a 14-day period (iOS only) when the Kardia phone app is turned to landscape view:

- Number of EKGs recorded, including the number of AF recordings and Normal Recordings
- Heart rate (bpm) in each EKG recording
- Symptoms, activities, diet, etc.
- Medications that were selected (iOS only)

NOTE: Your Insights are also available by logging into your account on www.alivecor.com. Insights data is available in 30-day increments, from when you first created your account. Note that this feature is available for individual users only, not for medical professionals.

16. HEALTH APP AND GOOGLE FIT INTEGRATION

The Kardia phone app is integrated with the Apple Health and Google Fit apps. Information about your activities and vitals helps us provide you with a monthly (premium) Personal Report. You have the option of turning off the integration within the Apple Health and Google Fit apps; however, doing so will limit the information available in your Personal Report. The Kardia phone app shares the following pieces of information with the Apple Health and Google Fit app:

- Heart Rate
- Height
- Weight

The Kardia phone app collects the following pieces of information from the Apple Health and Google Fit apps:

- Active Energy
- Blood Glucose
- Diastolic Blood Pressure
- Flights Climbed
- Heart Rate
- Height
- Oxygen Saturation
- Resting Energy
- Sleep Analysis
- Steps
- Systolic Blood Pressure
- Walking + Running Distance
- Weight
- Workouts

17. REFERRAL CODE

If you were prescribed Kardia by your doctor or through a cardiac monitoring service, you should have received 12-character referral code. The code may be entered during account creation or may be entered by tapping the heart icon located at the top right of the Home screen on the Kardia phone app. Once a valid code has entered, EKGs taken by you will be shared with the cardiac monitoring service. To see if you are sharing EKGs with a cardiac monitoring service, tap the heart icon located at the top right of the Home screen.

18. BLOOD PRESSURE

iOS

AliveCor has formed a partnership with Omron. The partnership allows us to upload blood pressure readings directly into the Kardia phone app.

Pair your Omron blood pressure monitor* to the Kardia phone app:

1. From the Home screen, tap Blood Pressure.
2. Turn on the blood pressure monitor.
3. On the blood pressure monitor, press and hold the Transfer or Clock button until you see a flashing “P” or “o”.
4. Tap the Pair now button in the Kardia phone app to begin pairing.

NOTE: If you experience an error, repeat the above steps

Upload your blood pressure readings into the Kardia phone app:

1. From the Home screen, tap Blood Pressure.
2. After taking a recording, with the results displayed on the monitor’s screen, tap the Transfer recording button in the Kardia phone app.

NOTE: *Only Omron blood pressure monitors that are compatible with the Apple iPhone. Check with Omron for more information.

Android

Blood pressure measurements may be transferred from Google Fit or manually entered into the Kardia phone app. If you have a blood pressure monitor that is connected to Google Fit, you may transfer your blood pressure measurements from Google Fit into the Kardia phone app.

Connect to Google Fit

1. From the Home screen, tap Blood Pressure.
2. Tap the Learn more button and tap Next on the next screen.
3. Tap the Connect to Google Fit button.

Manual entry

1. From the Home screen, tap Blood Pressure.
2. By default, the systolic value is set at 120 and the diastolic value is set at 80. Tap the + and – buttons to change the values.
3. Tap the Submit button to record the blood pressure measurements.

19. WEIGHT

Track your weight over time in the Kardia phone app. You have the option to enter your weight manually or the Kardia phone app my gather the weight data from the Apple Health or Google Fit app.

Connect to Apple Health or Google Fit.

1. From the Home screen, tap Weight.

2. Tap the Learn more button and tap Next on the next screen.
3. Tap the Connect to Google Fit or Connect to Health button.

Manual entry

1. From the Home screen, tap Weight.
2. Scroll the scale gradations to the left or right to set the correct weight. Use the + or – buttons to add or subtract 0.1 lbs.
3. Tap the Submit button to record the weight.

The Body Mass Index (BMI) value is calculated using a person's weight and height. Although BMI does not measure body fat directly, research has shown that BMI is moderately correlated with other body fat measurement techniques. The BMI categories are derived from the BMI value (see the CDC website at https://www.cdc.gov/healthyweight/assessing/bmi/index.html). To view the weight and BMI results, go to the Journal screen and tap Weight.

20. PERSONAL REPORT

The Personal Report, a premium feature, is a monthly report that displays any associations between your Kardia data and your activity data. The Personal Report provides you with analysis, insights, and actionable advice to help you care for your heart. The report quality improves as you share more of your activity data through the Apple Health app.

21. ACCESSING HELP

Learn more about using your Kardia Mobile by tapping the menu icon at the top left of the home screen. Tap "Support" to see all the options available.

- **Tutorials.** Review these tutorials to learn about to navigate all the features of the app.
  - Recording an EKG
  - Alternate Recording Positions
- **Reference.** Access the user manual and provide feedback.
  - User Manual
  - Feedback

Learn more about using your Kardia Band by tapping the information icon accessed through the Home screen in the Kardia watch app (force touch on the Home screen). Instructions for accessing the user manual will appear.

22. EDITING USER PROFILE (KARDIA PHONE APP ONLY)

- Launch the Kardia phone app.
- Tap menu icon at the top left of the home screen.
- Tap "Your Profile".
- All user details can be edited.

23. ACCESSING EDUCATION (KARDIA PHONE APP ONLY)

- Launch the Kardia phone app.
- Tap menu icon at the top left of the home screen.
- Tap “Heart Education”. Users have the ability to learn about:
    - Cardiac Anatomy
    - What is an EKG
    - Arrhythmia Library
    - External Resources

NOTE: The information contained within this section is for educational purposes only. This information has been written and verified by medical professionals.

Do not attempt to use this information to interpret your own EKG. This information is not intended to replace medical advice, please seek professional medical assistance if you are suffering from any medical problem.

24. TROUBLESHOOTING

Problem	Solution
My Kardia Mobile is not working.	If you're taking your first recording, ensure that your Apple iPhone "Portrait Orientation Lock" is not on as you must be able to turn your phone to landscape orientation (bottom of the iPhone in your right hand) in order to take a recording. If you're using iOS 7 or greater, ensure that the Kardia phone app has access to the iPhone microphone: 1. Tap on iPhone "Settings" 2. Tap on "Privacy" 3. Tap on "Microphone" 4. Ensure that "Kardia" is turned on (the background of the slider is green) Change the battery 1. Expose the battery door at the back of Kardia Mobile: a. Remove the case from the smartphone or tablet by pushing the iPhone through the camera cutout, while peeling back Kardia Mobile from this corner. OR b. Remove Kardia Mobile from the attachment plate: 1. AC-001 - AC-007: Place your thumbs on the electrodes and press down firmly. Turn counterclockwise about 45 degrees to "unlock" Kardia Mobile. Once it's "unlocked", Kardia Mobile can then be lifted out of the plate. 2. AC-009: Use your thumbs to slide Kardia Mobile toward the open end of the plate. 2. Remove the battery door: a. AC-001 - AC-007: Use a 1.6mm Phillips screwdriver, press down firmly and turn counterclockwise to remove the screw in the battery door. b. AC-009: Insert a pen, pencil or other similarly shaped object into the cutout next to the battery door to pop the battery door off. 3. Remove the used battery and replace it with a new 3V coin cell battery matched to your model. 4. Orient the battery with the positive terminal up, so that you can see the writing. Remove the protective sticker from the battery, as applicable.

Problem	Solution
My Kardia Band is not working.	Ensure that the Kardia watch app has access to the smartwatch's microphone: 1. On the iOS smartphone, tap the "Settings" app. 2. Scroll down the screen until you see Kardia and tap it. 3. Tap the "Microphone" toggle. 4. Ensure that "Kardia" is turned on (the background of the slider is green) Check for obstructions Ensure that the watch microphone is unobstructed. In the event an obstruction exists, consult your watch user manual. Change the battery 1. Gently pull the watchband and gently push the Kardia Band sensor from the groove of the watchband. 2. Remove the battery door. Use a Torx T3 screwdriver, press down firmly and turn counterclockwise to remove the screw in the battery door. Repeat for the remaining screws. 3. Remove the used battery and replace it with a new 3V CR1620 coin cell battery. 4. Orient the battery with the positive terminal up, so that you can see the writing. Remove the protective sticker from the battery, as applicable. 5. Replace the battery door; note that the battery door only fits in one orientation and you may need to rotate the door to achieve the correct fit. 6. Replace the four screws and hand-tighten with the Torx T3 screwdriver.

Problem	Solution
I have a lot of artifact, noise, interference, or see “No EKG” in my recording	Try the following tips for acquiring the best quality EKG recording: • Ensure that the “Enhanced Filter” is on. • Clean the electrodes on Kardia Mobile with an alcohol-based sanitizer. • If hands are very dry, use a water-based lotion before recording. • When recording from the hands, relax the arms and hands to reduce muscle noise. Rest the forearms and hands on a flat surface and let Kardia Mobile rest on the hands. Do not squeeze Kardia Mobile. • Ensure that your smartphone or tablet is not charging/syncing and you are not using headphones with your smartphone or tablet during the recording. • Make sure that both the smartphone or tablet and the user remain still during EKG recordings. Movement during recordings will cause noise in the tracing. • Make sure Mains Filter is set appropriately for your geographical location. This can be adjusted under the Kardia phone app Settings.
The EKG rhythms appear upside down	In the future, ensure that the left hand contacts the electrode closer to the top of the smartphone or tablet, and the right hand contacts the electrode closer to the bottom of the smartphone or tablet. To invert a recording on your smartphone or tablet, see “Invert the EKG recording” under “Recording Adjustments”.
I forgot my password and I’m unable to reset it	To reset your password, go to www.alivecor.com and click "Sign In" at the bottom of the screen. Click "Forgot your password?" link below the Password field, enter your email address, and click Submit. Follow the reset instructions in the email. Note, the reset link contained in the email is only active for a short while.
The PDF Report looks slightly different on the Web and in my App	There is a 2.5 millisecond (thousandth of a second) difference in where the PDF starts for the Web Application and the Mobile Application. There is no difference in the recording and it will not impact how your EKG is interpreted.
My personal information (name, DOB, etc.) disappears when I’m trying to create an account	If you navigate backwards when creating your account, the personal information you entered on the previous page is deleted and will have to be re-entered.

Problem	Solution
The HUD symbol is covered up when I rotate my phone	The heads up display (HUD) symbol can sometimes be partially obstructed when you rotate your phone while it's busy. This isn't a concern; the HUD symbol is just letting you know that the app is working. This doesn't impact your recording or any of your information.
I see large spikes at the start of my recording	Large amounts of noise/artifact can be seen for the first few milliseconds of a recording when the Enhanced Filter is looking for your heartbeat. This is a very rare problem that lasts until your first heartbeat is seen in the app and doesn't affect the rest of your recording.
The real-time display of my EKG recording is lagging and jumps	If you are using an iPhone 4 and syncing a large amount of recordings from the server the real-time display of your EKG may be slow. This is an issue that has been reported for iPhone 4 and occurs after an update or after a new install of the application on a new phone. This does not impact the EKG recording itself. Waiting for sync to complete (can take up to 30 minutes) after re-installing the application will prevent this error from occurring.
The EKG was lost when I was recording it	Rotating your phone while recording so that the screen "flips" from portrait to landscape mode will automatically stop the recording and that EKG will not be saved. Please do not rotate your phone while recording as this will impact the quality of your recording.
I can't see my age in the PDF report	If your first and last names are longer than 35 characters combined, your age may be covered due to size restrictions in the PDF report. Please consider using initials for your first or last name in order to ensure you age is visible.
My credit card isn't being accepted	In rare occasions, the error message indicating that your credit card is incorrect or invalid is automatically cleared by rotating the phone from portrait to landscape or vice versa. Please ensure that your credit card information is valid before processing payments.
I need a printed version of the manual	Contact support@alivecor.com for a printed copy of this manual.
Is the manual available in another language?	This manual is available in English, Dutch, French, German, Italian, and Spanish.

25. KARDIA SPECIFICATIONS

Performance Characteristics

EKG Channel .....Single Channel
Input Dynamic Range.....10mV Peak-to-Peak
Memory length .....Practically Unlimited
Recording Format .....Continuous
Shelf Life .....Estimated 2 years

Circuitry

Frequency Response ..... 0.5 Hz to 40 Hz
CMRR..... 76 dB
Input Impedance ..... > 100 MOhm
Differential Range ..... +/- 5 mV
A/D Sampling Rate ..... 300 samples/second
Resolution ..... 16 bit
DC Offset Correction ..... +/- 300 mV

Output

Modulation .....Frequency Modulated Ultrasonic Audio Tone
Center Frequency .....19 kHz
Frequency Deviation ..... 200 Hz/mV

Power Requirements

Battery Type (AC-001) CR2016
Battery Type (AC-003) CR2025
Battery Type (AC-004 & AC-007) CR2032
Battery Type (AC-009) CR2016
Battery Type (AC-011) CR1620
Battery life (Kardia Mobile) ..... min. 200 Hours Operational Time, 12 months typical use
Battery life (Kardia Band)..... min. 90 Hours Operational Time, 2 years typical use

Physical Characteristics

AC-001 (for iPhone 4/4s) ..... 40 grams 118 x 62 x 15 mm 9 cm^2 Electrode
AC-003 (for iPhone 5/5s) ..... 41 grams 128 x 62 x 15 mm 9 cm^2 Electrode
AC-004 & AC-007-I5-A (for iPhone 5/5s)..... 33 grams 126 x 62 x 11 mm 10cm^2 Electrode
AC-004 & AC-007-UA-A (w/Attachment Plate). 28 grams 89 x 48 x 9 mm 10cm^2 Electrode
AC-009 .....18 grams 82 x 32 x 3.5 mm 9 cm^2 Electrode
AC-009-UA-DI .....18 grams 82 x 32 x 3.5 mm 9 cm^2 Electrode
AC-011 (sensor only).....30.6 grams 2.1 x 2.0 x 0.8 cm 3 cm^2 Electrode

Environmental Specifications

Operational Temperature ..... +10 to +45 degrees C
Operational Humidity .....10% to 95% (non-condensing)

Operational Altitude ..... based on your smartphone, smartwatch, or tablet specification

Storage Temperature ..... -20 to +60 degrees C

Storage Humidity ..... 10% to 95% (non-condensing)

Ingress Protection Marking. Kardia Band is IP22 rated. Kardia Band is protected against insertion of fingers and is not affected by vertically dripping water. Kardia Band is compliant with standard IEC60601-1-11:2015.

Expected Service Life. The expected service life is 2 years for Kardia Band.

Warm up time. Warm up time is not required for Kardia Band for its intended use.

User Interface

Two stainless-steel electrodes are exposed on the back of Kardia Mobile. These electrodes make contact with the user's skin. For the Kardia Band, two stainless-steel electrodes are exposed on the front and back of the Kardia Band. These electrodes make contact with the user's skin.

The Kardia Band sensor may be removed and inserted a maximum of 50 times without performance degradation.

26. EUROPEAN AUTHORIZED REPRESENTATIVE

Obelis SA
BD General Wahis 53
1030, Brussels
Belgium
Tel: +(32) 2. 732.59.54
Fax: +(32) 2.732.60.03
E-Mail: mail@obelis.net

27. ALIVECOR CONTACT INFORMATION

AliveCor, Inc.
444 Castro Street, Suite 600
Mountain View, CA 94041
United States
www.alivecor.com

AliveCor, Ltd.
Herschel House
58 Herschel Street
Slough
SL1 1PG
United Kingdom

28. ELECTRICAL SAFETY

28.1. KARDIA MOBILE ELECTRICAL SAFETY

Guidance and manufacturer's declaration - electromagnetic emissions		
Kardia Mobile is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Kardia Mobile uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Kardia Mobile is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration—electromagnetic immunity			
Kardia Mobile is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of Kardia Mobile requires continued operation during power mains interruptions, it is recommended that the Kardia Mobile be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE— U_T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration—electromagnetic immunity</th></tr>
<tr><td colspan="4">Kardia Mobile is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 V</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of Kardia Mobile, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = [\frac{3.5}{V_1}]\sqrt{P}$
$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Kardia Mobile is used exceeds the applicable RF compliance level above, Kardia Mobile should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Kardia Mobile.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and Kardia Mobile

Kardia Mobile is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Kardia Mobile can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Kardia Mobile as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

28.2. KARDIA BAND ELECTRICAL SAFETY

The Kardia Band has been tested and deemed in conformance with the relevant requirements in IEC60601-1-2:2014 Class BG for Electromagnetic Compatibility (EMC).

Guidance and manufacturer's declaration - electromagnetic emissions		
Kardia Band is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Band should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Kardia Band uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Kardia Band is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration—electromagnetic immunity			
Kardia Band is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Band should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

<table>
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<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>N/A

3 V/m
80 MHz to 2.7 GHz</td><td>N/A

10 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of Kardia Band, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Kardia Band is used exceeds the applicable RF compliance level above, Kardia Band should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Kardia Band.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and Kardia Band

Kardia Band is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Kardia Band can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Kardia Band as recommended below, according to the maximum output power of the communications equipment.

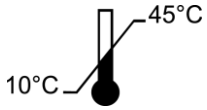
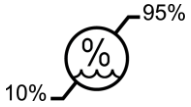
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.7 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.035	0.035	0.070
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

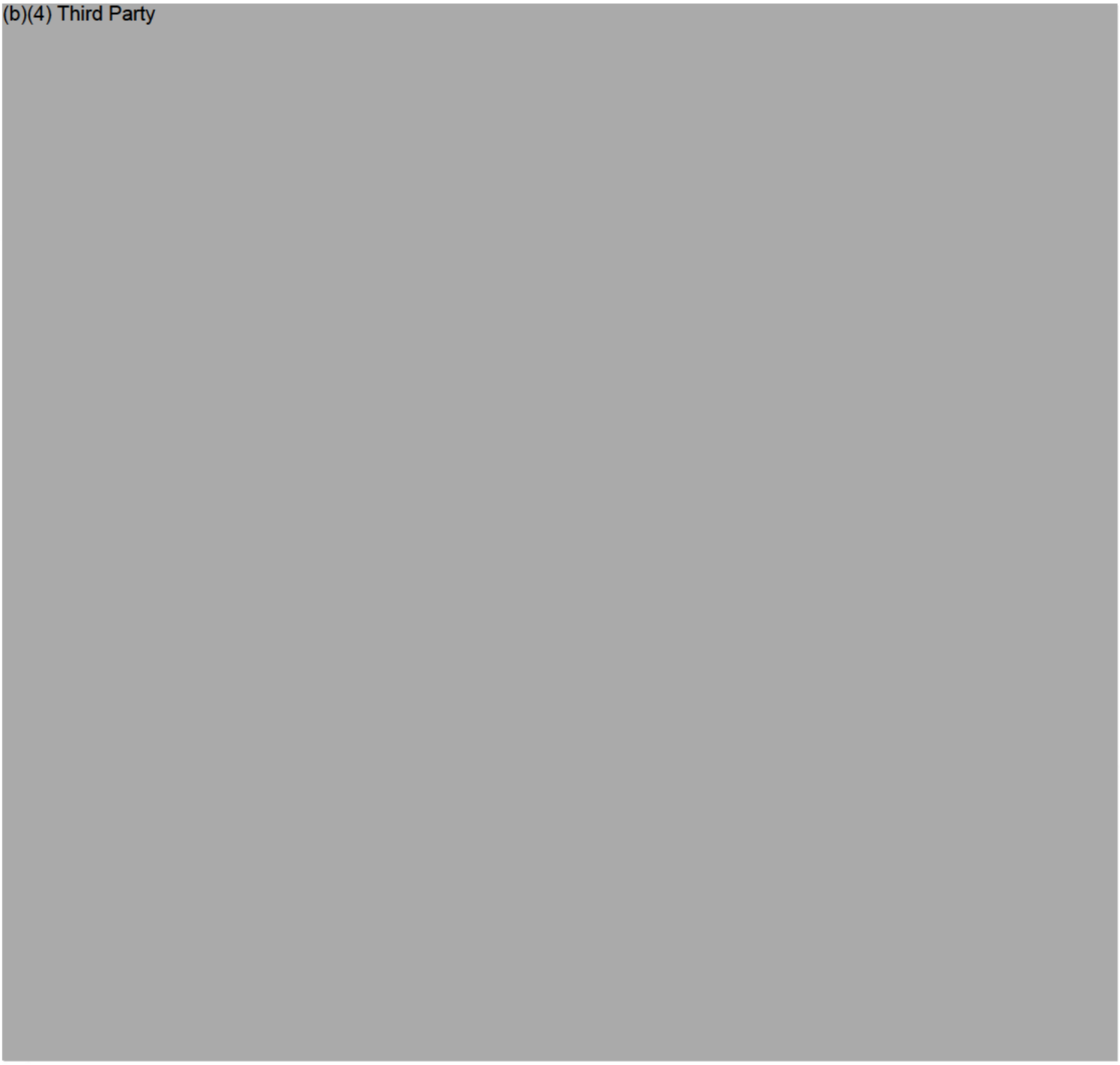
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

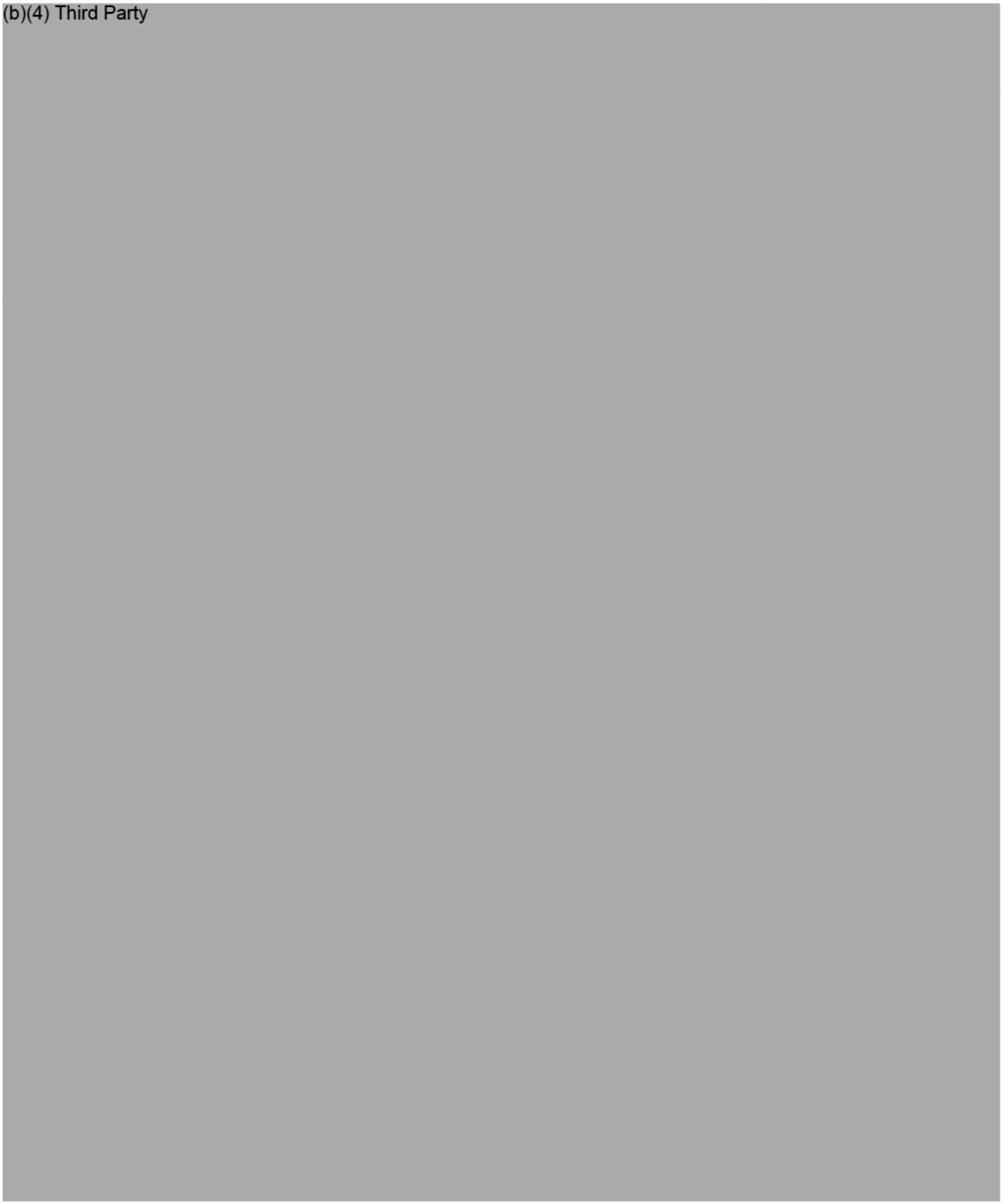
29. SYMBOLS USED SYSTEM OR PACKAGE LABELING

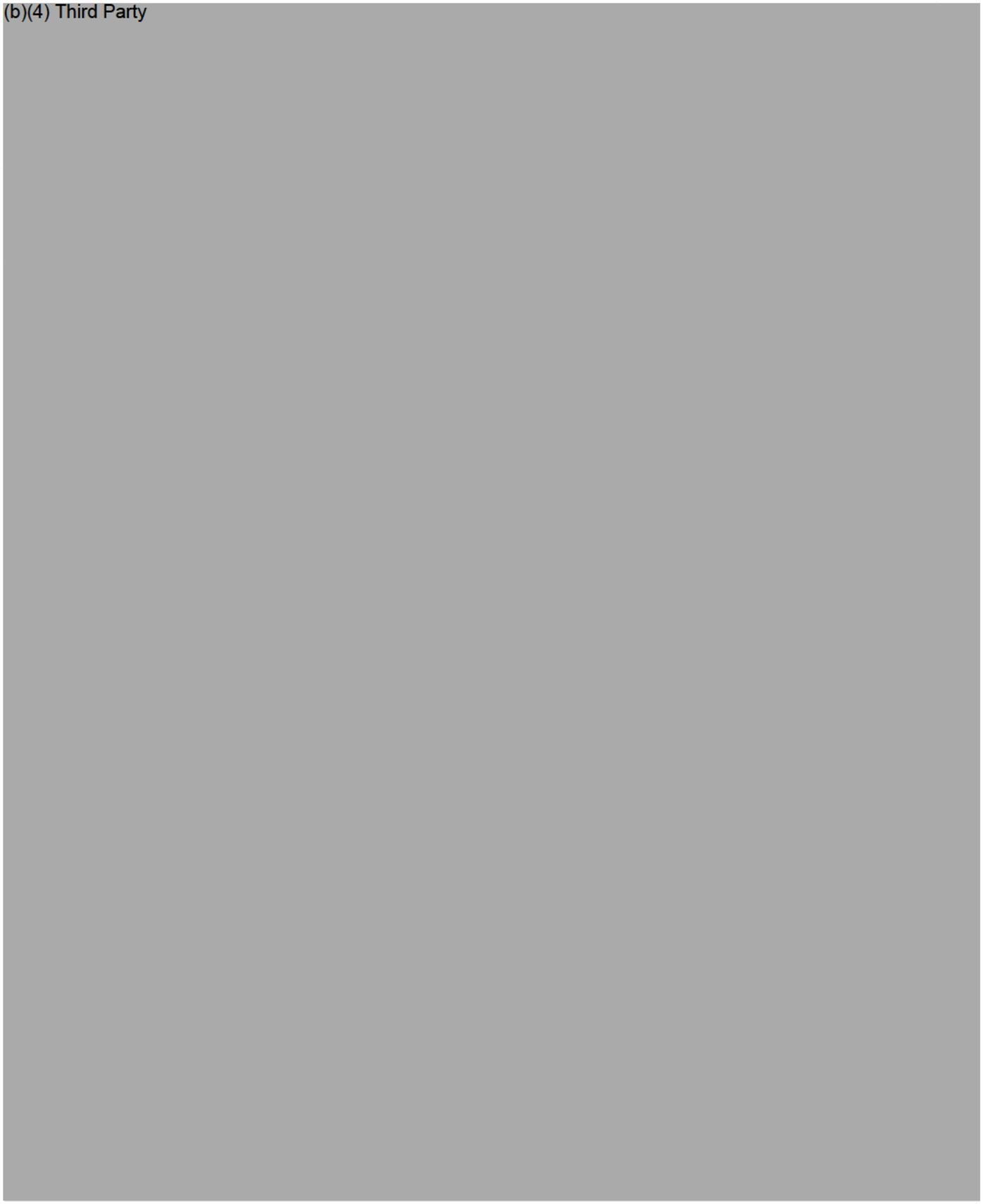
	Type BF Applied Part (Kardia Band)
	Type CF Applied Part (Kardia Mobile)
	European Conformity Mark
	Do not dispose with household waste
	Read instructions before use
	Manufacturer
	Temperature range
	Humidity range
REF	Model number
SN	Serial number

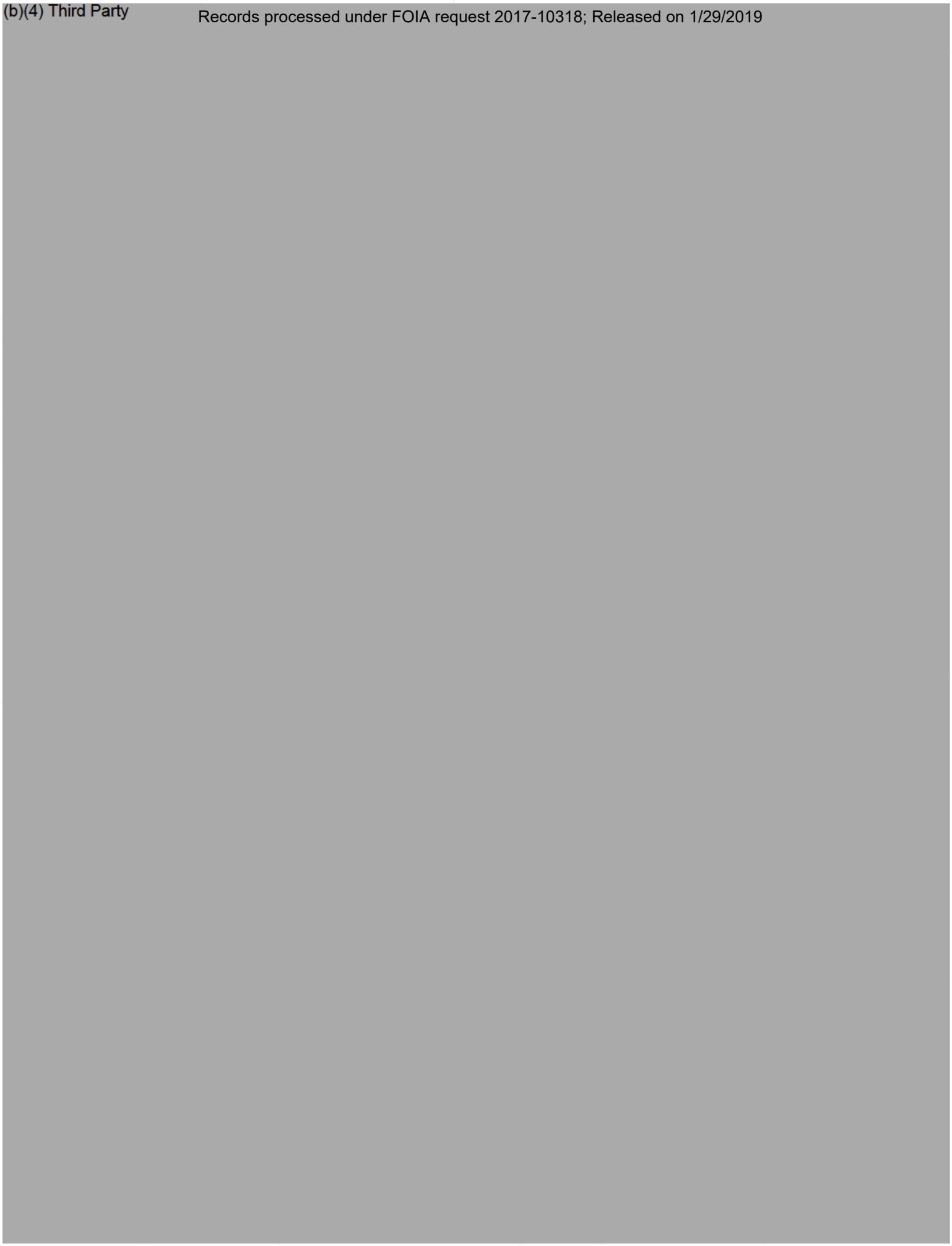
(b)(4) Third Party

(b)(4) Third Party









APPENDIX 4
PREDICATE DEVICE 510(K) SUMMARY

Provided in this appendix is the 510(k) Summary for the predicate device, the AliveCor Heart Monitor (K142743).

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

January 27, 2015

AliveCor, Inc.
Albert Boniske
Director of Regulatory Affairs
30 Maiden Lane, 6th Floor
San Francisco, California 94108

Re: K142743
Trade/Device Name: Alivecor Heart Monitor
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH, DPS
Dated: December 15, 2014
Received: December 18, 2014

Dear Albert Boniske,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K142743

Device Name: AliveCor Heart Monitor

Indications For Use:

The AliveCor Heart Monitor is intended to record, store and transfer single channel electrocardiogram (ECG) rhythms. The AliveCor Heart Monitor also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The AliveCor Heart Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and it is not intended for pediatric use.

Prescription Use __X__	And/Or	Over the Counter Use __X__
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

510(k) Premarket Notification: K142743

GENERAL INFORMATION

Applicant:
AliveCor, Inc.
30 Maiden Lane, 6th Floor
San Francisco, CA 94108

Contact Person:
Albert Boniske
Director of Regulatory Affairs
AliveCor, Inc.
Phone: 415-795-9811
Fax: 415-397-0440

Date Prepared:
September 22, 2014

DEVICE INFORMATION

Trade Name:
AliveCor Heart Monitor

Generic/Common Name:
Telephone electrocardiograph transmitter and receiver

Classification:
21 CFR§870.2920, Transmitters and Receivers, Electrocardiograph, Telephone, Class II

Product Code:
DXH, DPS

PREDICATE DEVICE(S)

- K140933 – AliveCor Heart Monitor

510(K) SUMMARY

INDICATIONS FOR USE

The AliveCor Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Heart Monitor also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The AliveCor Heart Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested for and it is not intended for pediatric use.

DEVICE DESCRIPTION

The AliveCor Heart Monitor (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. The device utilizes the processing power of a mobile computing platform (MCP) while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The AliveCor Heart Monitor can also analyze ECG signals and indicate the presence of noise, normal sinus rhythm and atrial fibrillation for each ECG recording.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the AliveCor Heart Monitor are substantially equivalent to the indications for use for the predicate device. The AliveCor Heart Monitor operates using the same technological characteristics for the same intended use as its predicate device. Each device records and stores ECGs and indicates the presence of abnormalities in the recording. The nonclinical testing results demonstrate that any differences in the technological characteristics between the subject and predicate device do not raise any new issues of safety or effectiveness. Thus, the AliveCor Heart Monitor is substantially equivalent to the predicate device.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the AliveCor Heart Monitor to support a determination of substantial equivalence to the predicate device and demonstrate conformity to recognized standards

- AAMI / ANSI / IEC 62304:2006 Medical device software - software life cycle processes,
- ISO 14971: 2007 Medical devices -- Application of risk management to medical devices, and
- AAMI/ANSI EC57: 2012 Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms.

510(K) SUMMARY

The non-clinical testing included software verification and algorithm validation to demonstrate the functionality of the software application and the performance of the algorithms. The databases recommended by EC57 and data captured from the AliveCor Heart Monitor were used to validate the algorithms' performance. The collective results of the non-clinical testing demonstrate that the AliveCor Heart Monitor meets the established specifications necessary for consistent performance for its intended use.

CONCLUSION

The results of the nonclinical testing demonstrate that the AliveCor Heart Monitor is substantially equivalent to the predicate device.

APPENDIX 5
BIOCOMPATIBILITY

Provided in this appendix is the biocompatibility test report, "Biocompatibility Test Report for Kardia Band" (b) (4) for the Kardia Band System.

(b)(4) Biocompatibility Test Report

(b)(4) Biocompatibility Test Report

(b)(4) Third Party Testing

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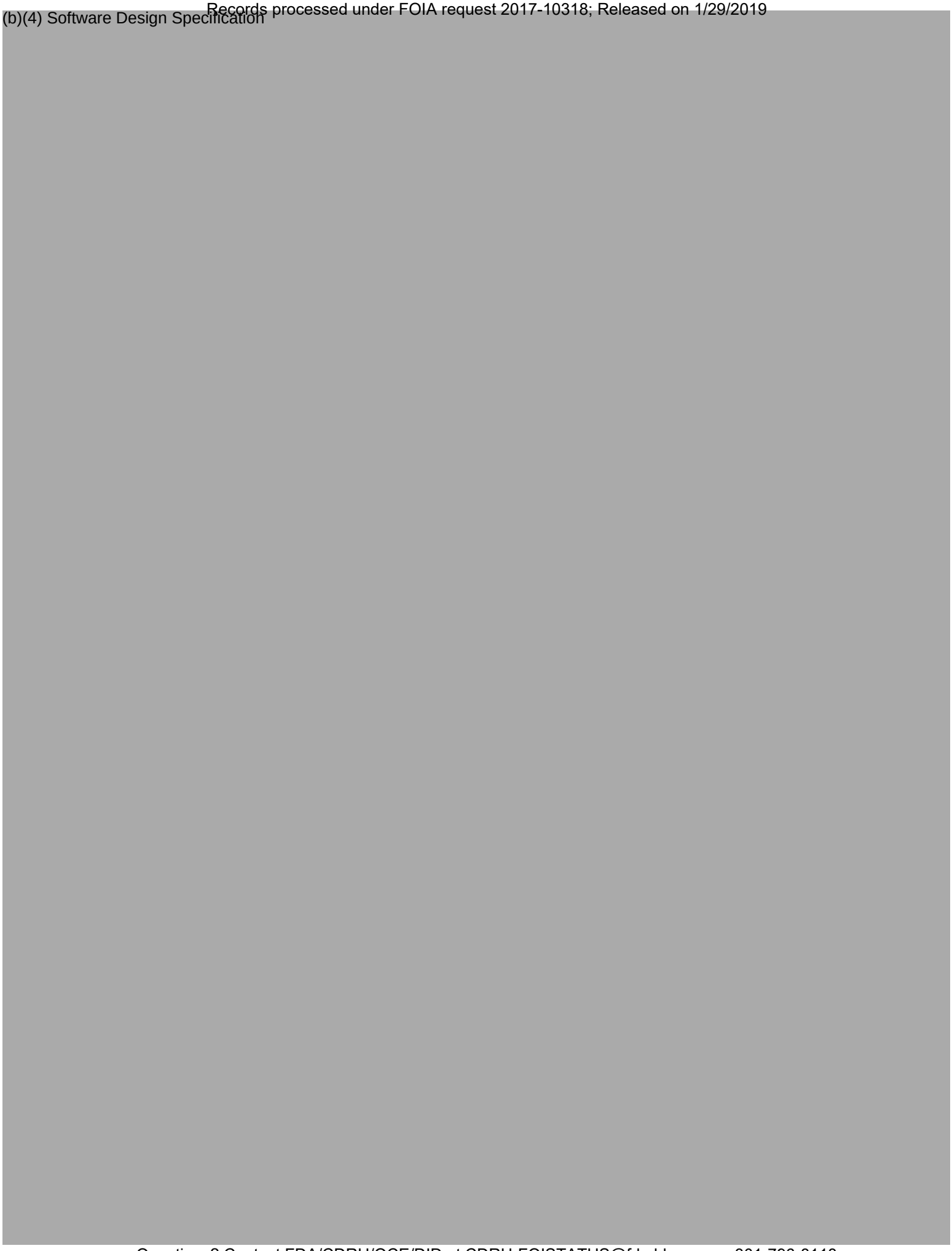
APPENDIX 6
SOFTWARE

Provided in this appendix are the following software documents discussed within this 510(k) submission:

(b) (4)

(b)(4) Software Design Specification



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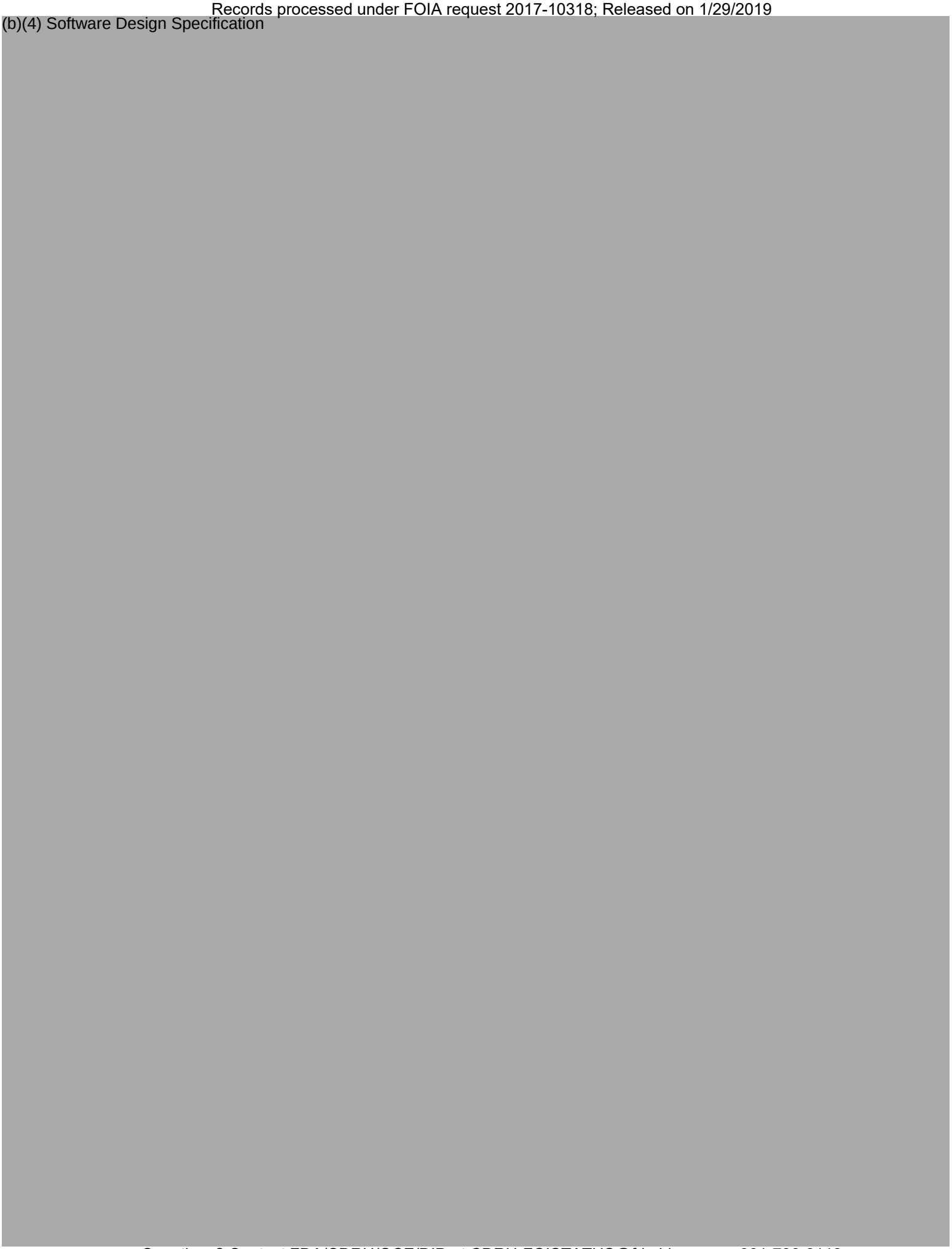

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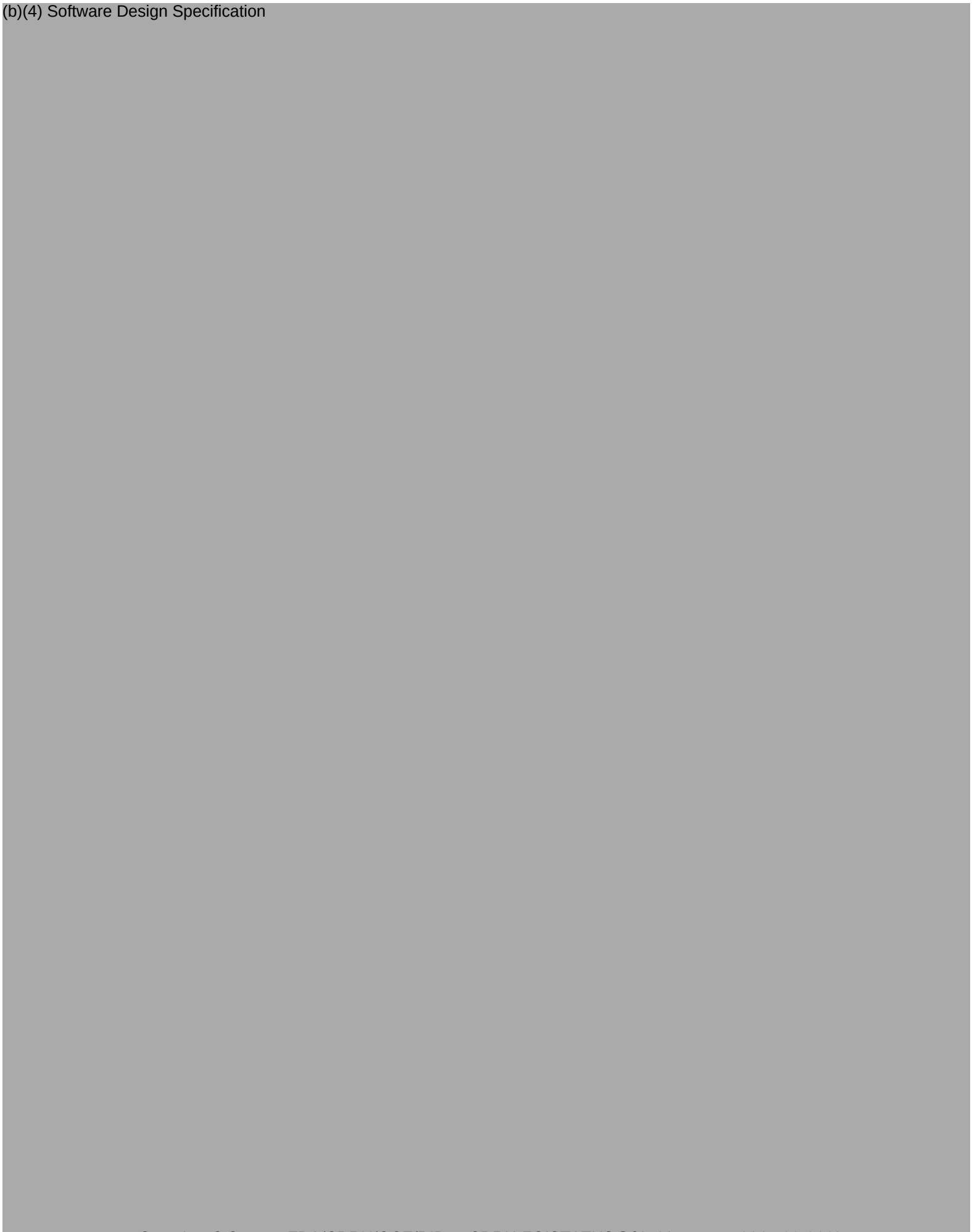

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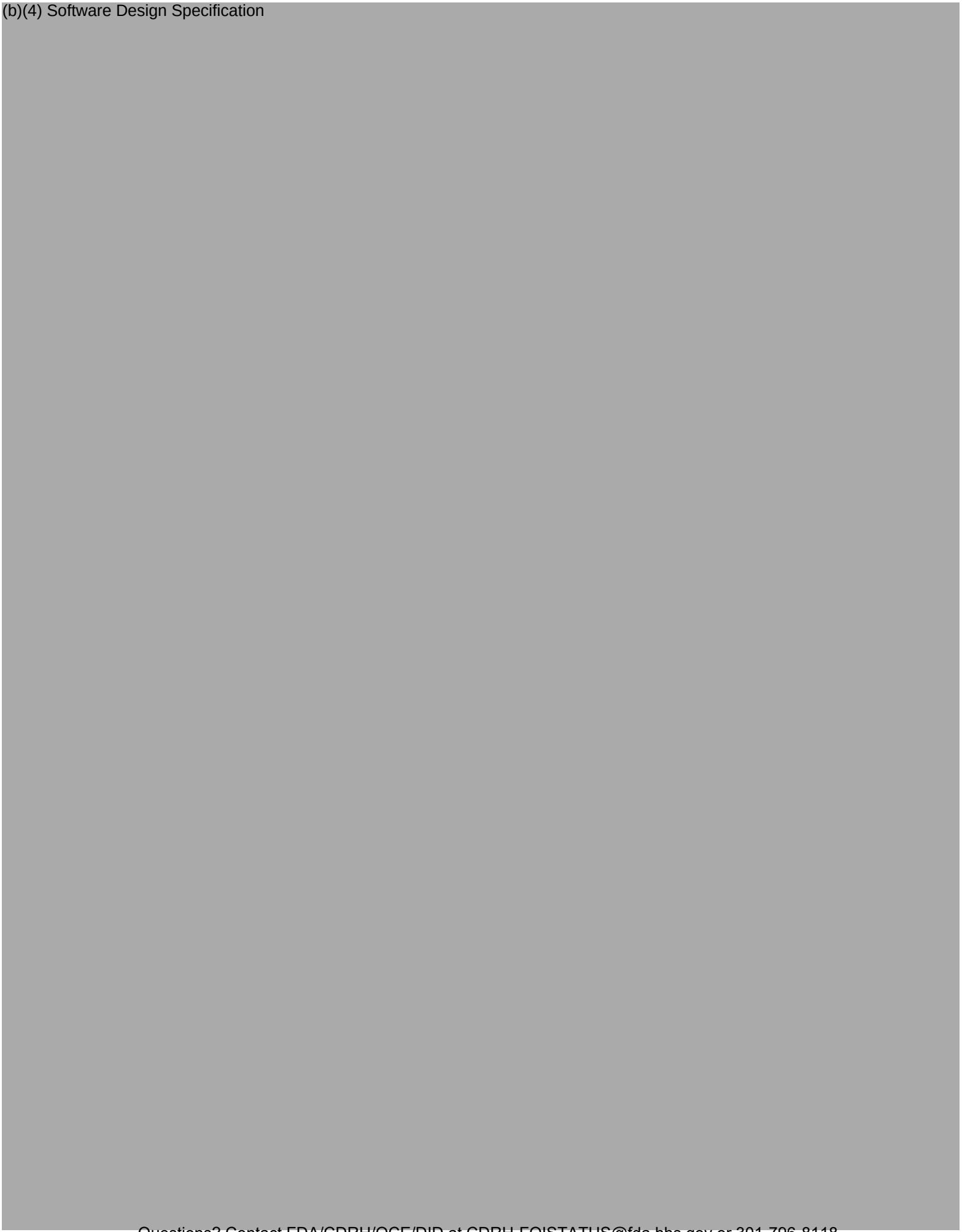

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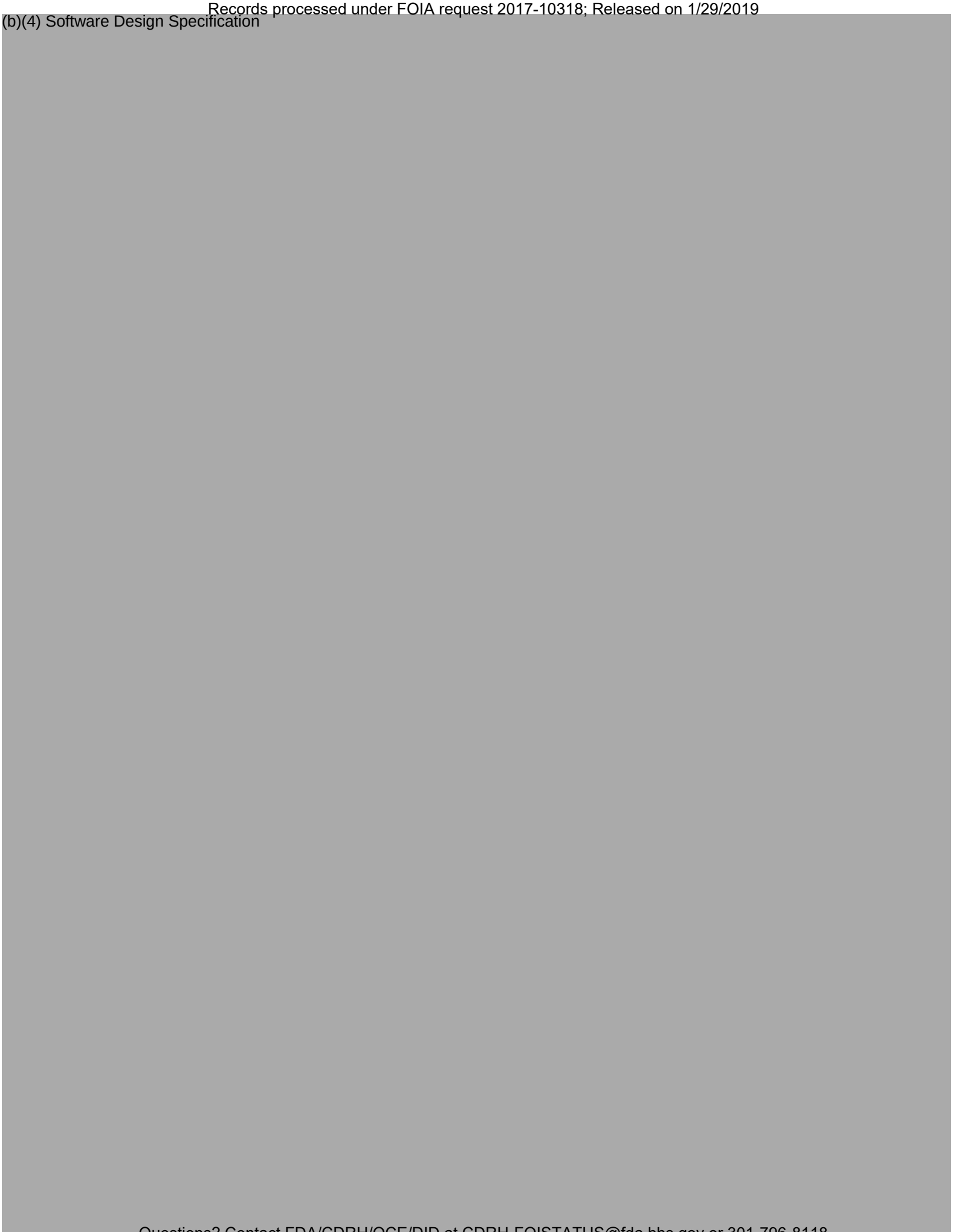

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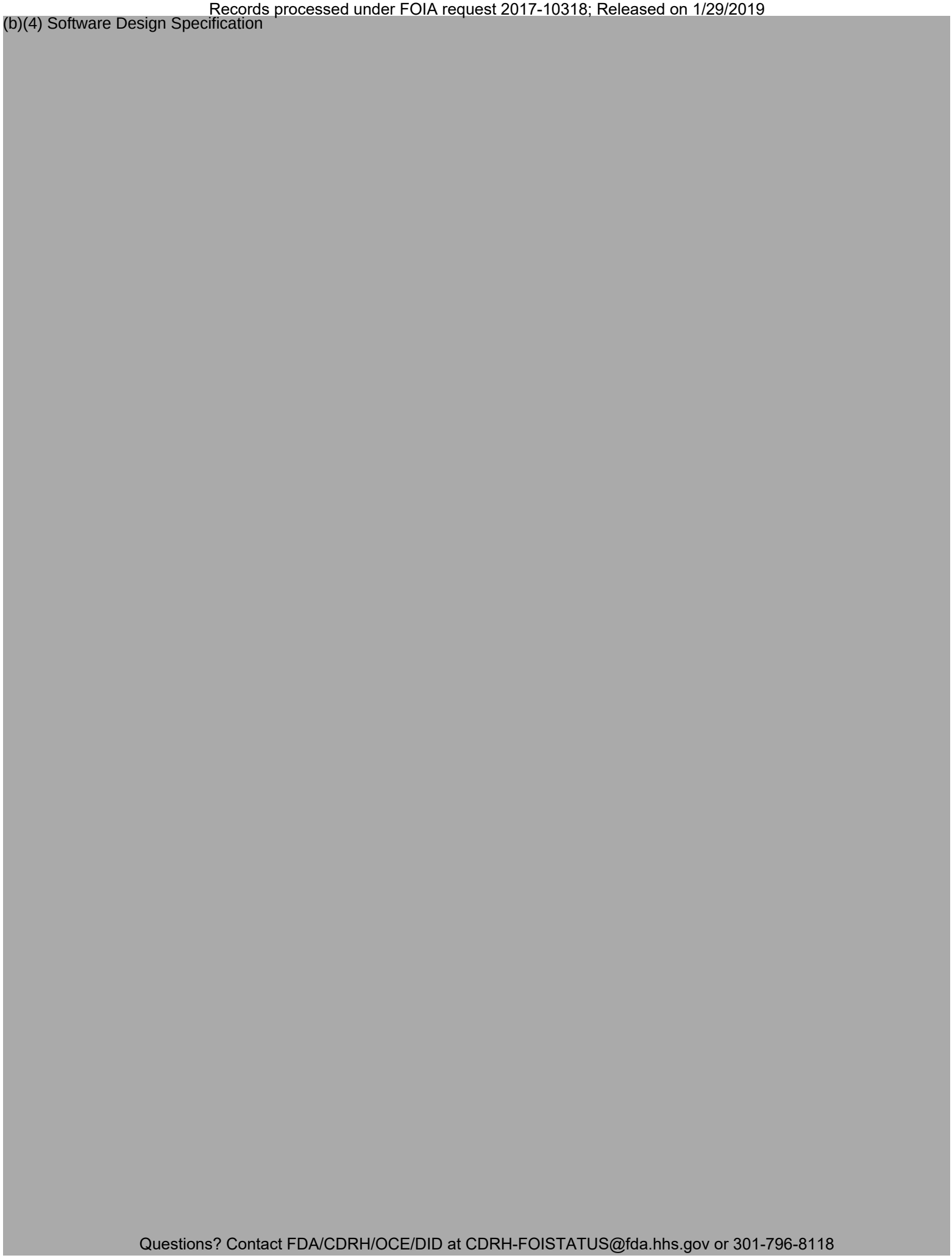

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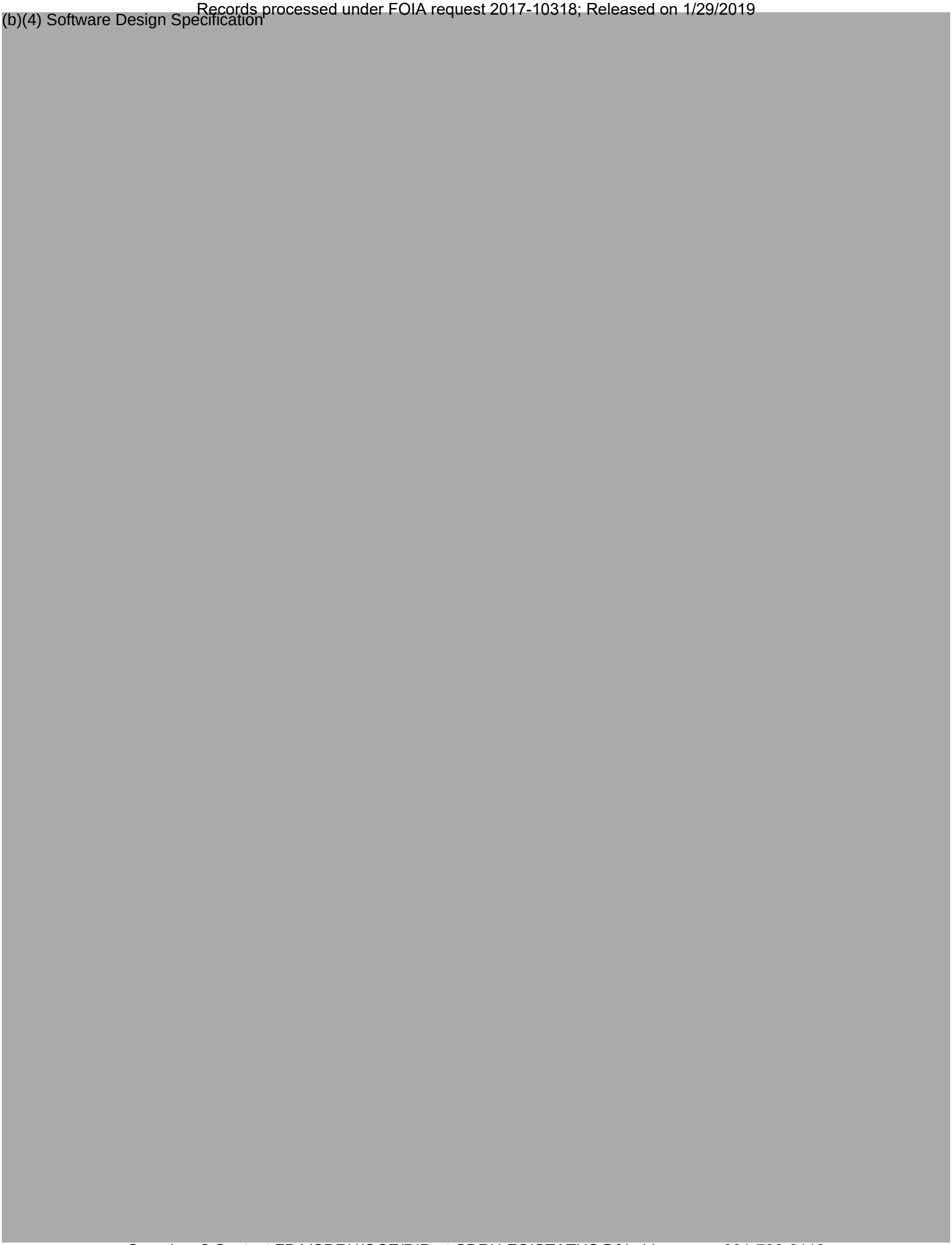

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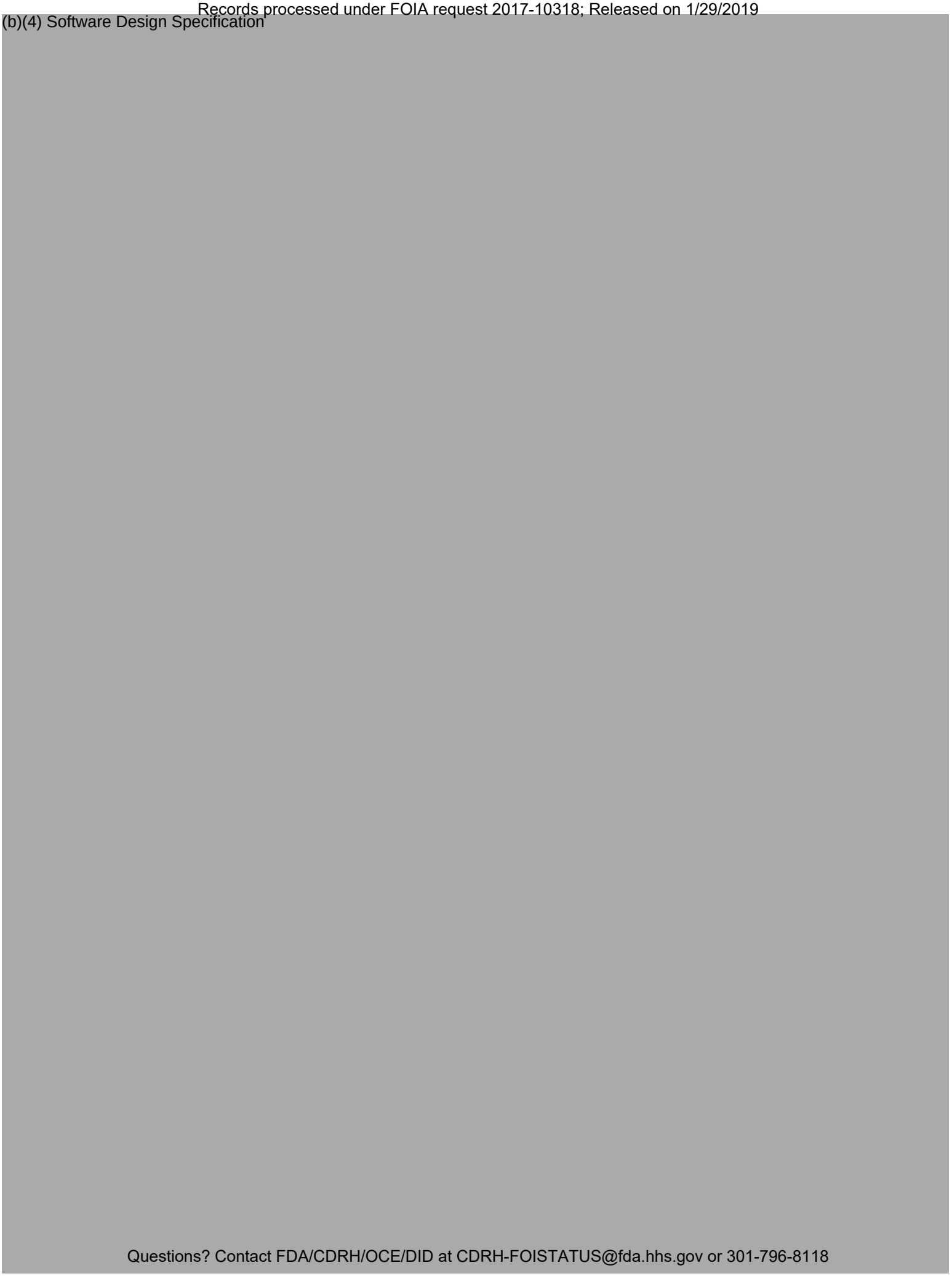

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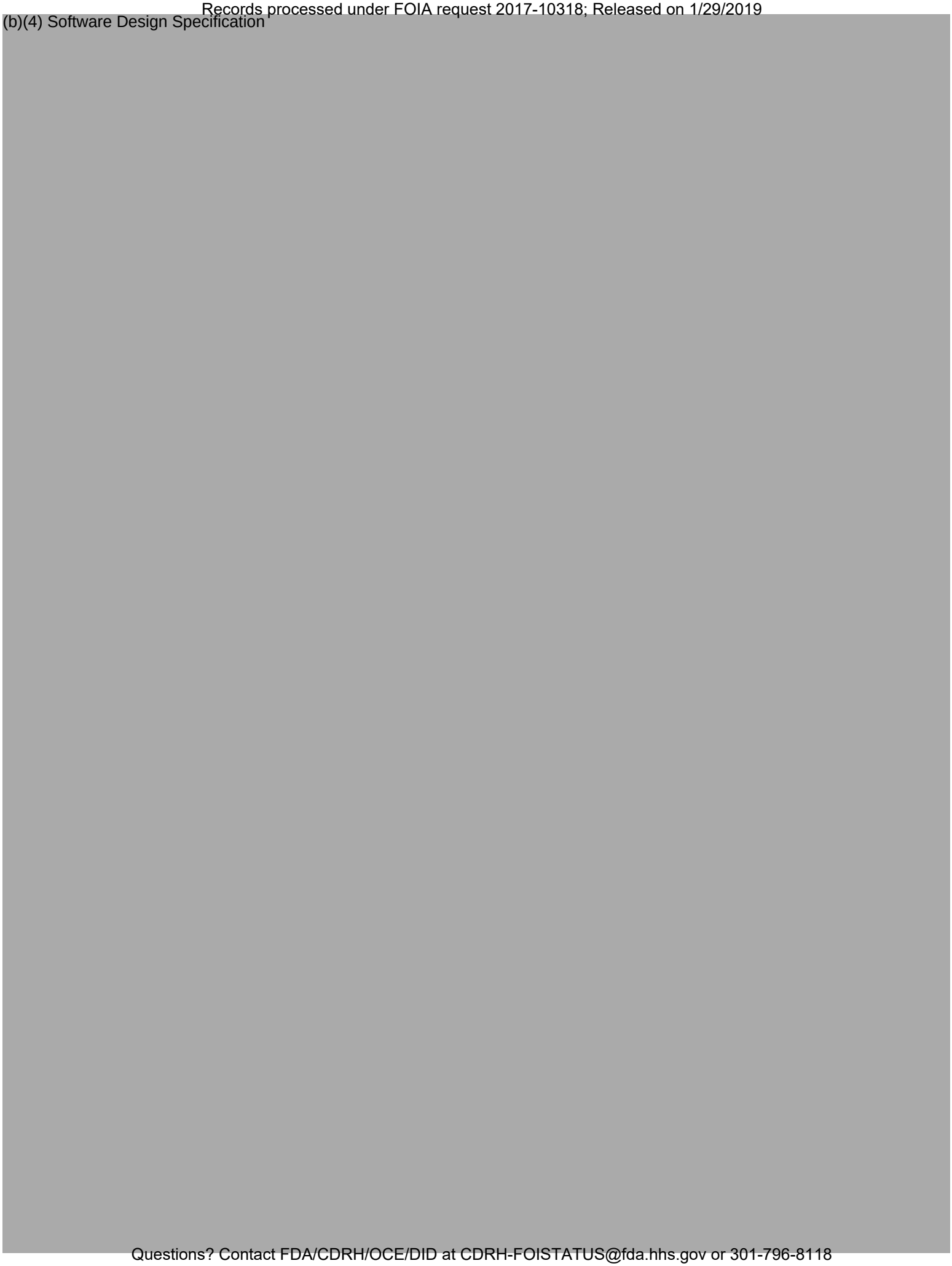

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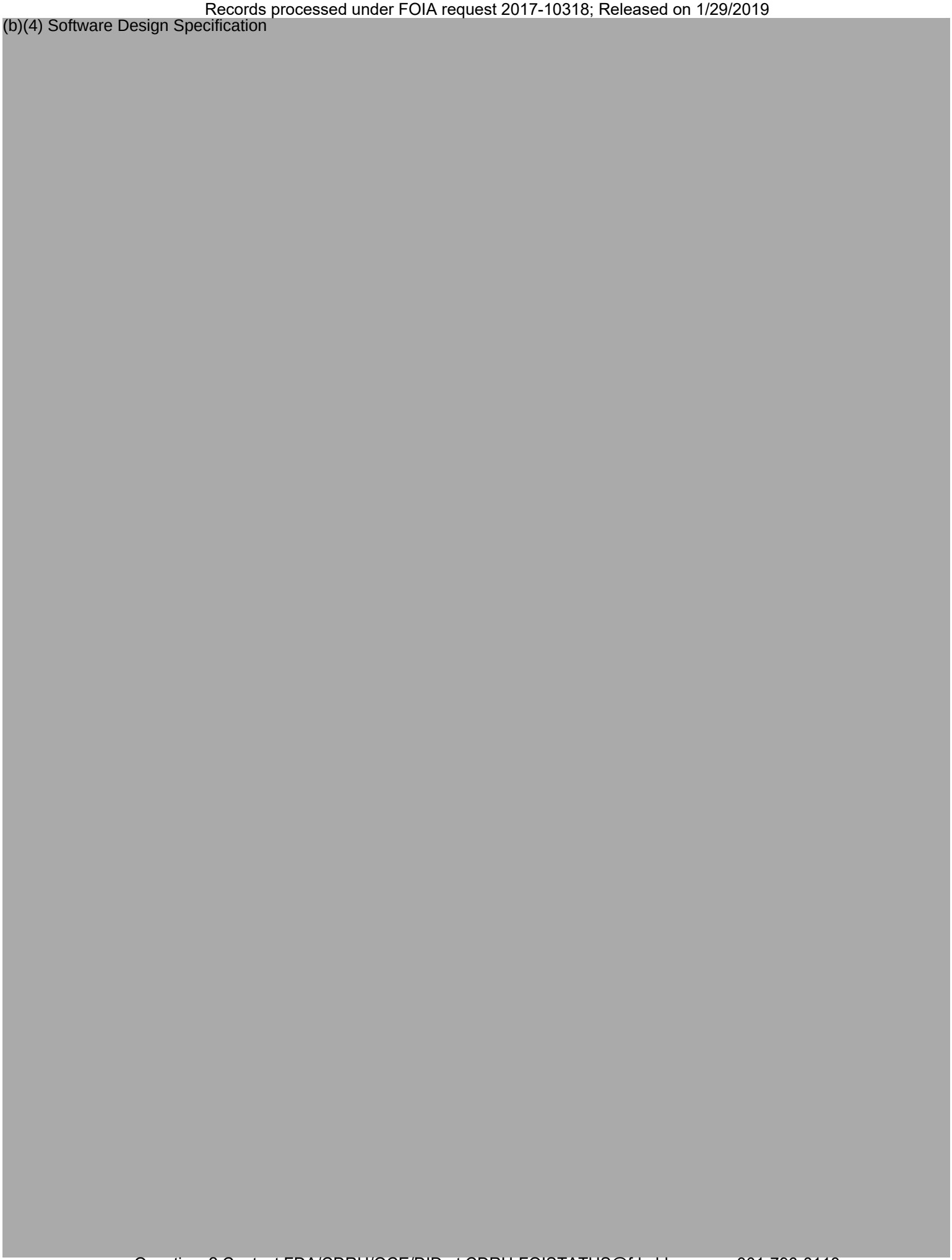

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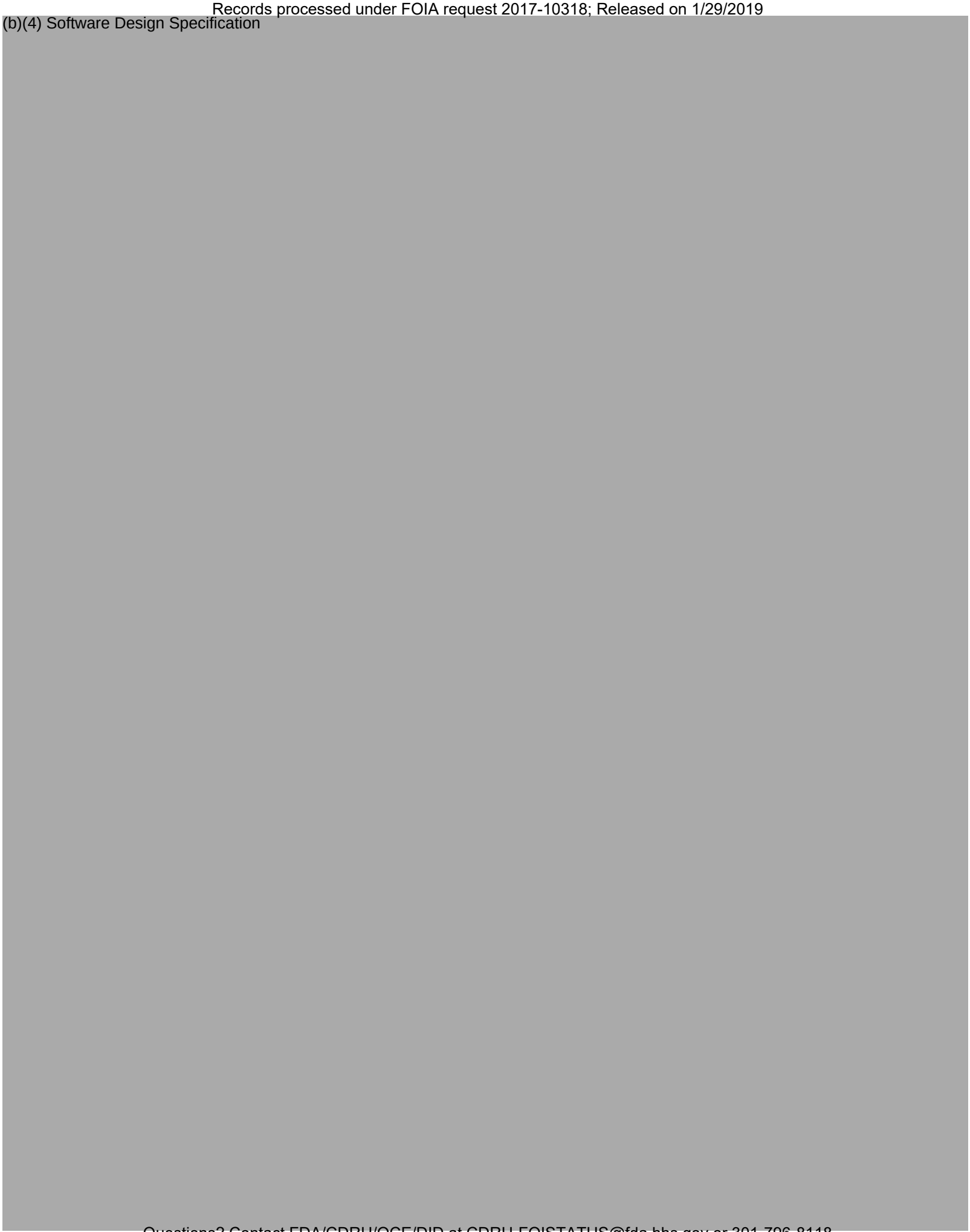

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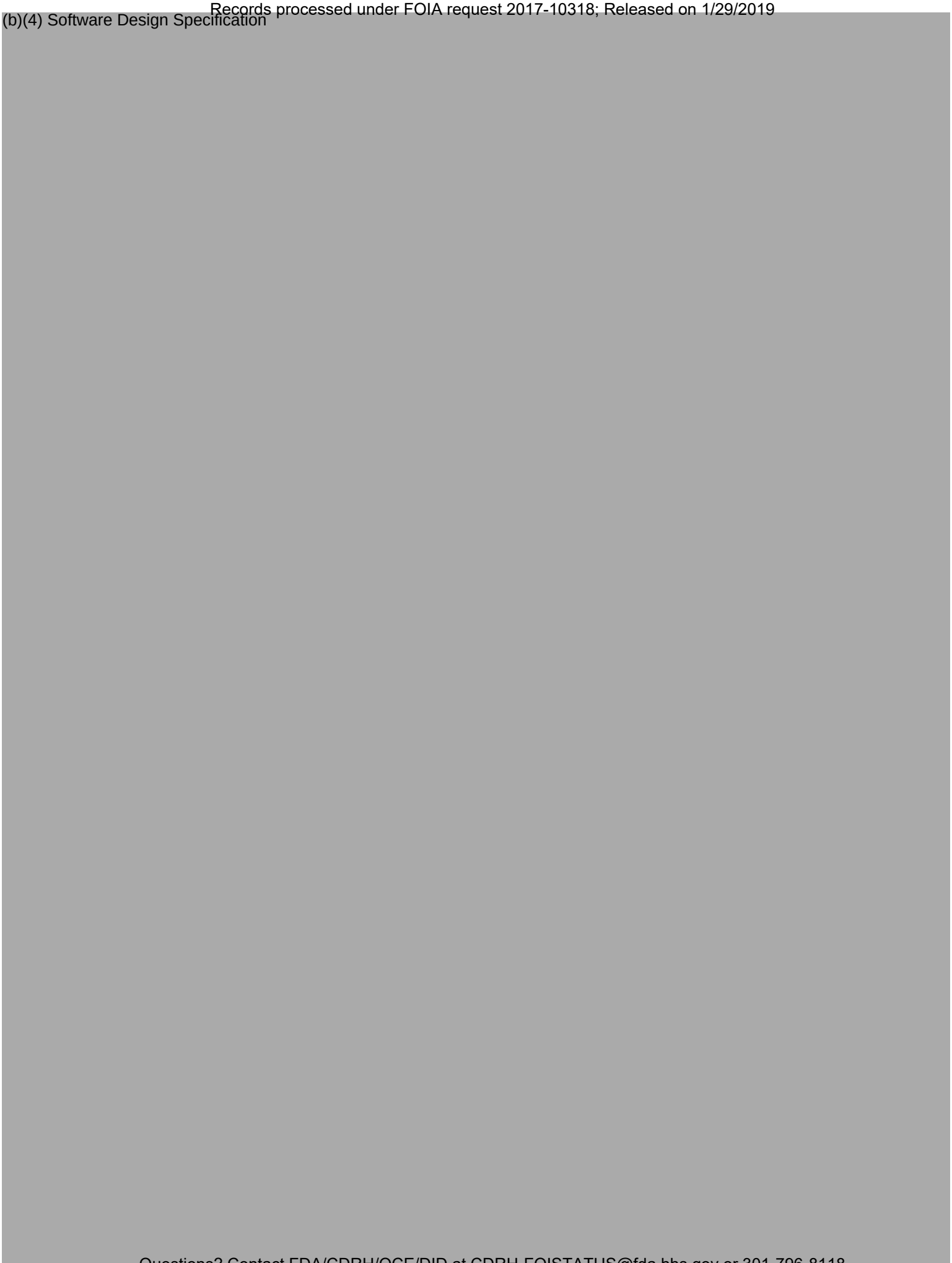

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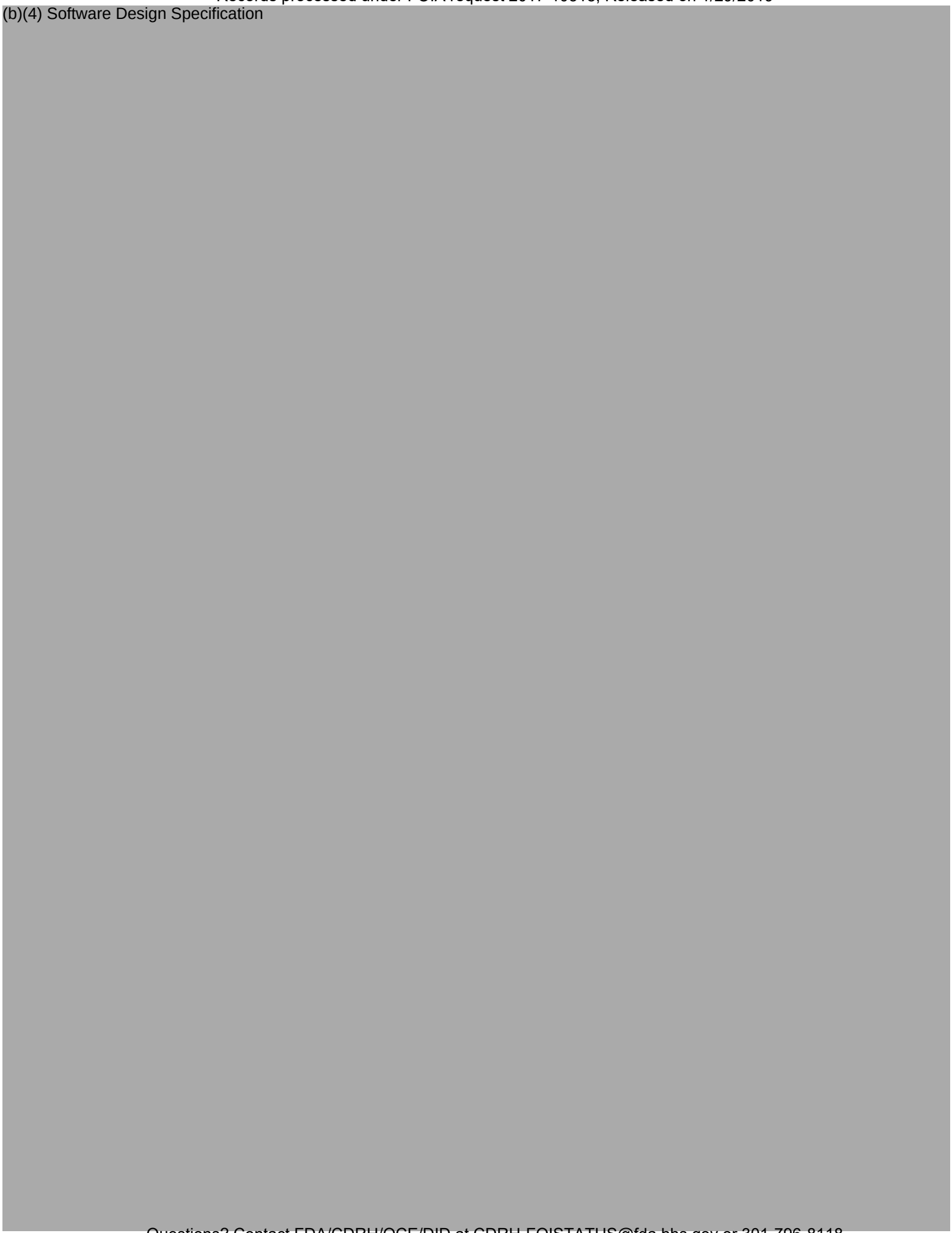

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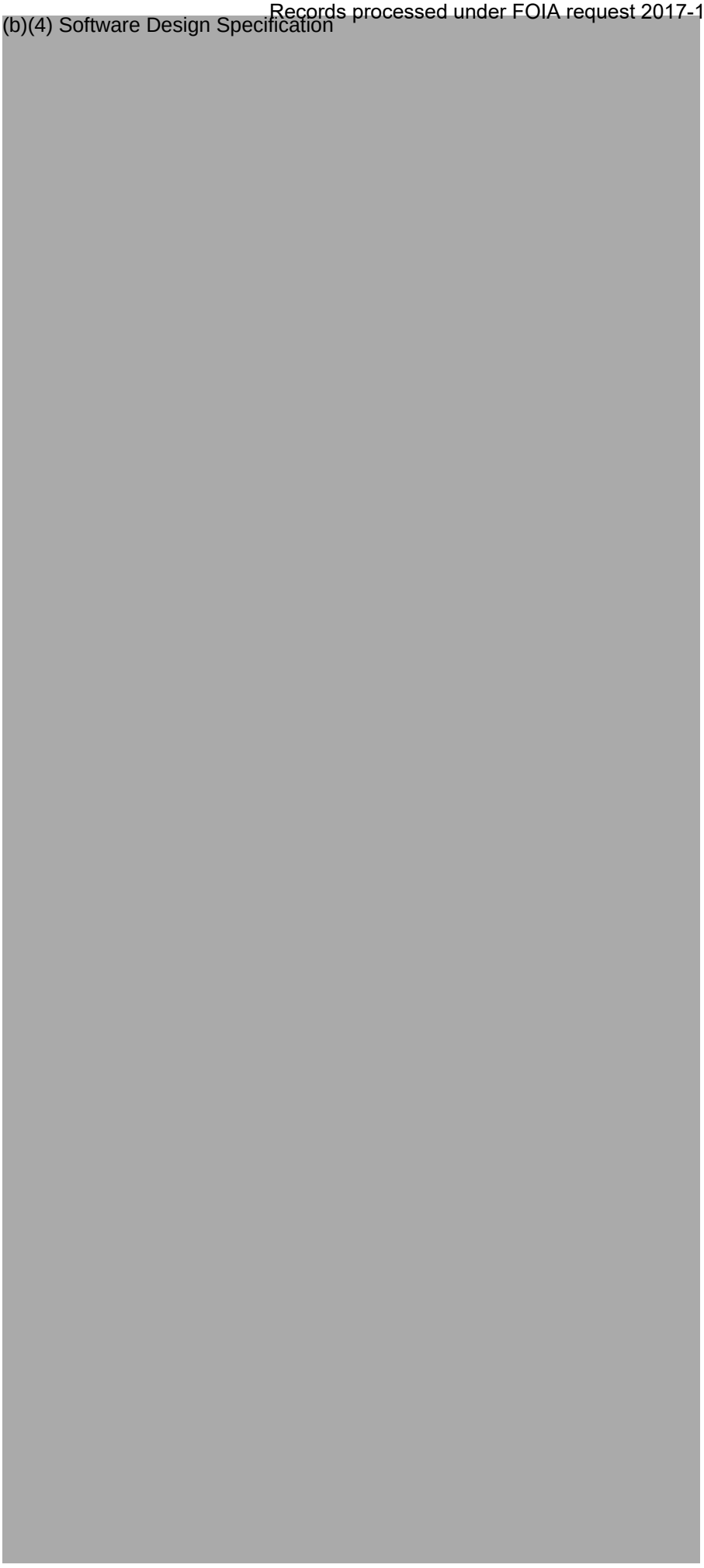

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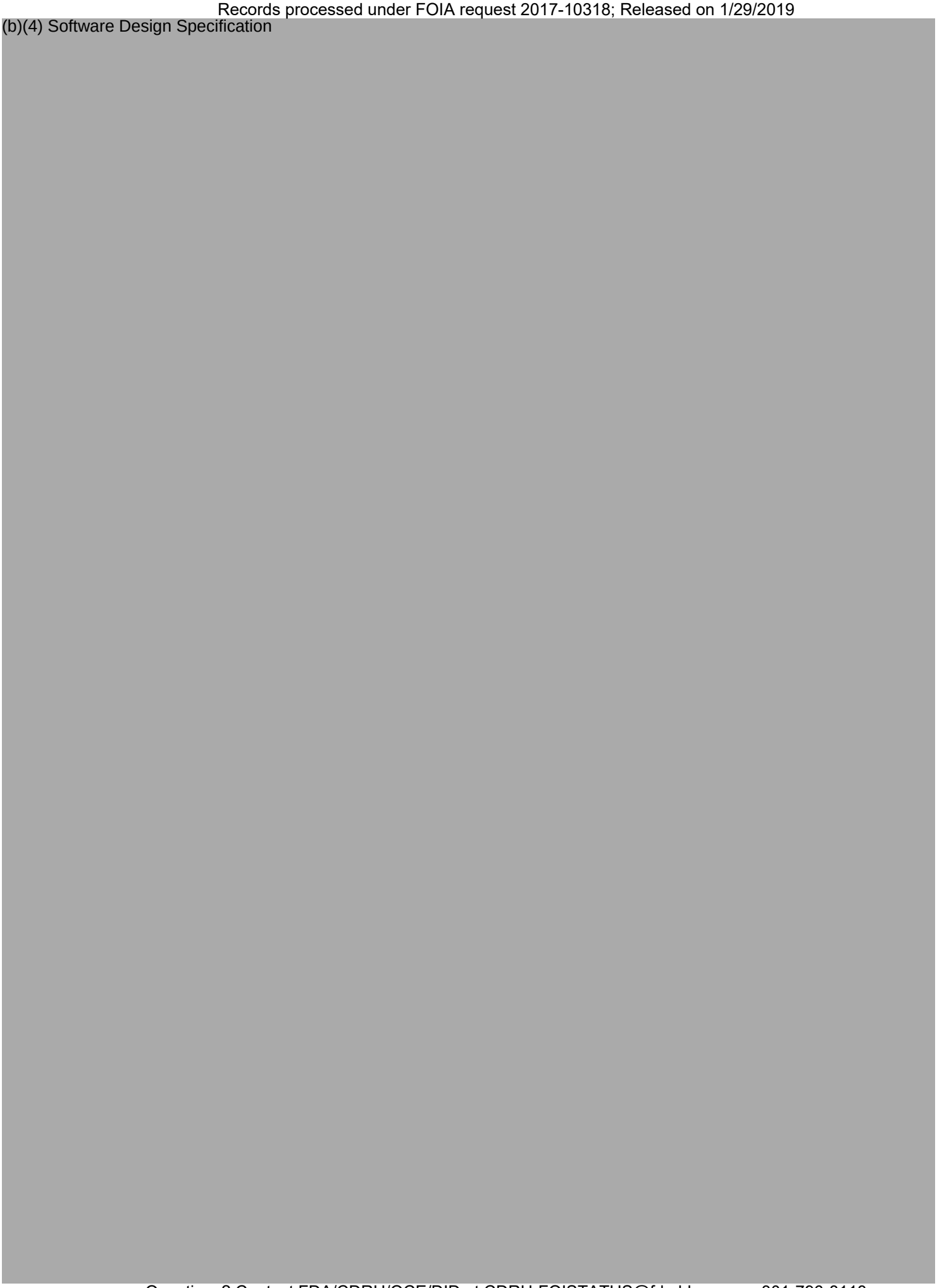

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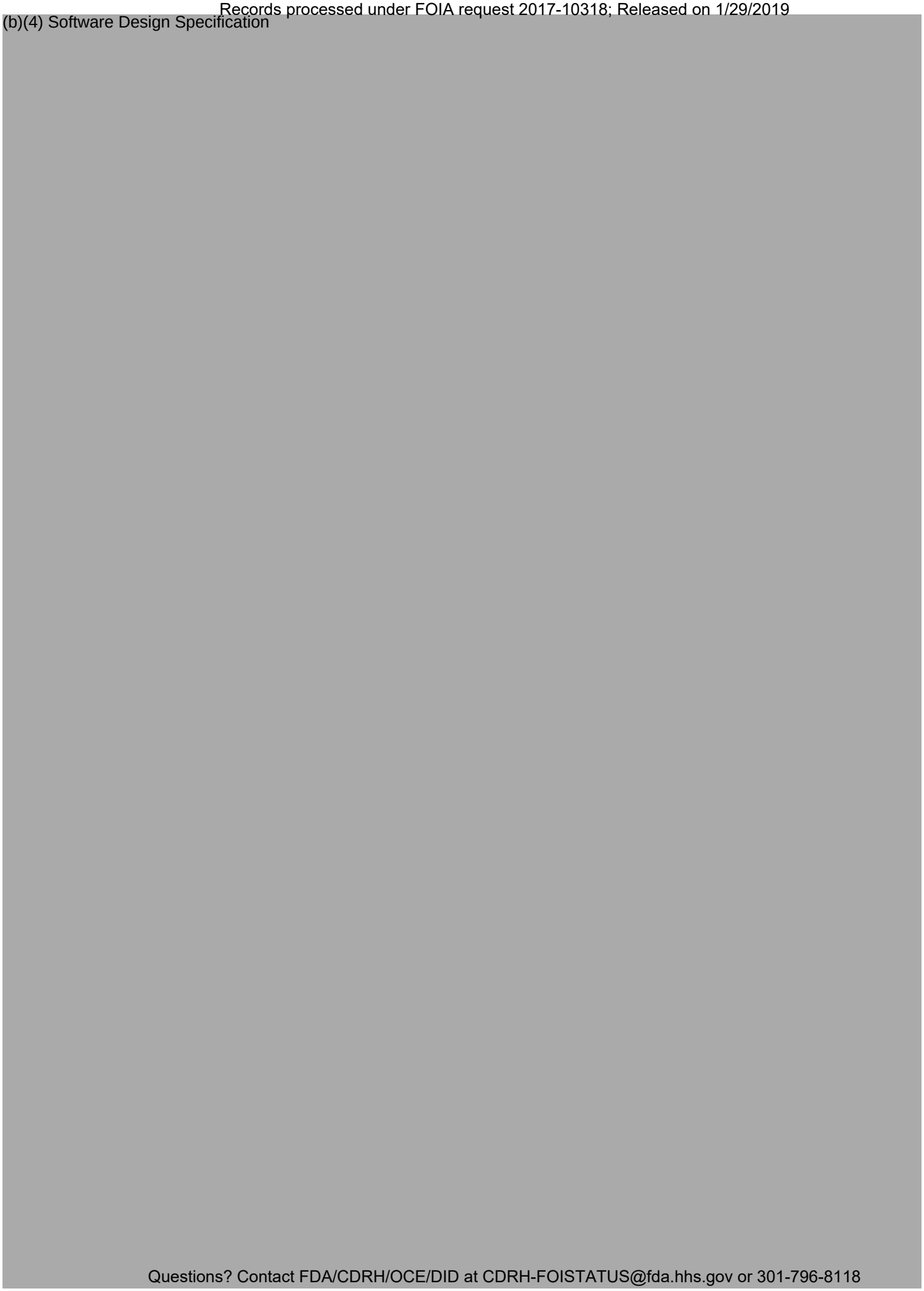

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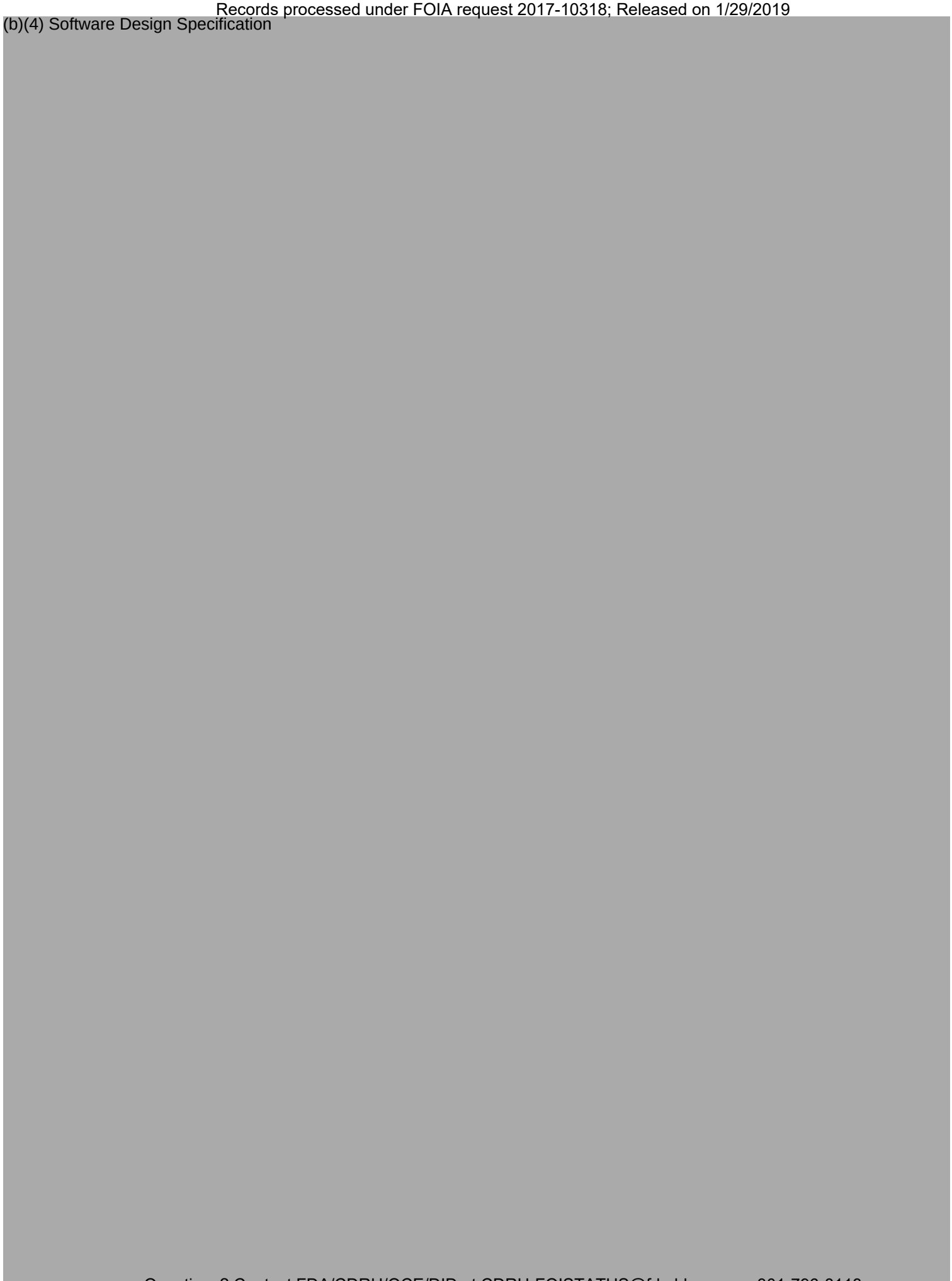

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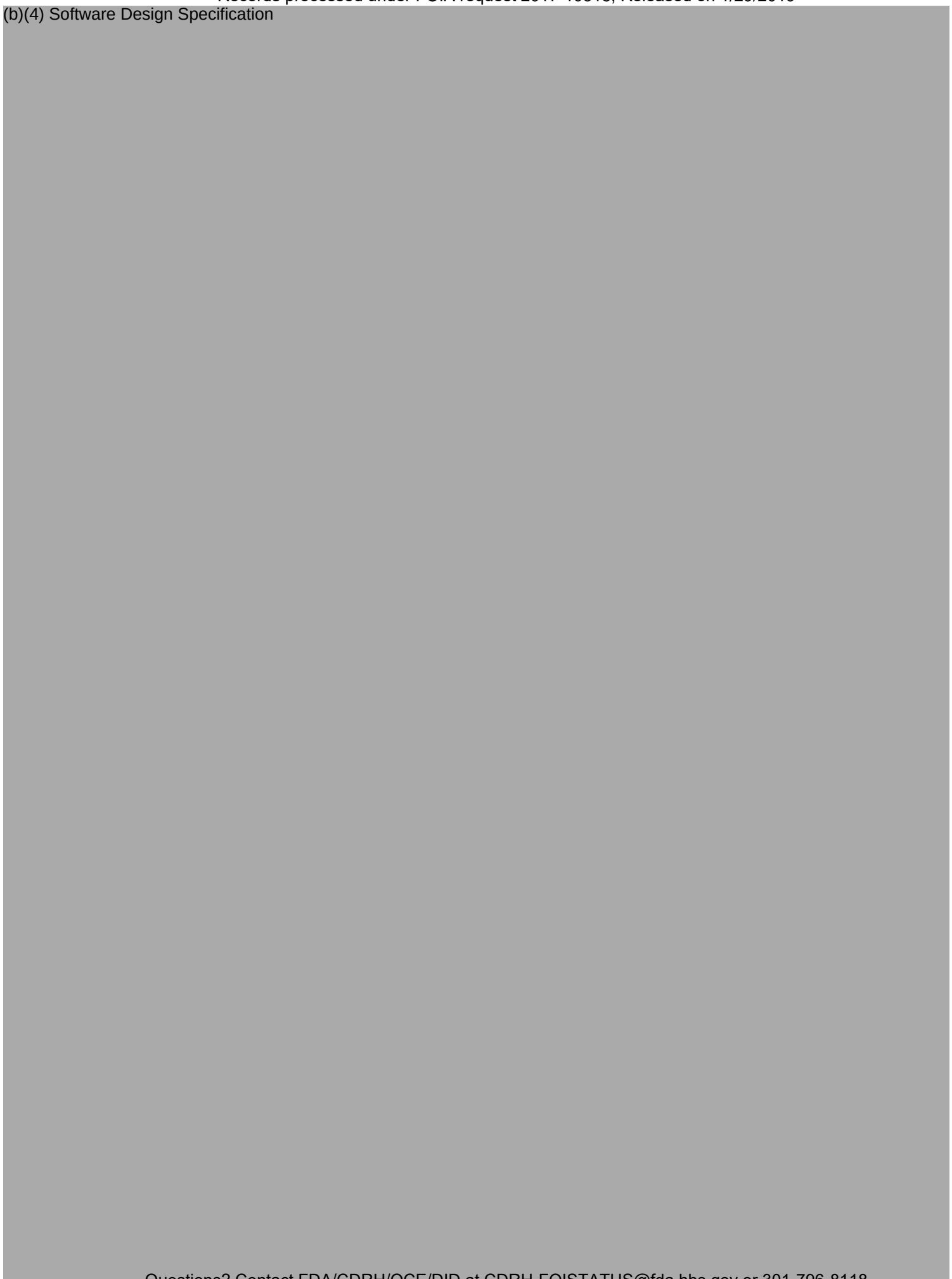

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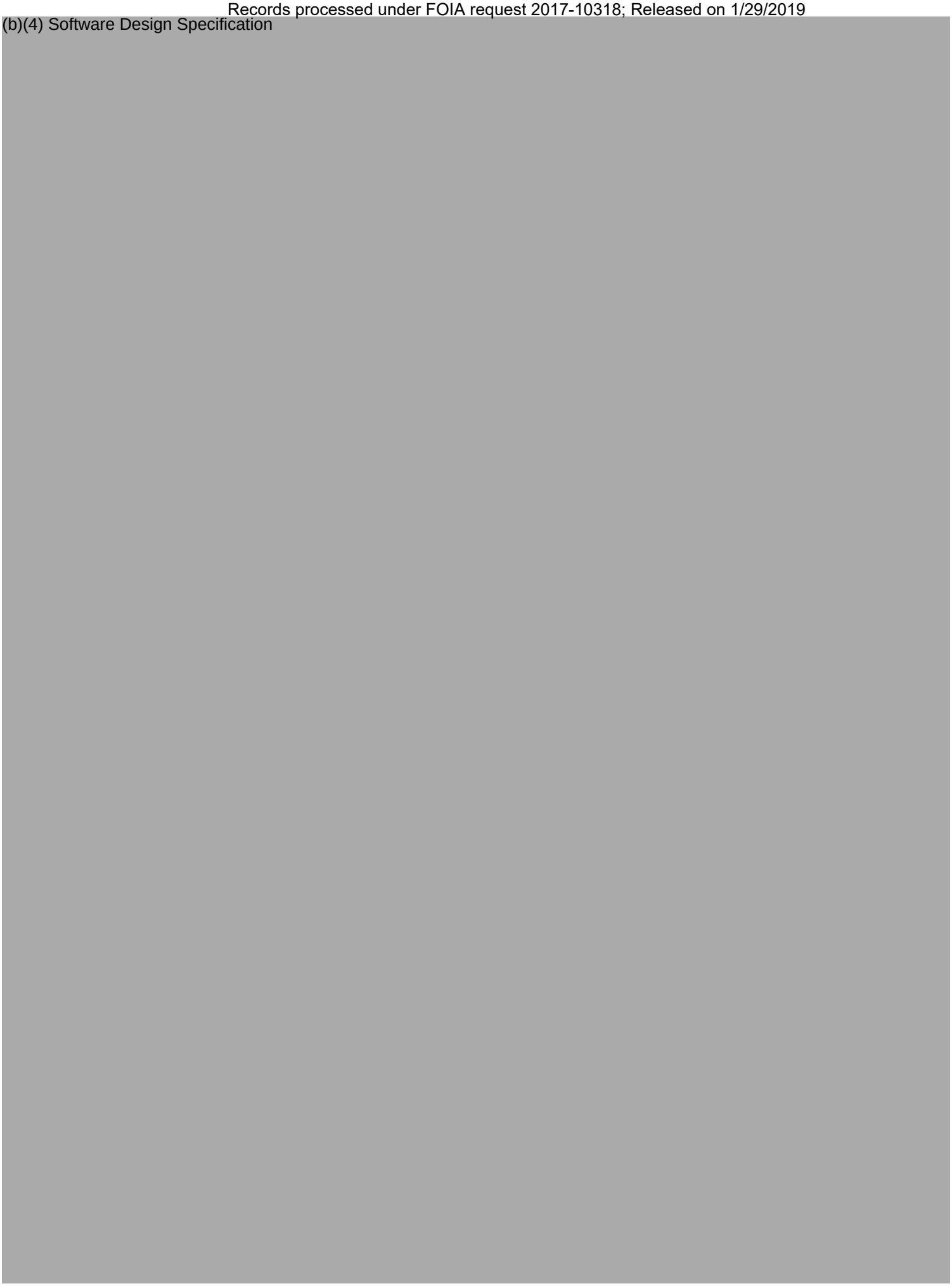

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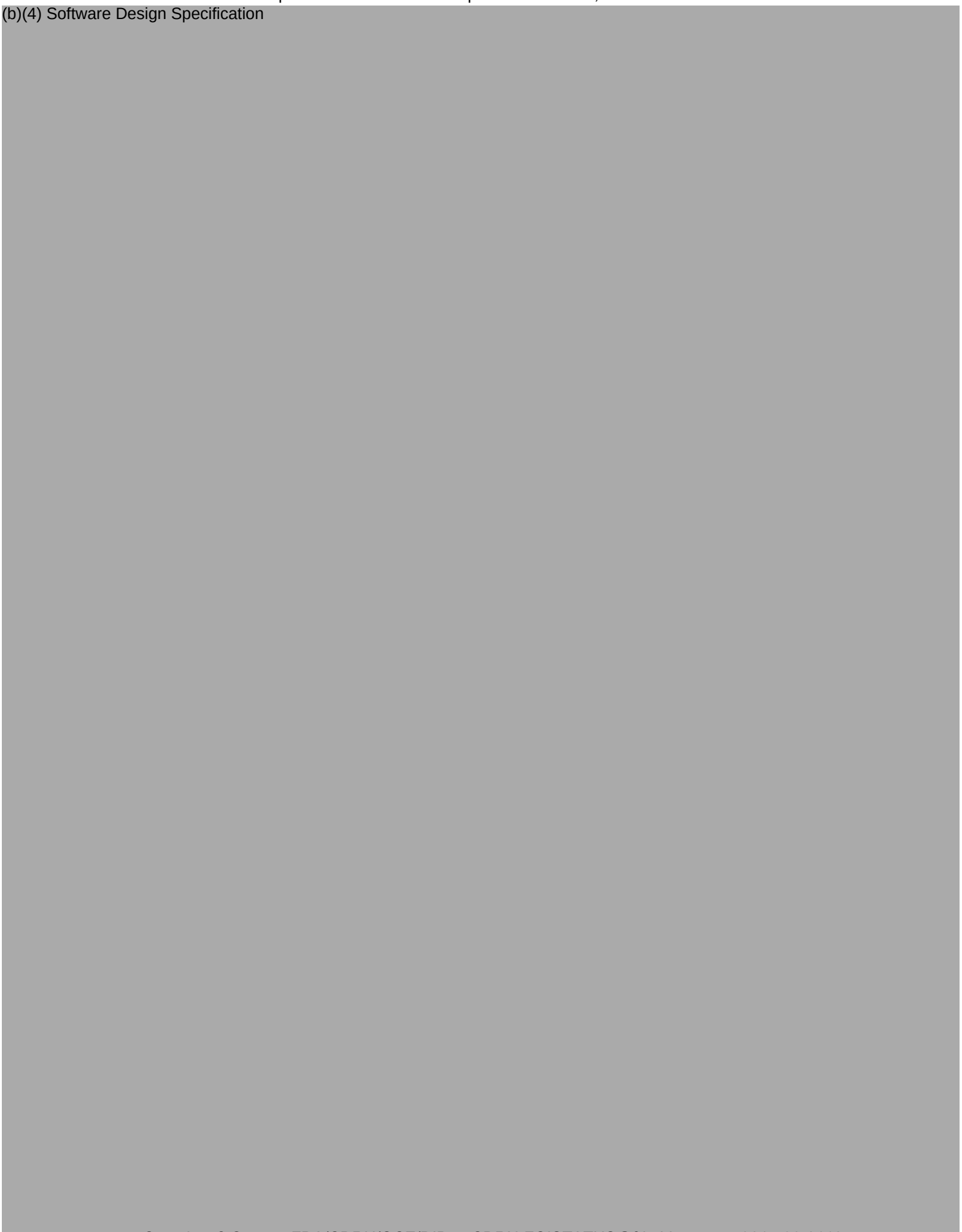

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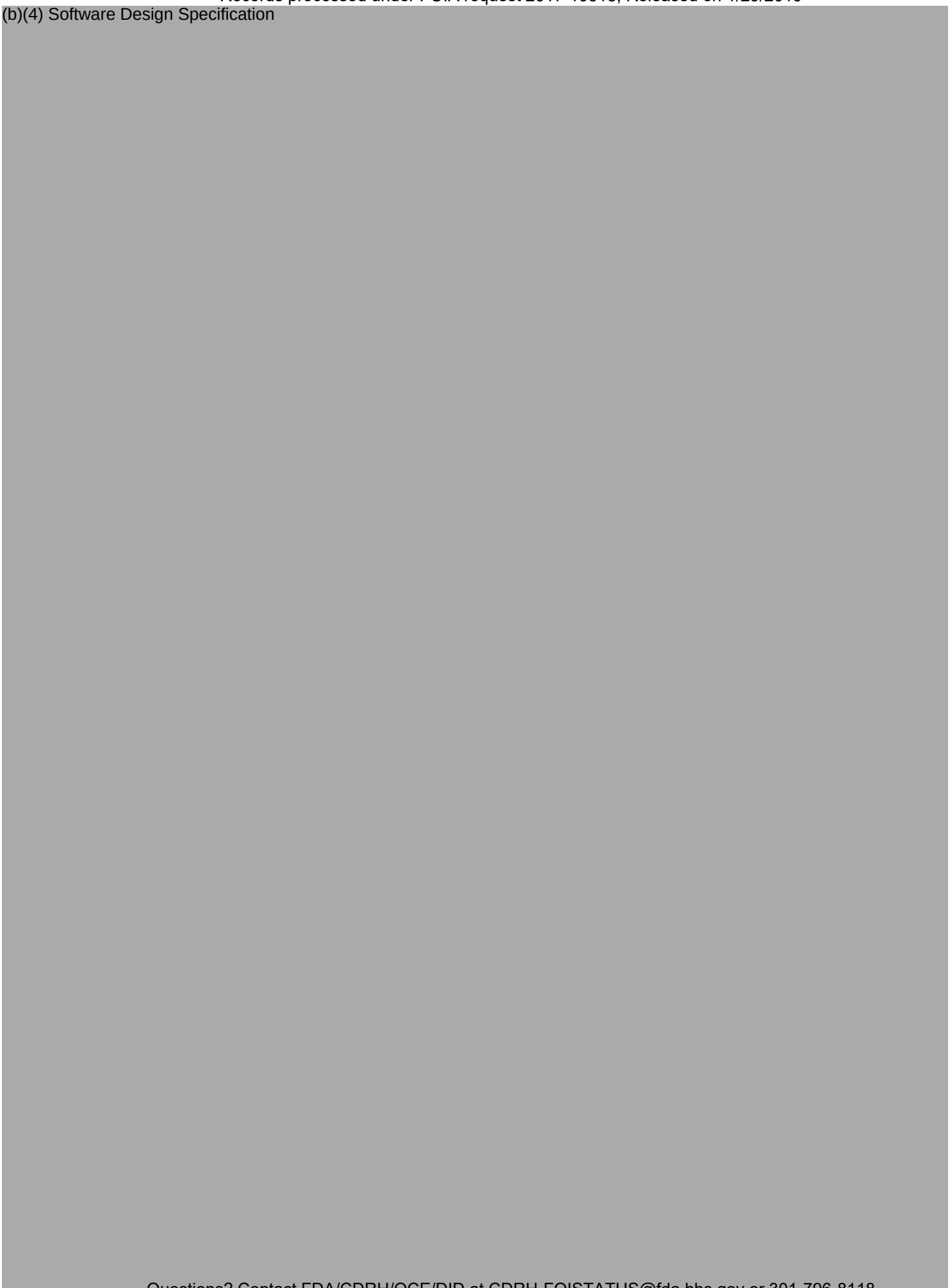

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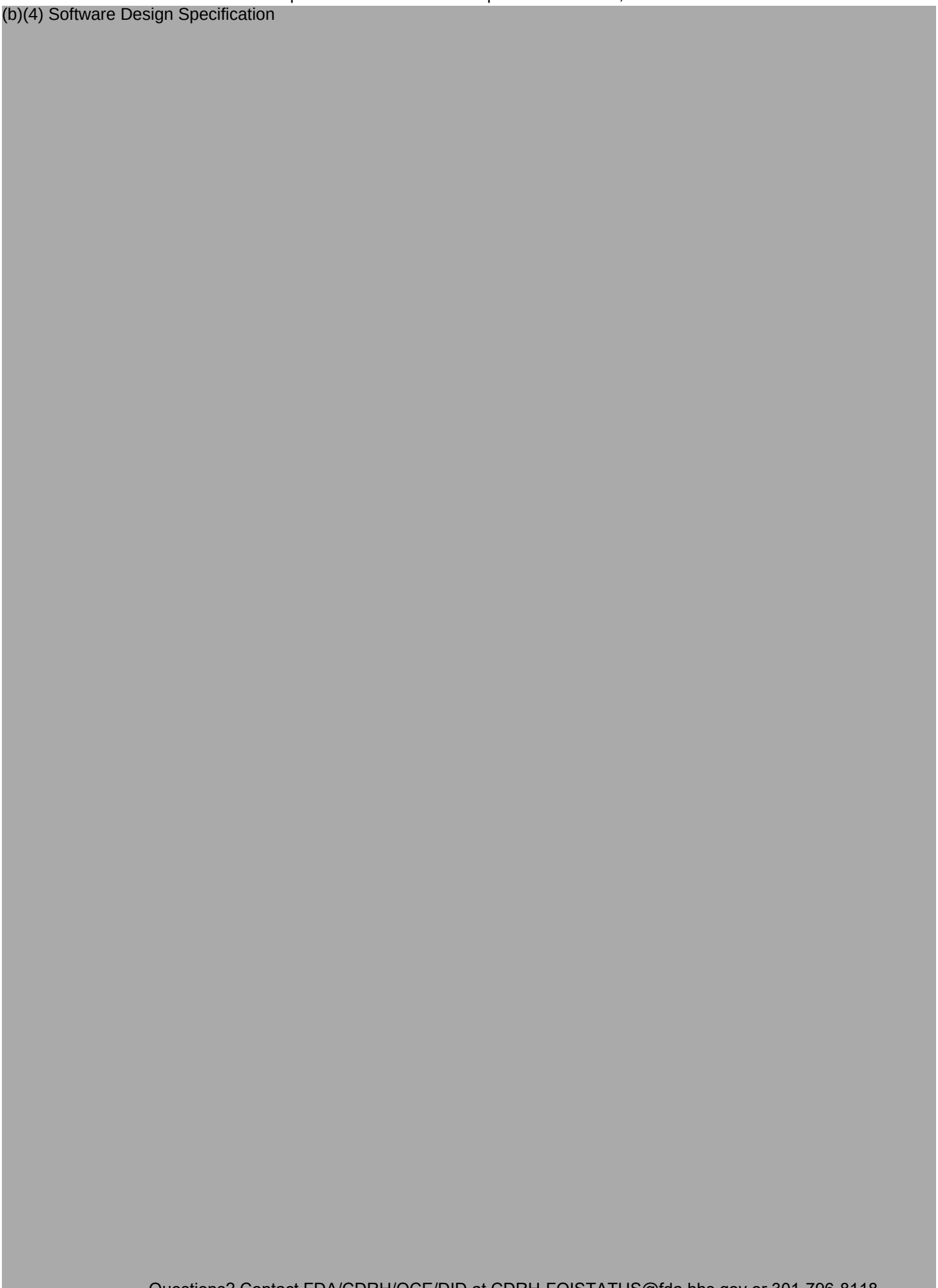

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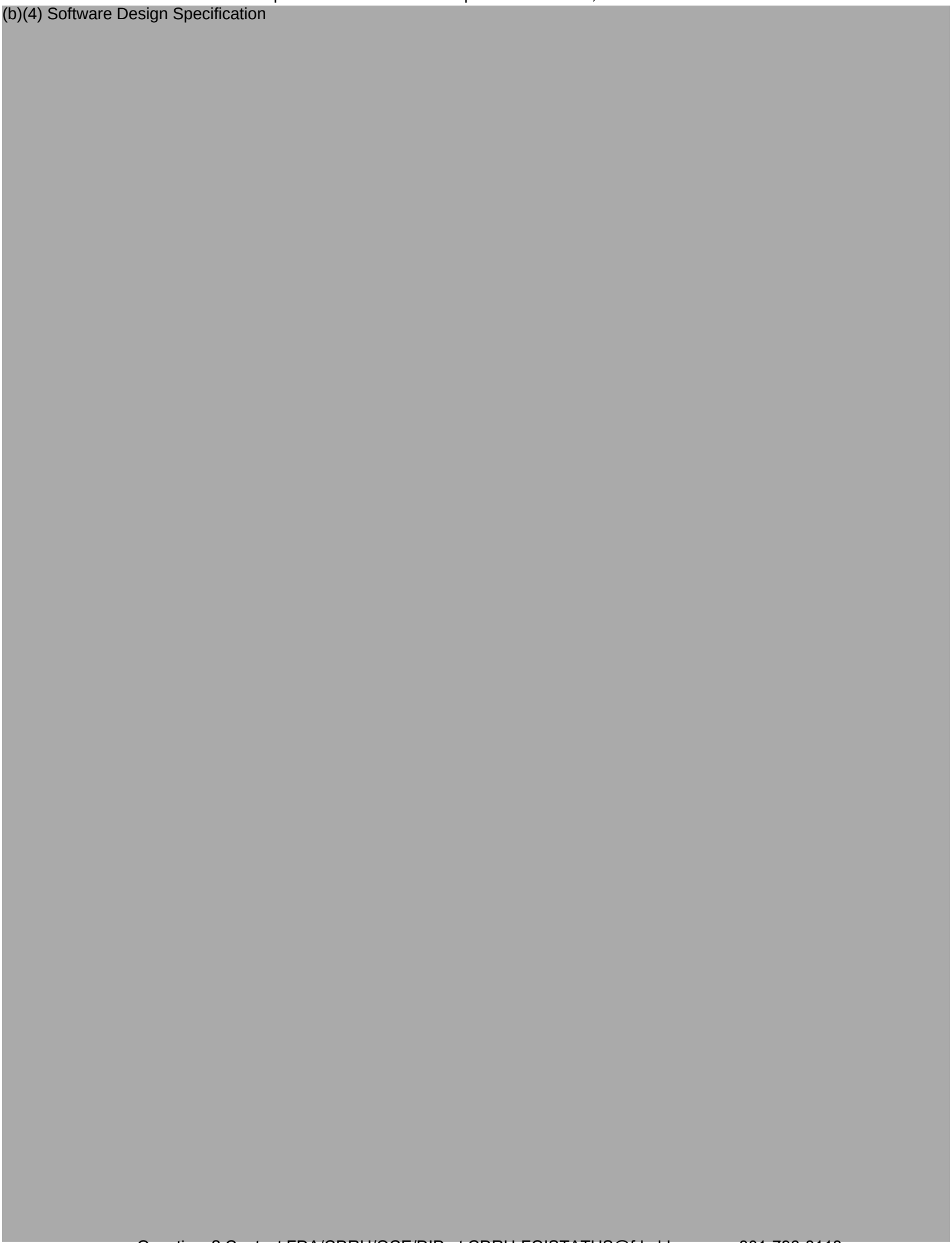

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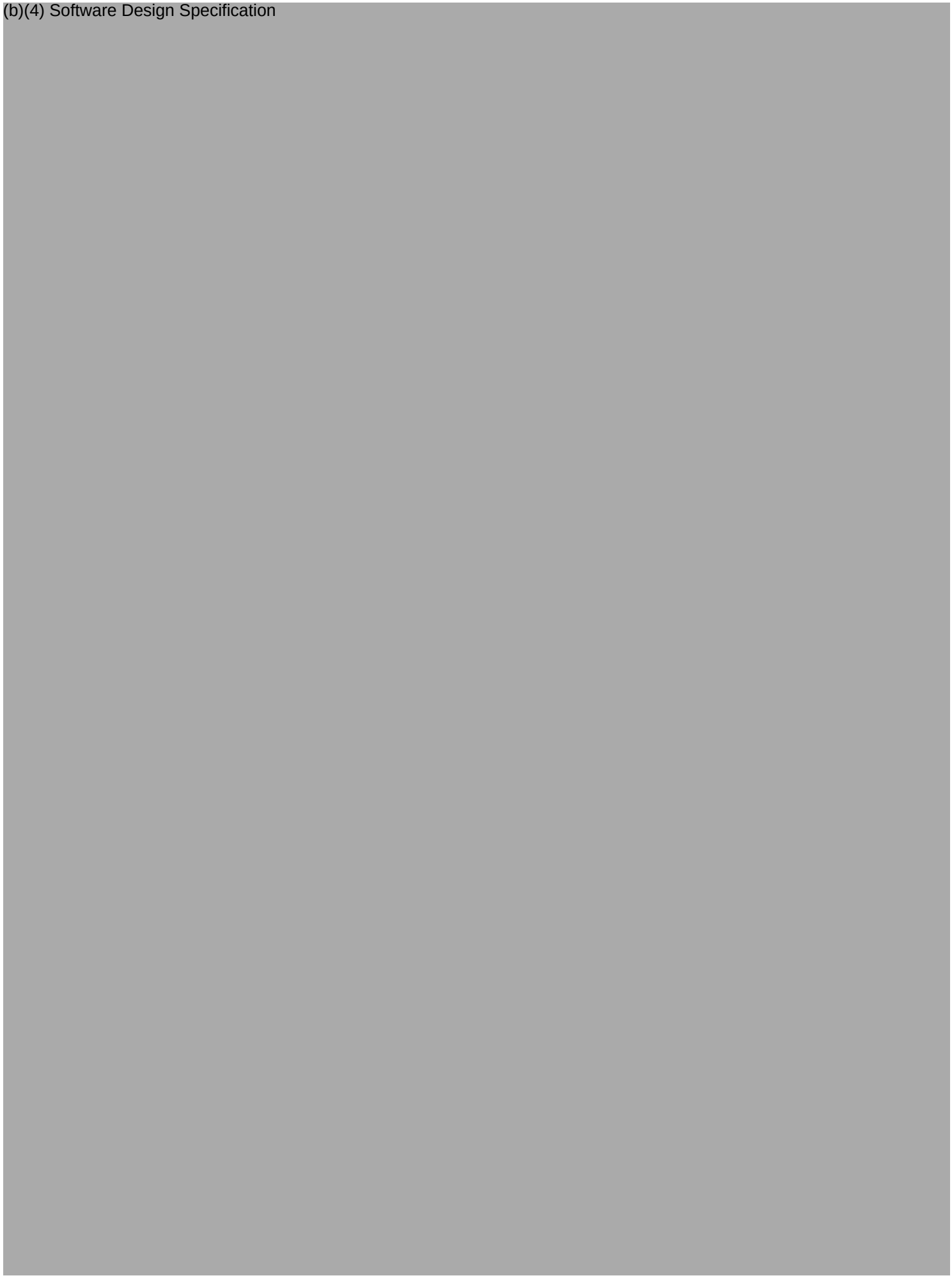

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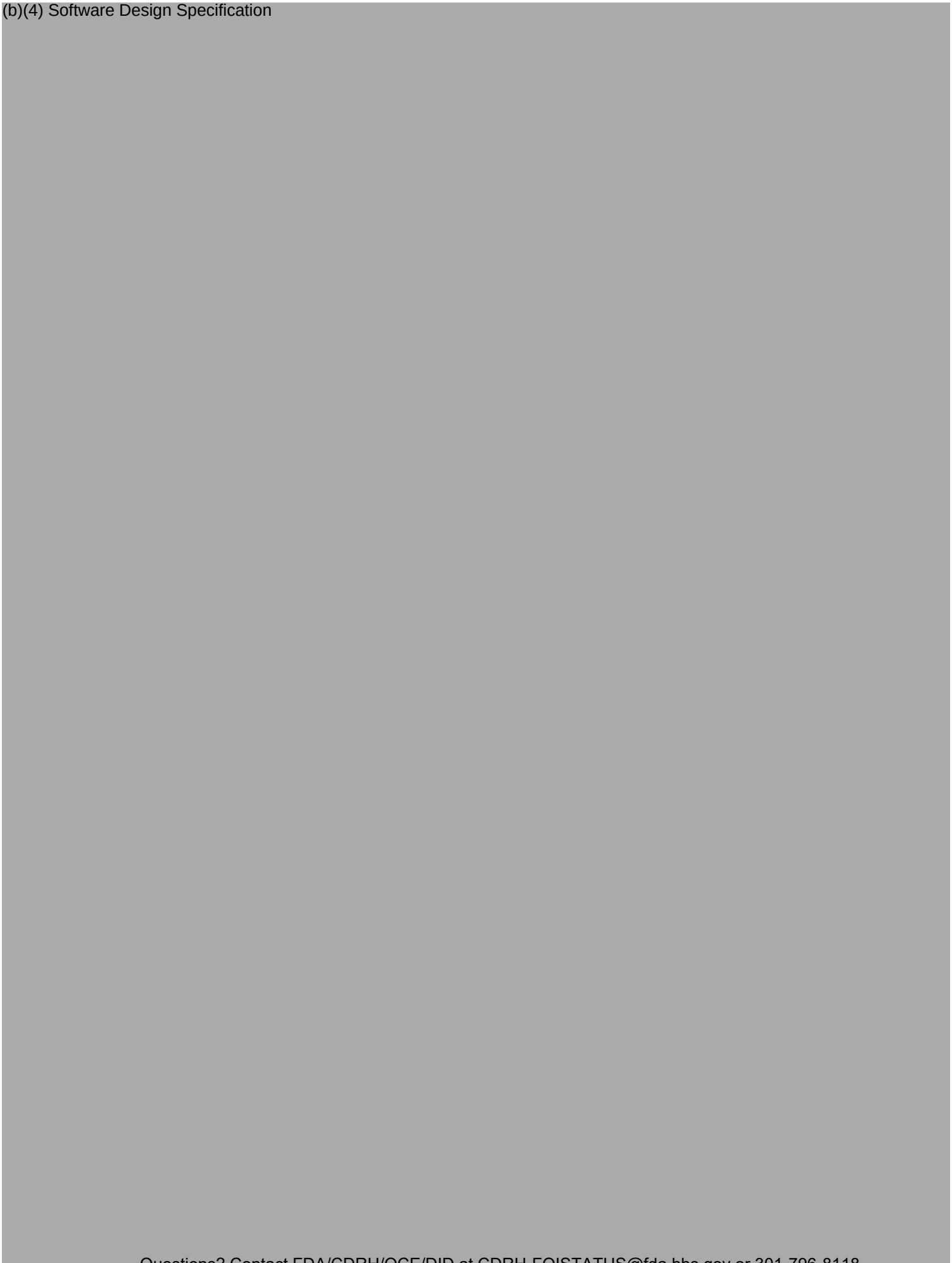

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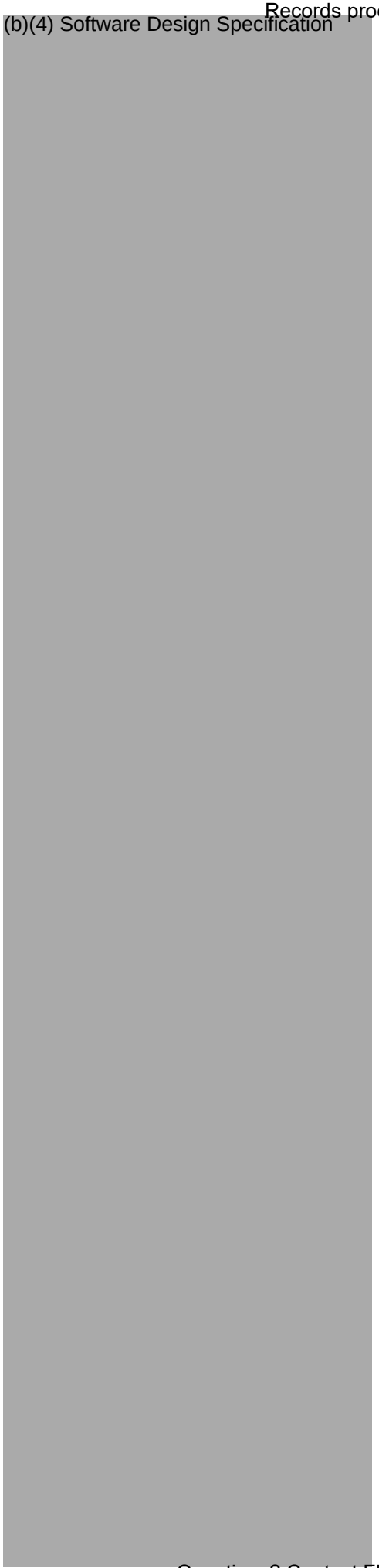

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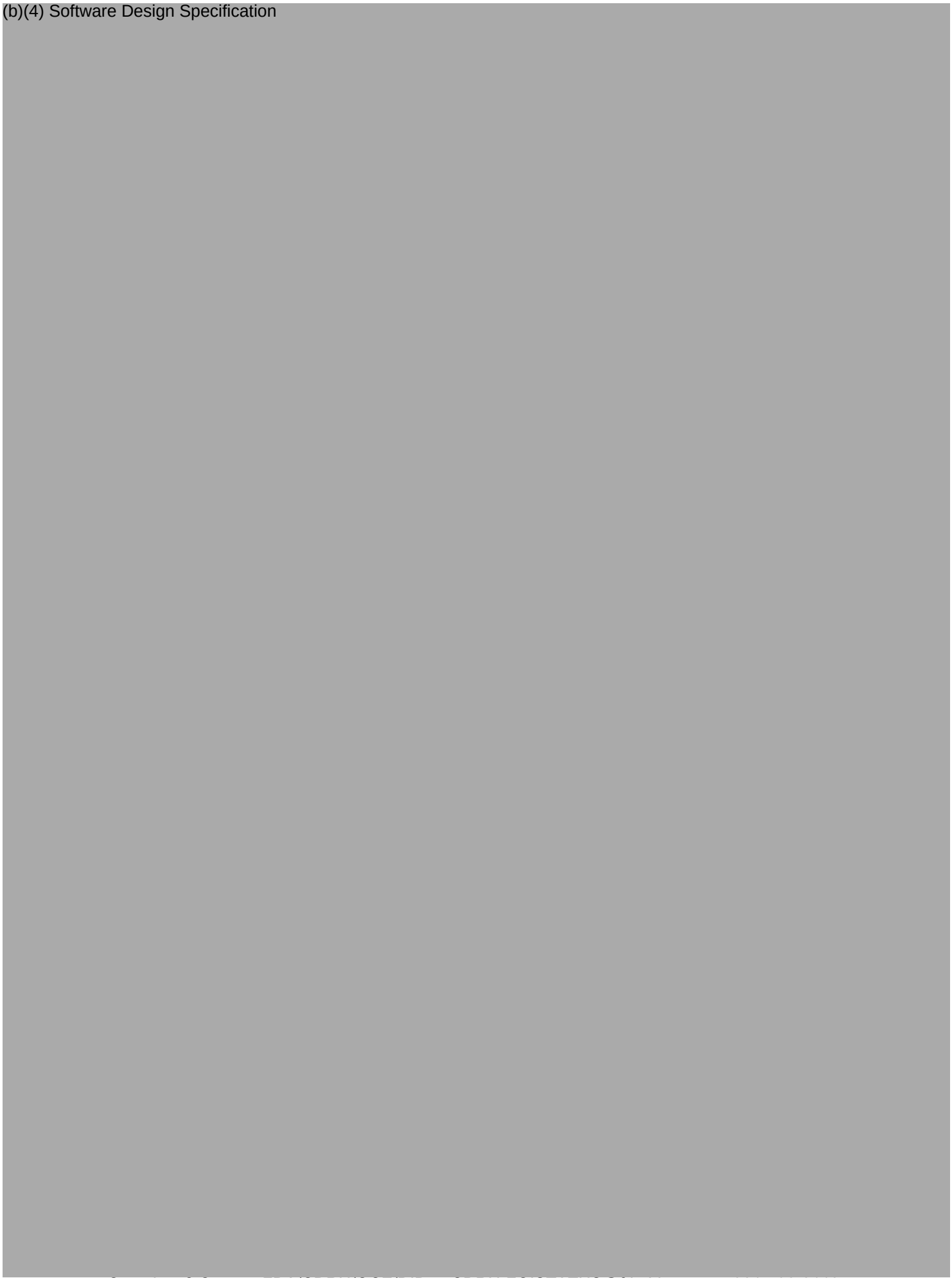

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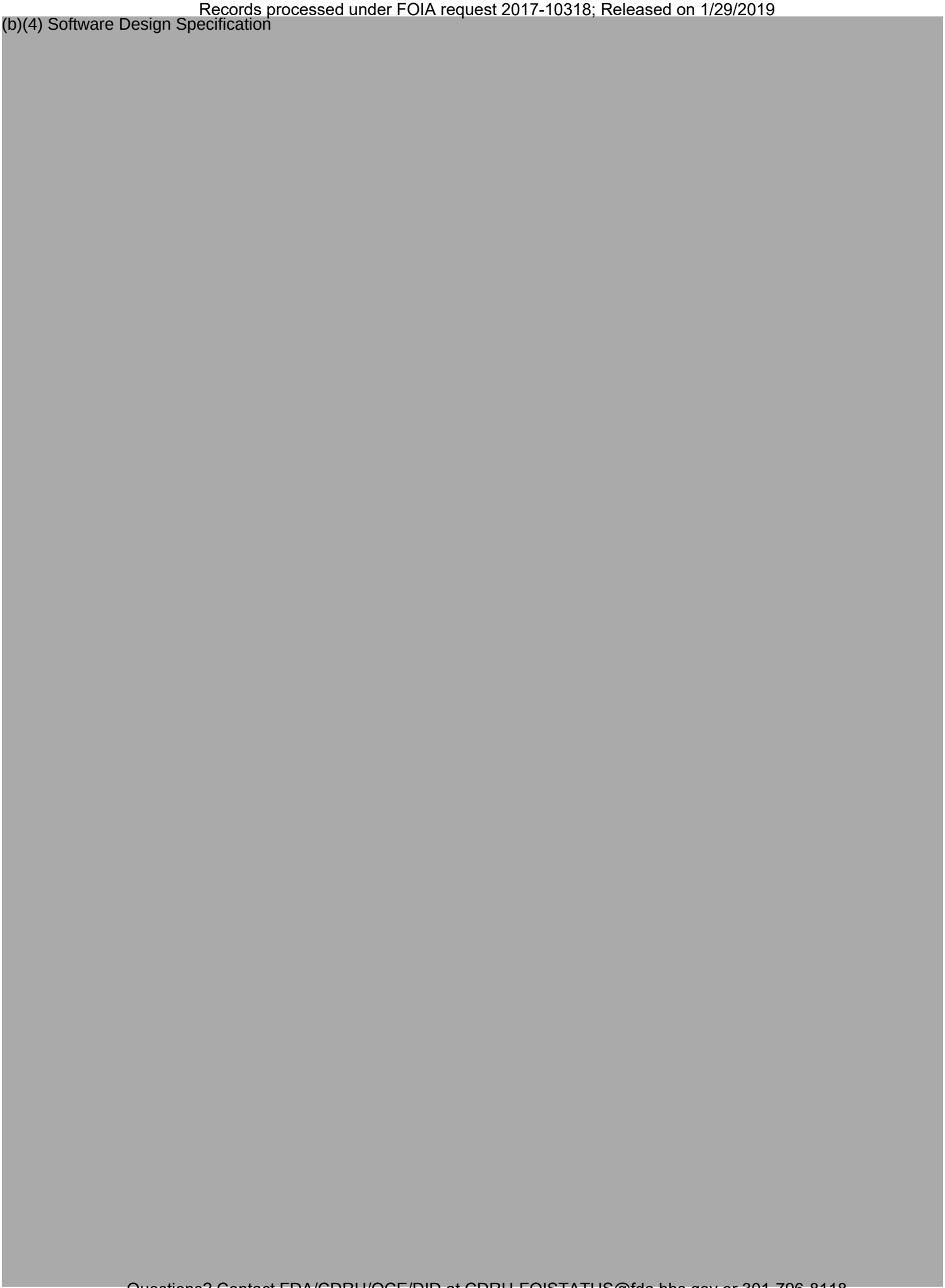

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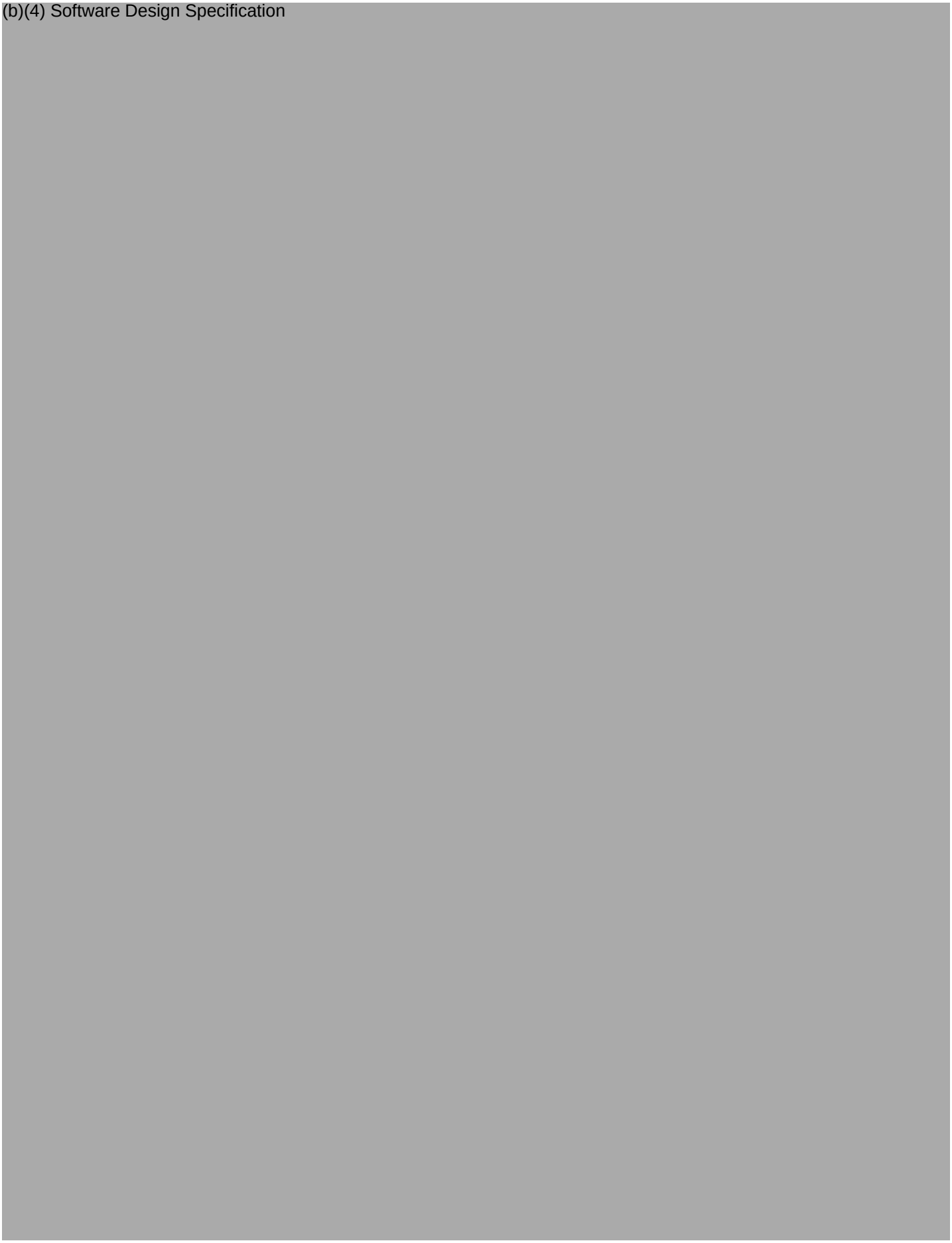

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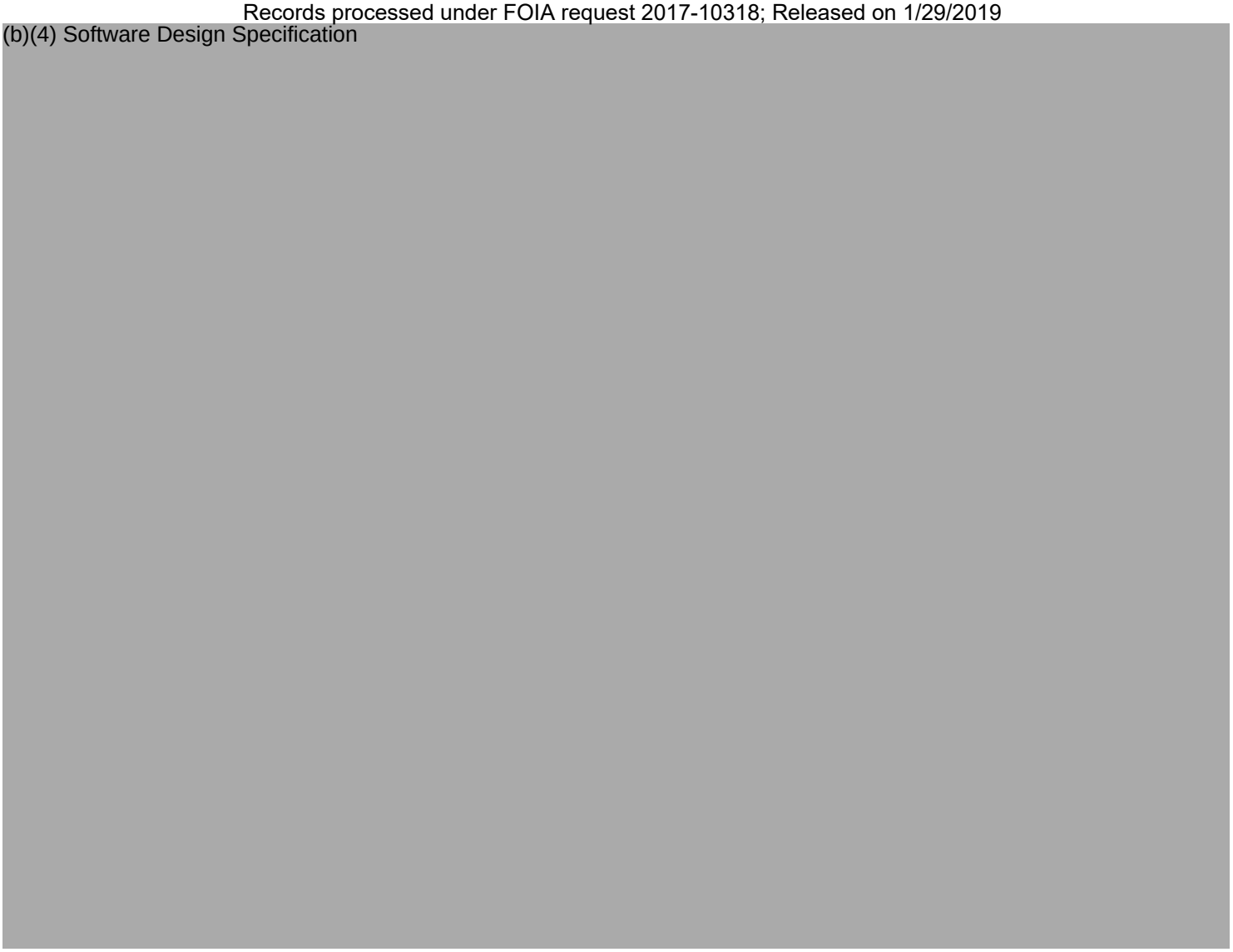

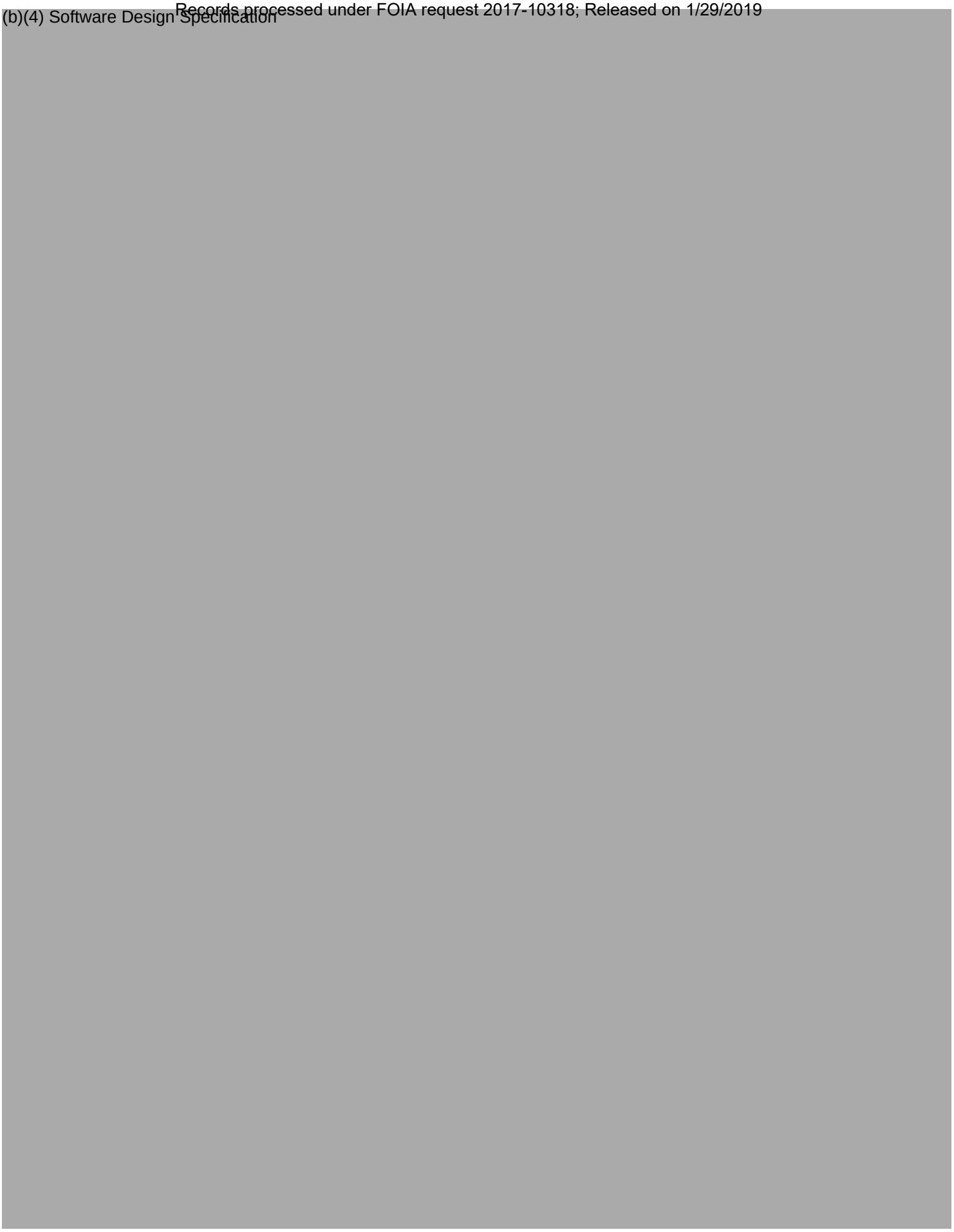

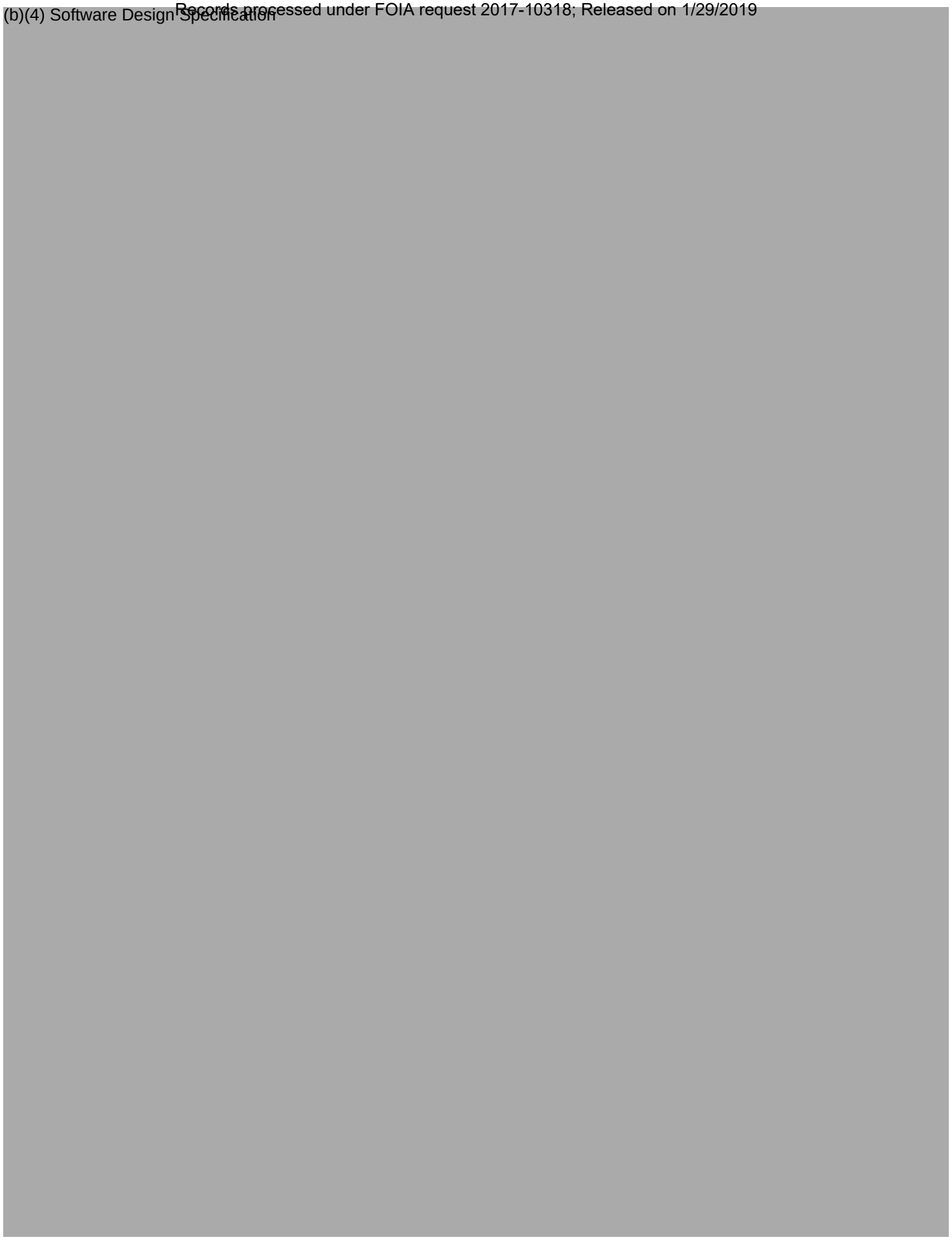

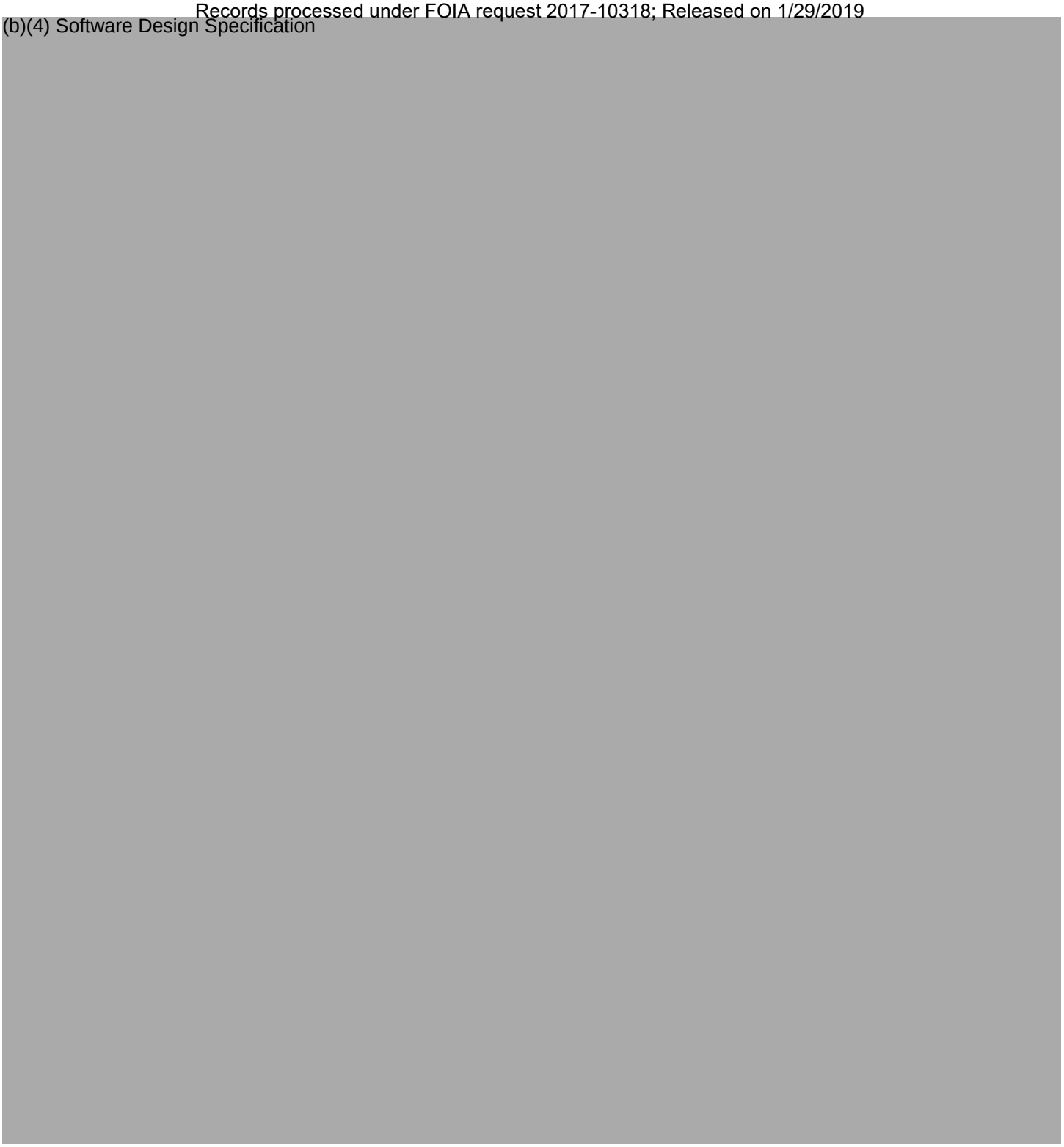

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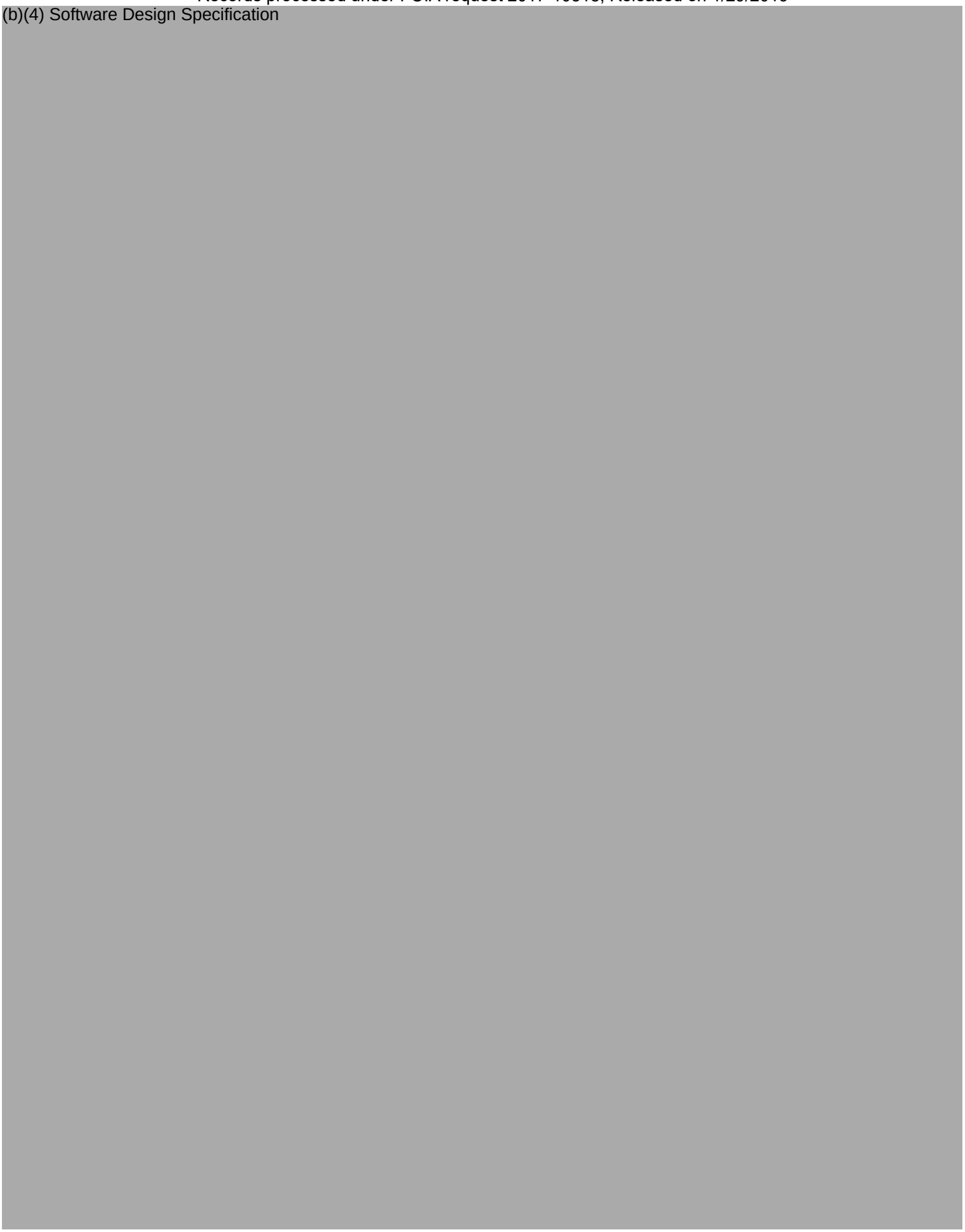

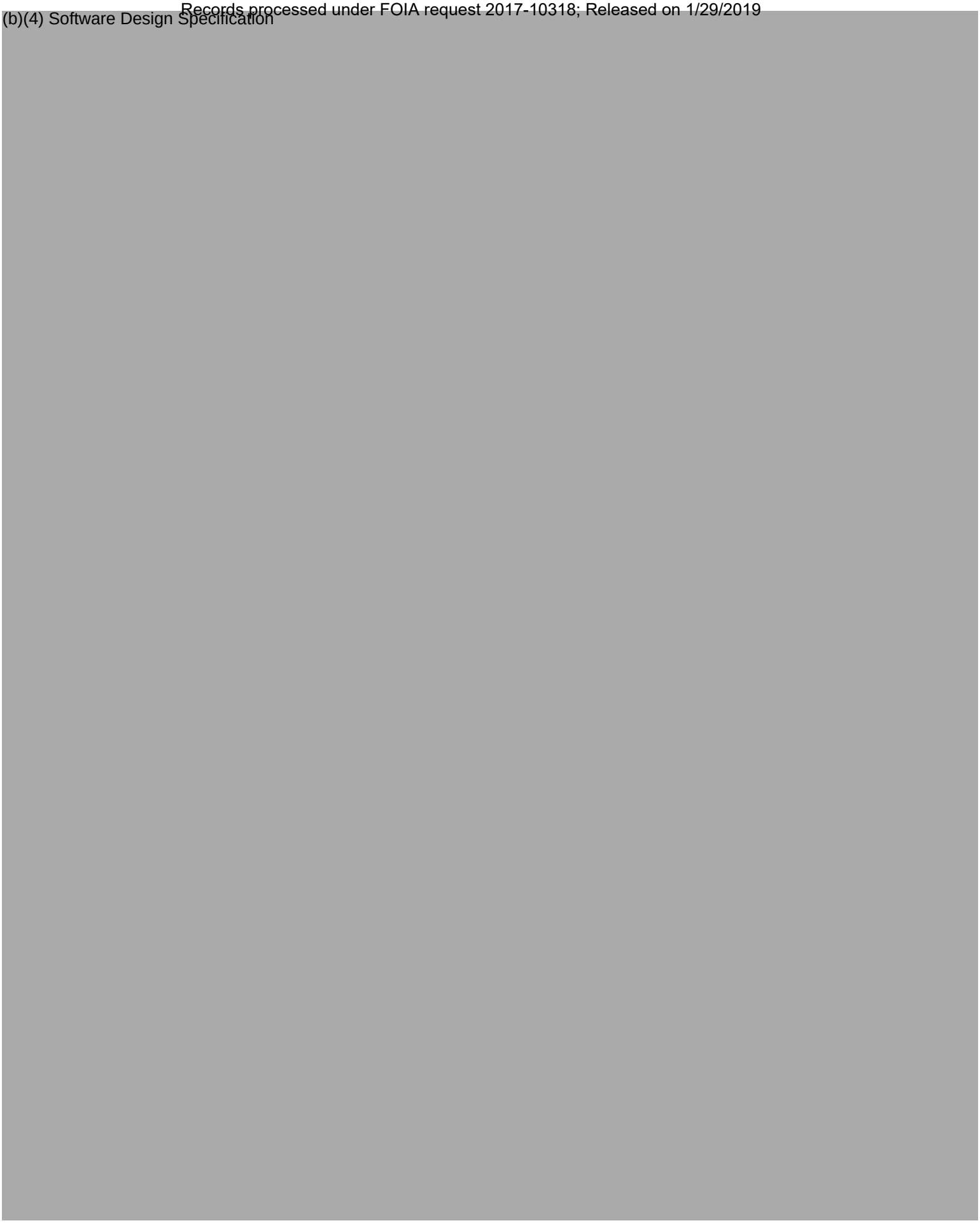

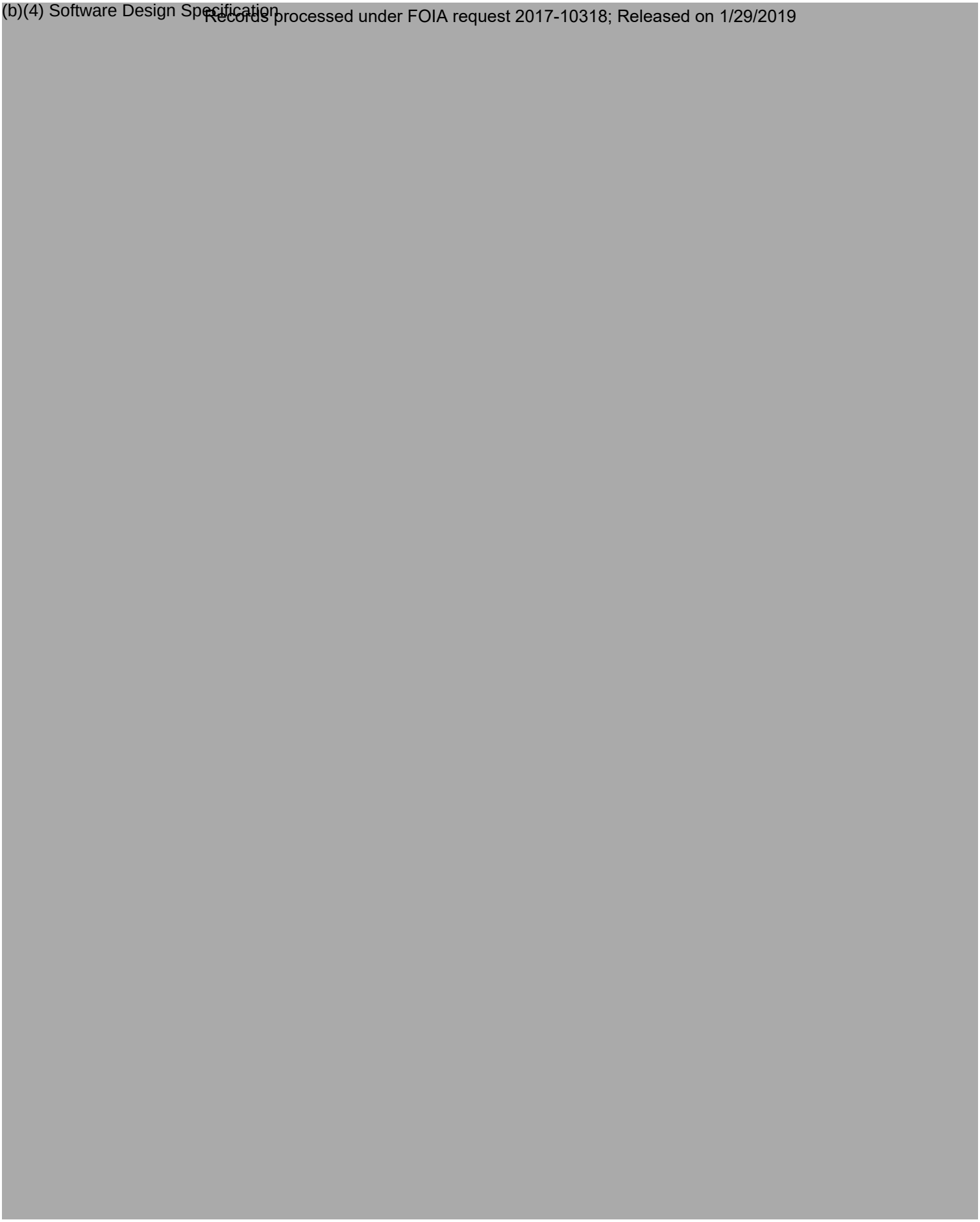

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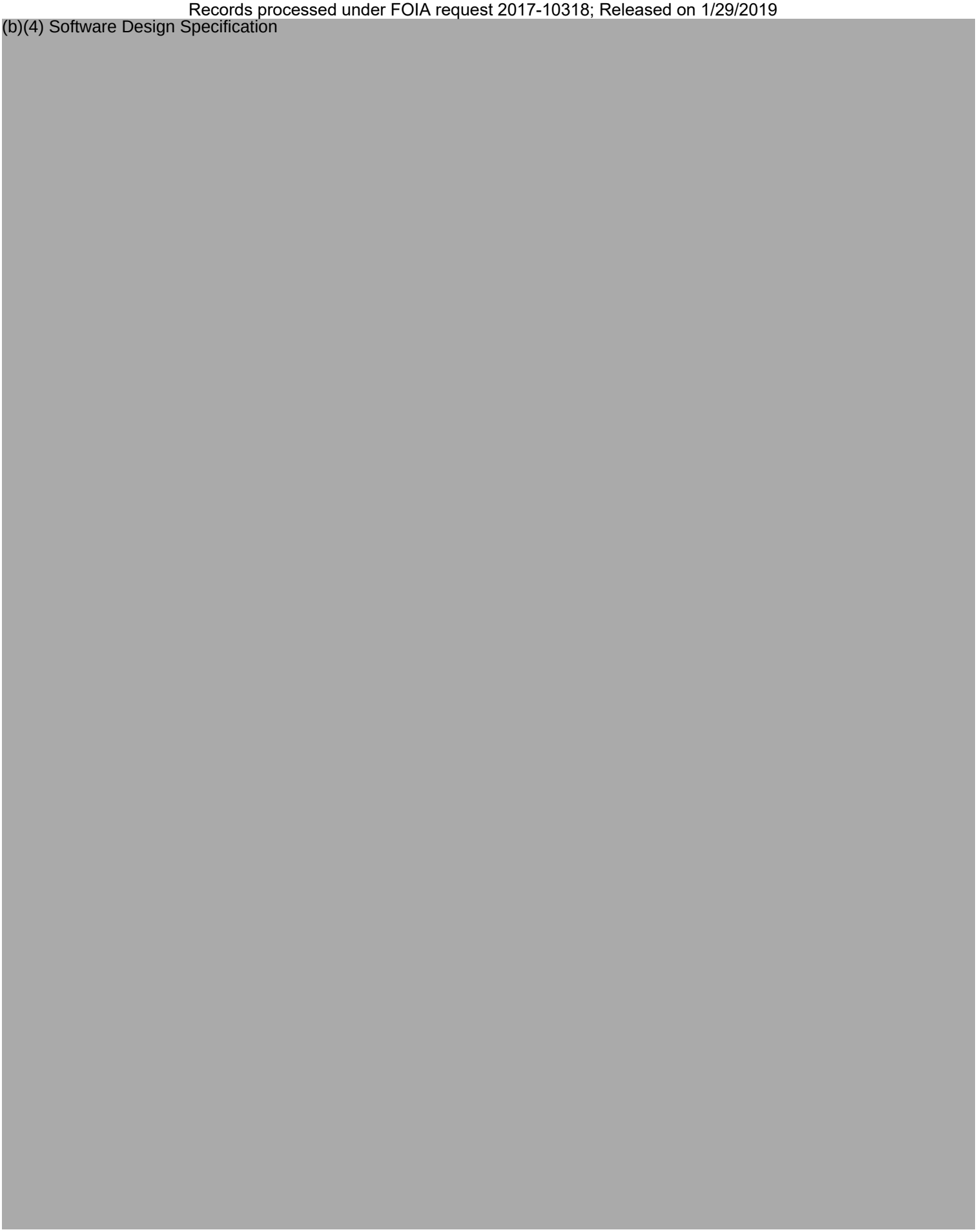

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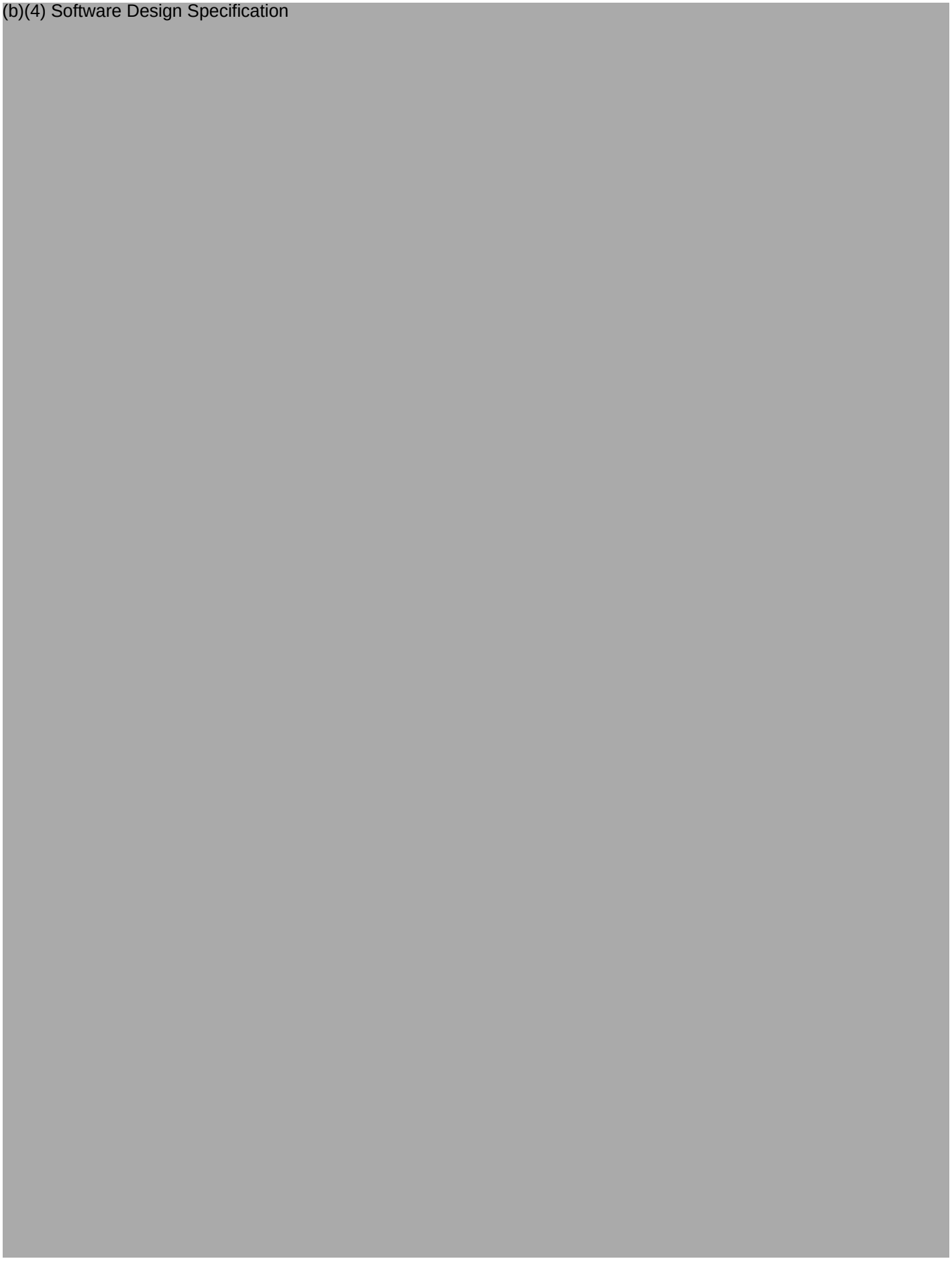

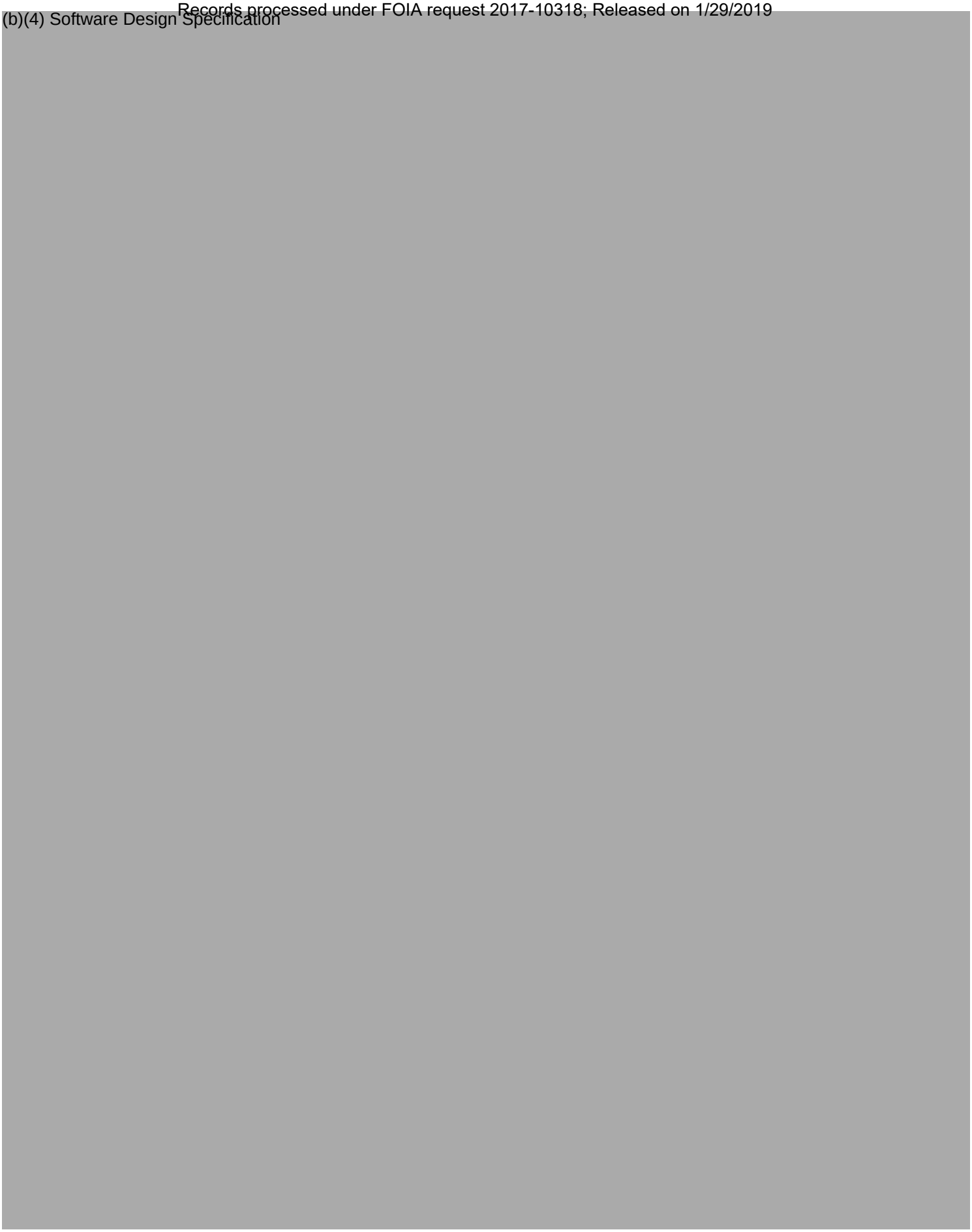

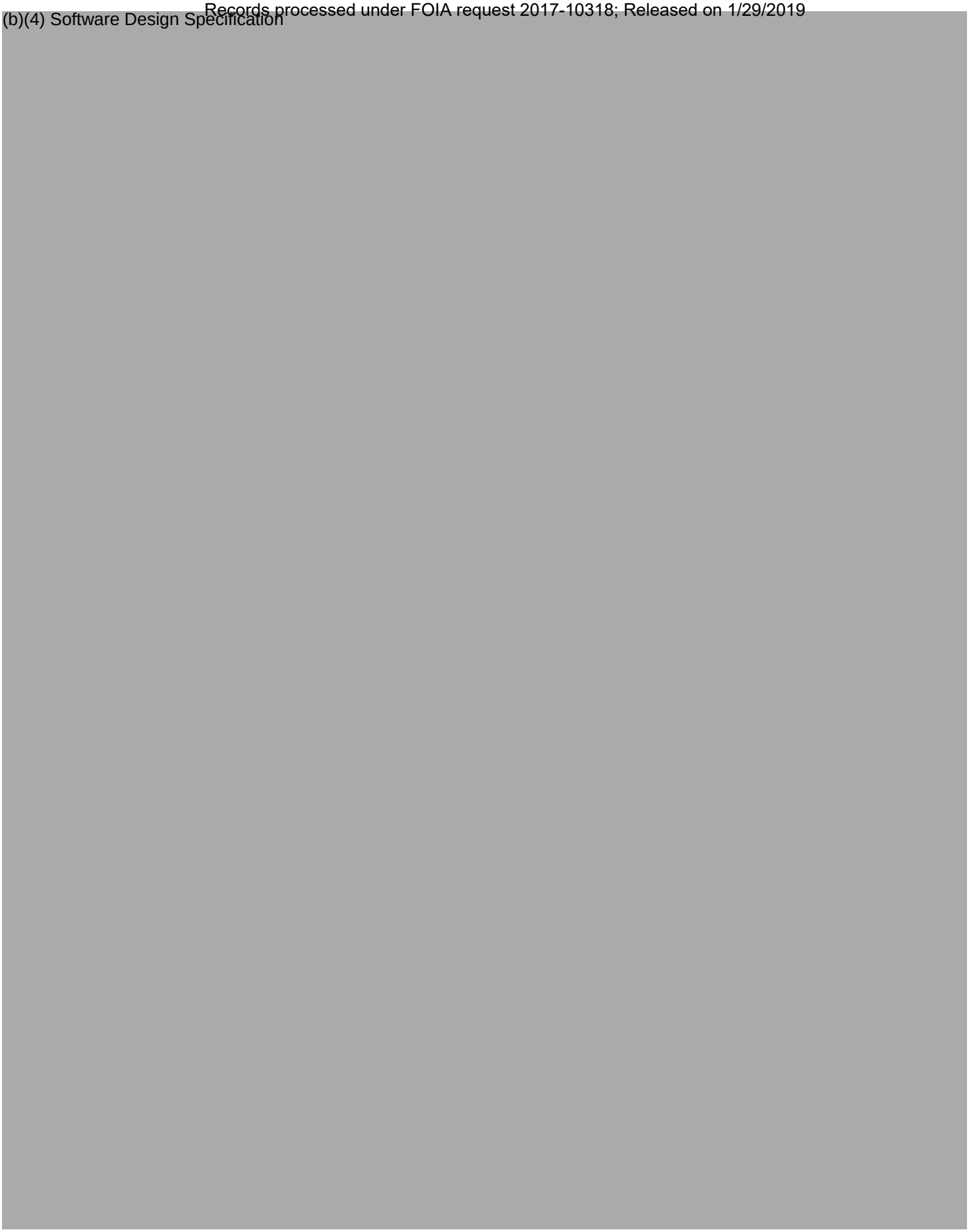

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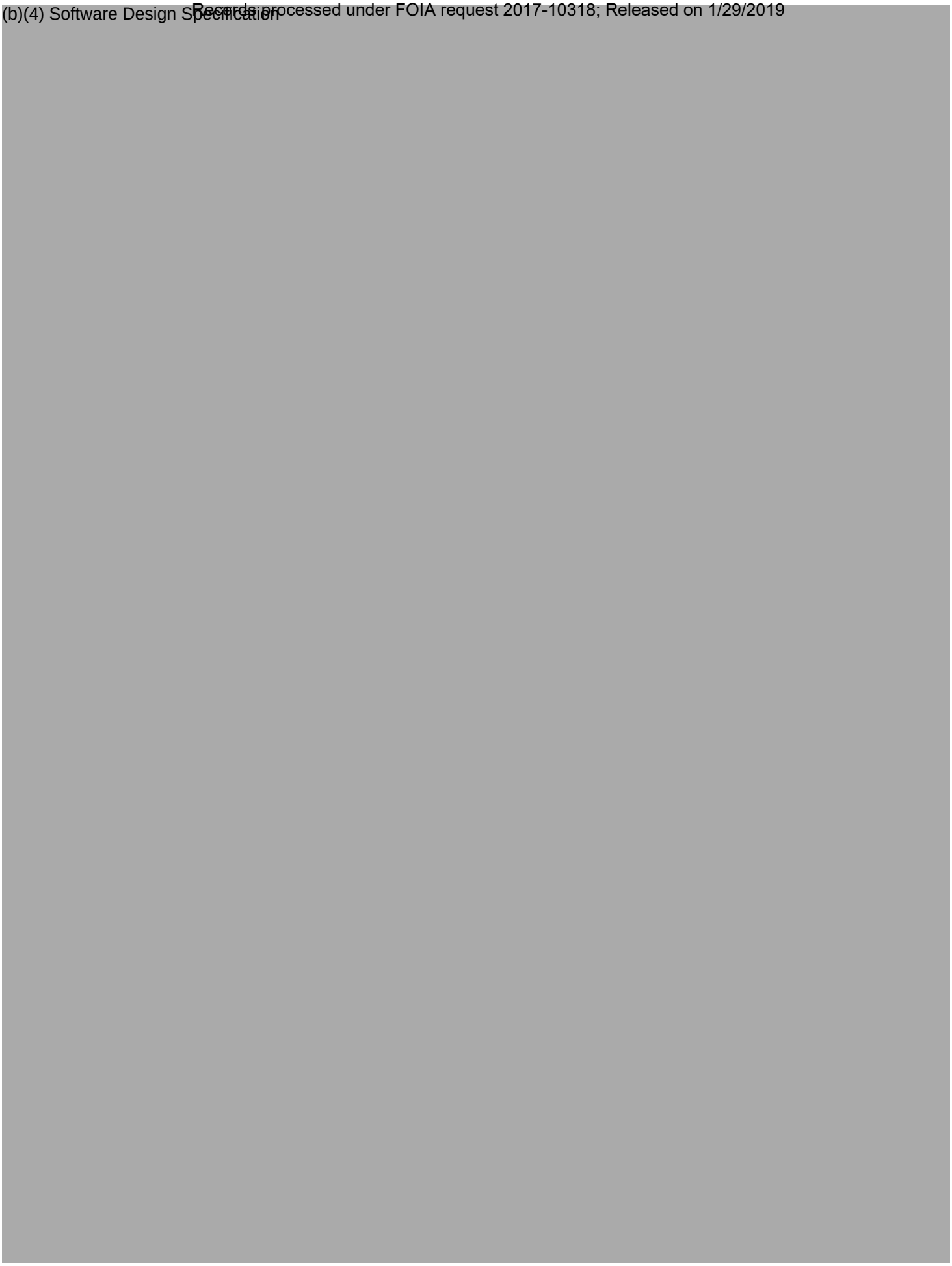

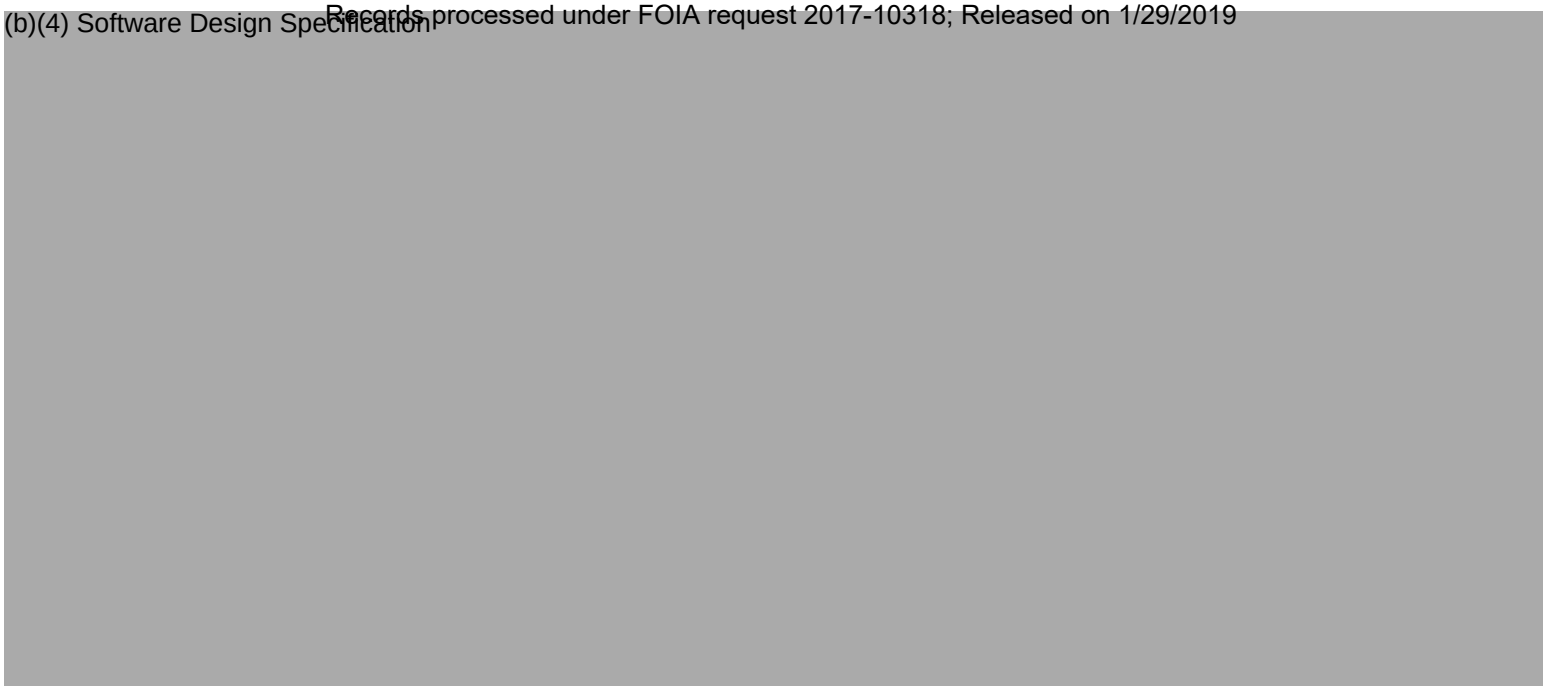

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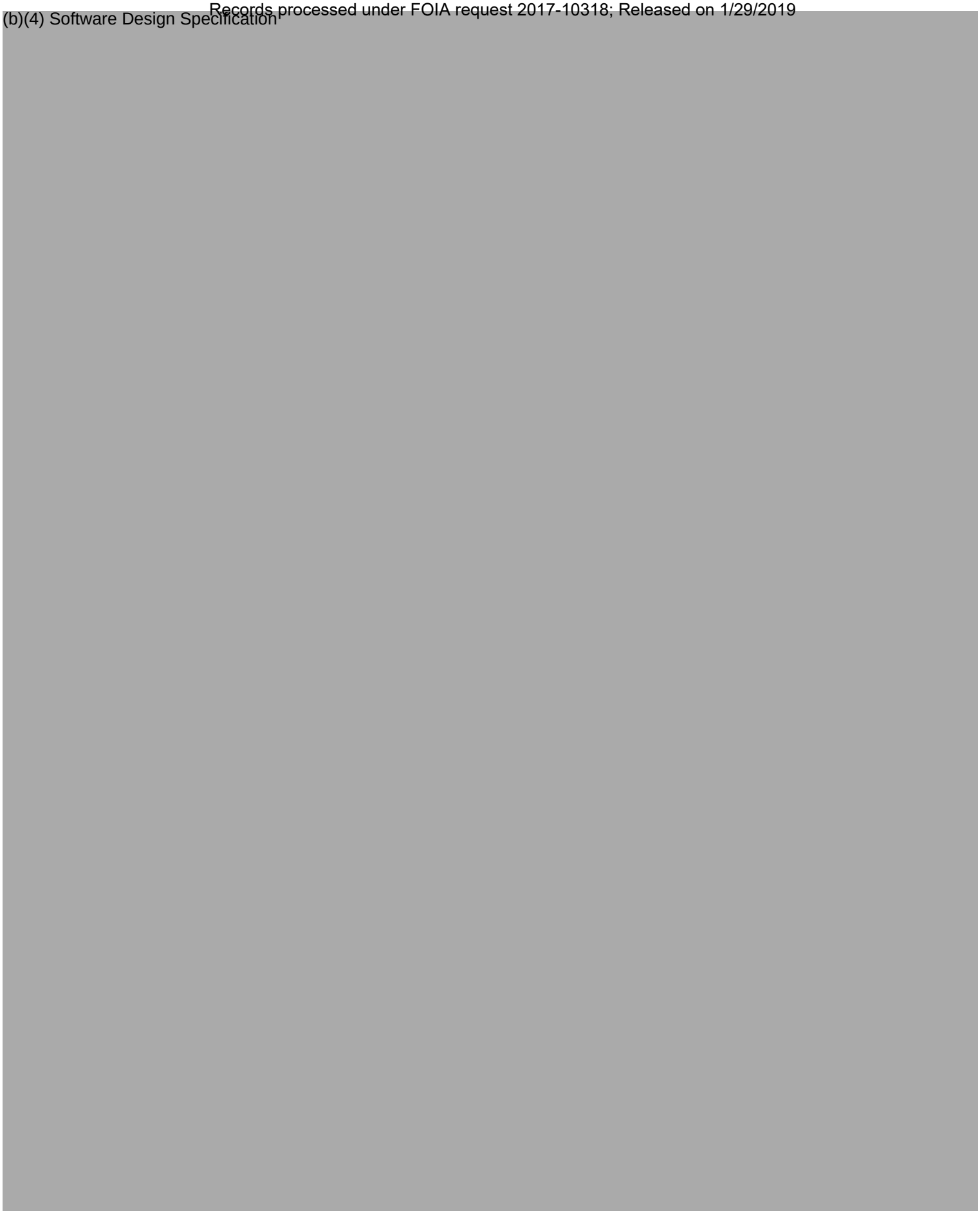

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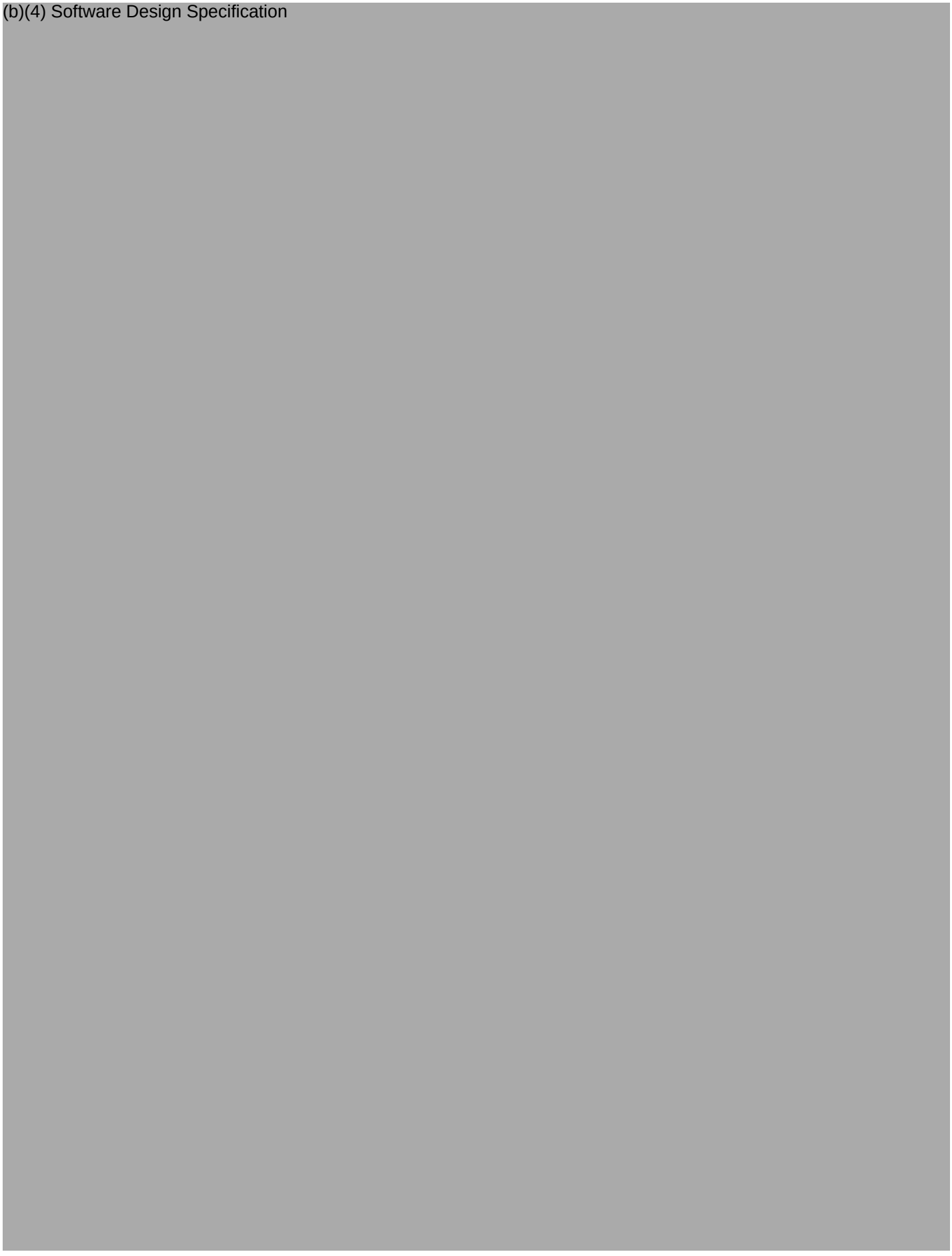

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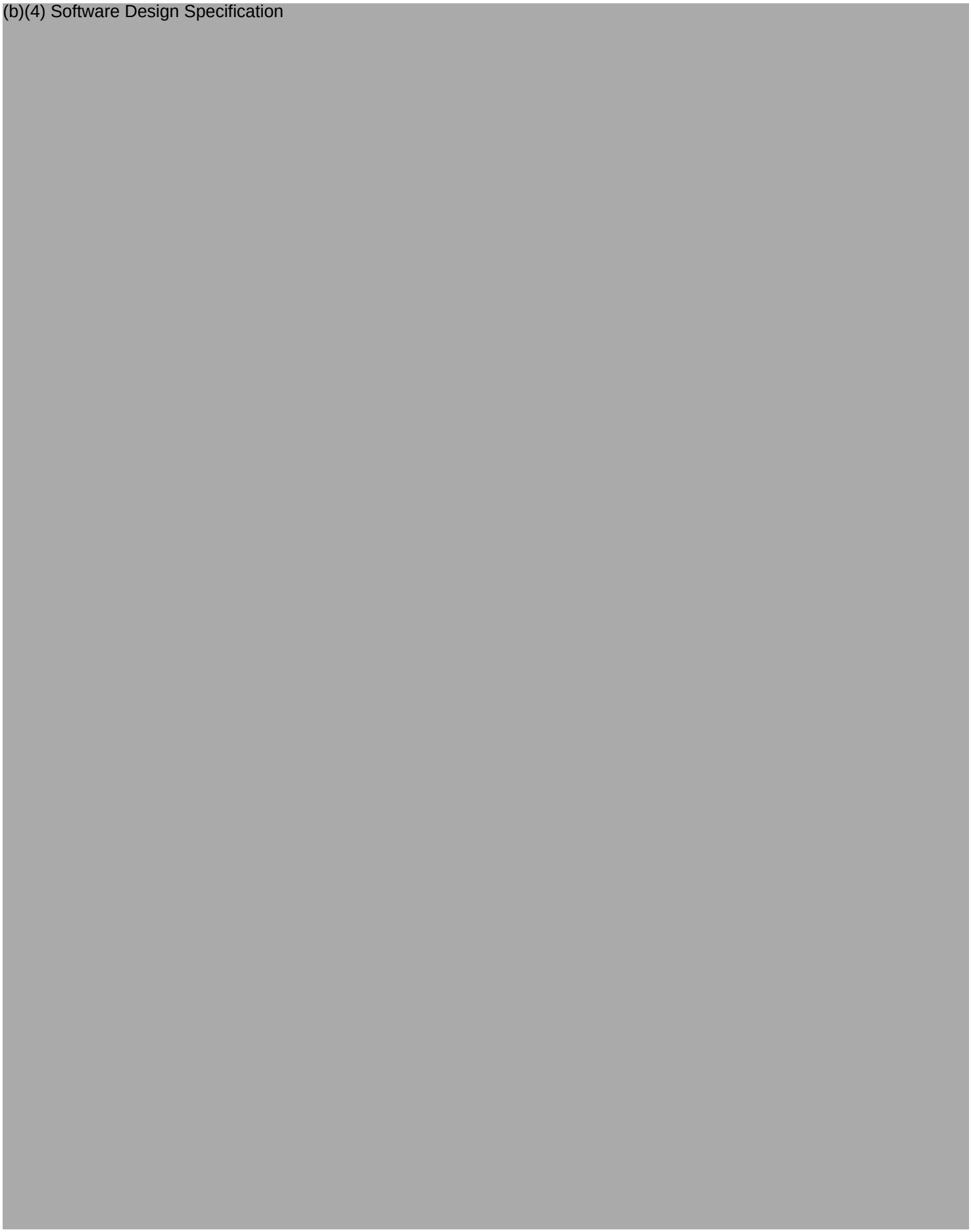

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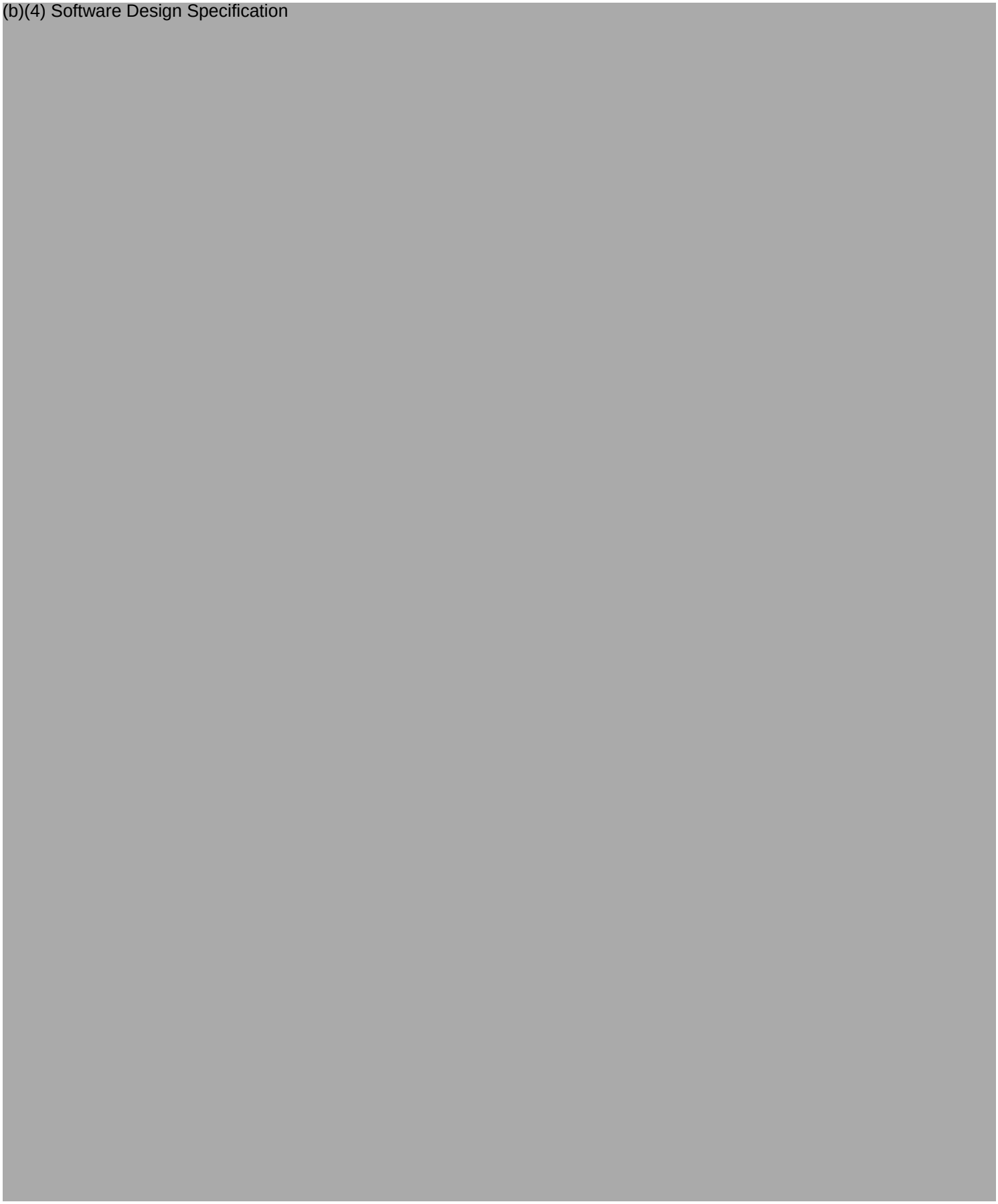

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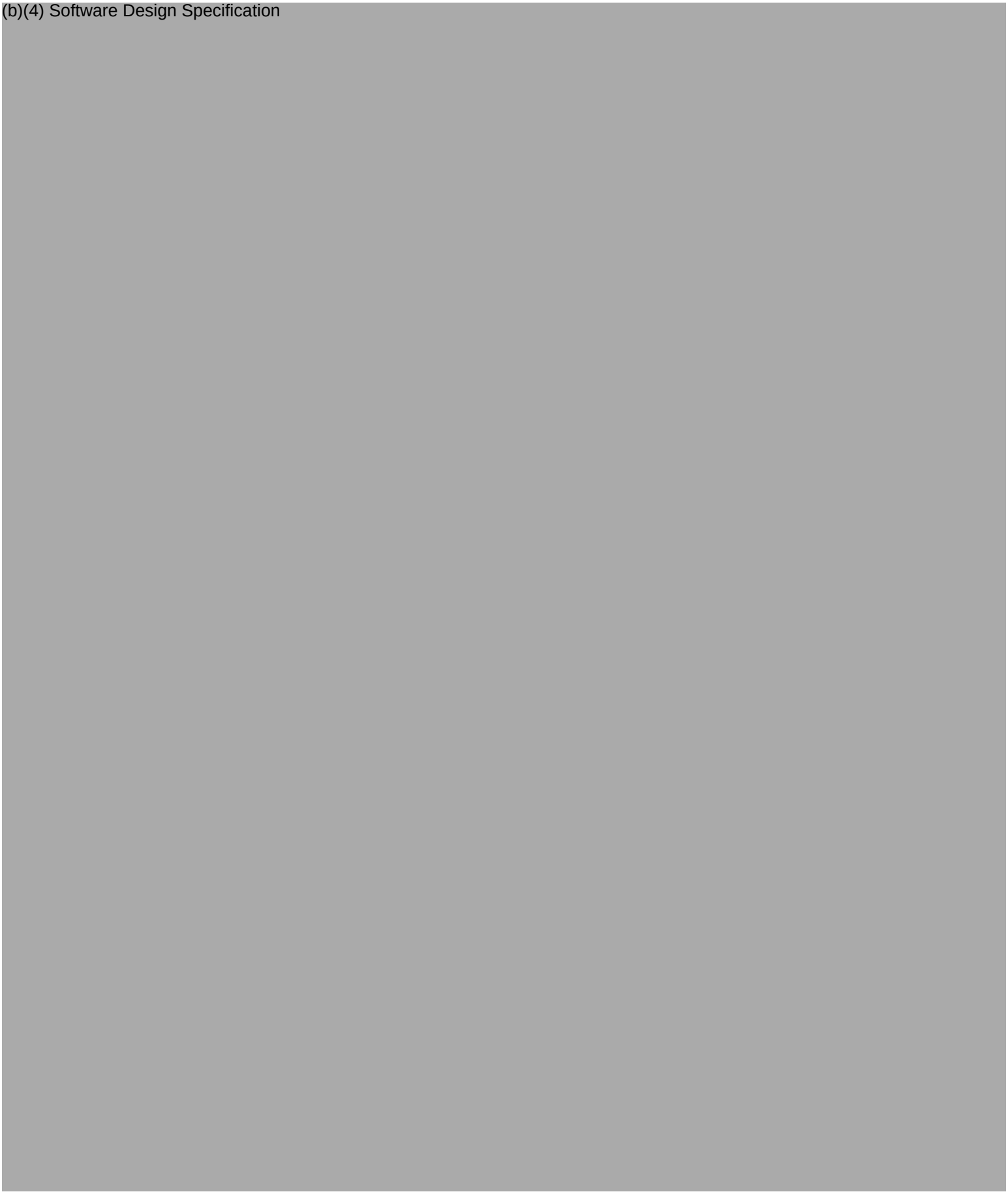

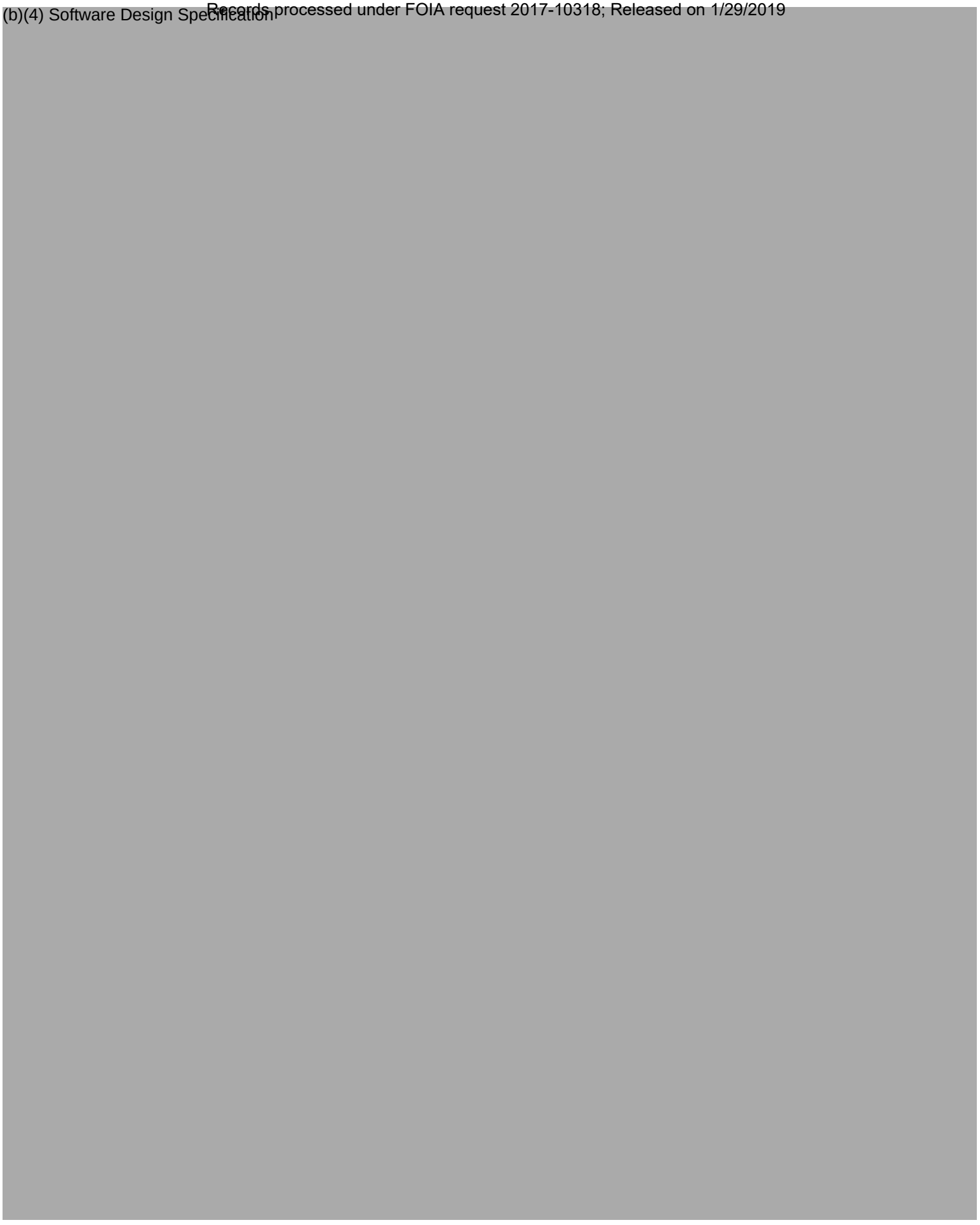

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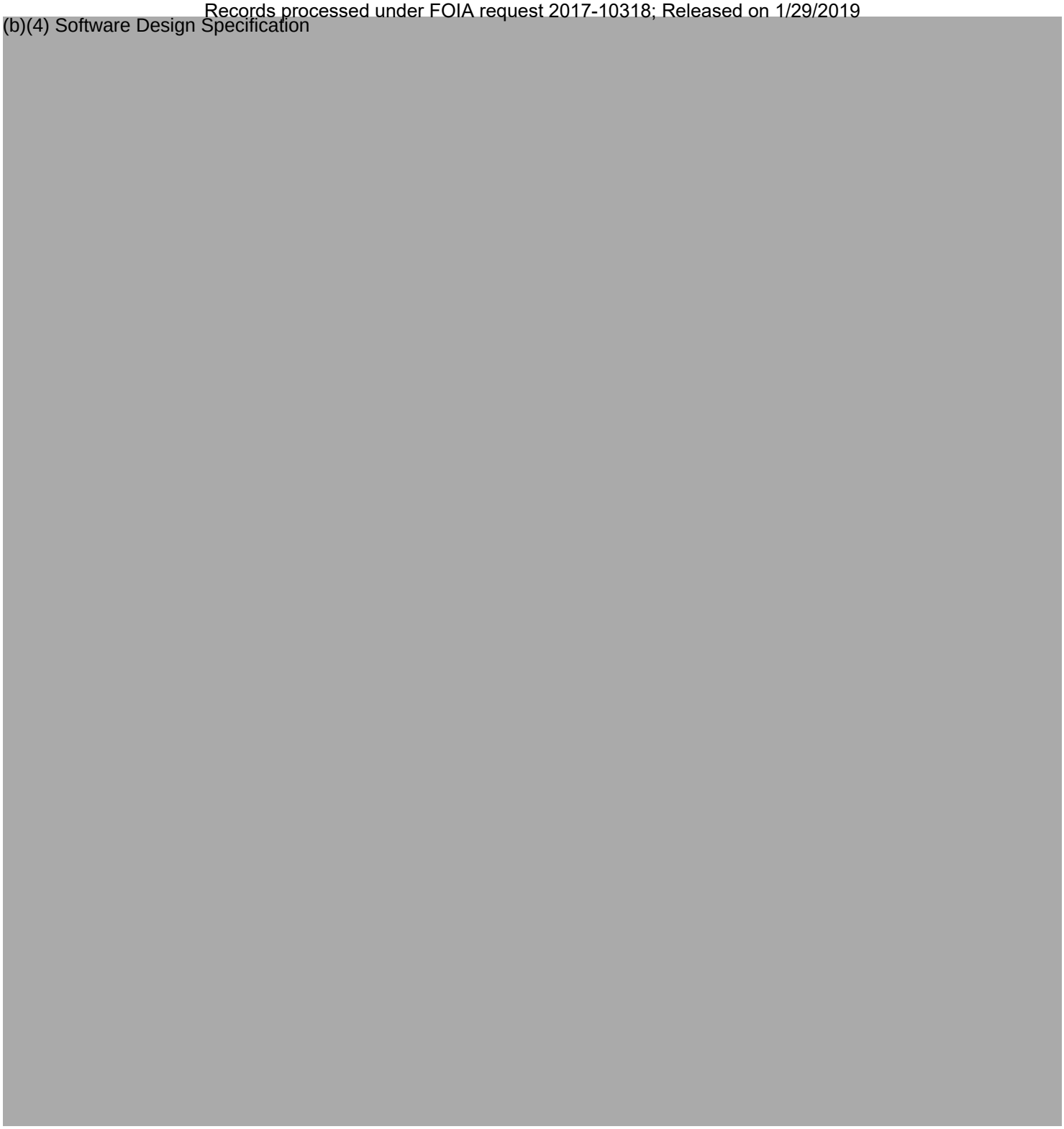

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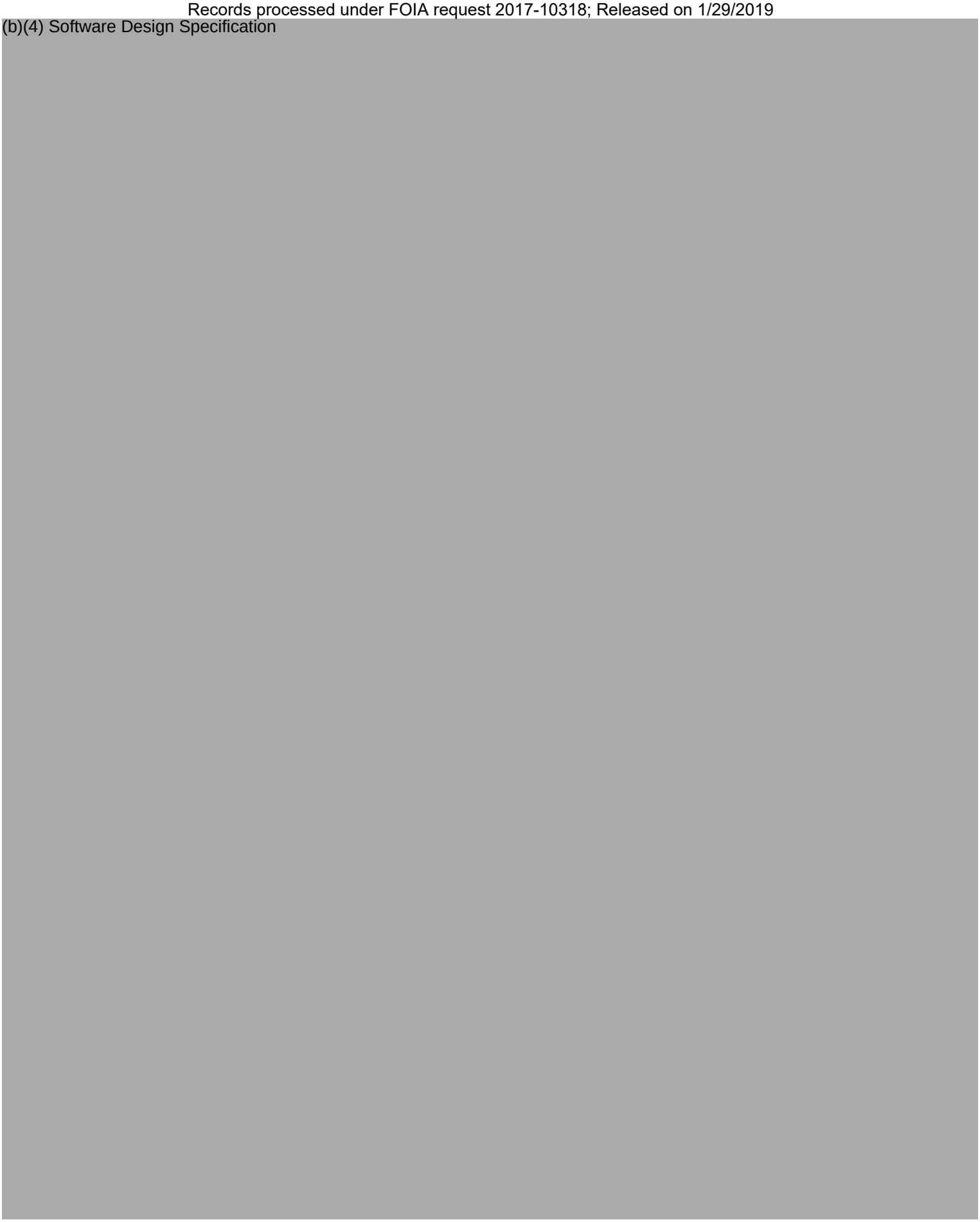

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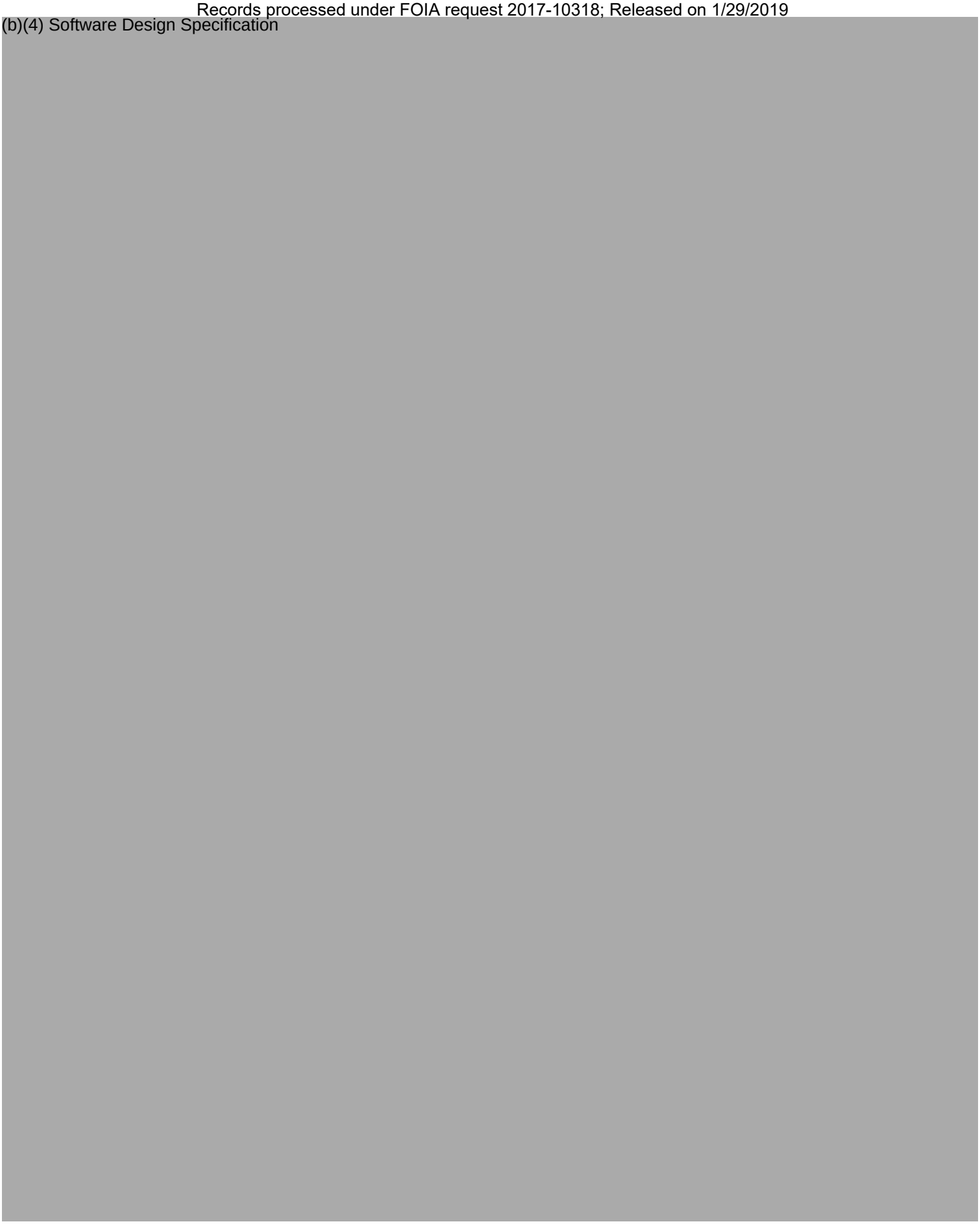

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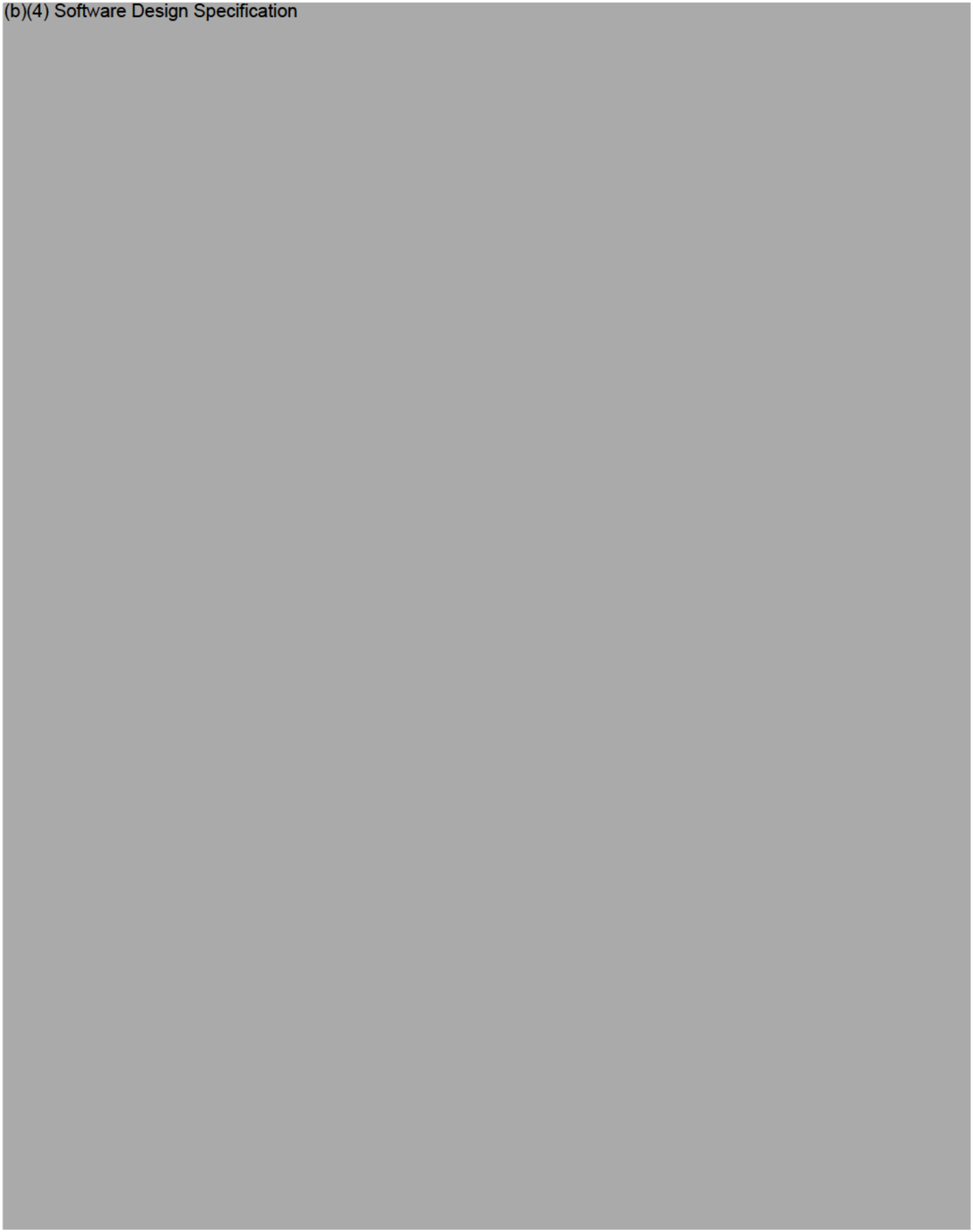

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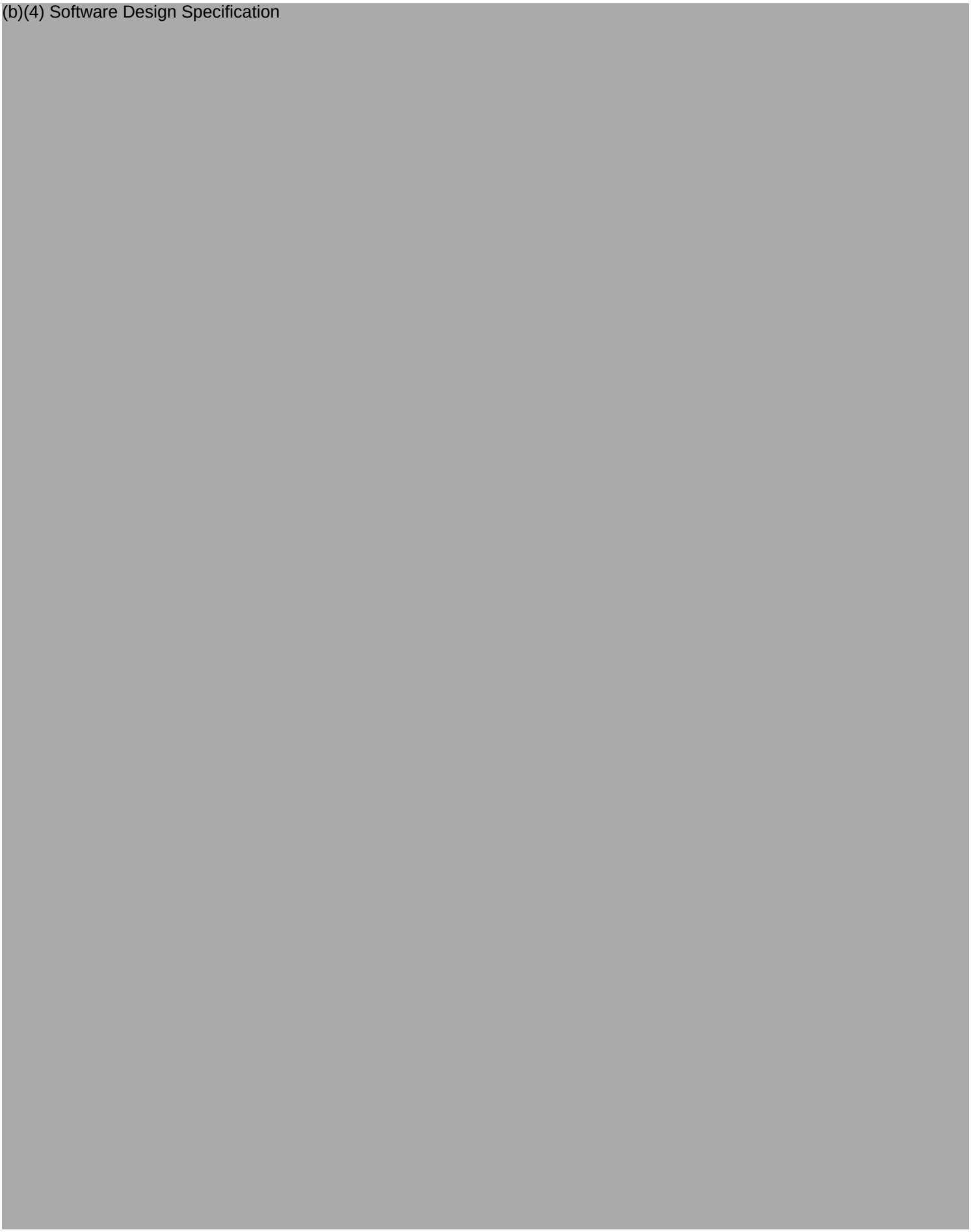

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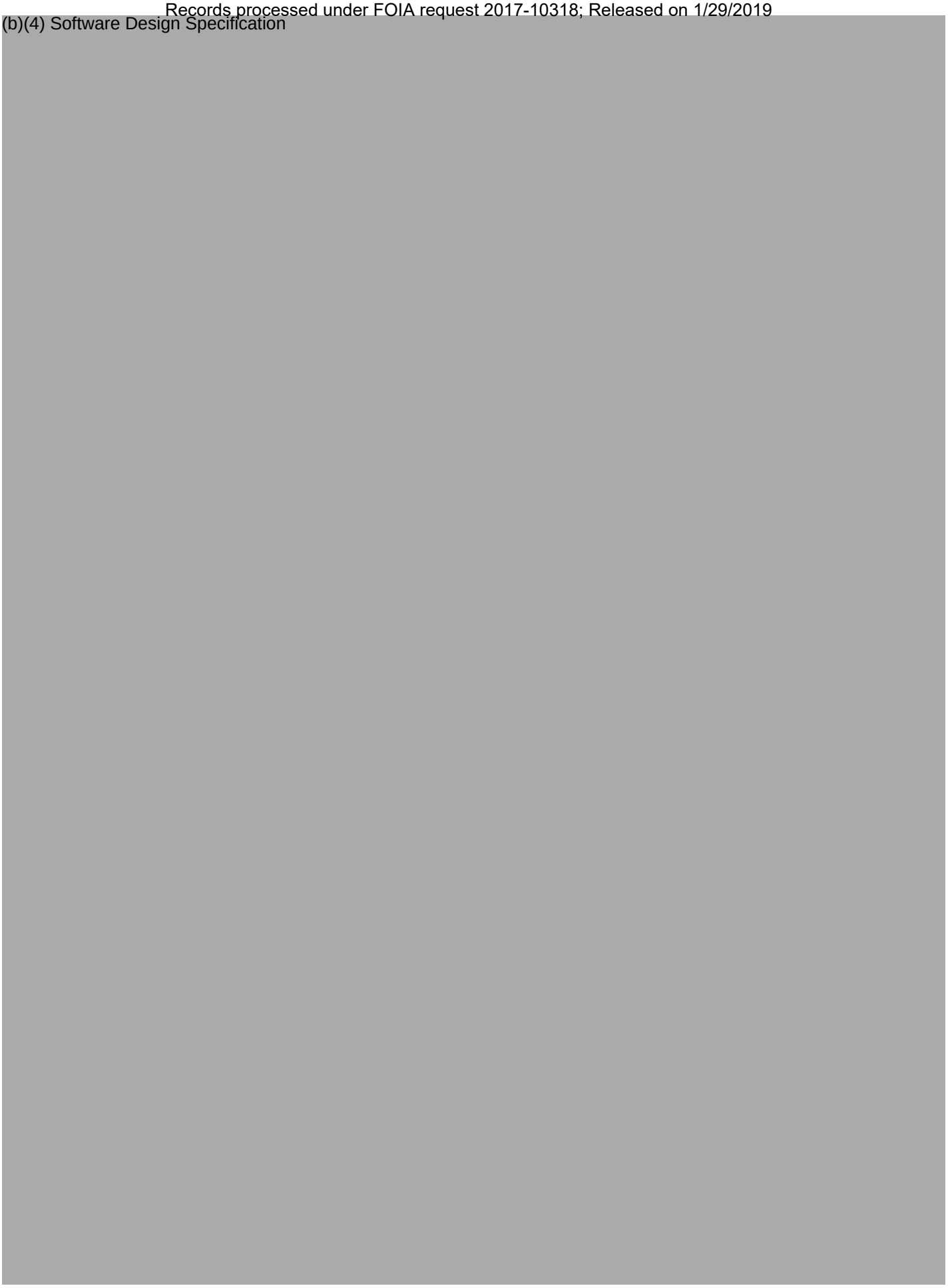

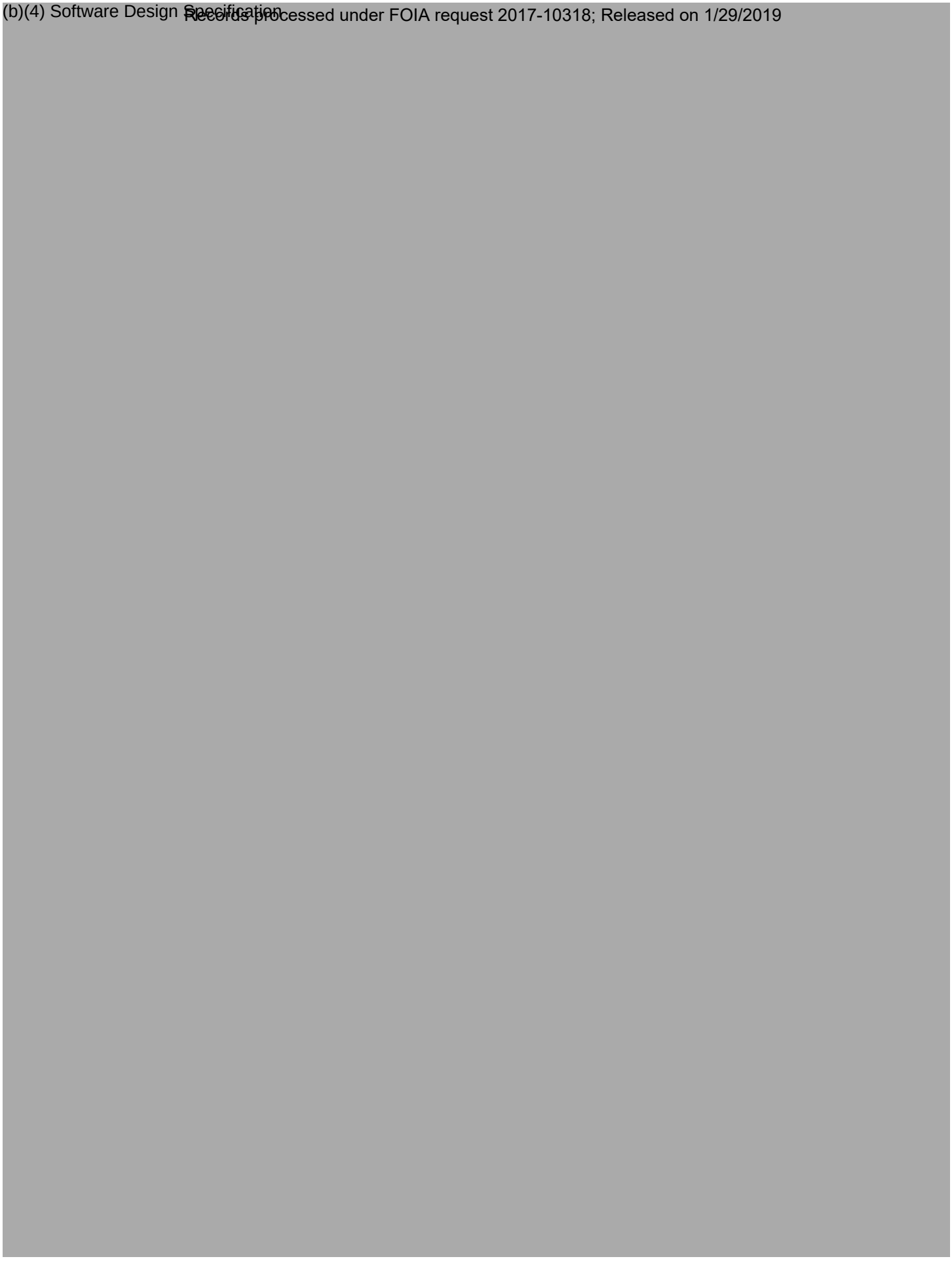

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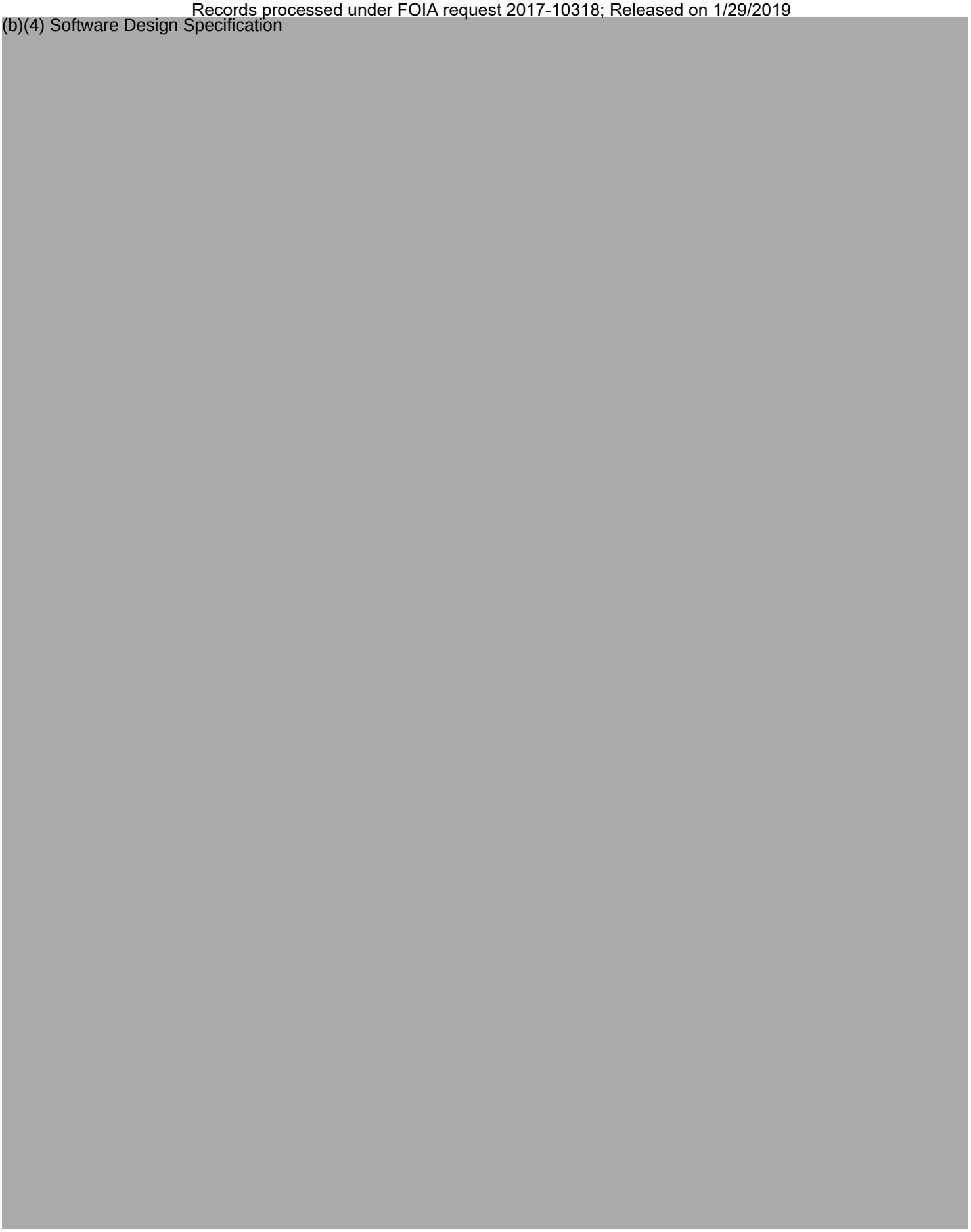

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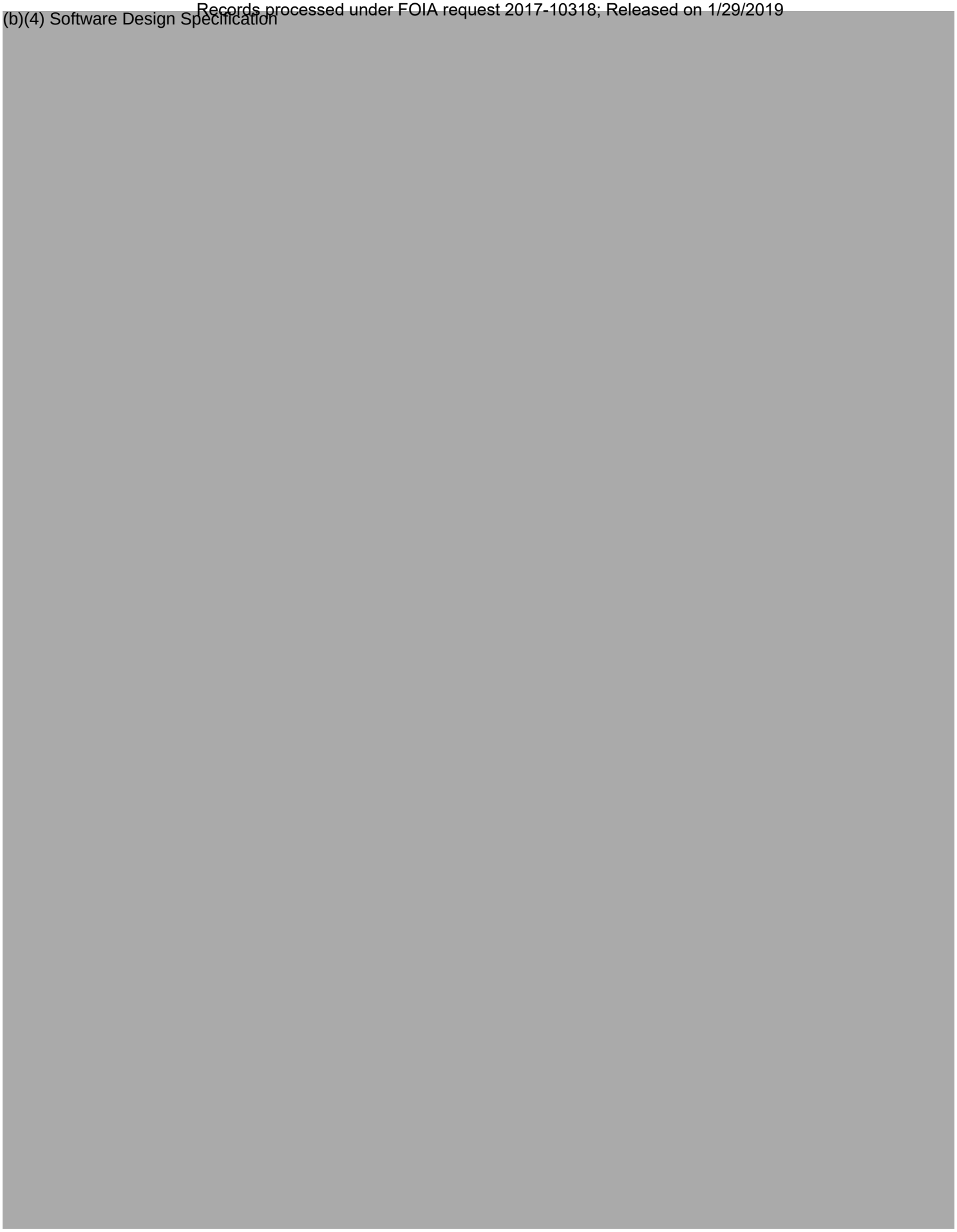

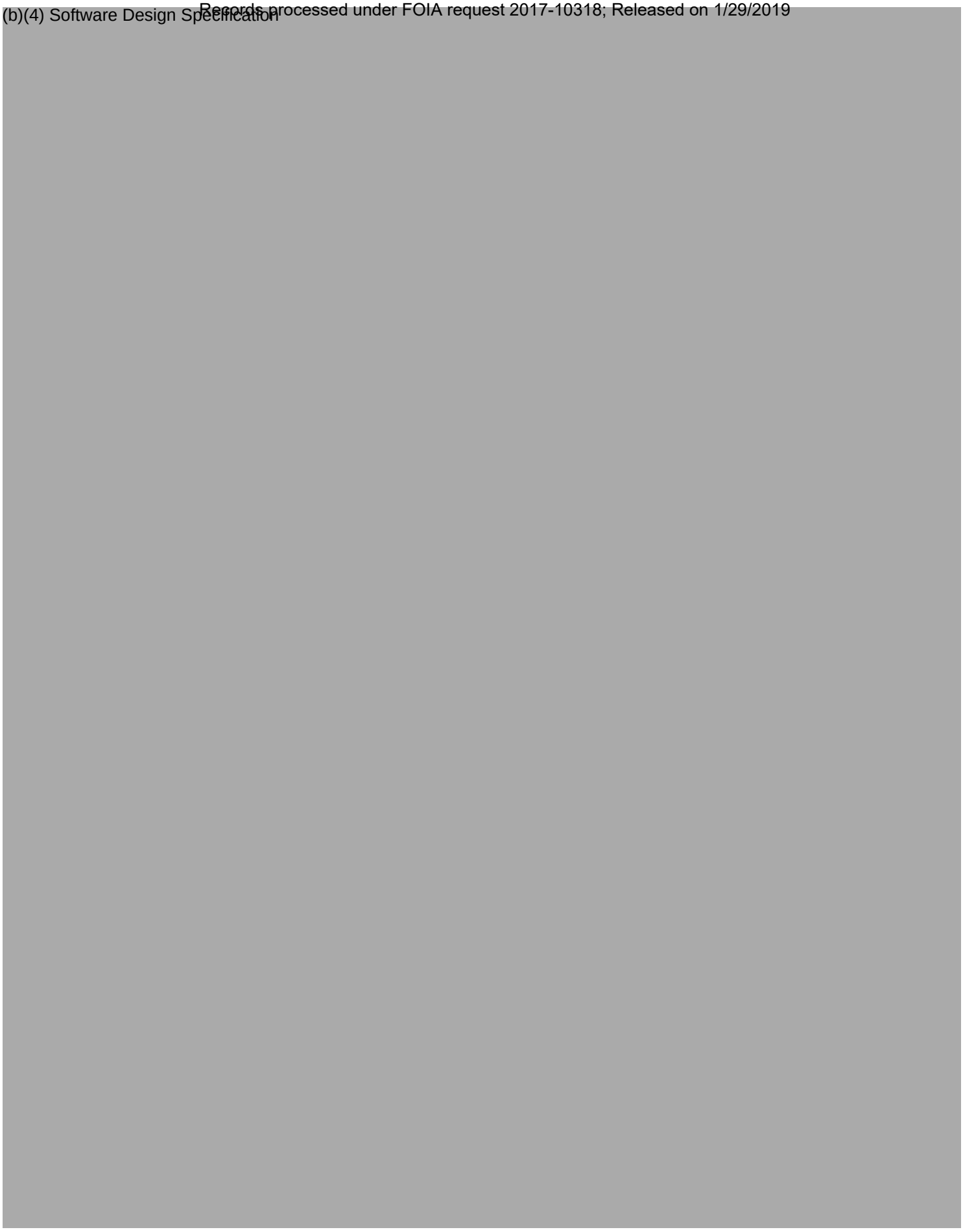

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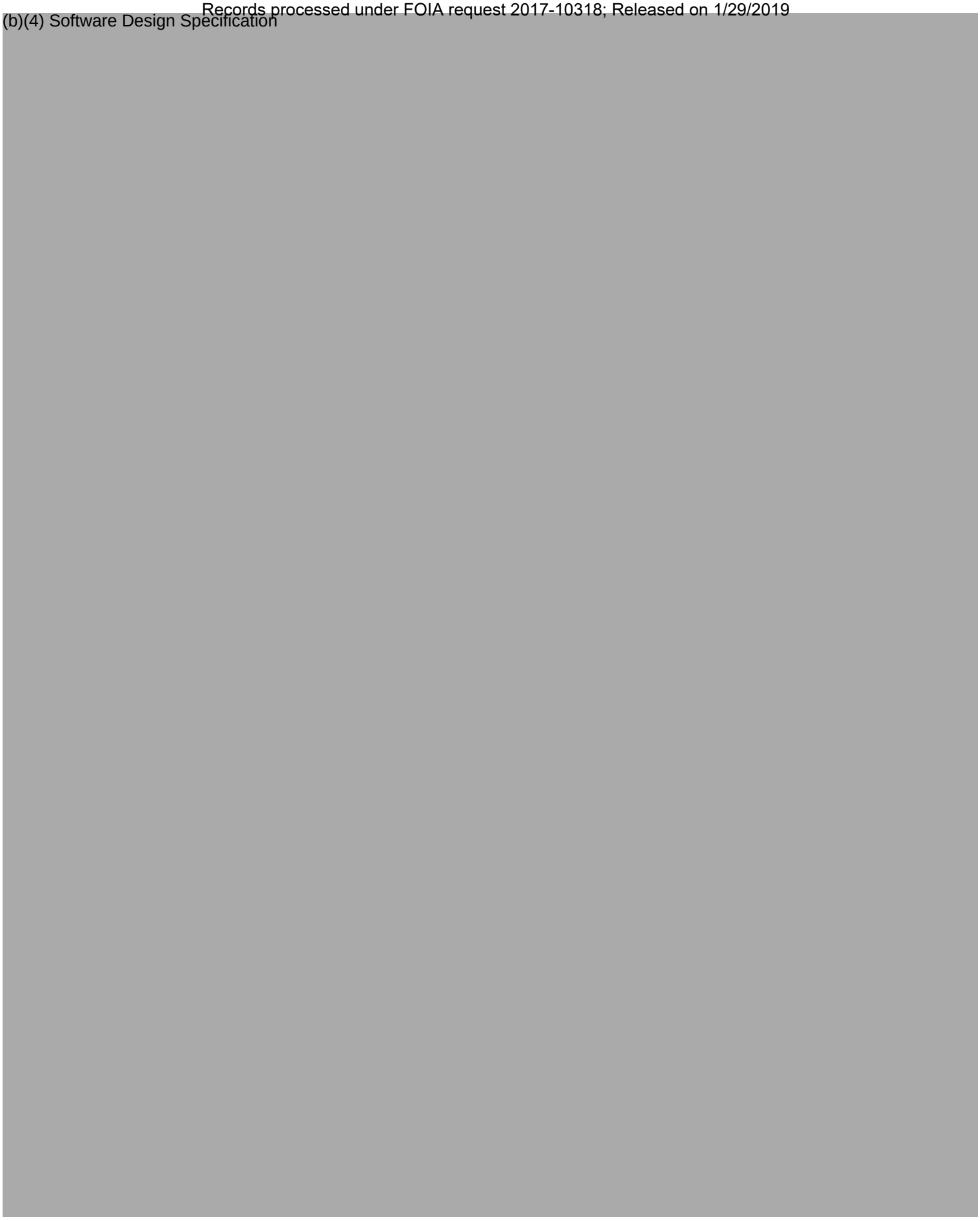

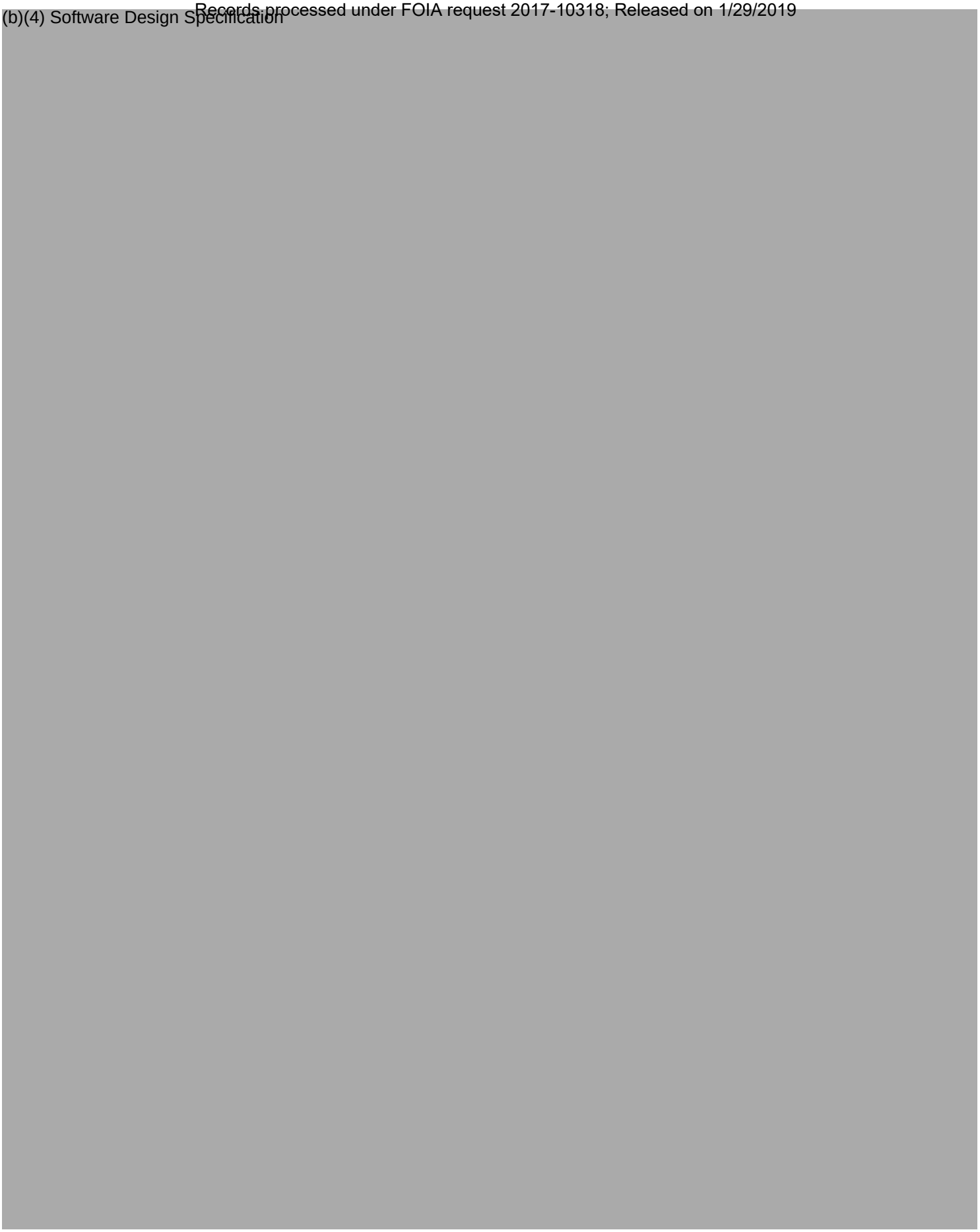

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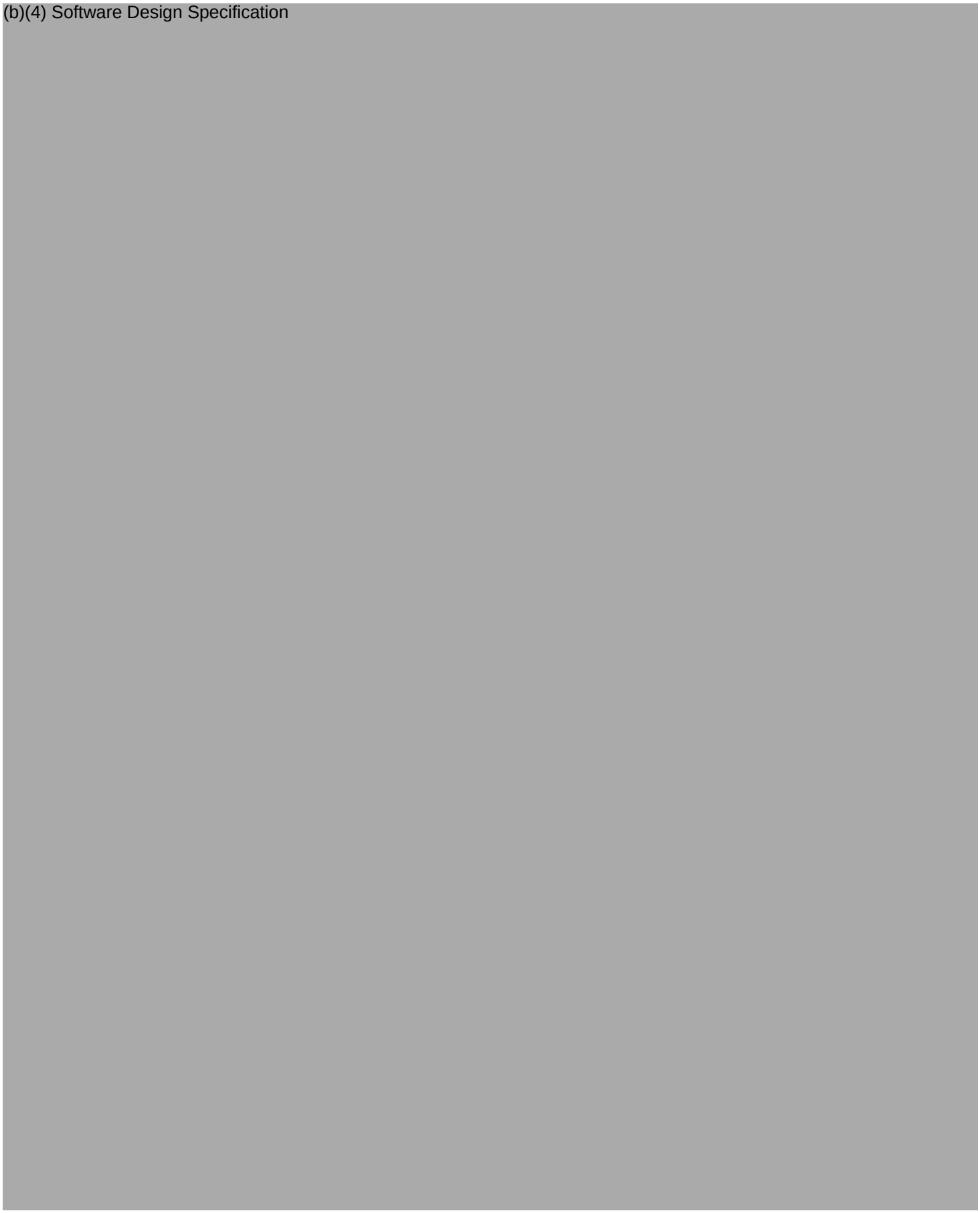

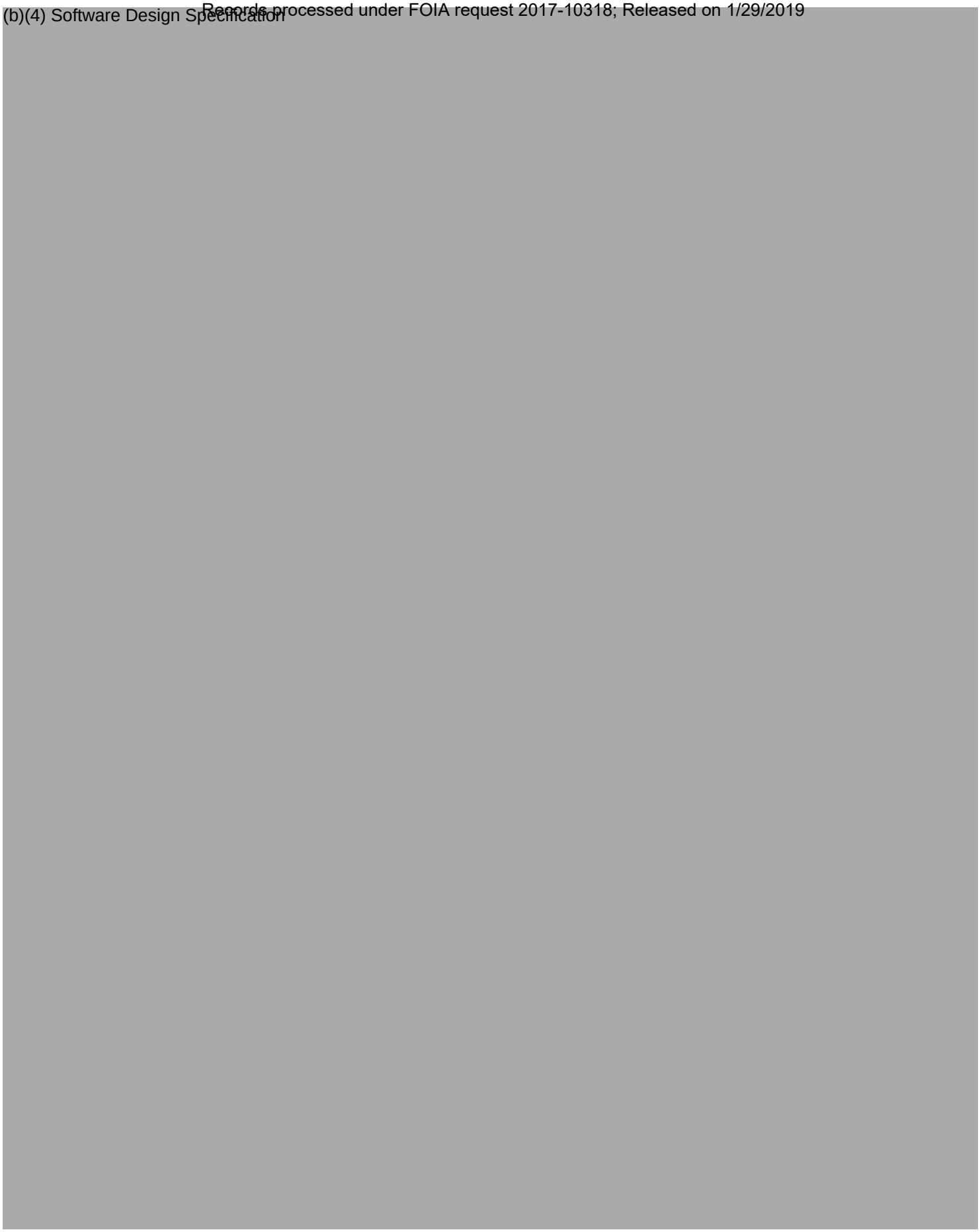

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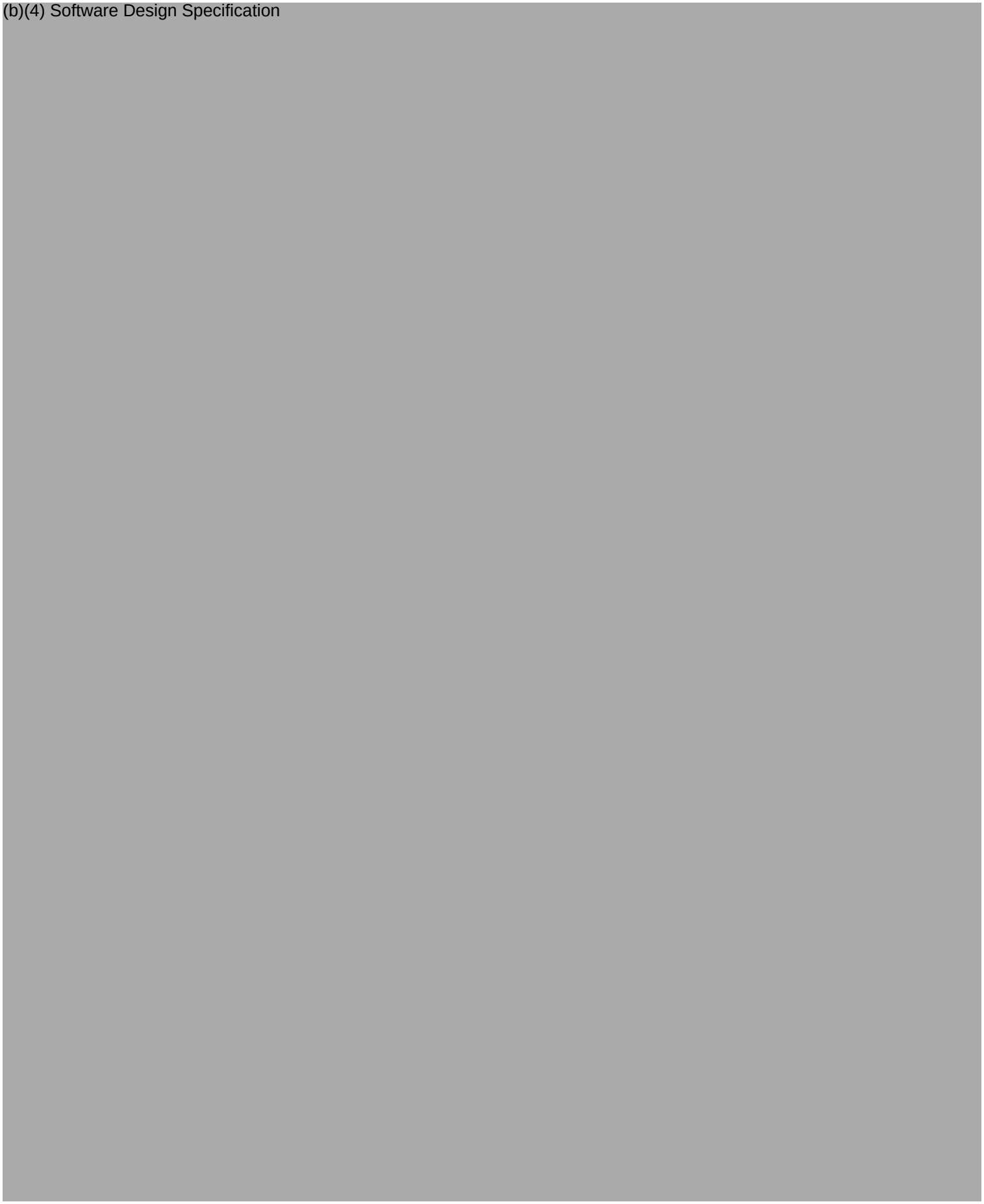

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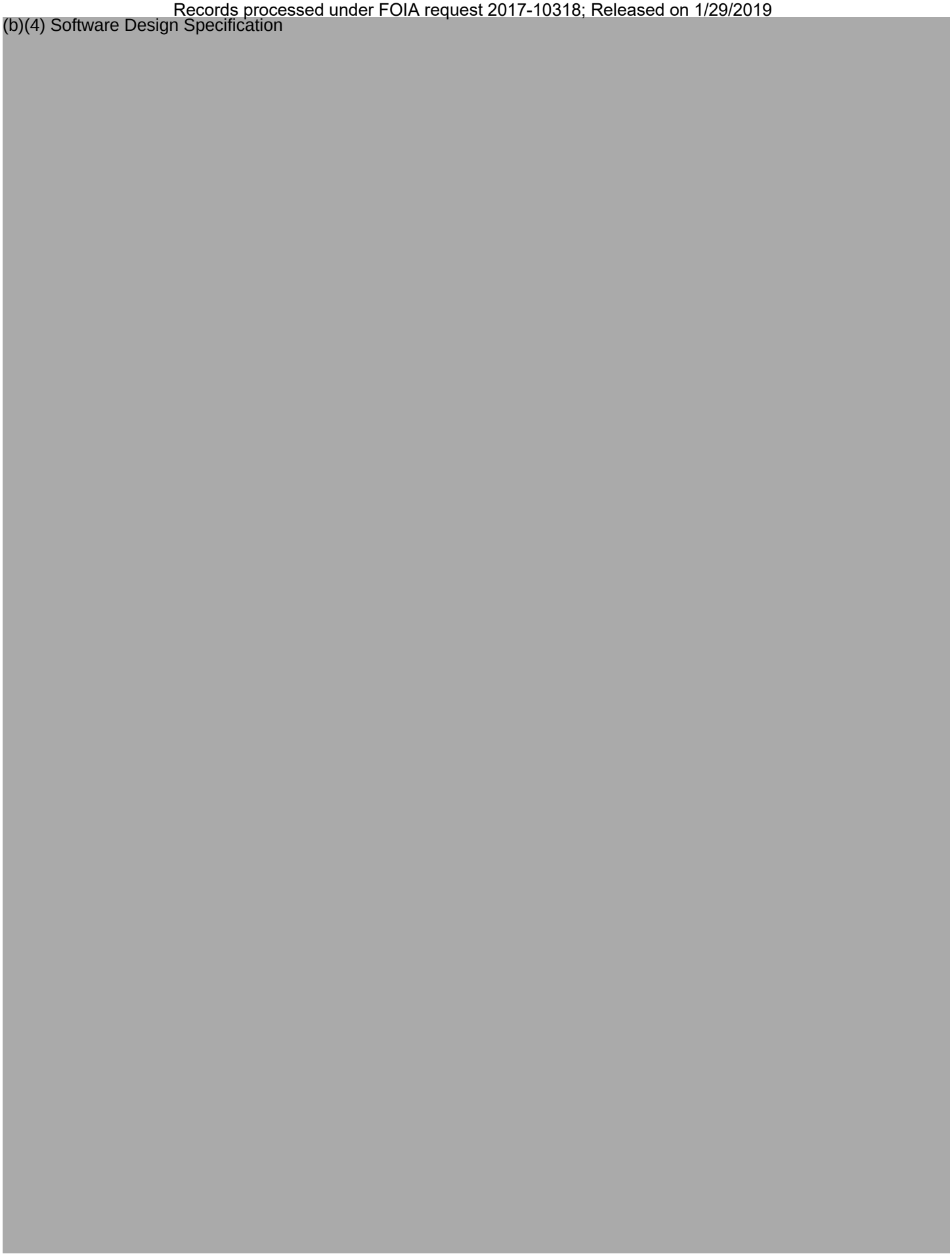

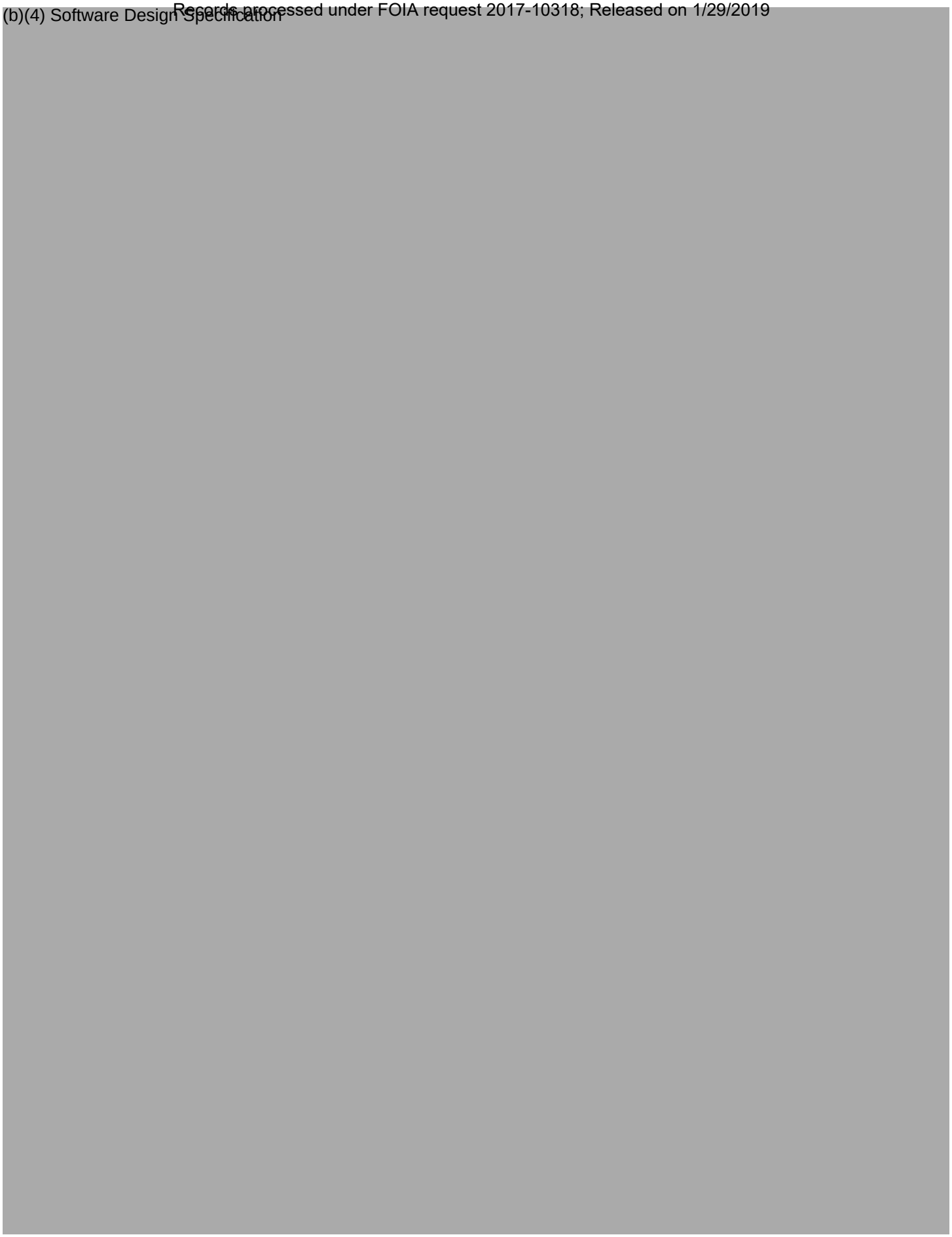

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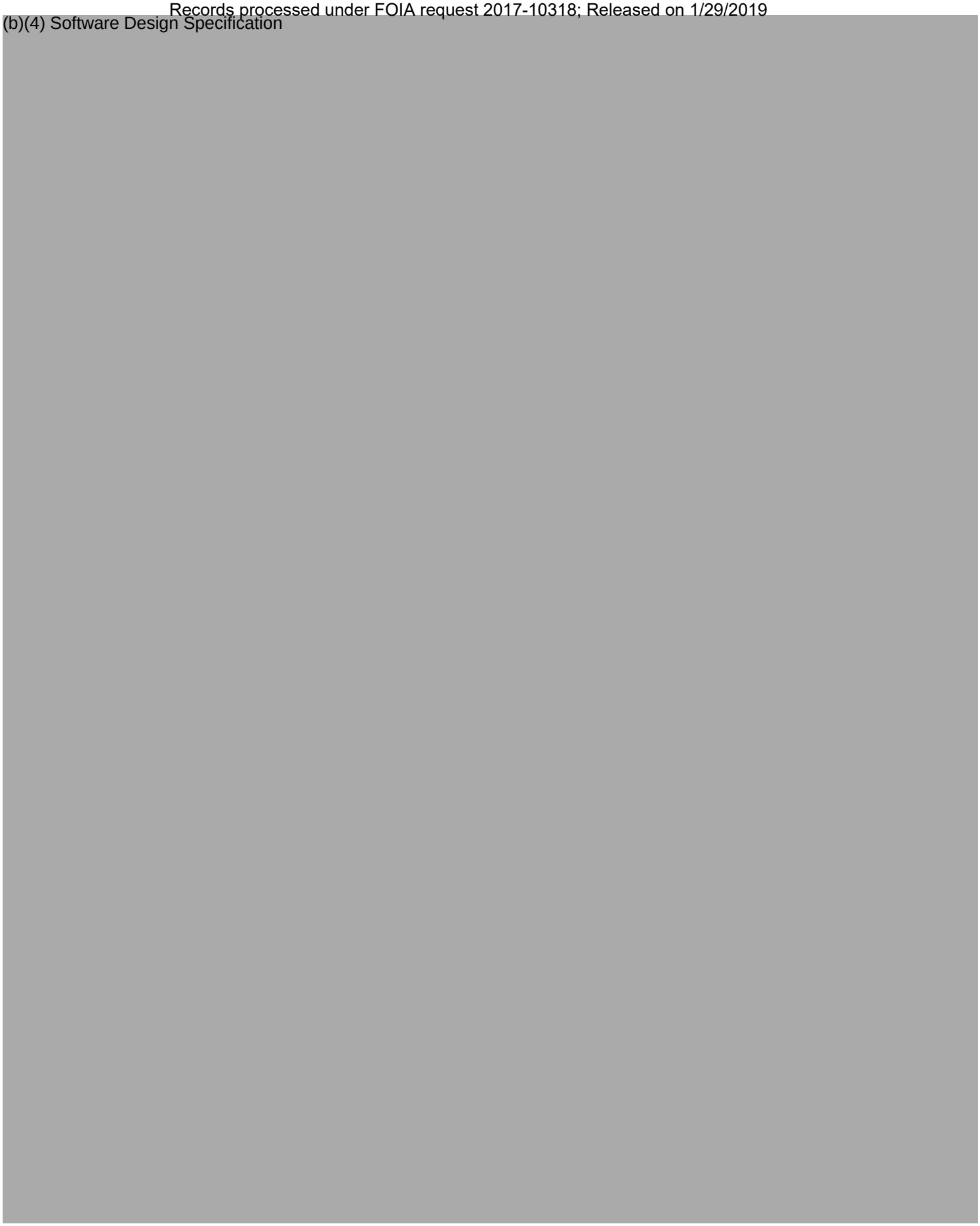

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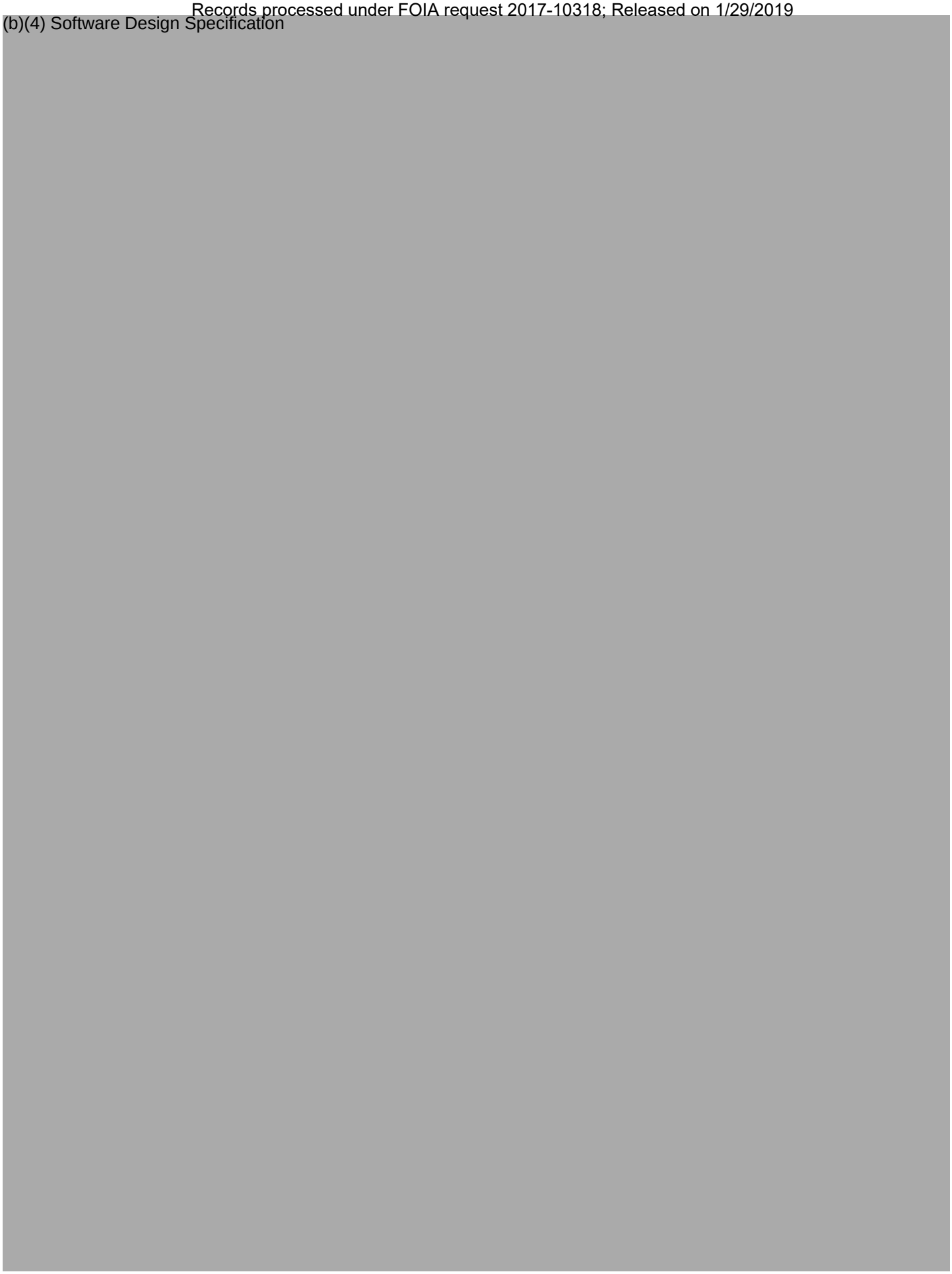

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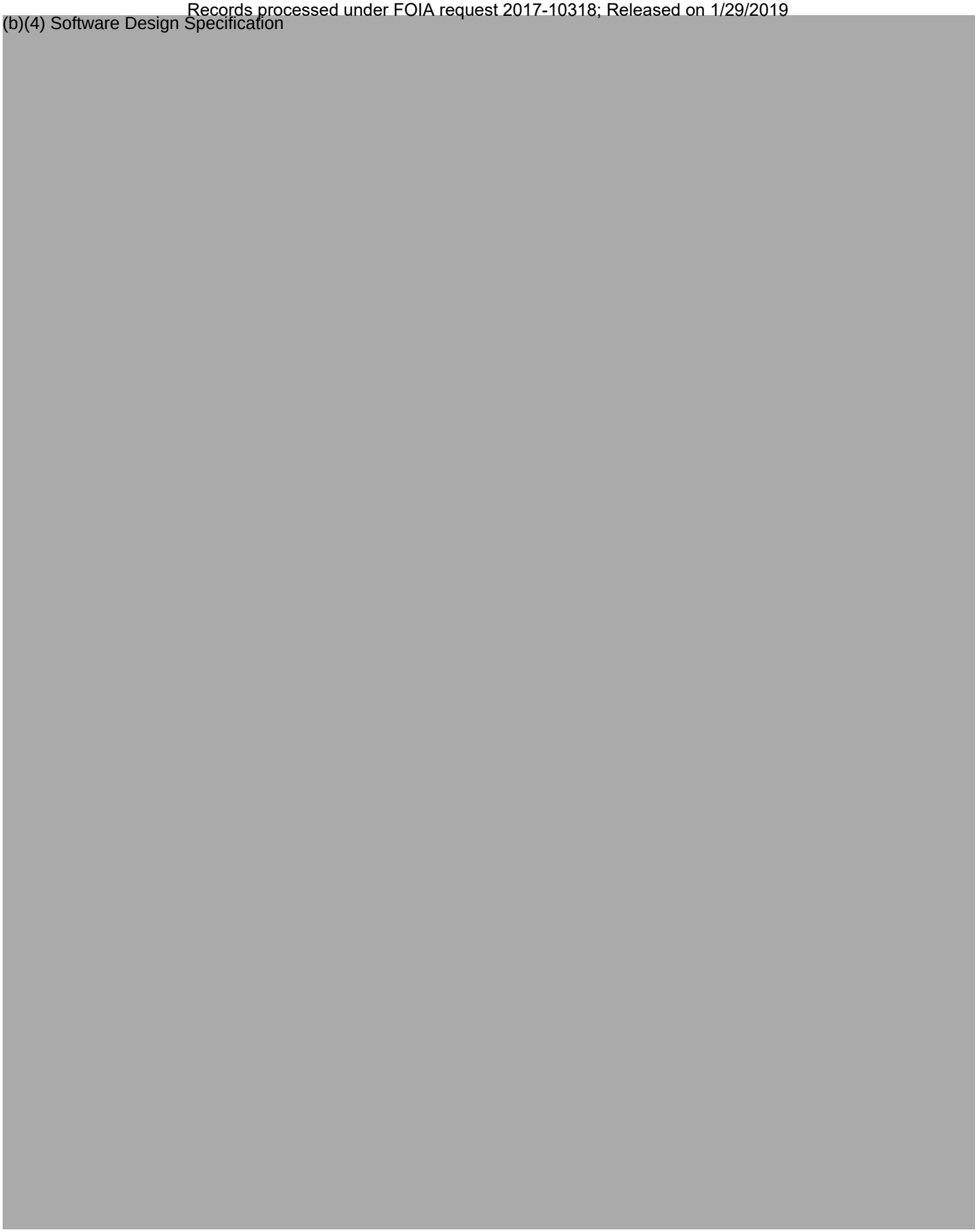

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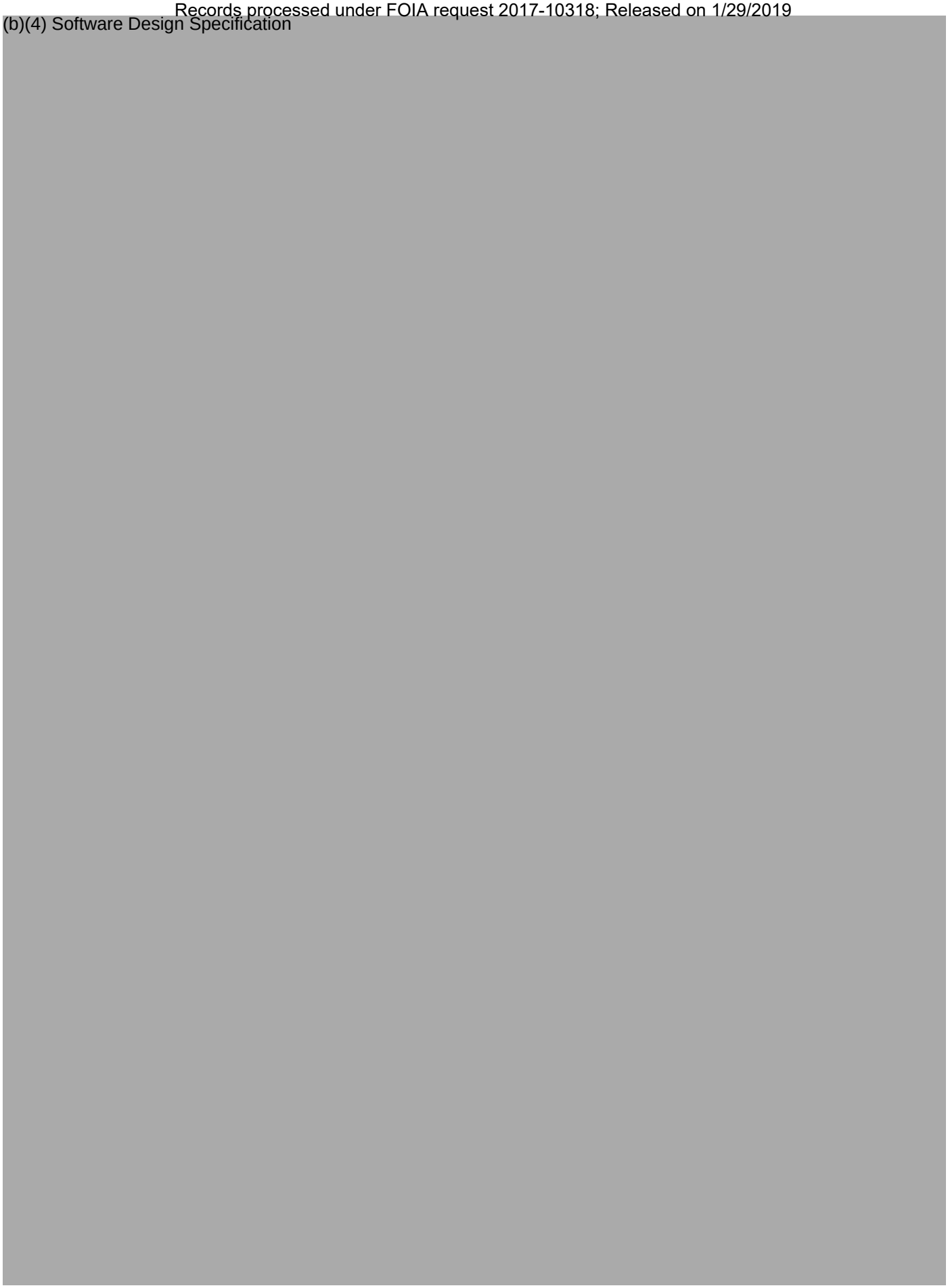

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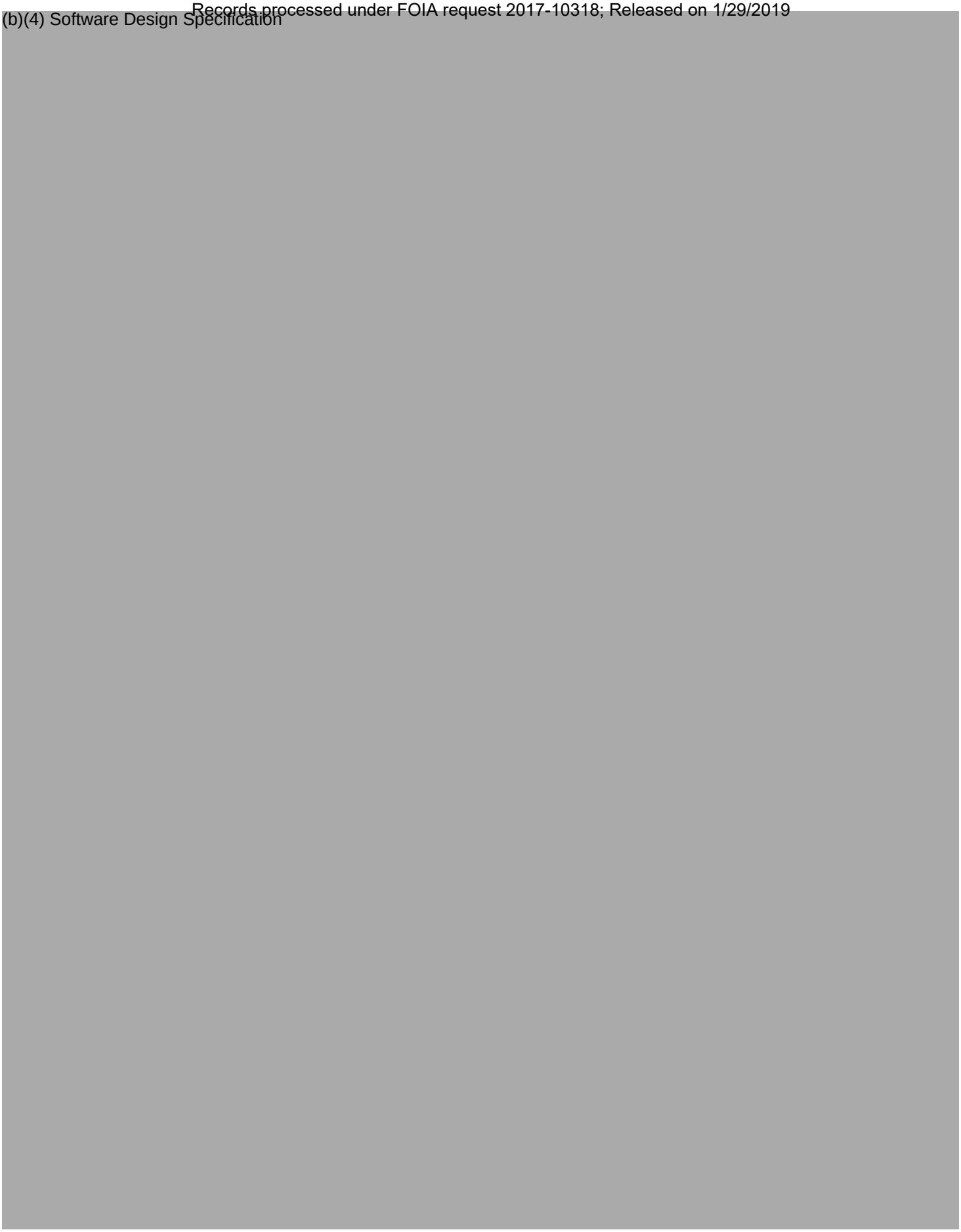

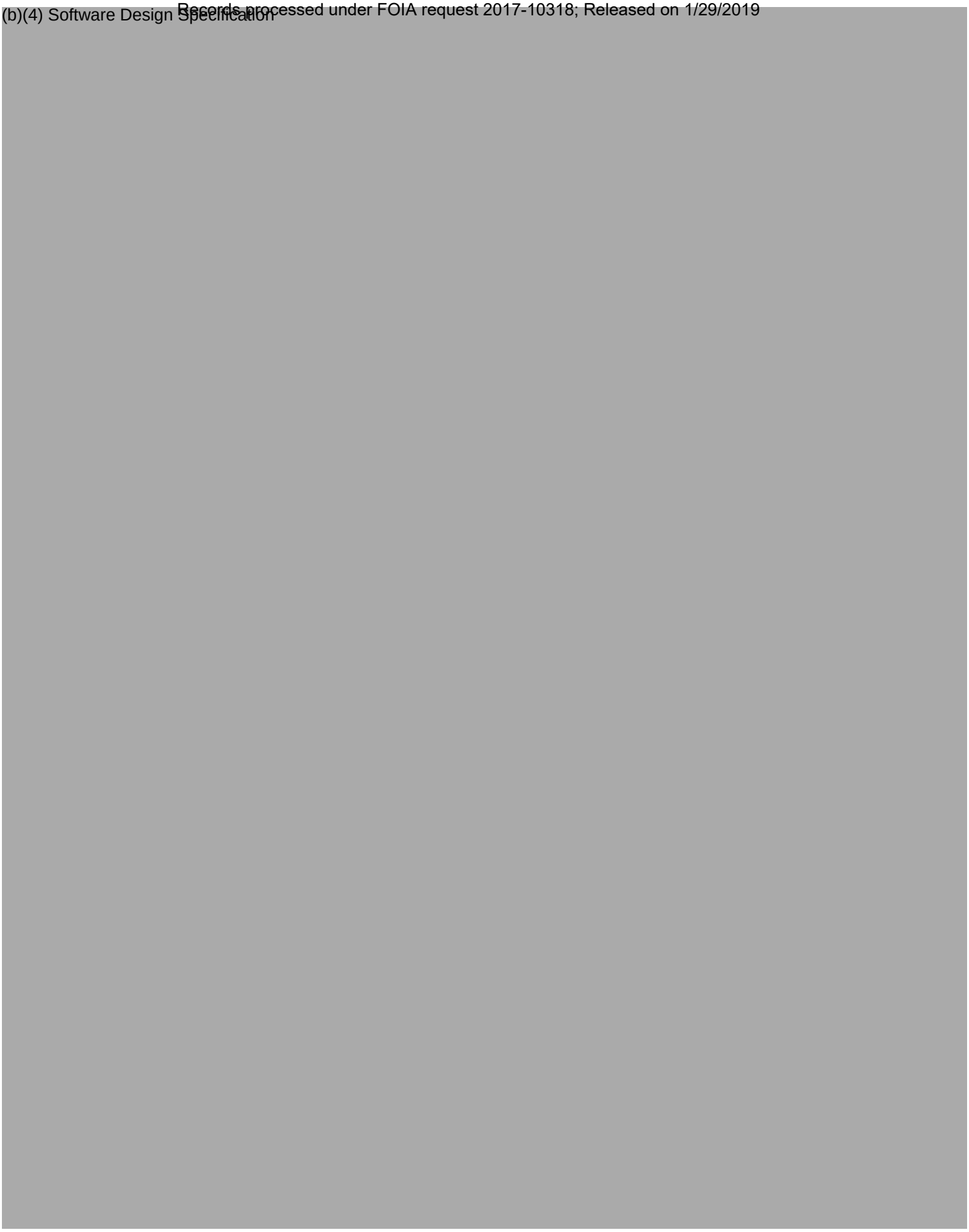

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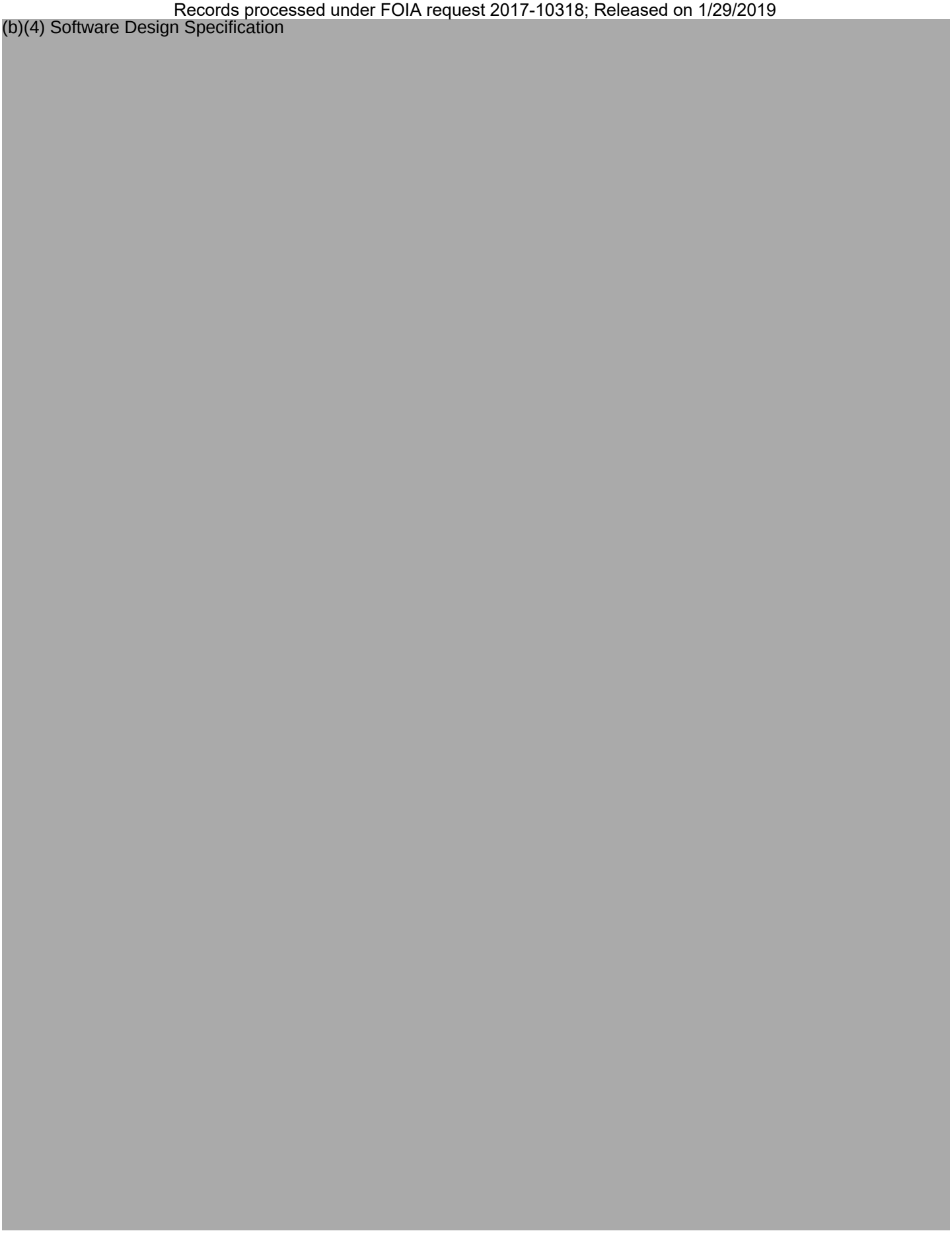

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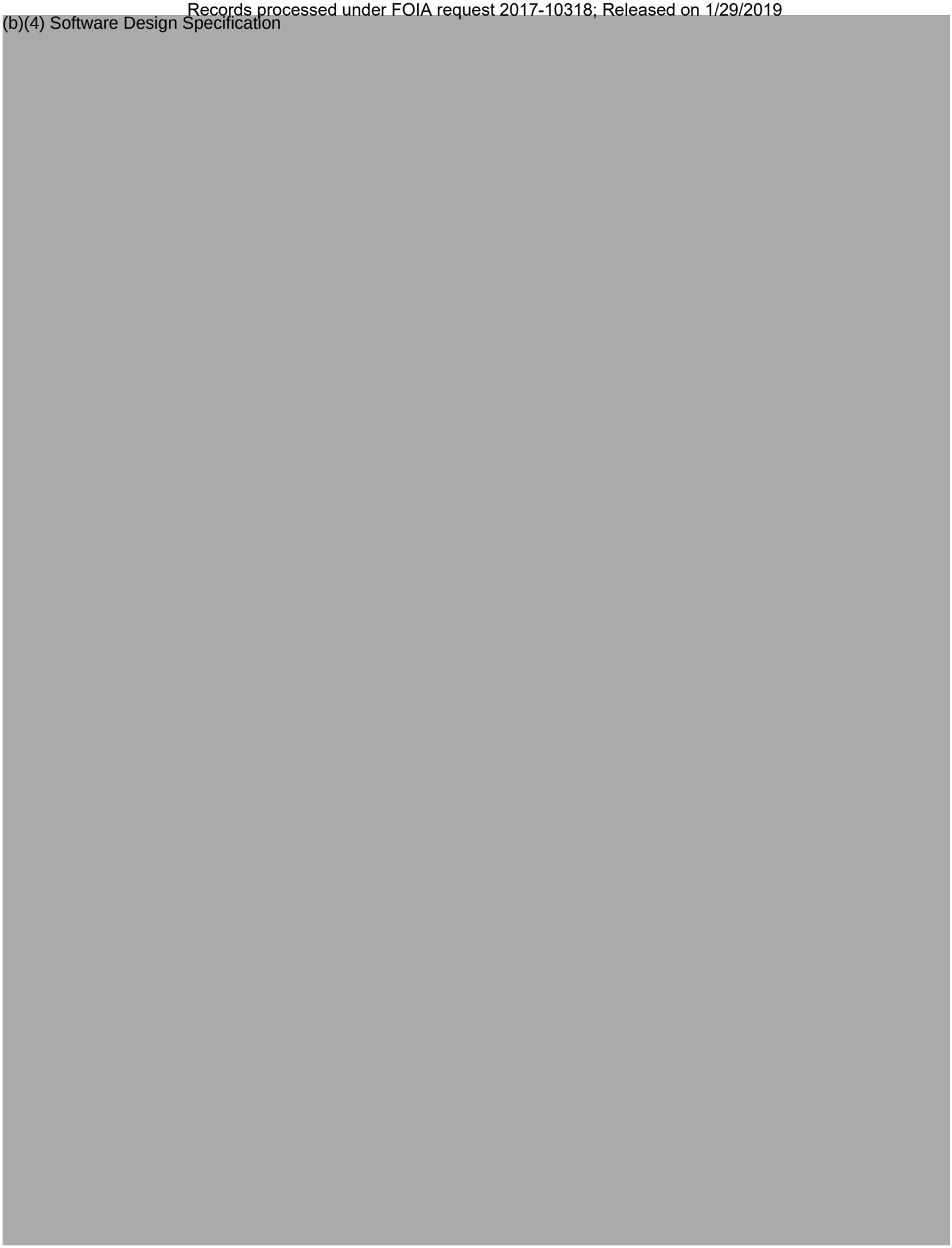

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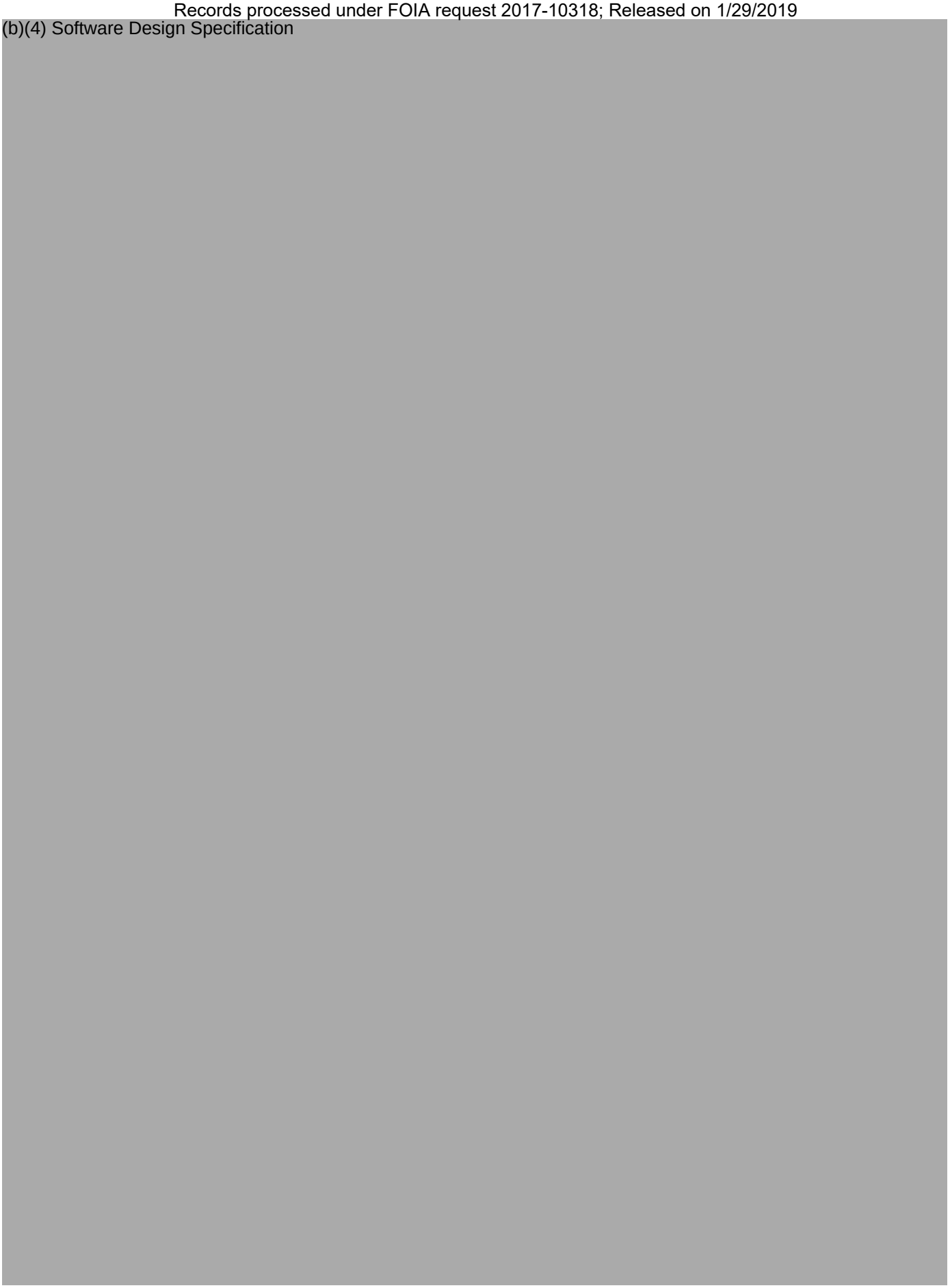

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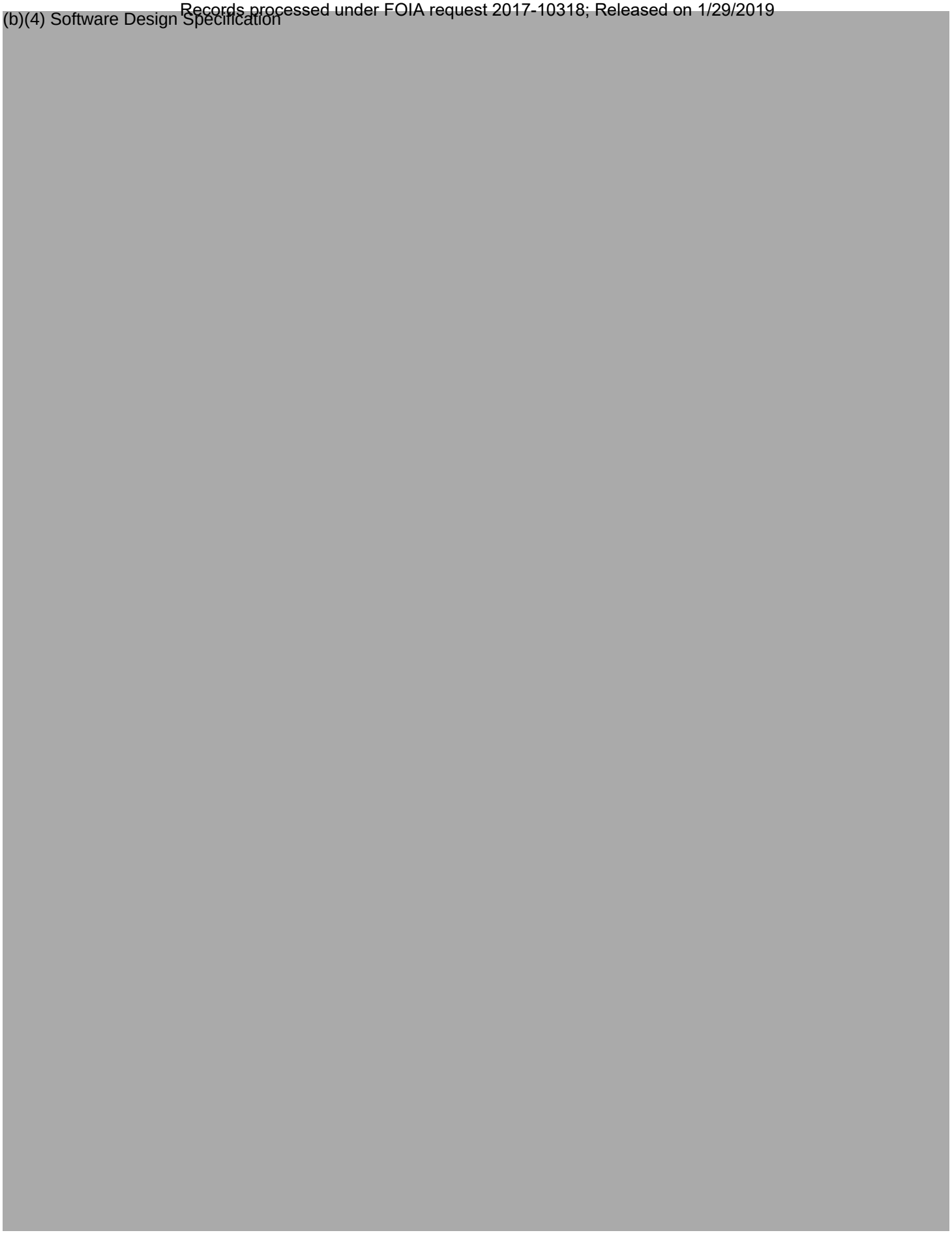

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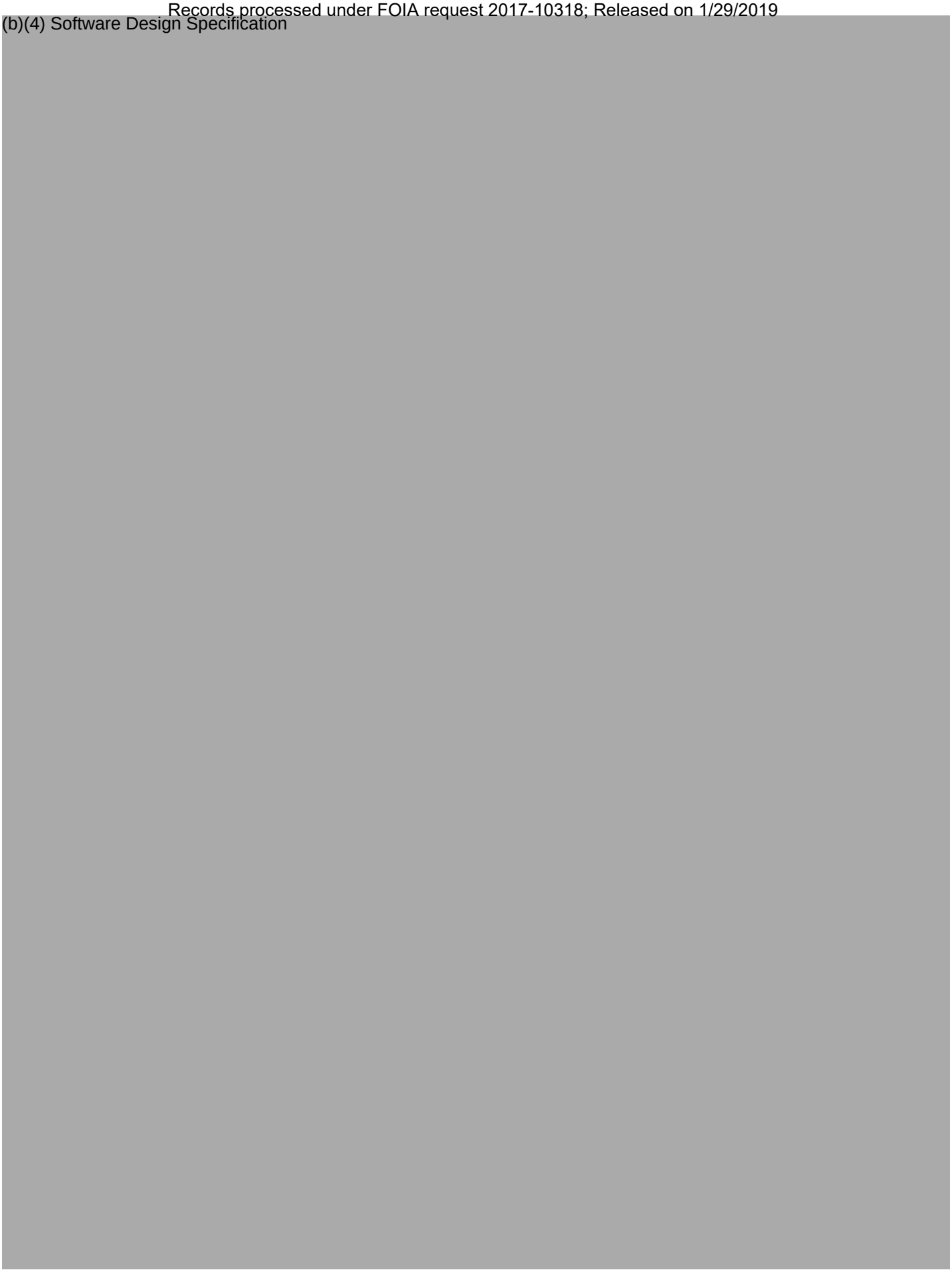

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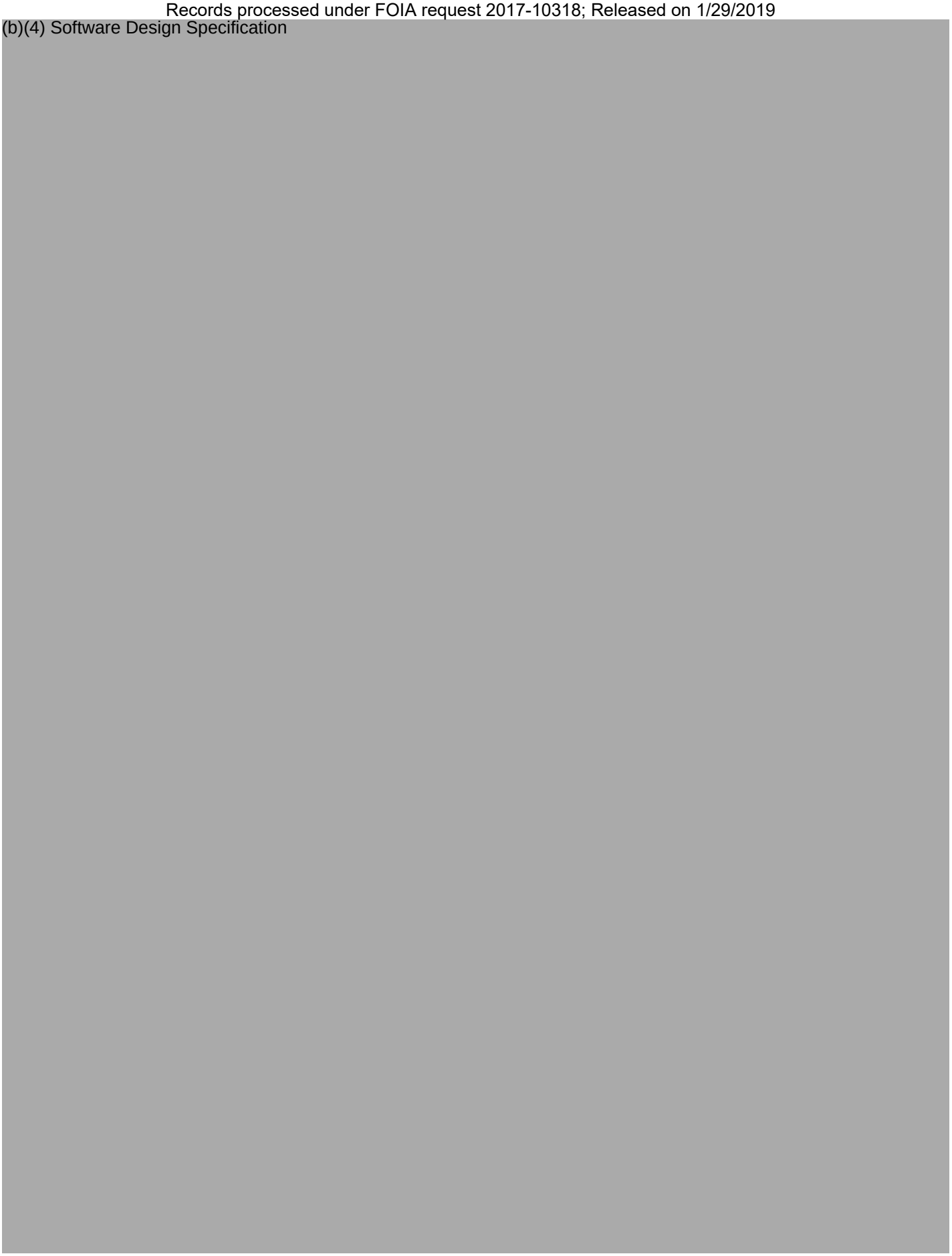

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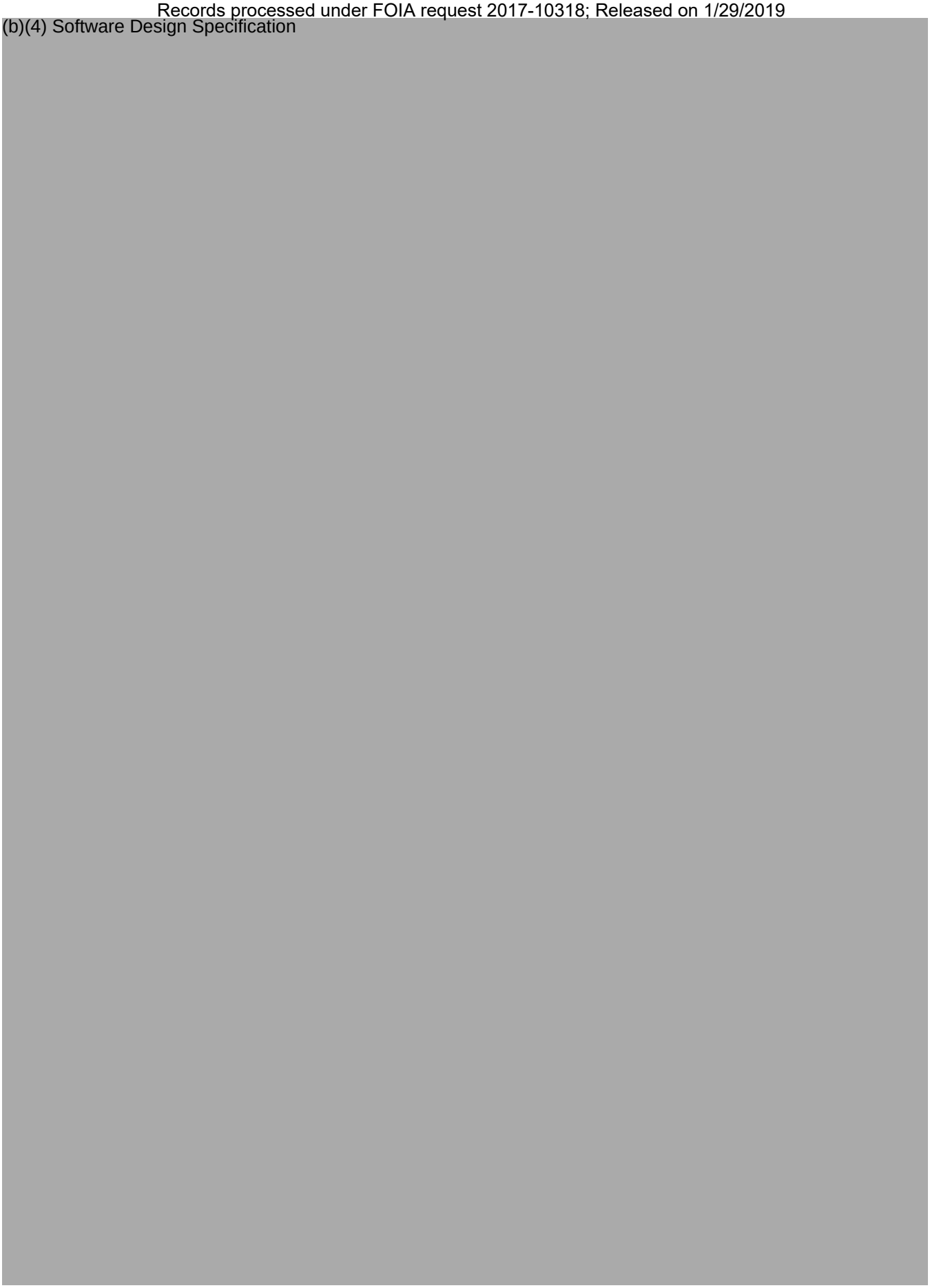

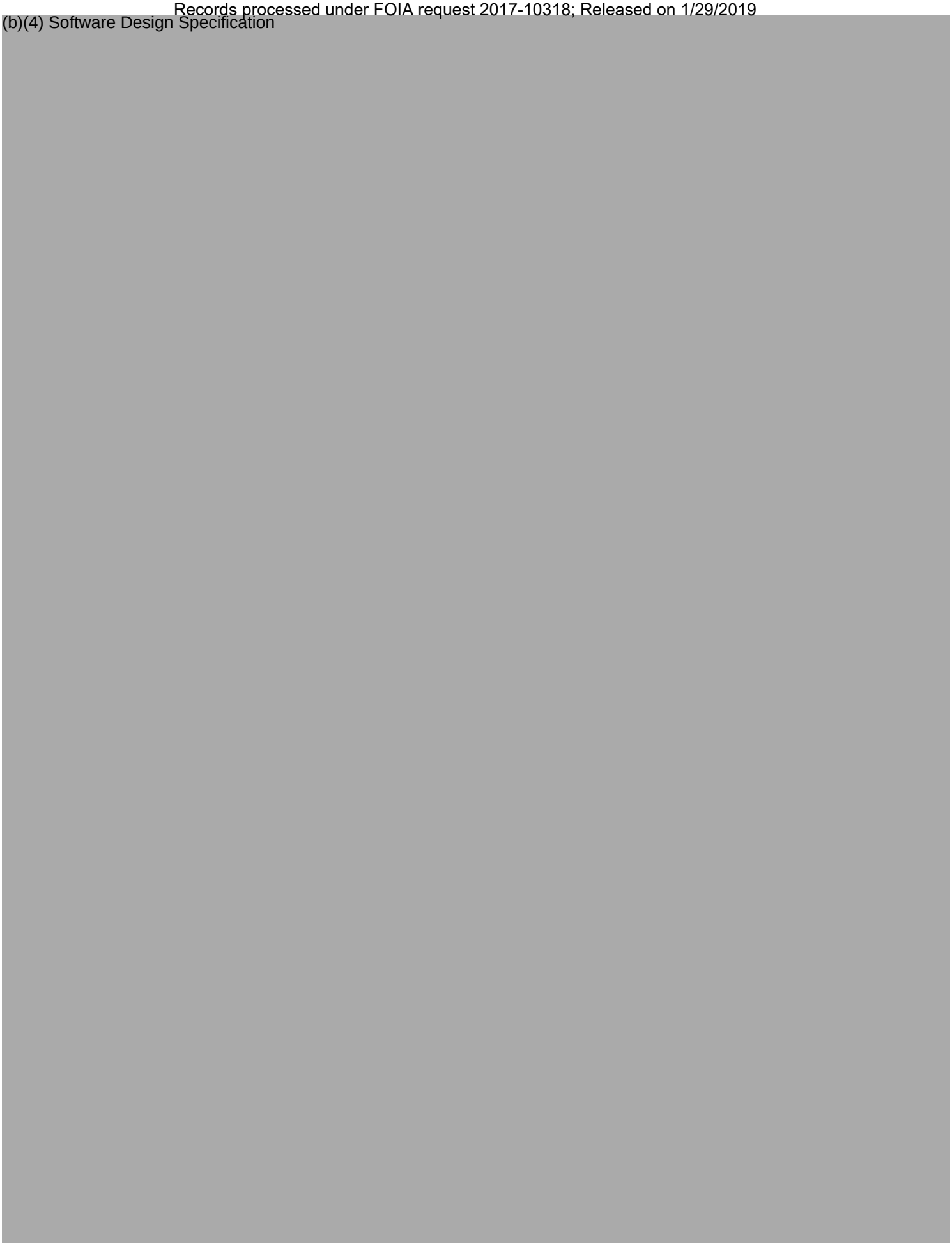

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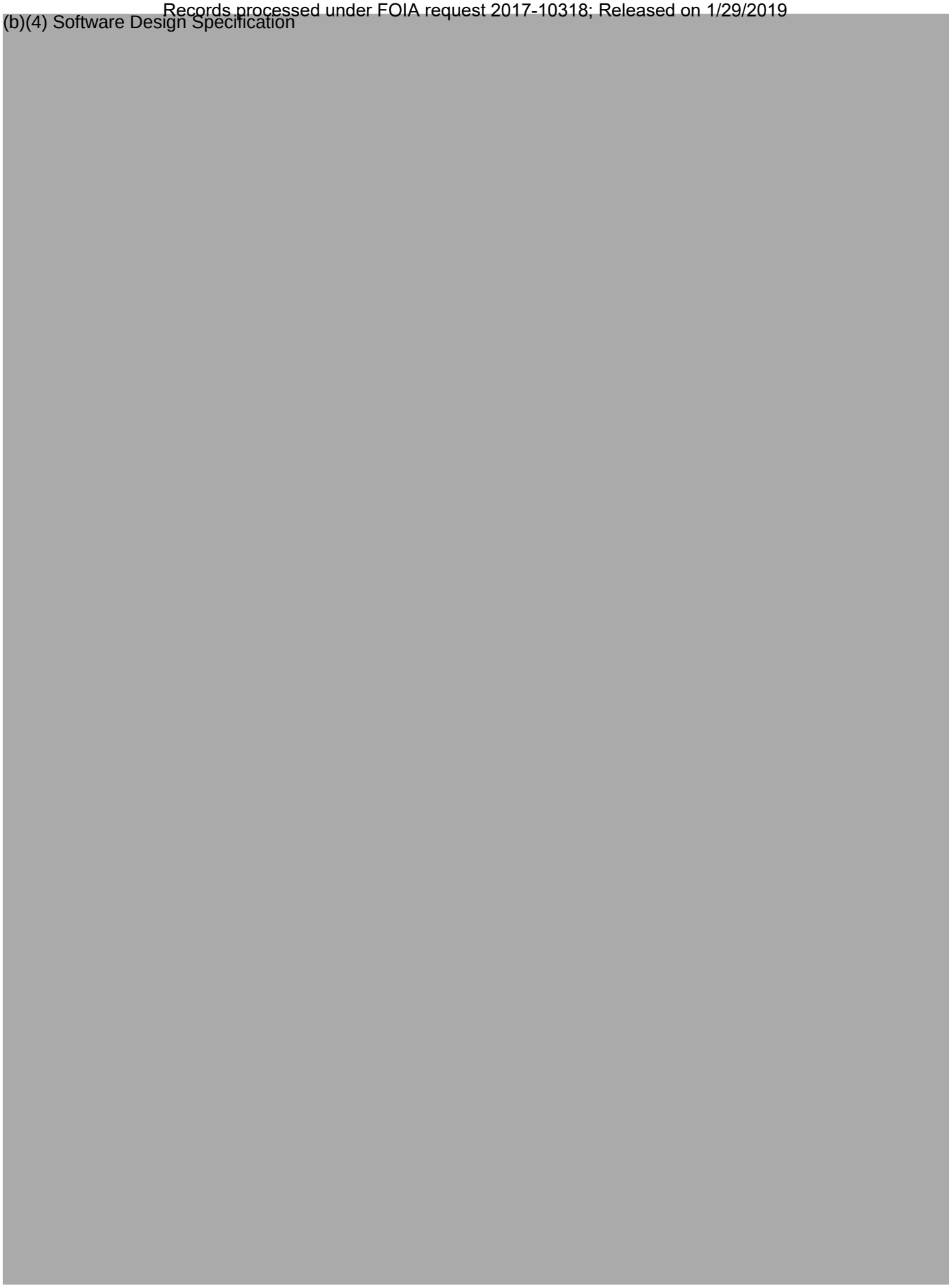

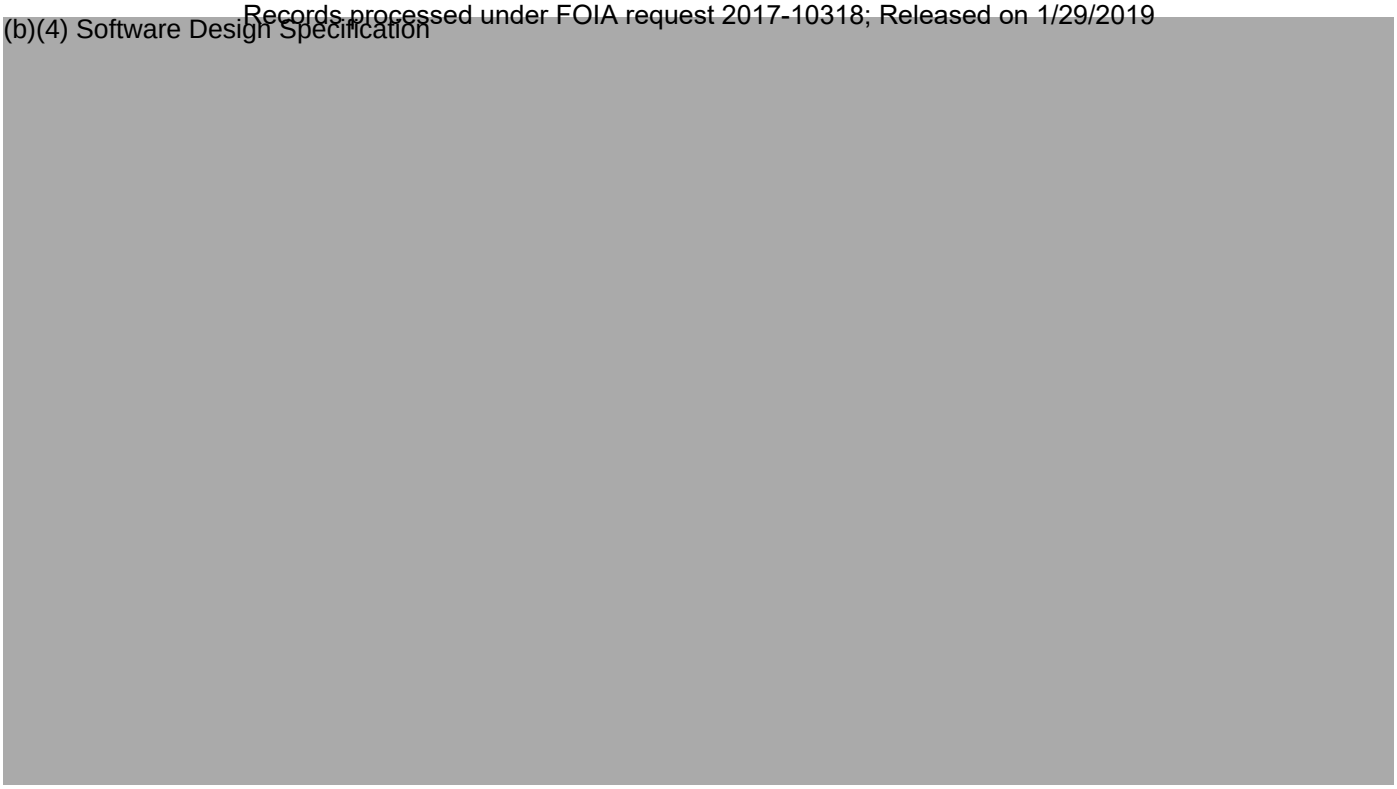

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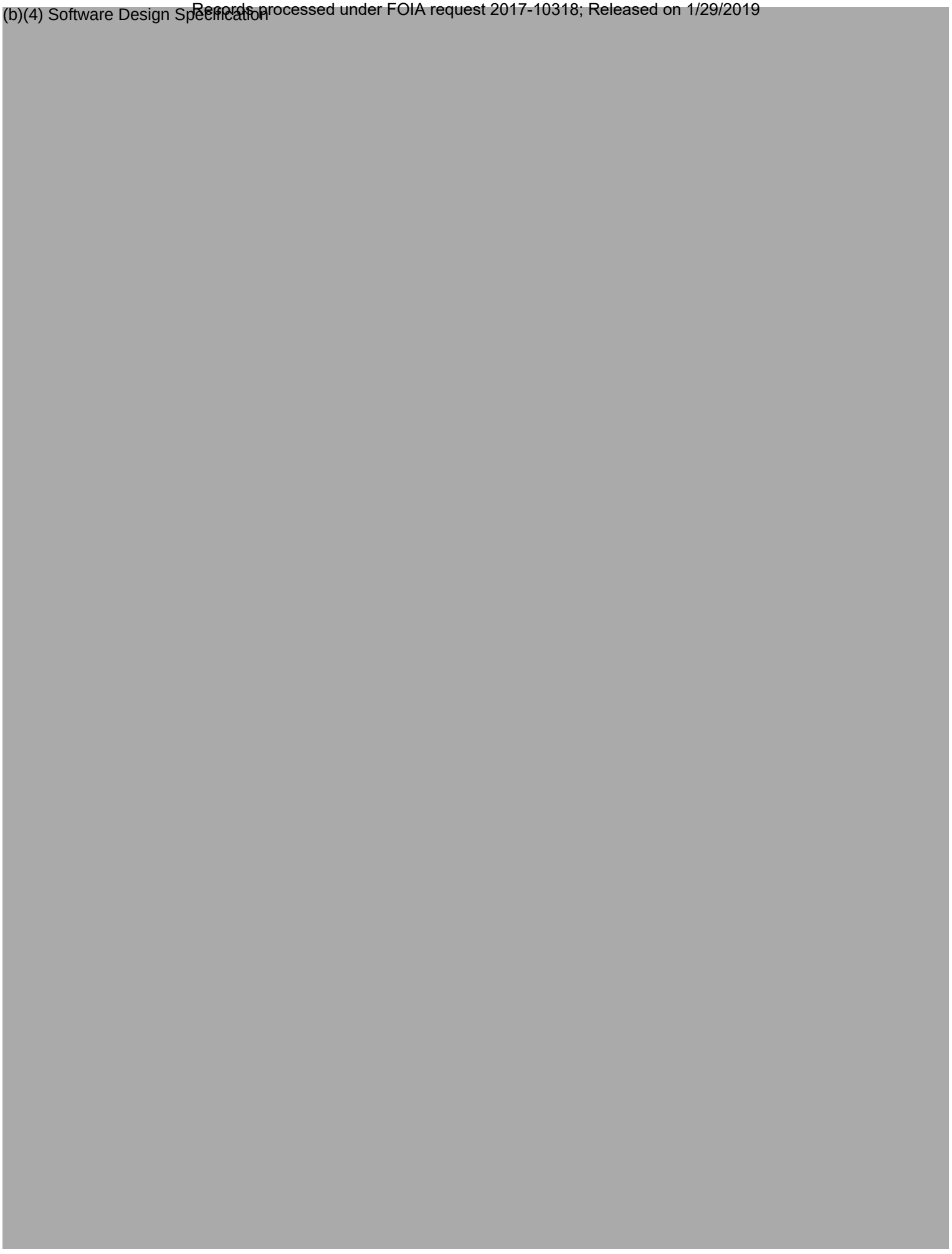

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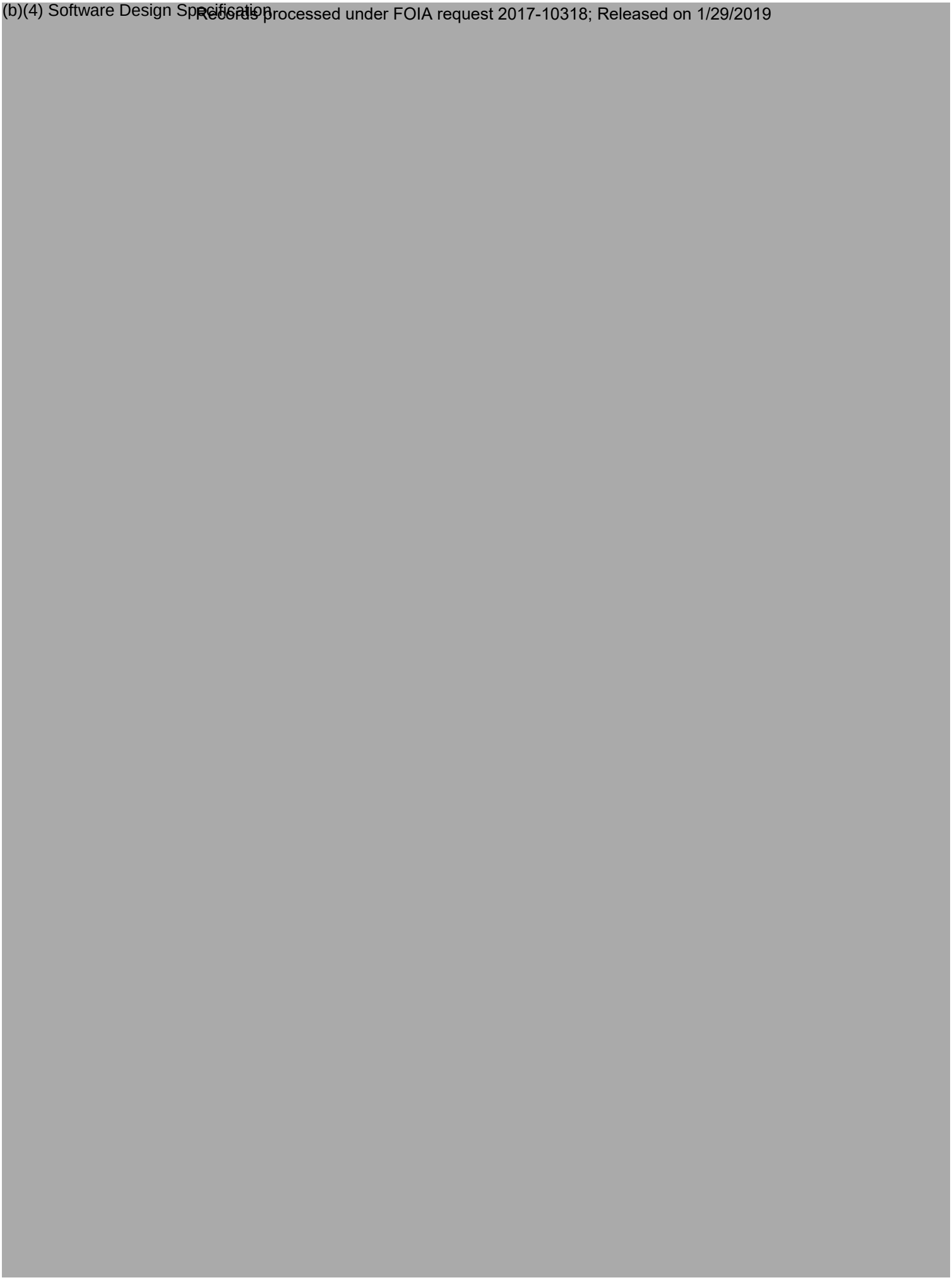

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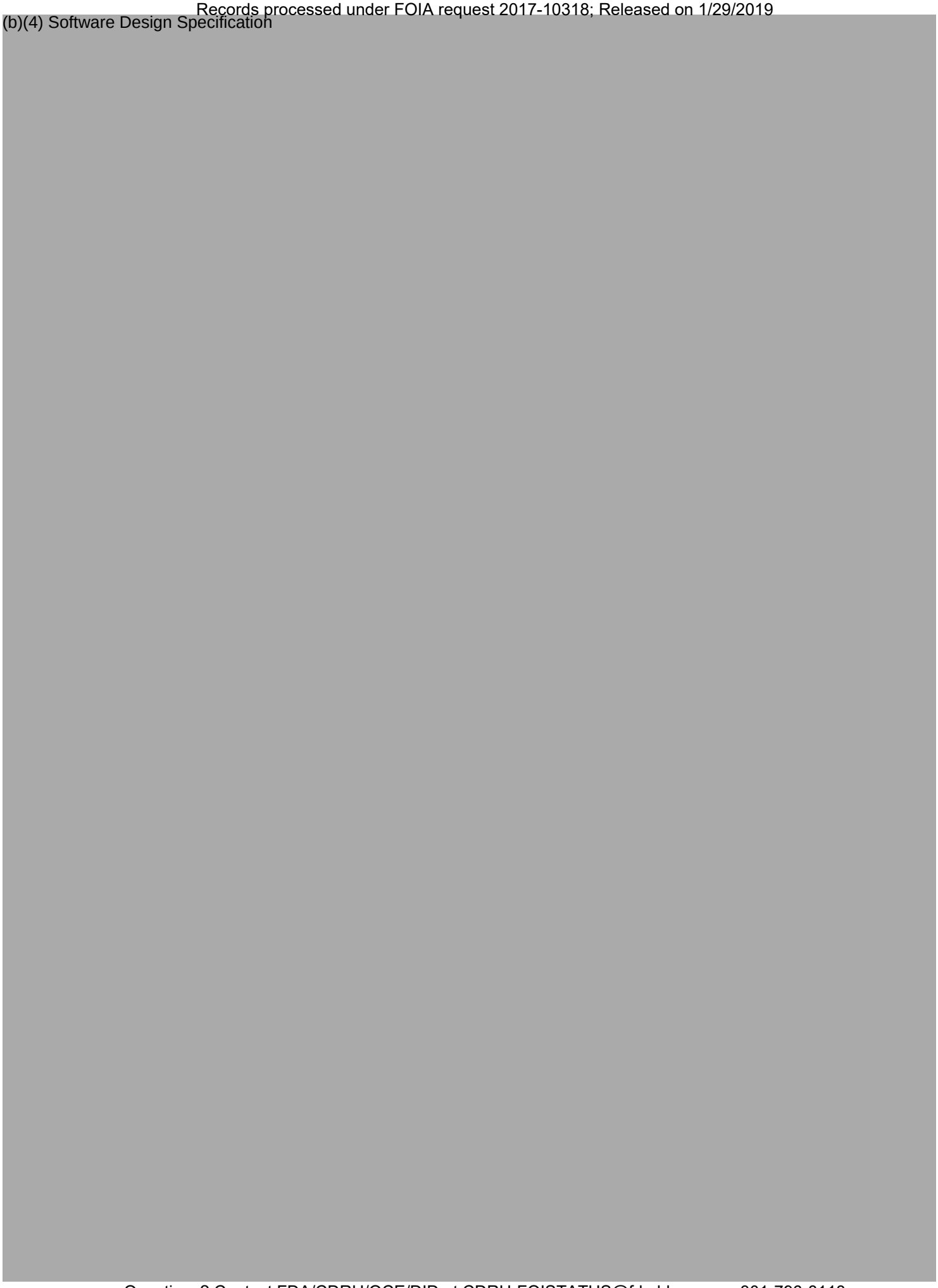

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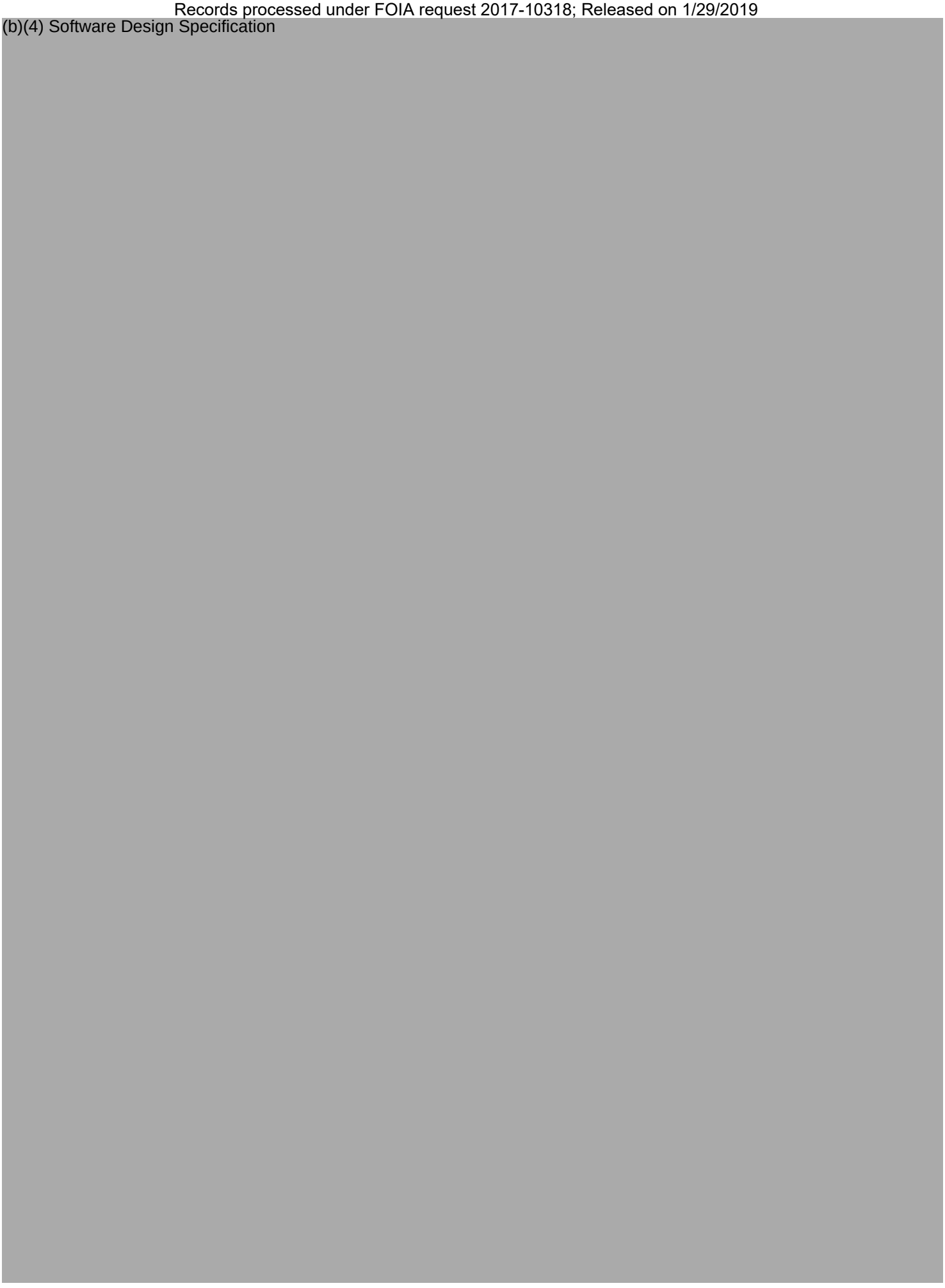

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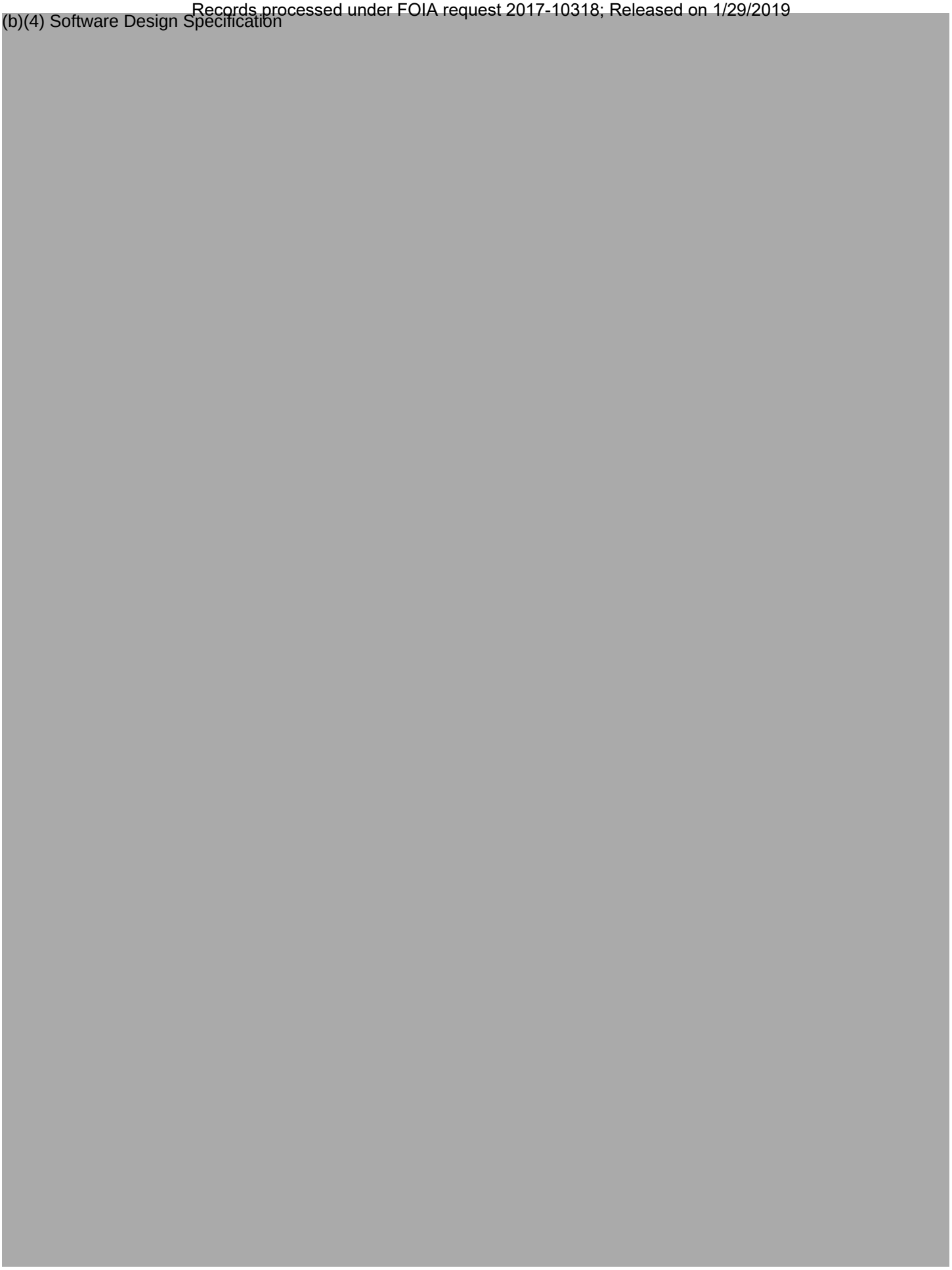

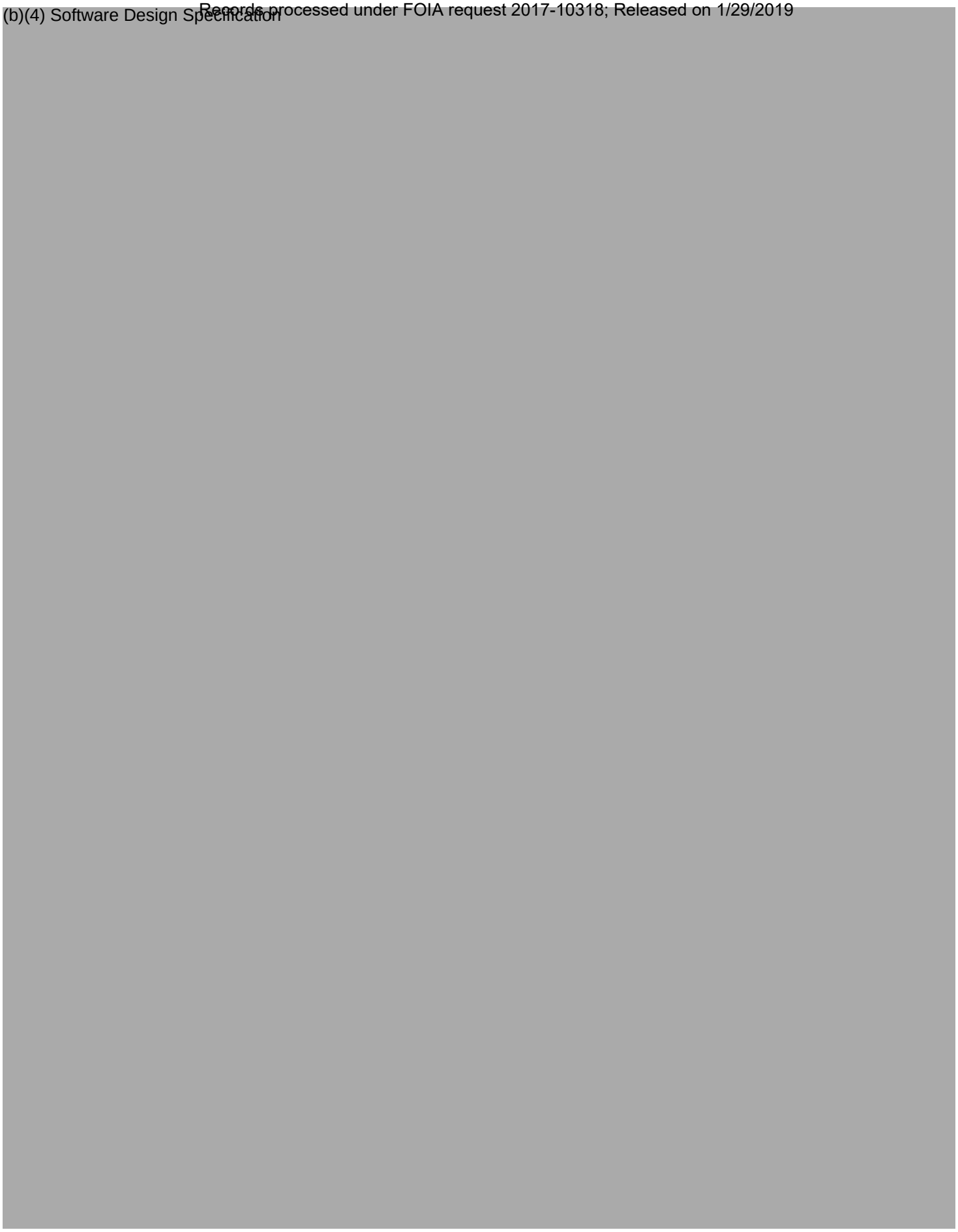

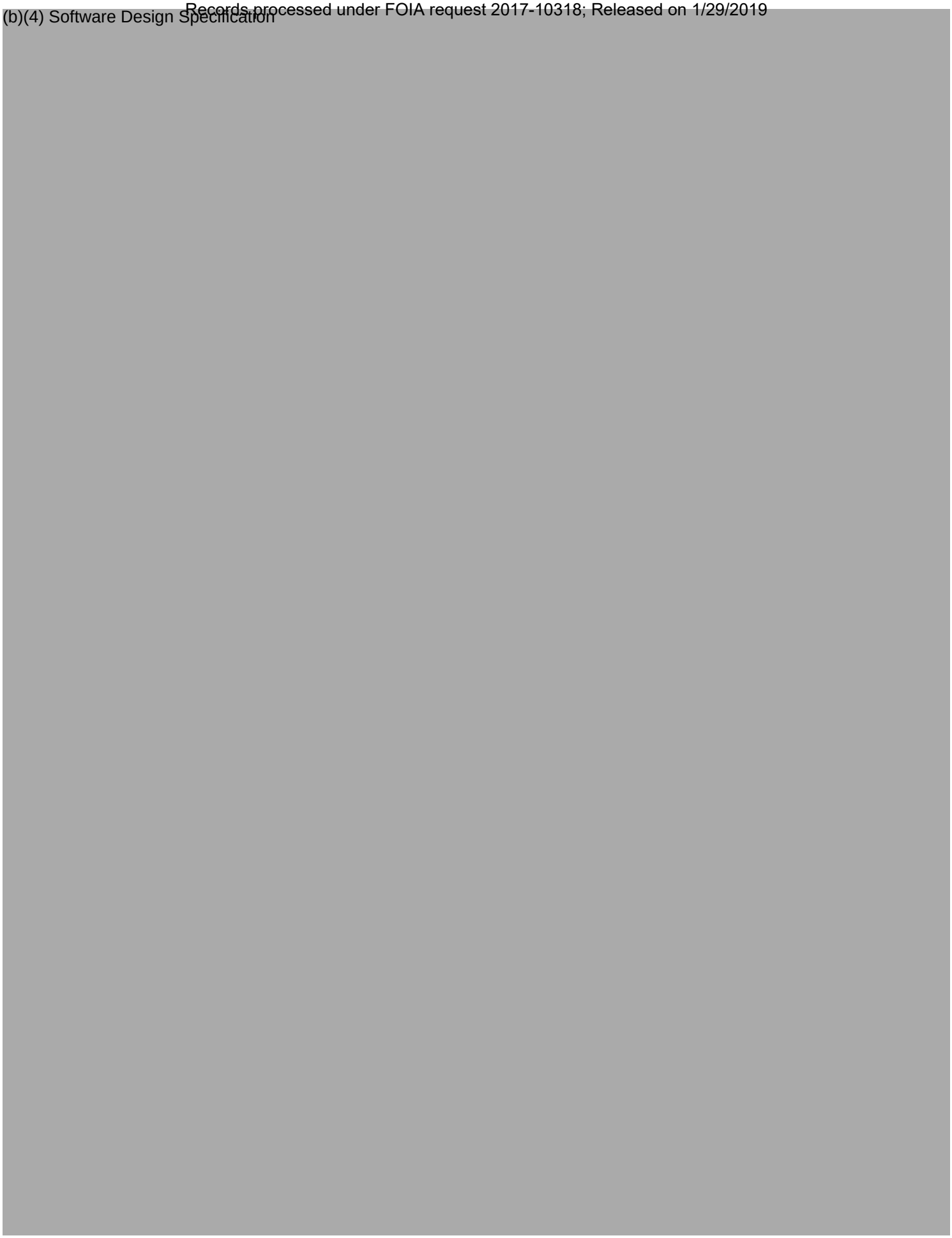

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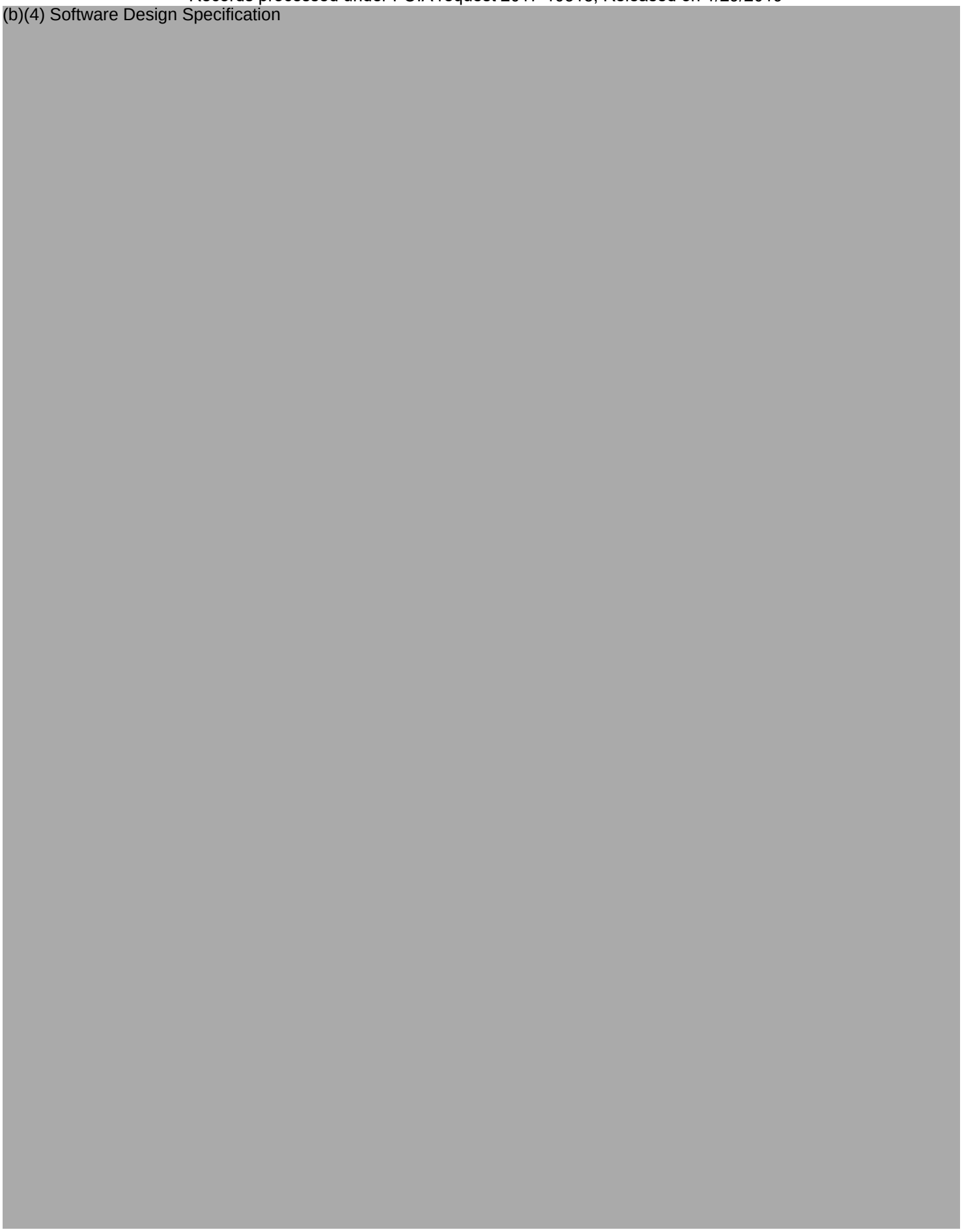

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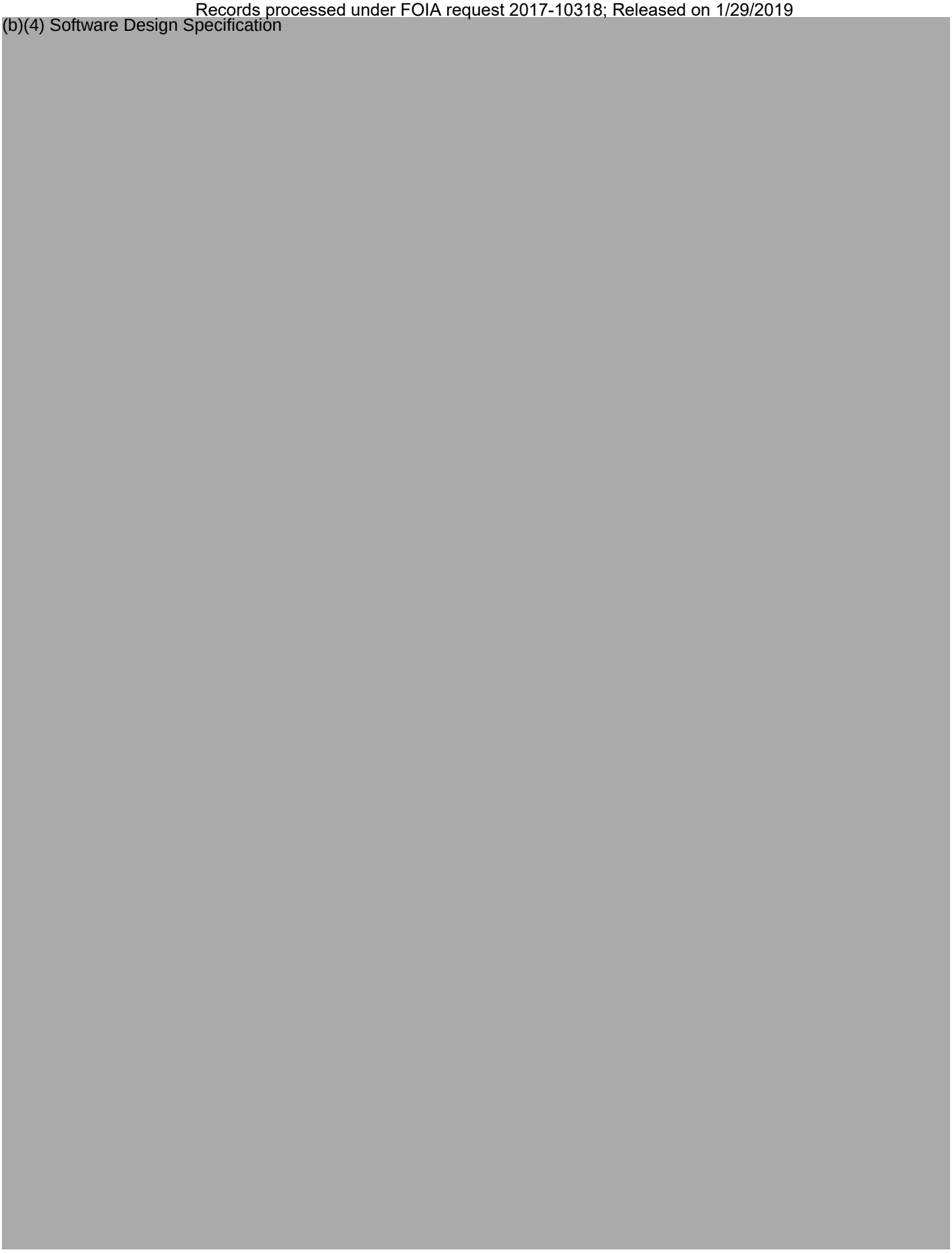

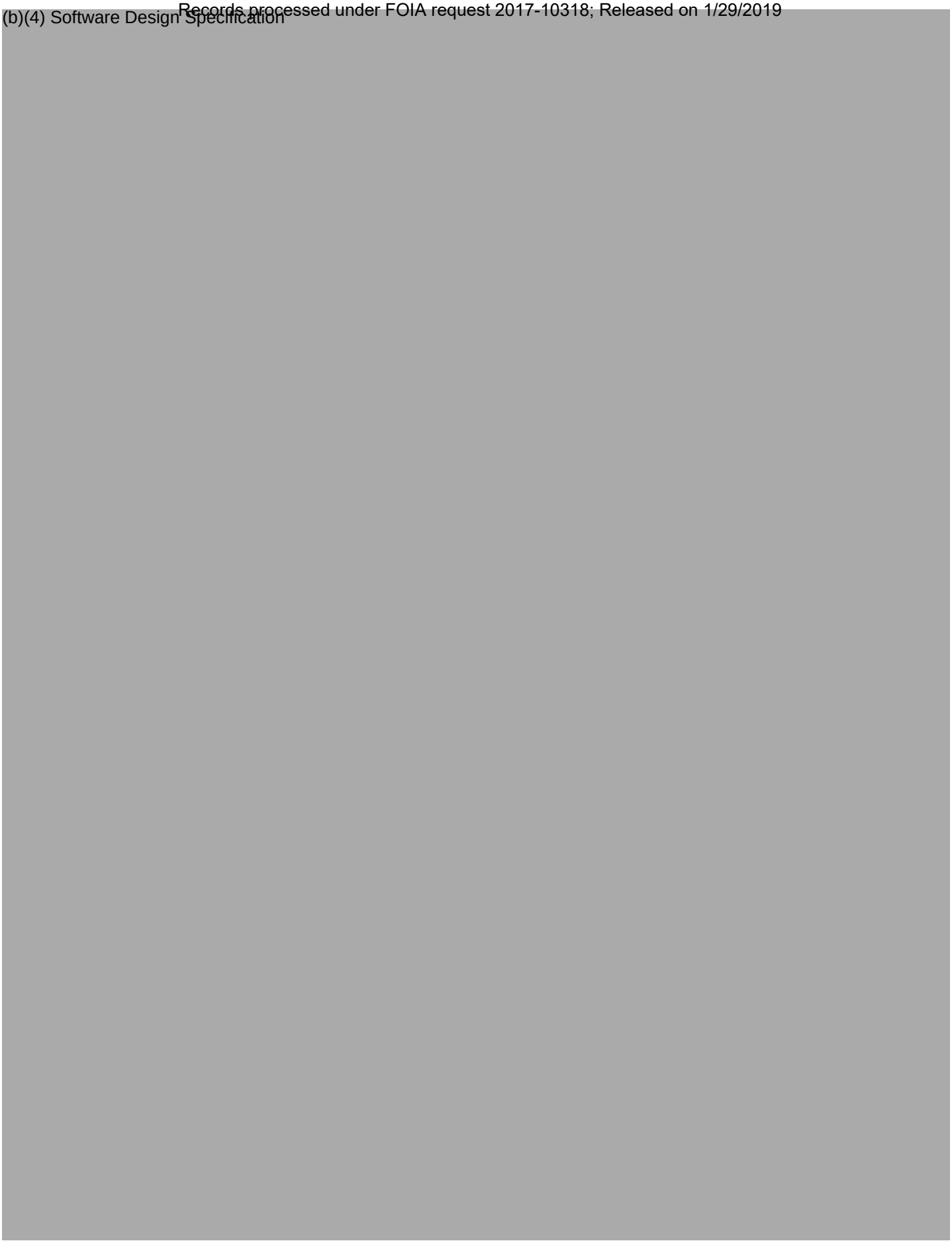

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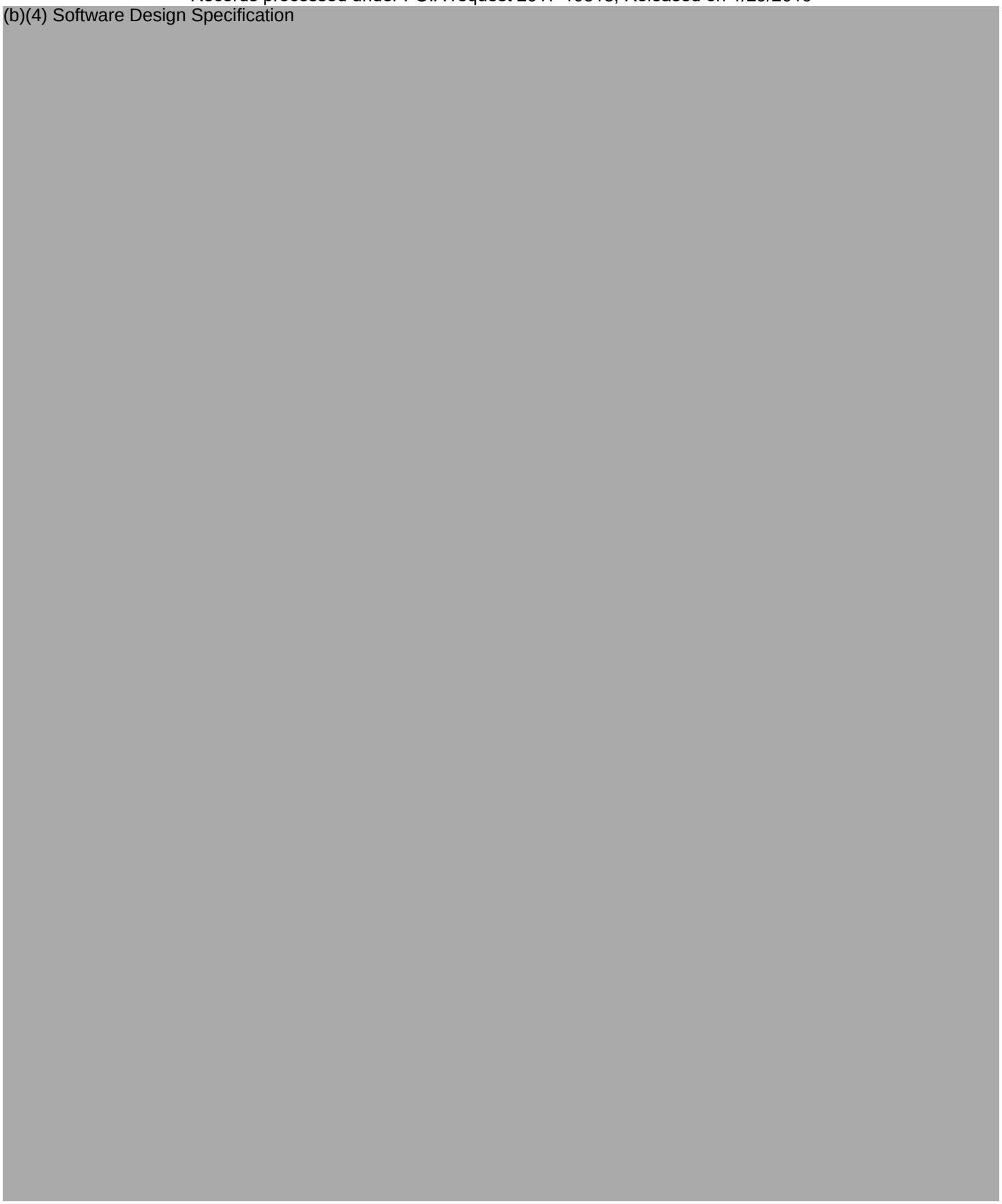

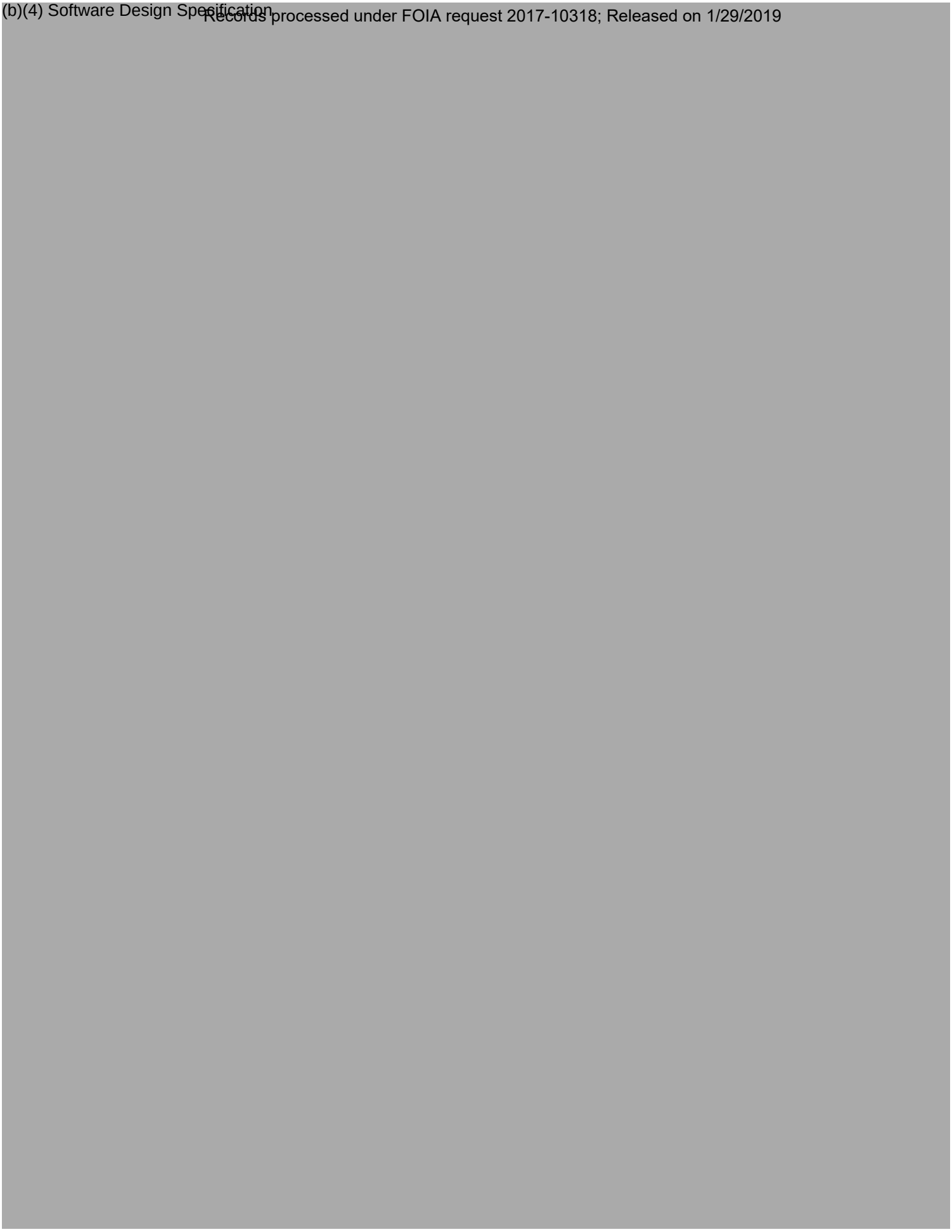

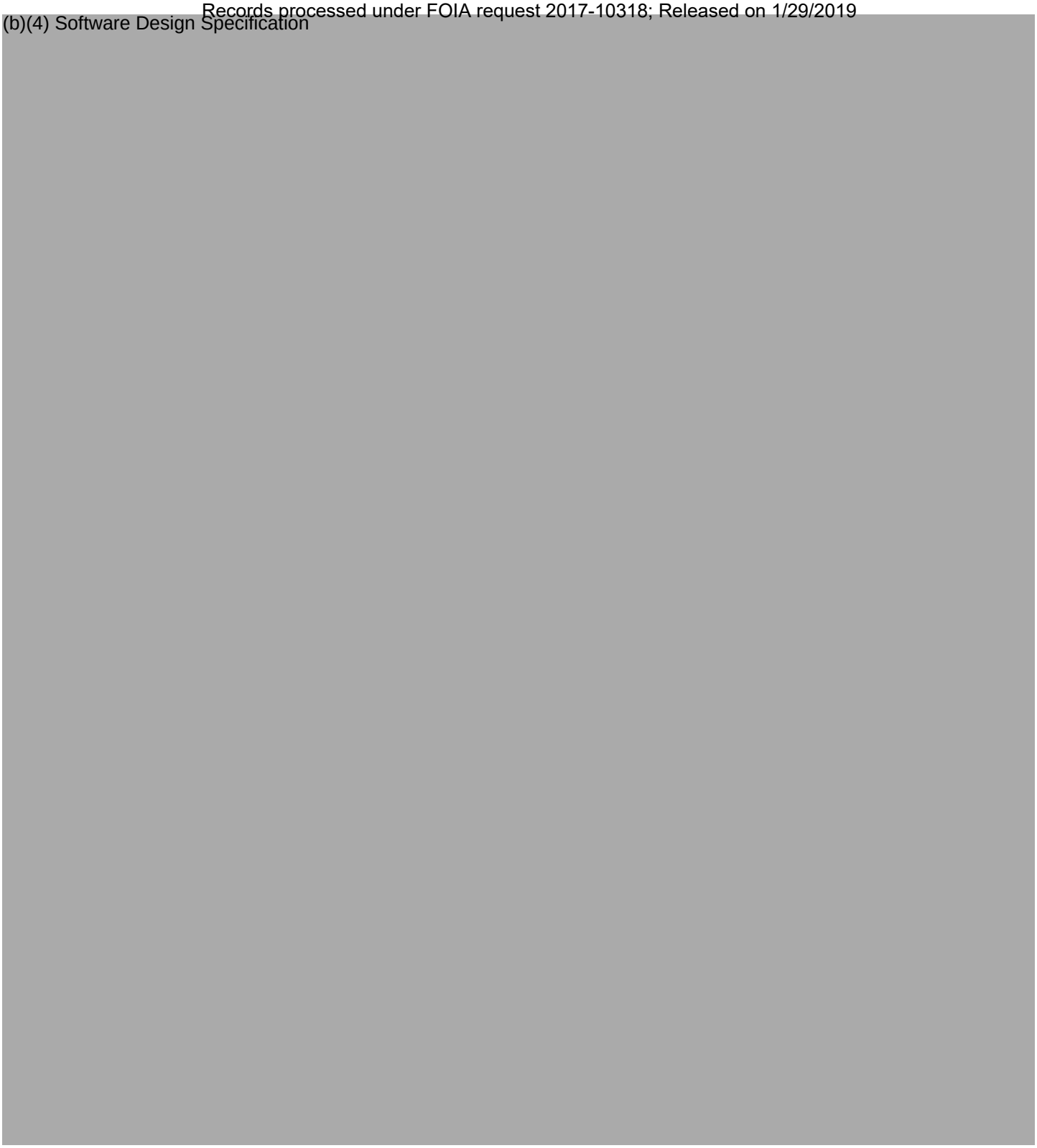

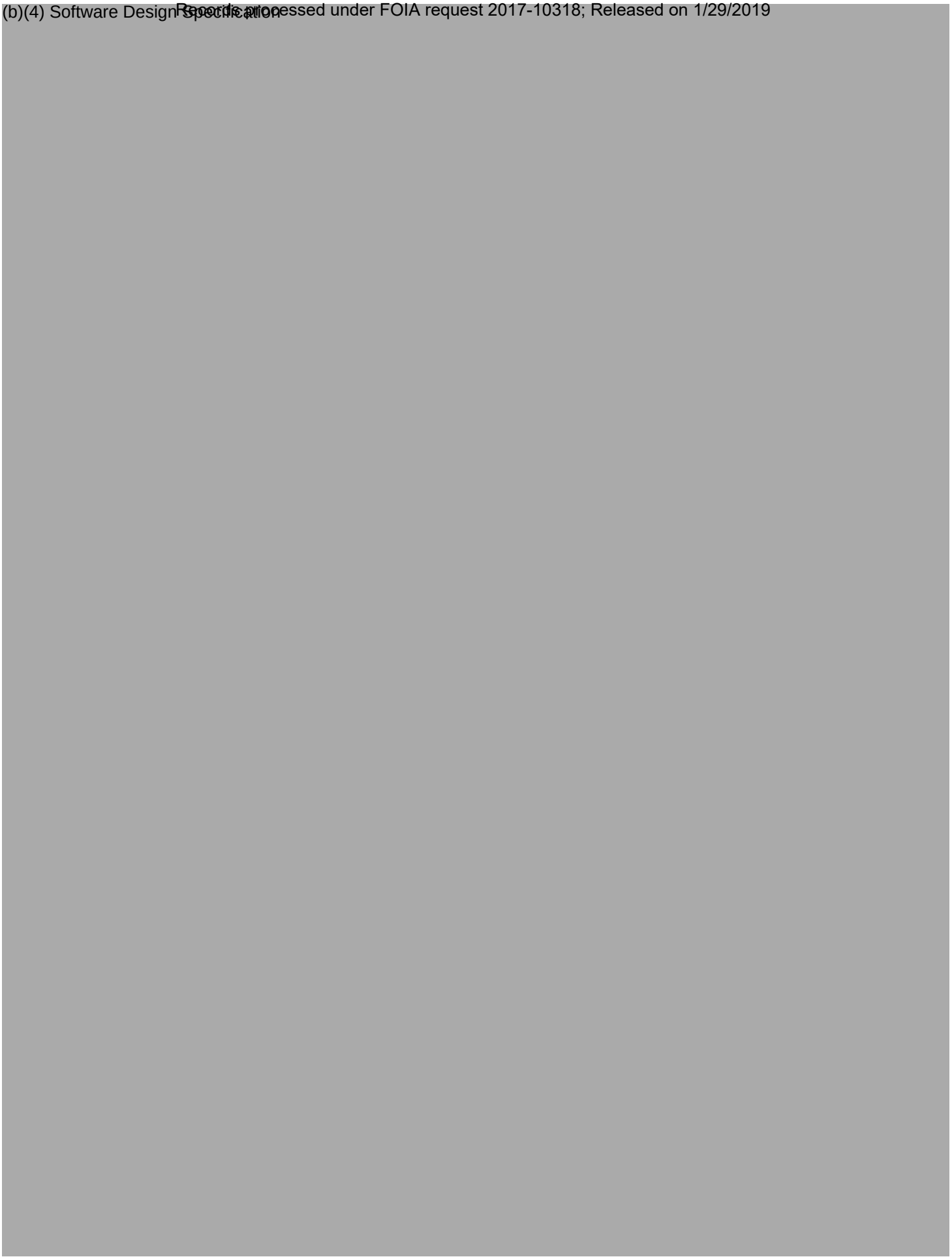

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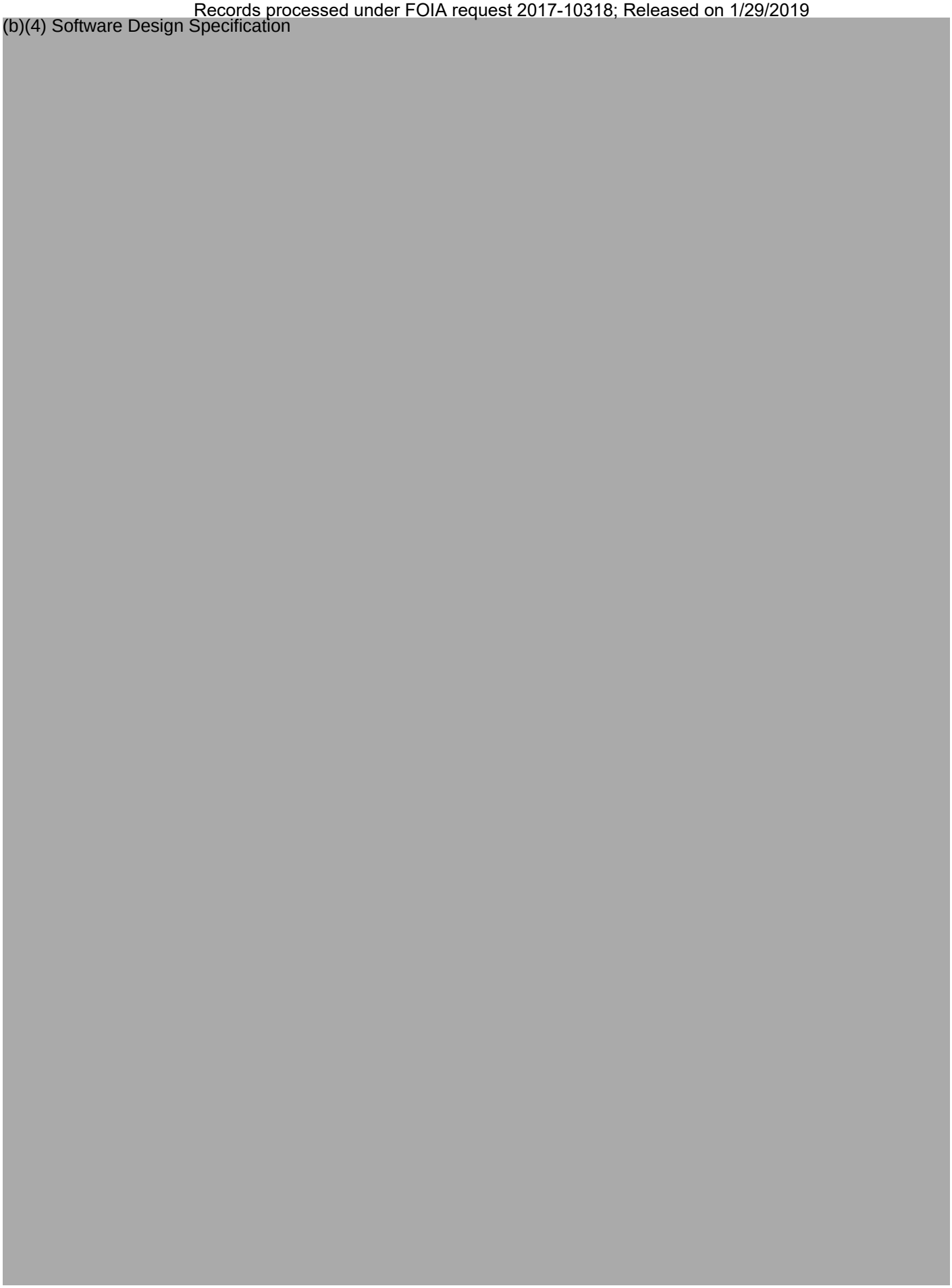

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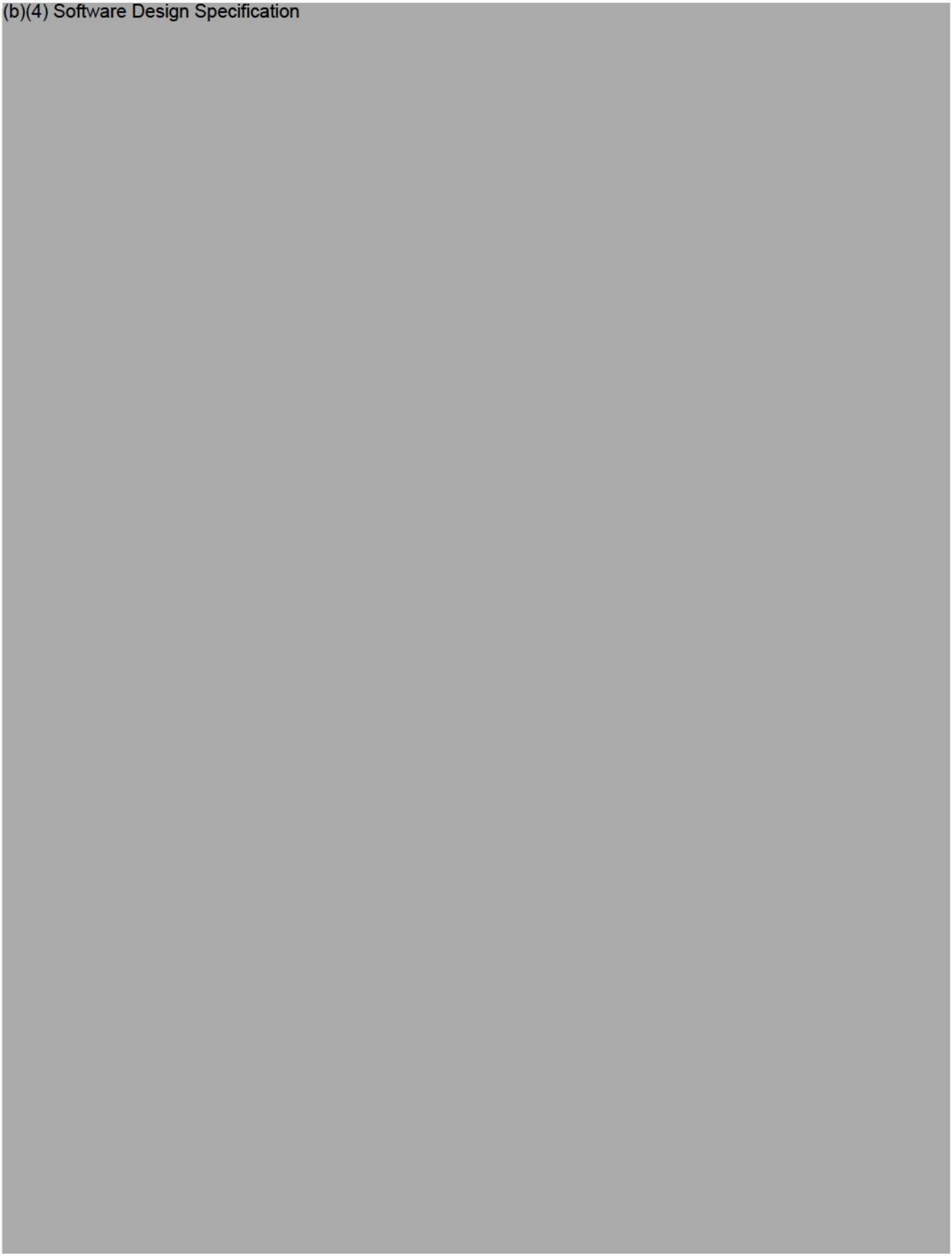

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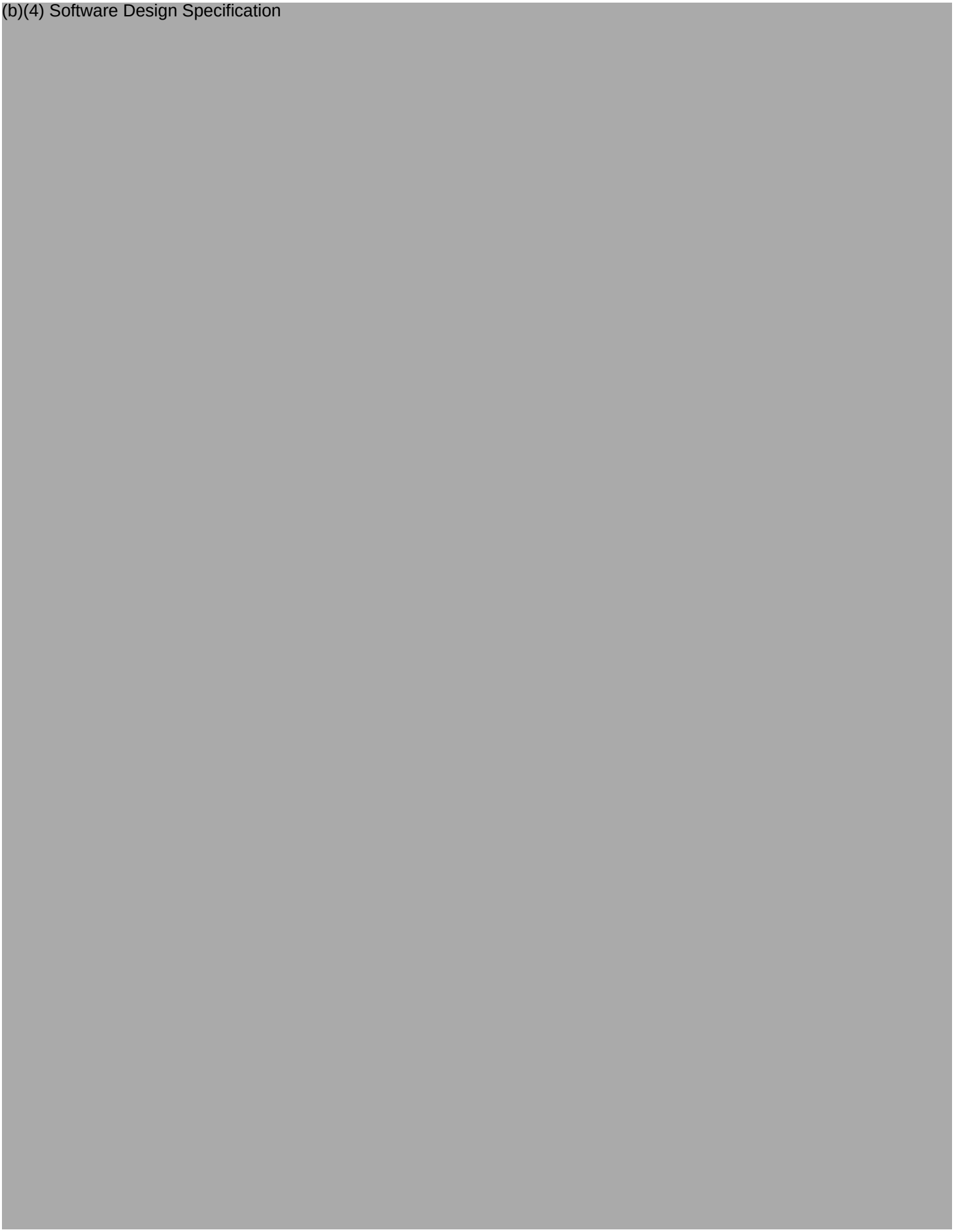

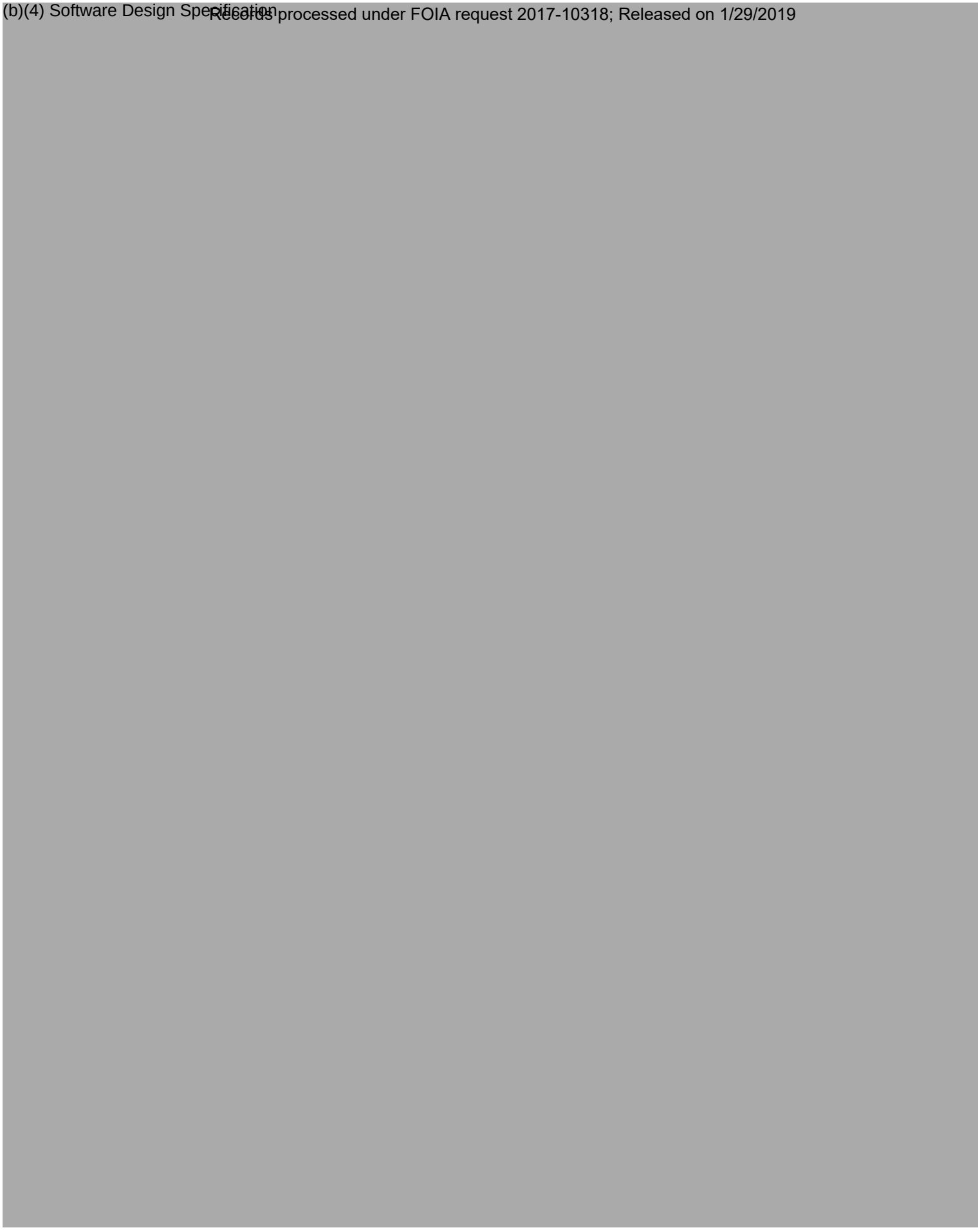

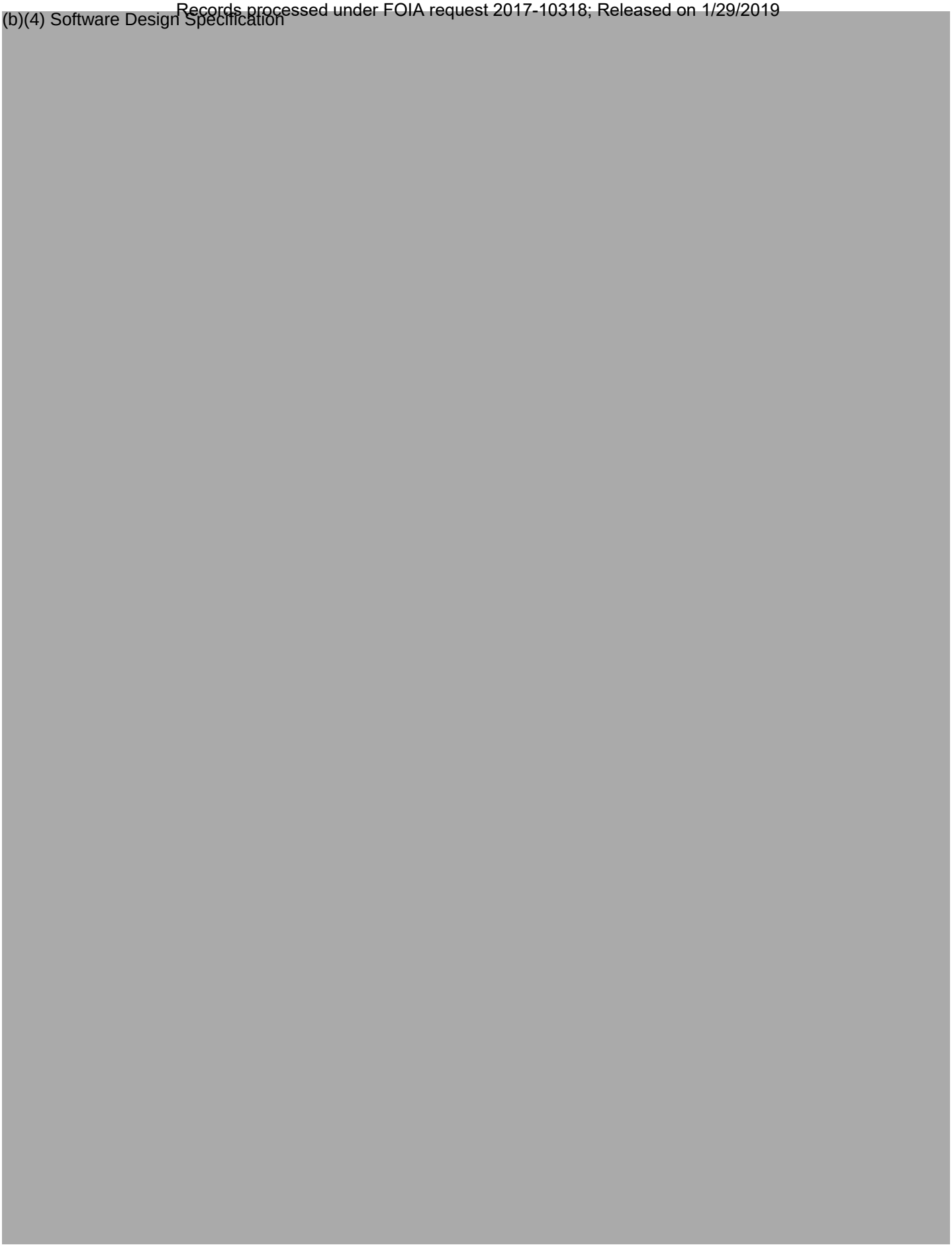

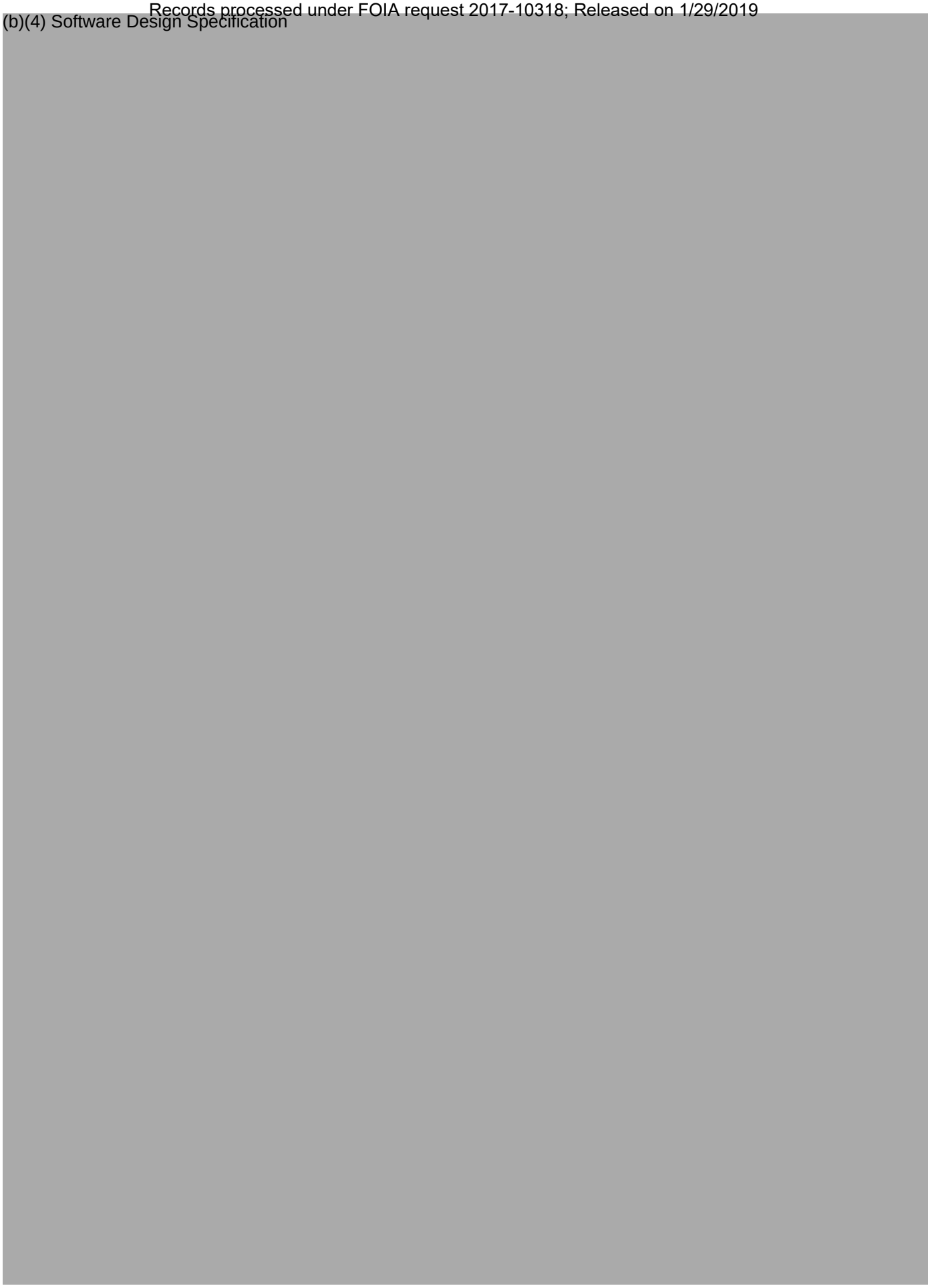

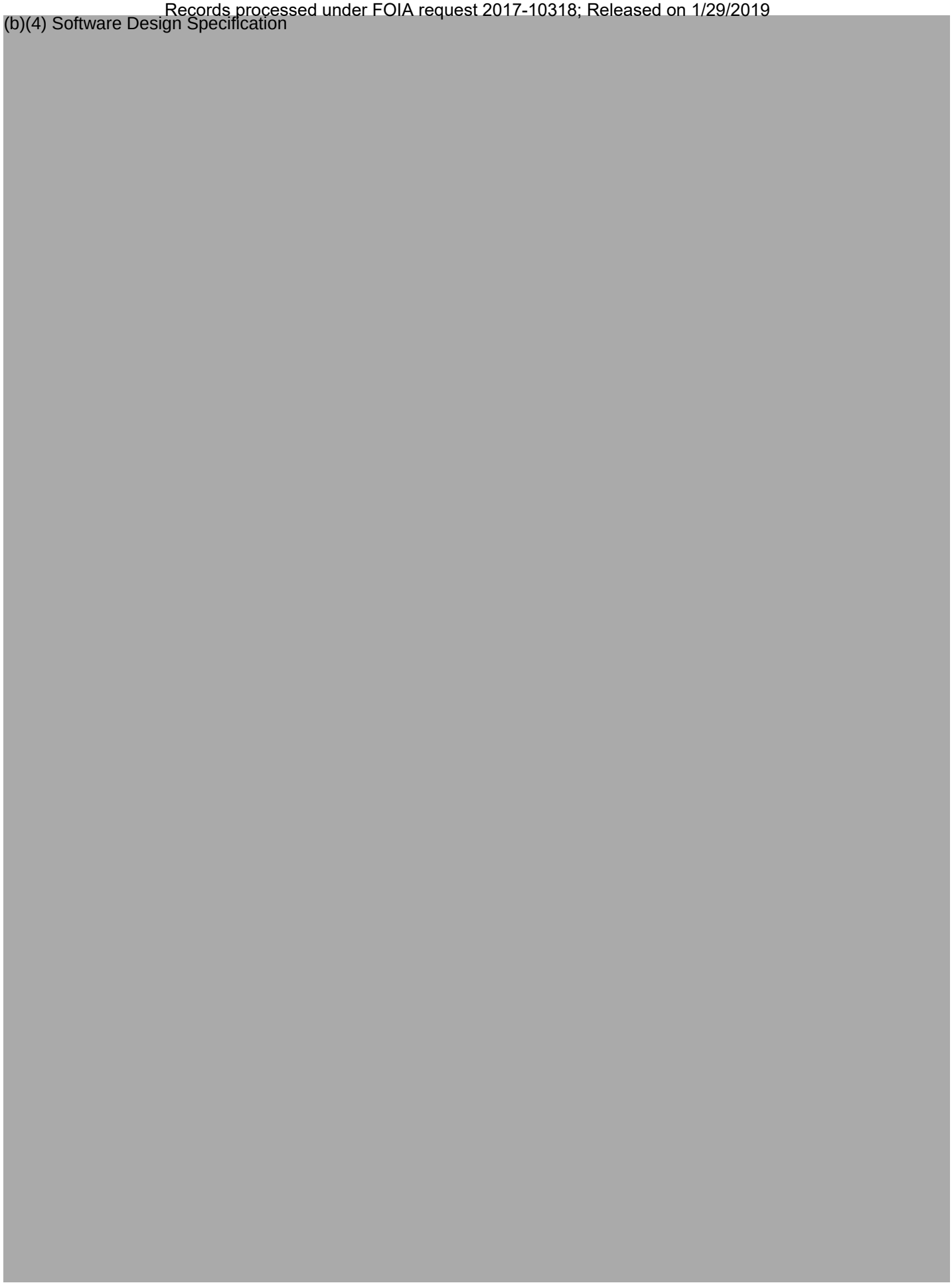

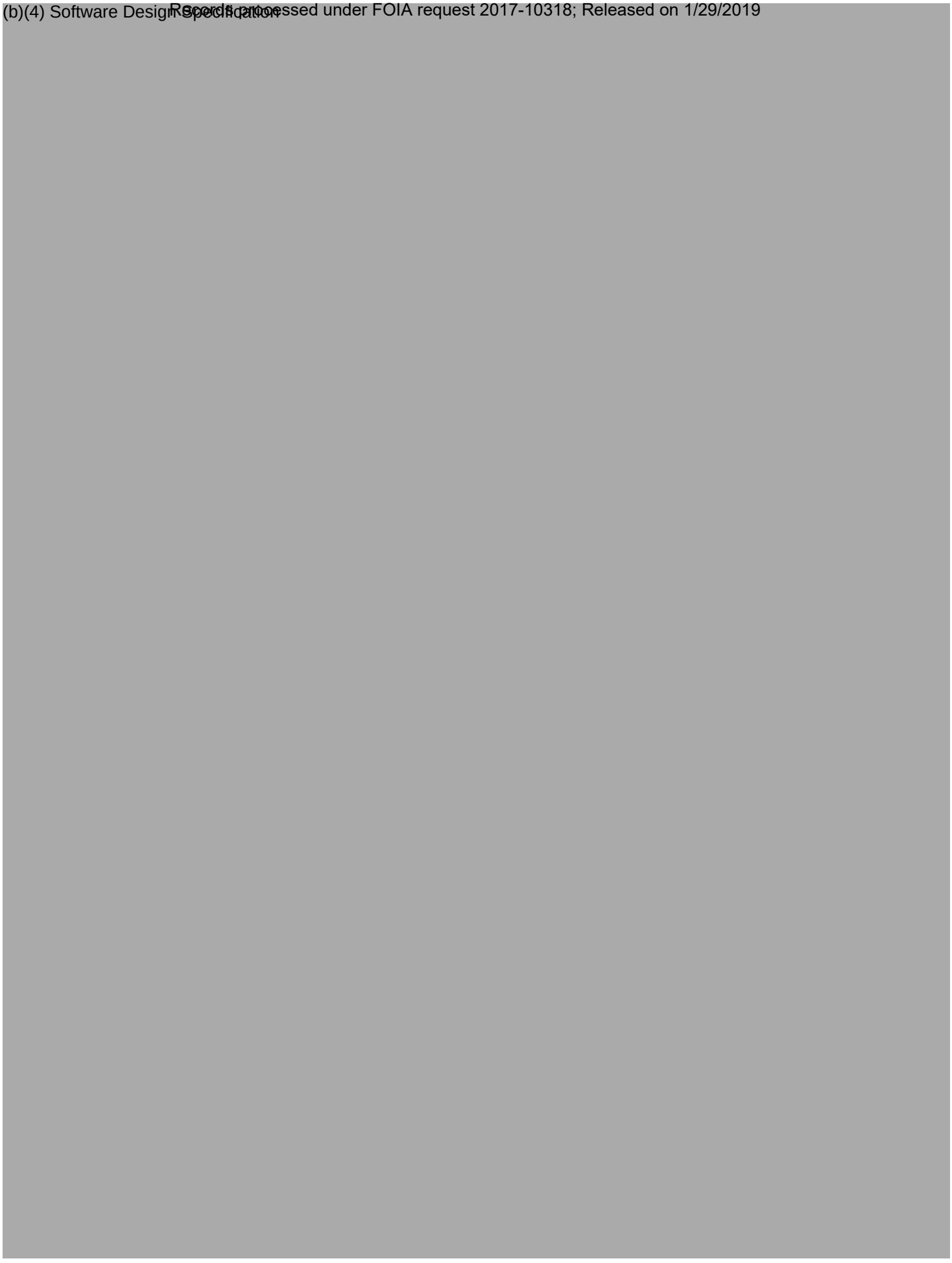

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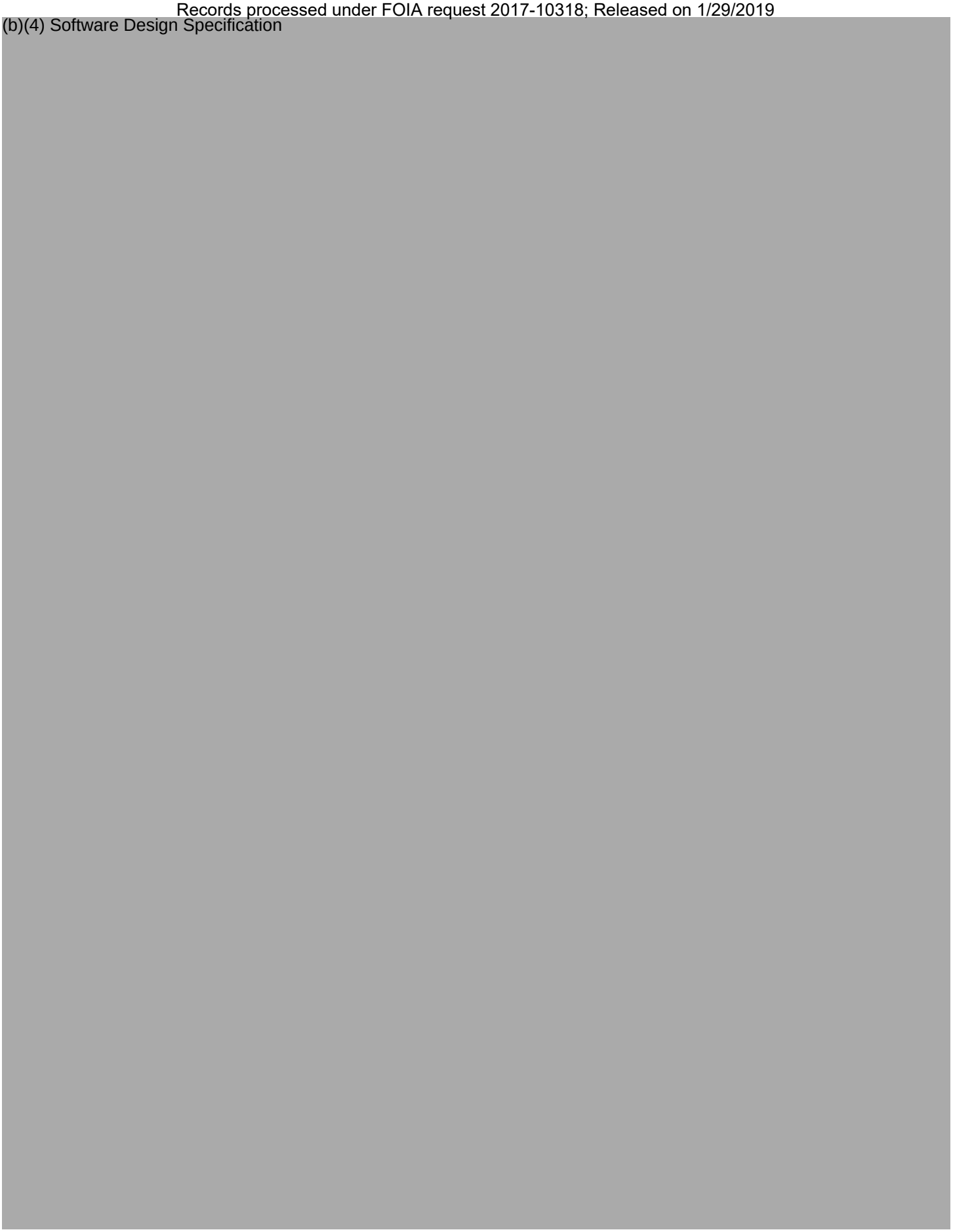

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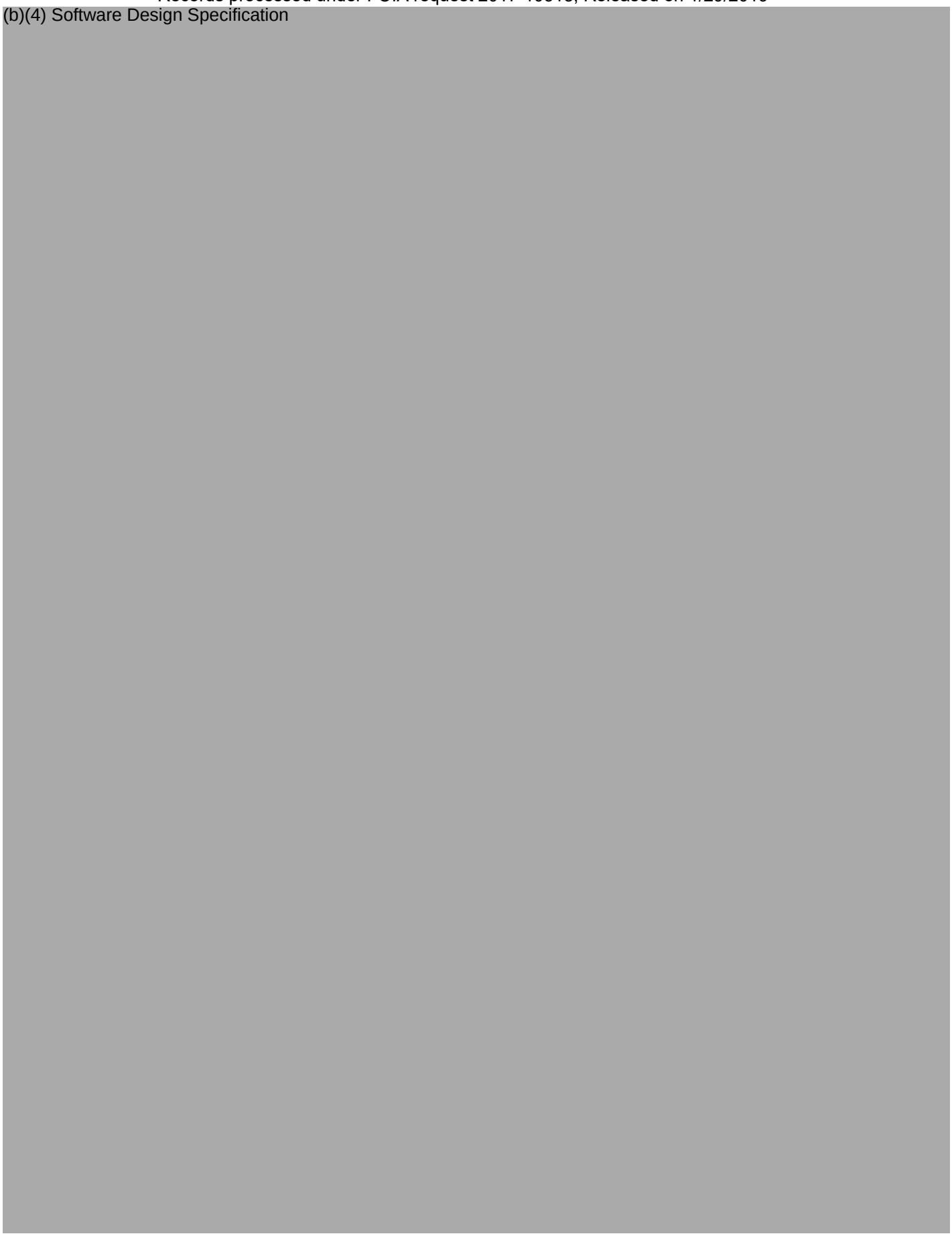

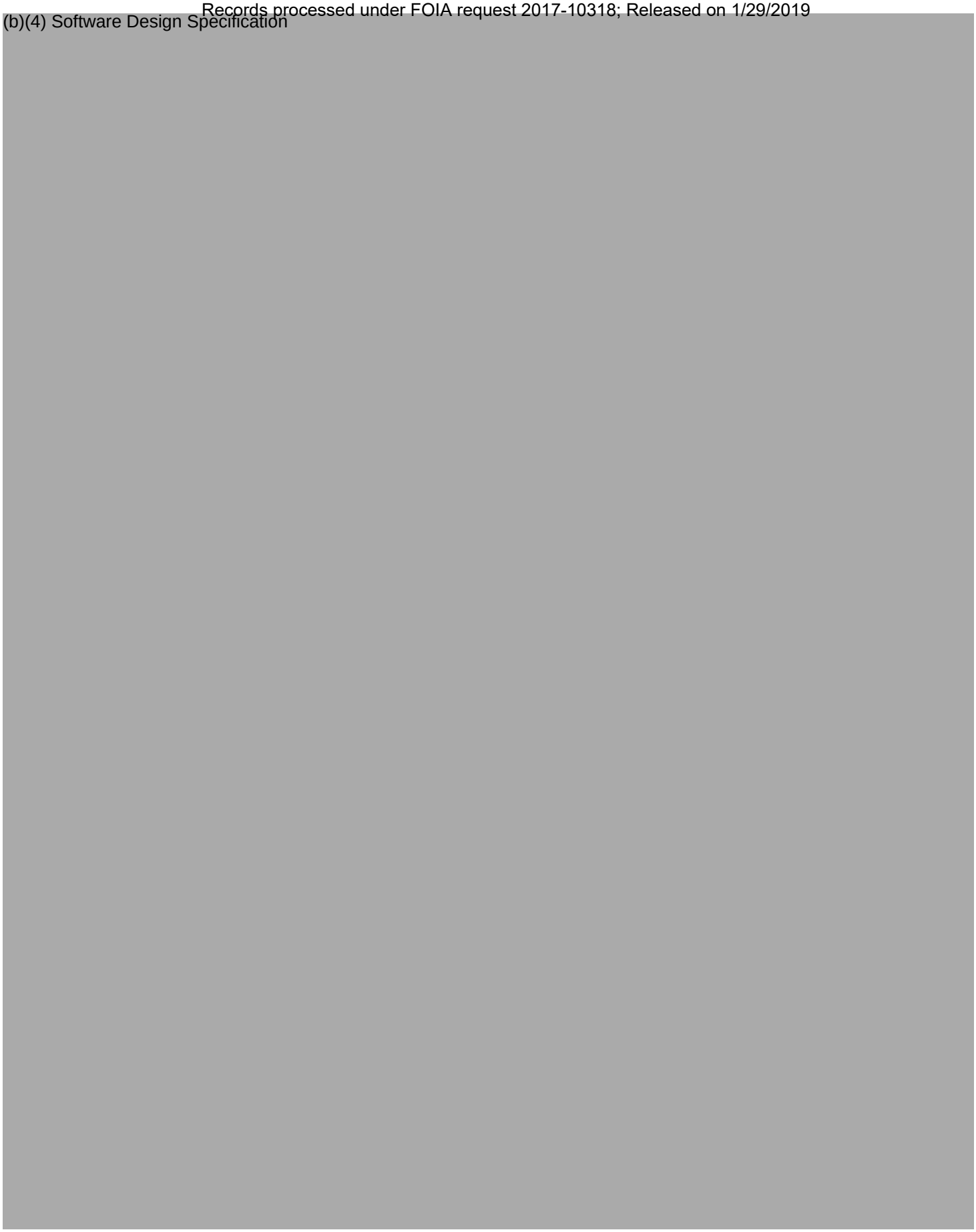

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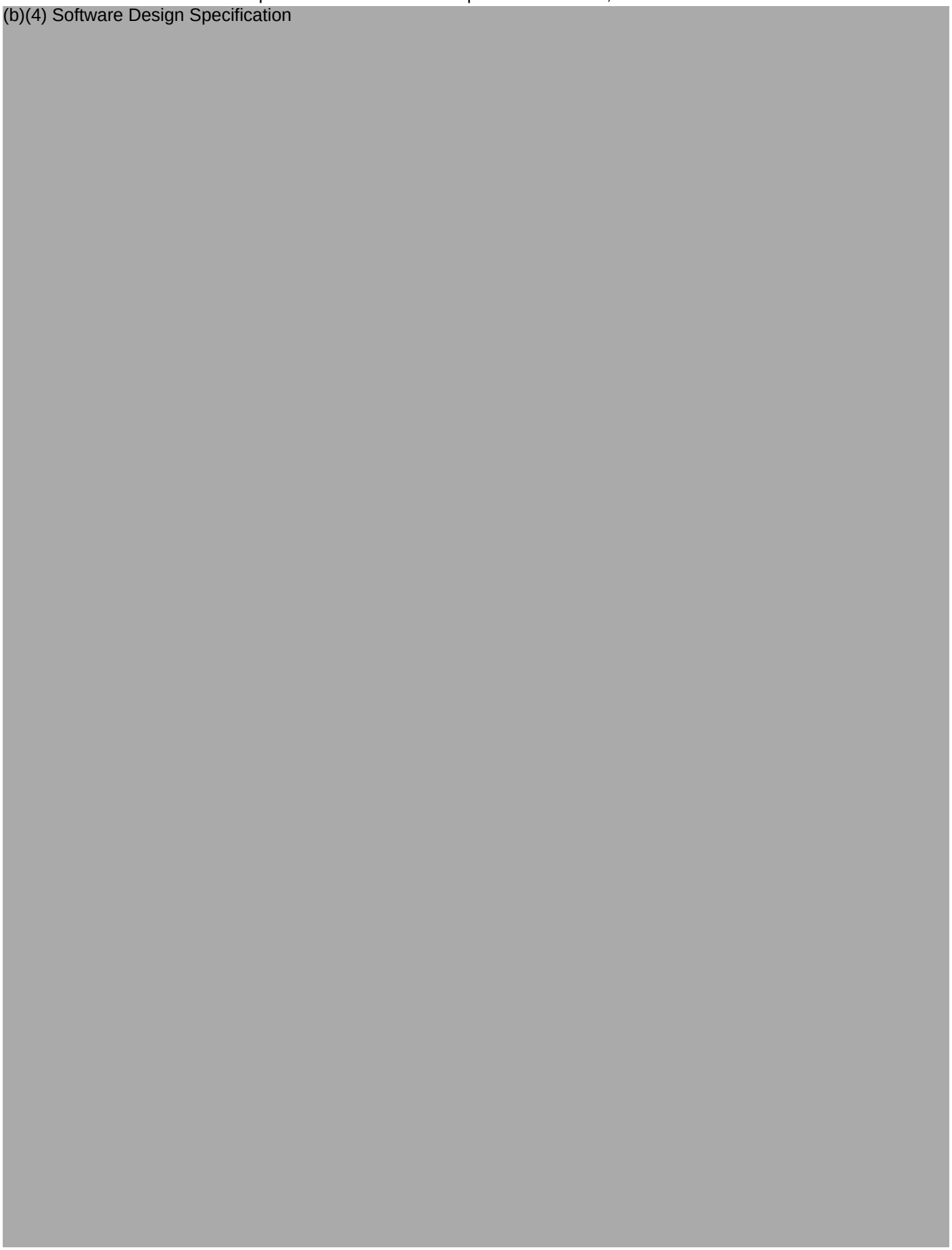

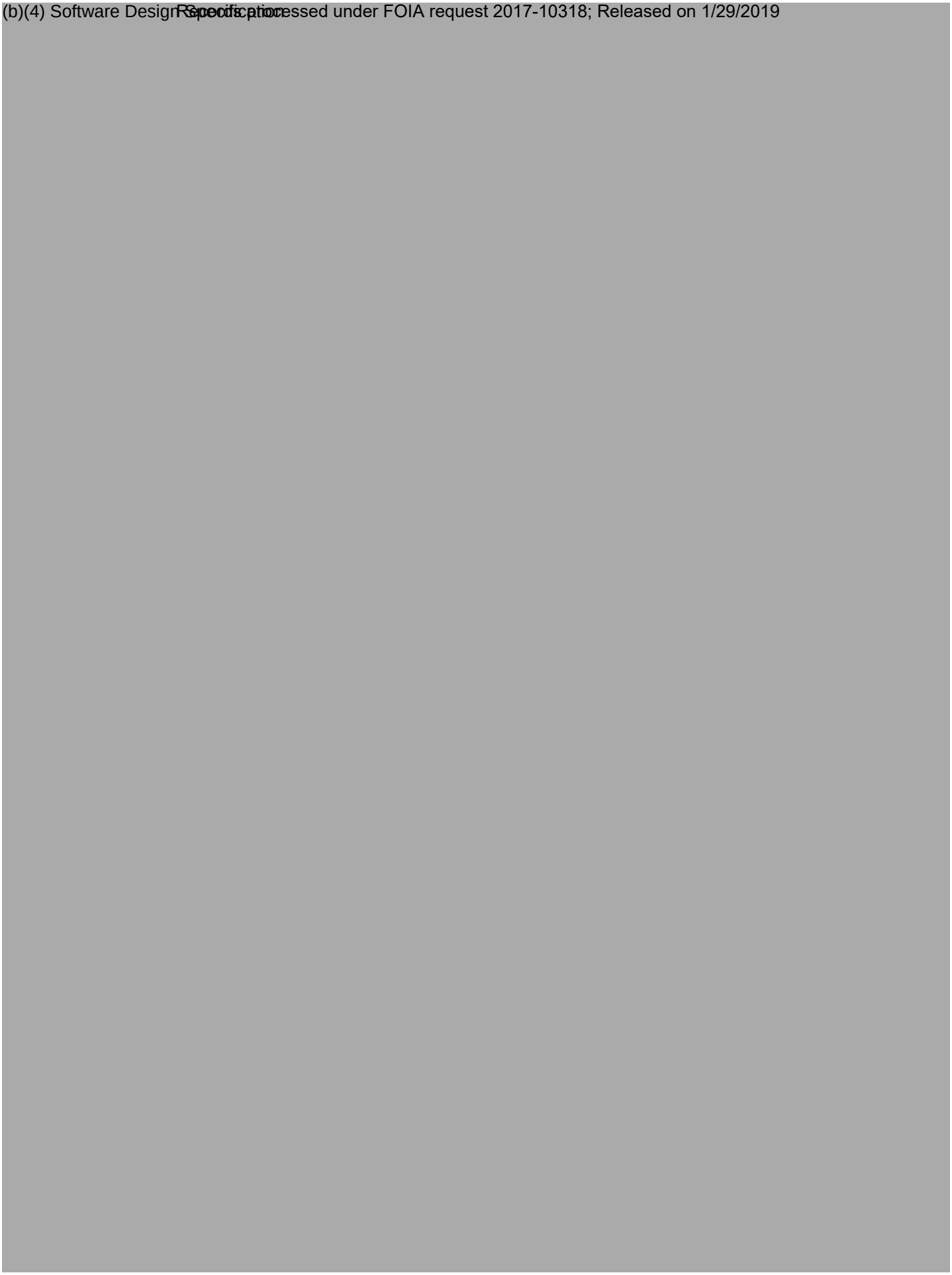

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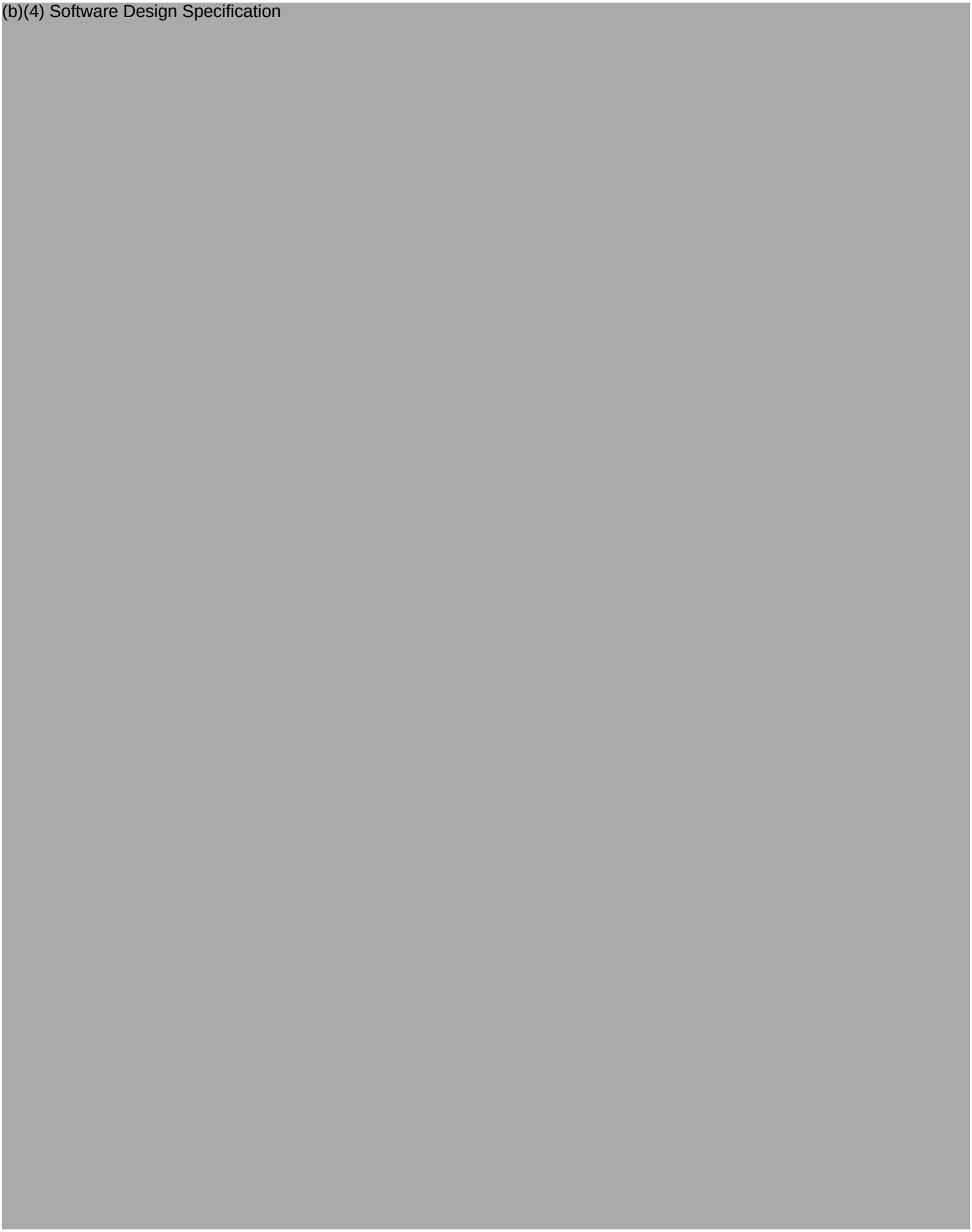

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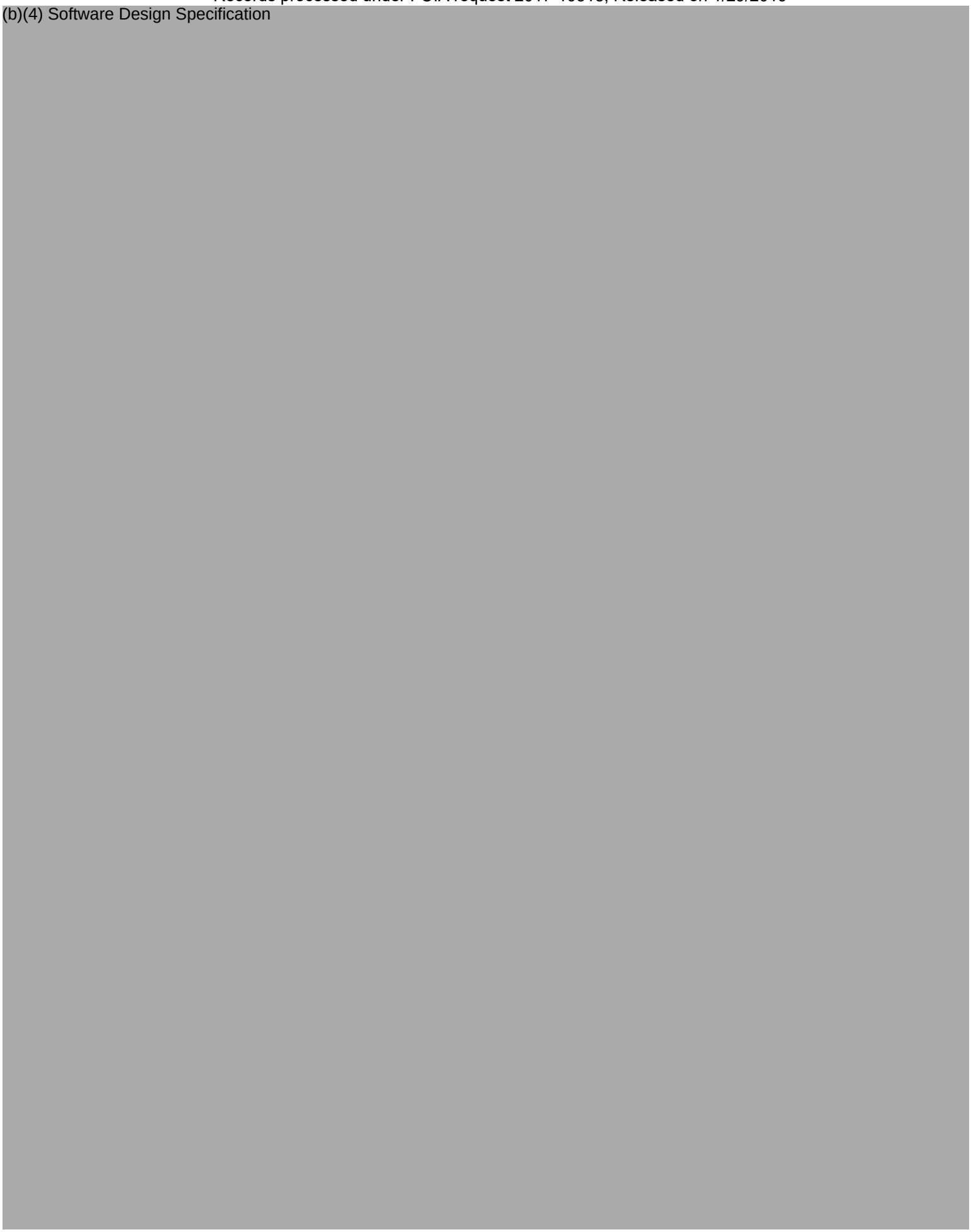

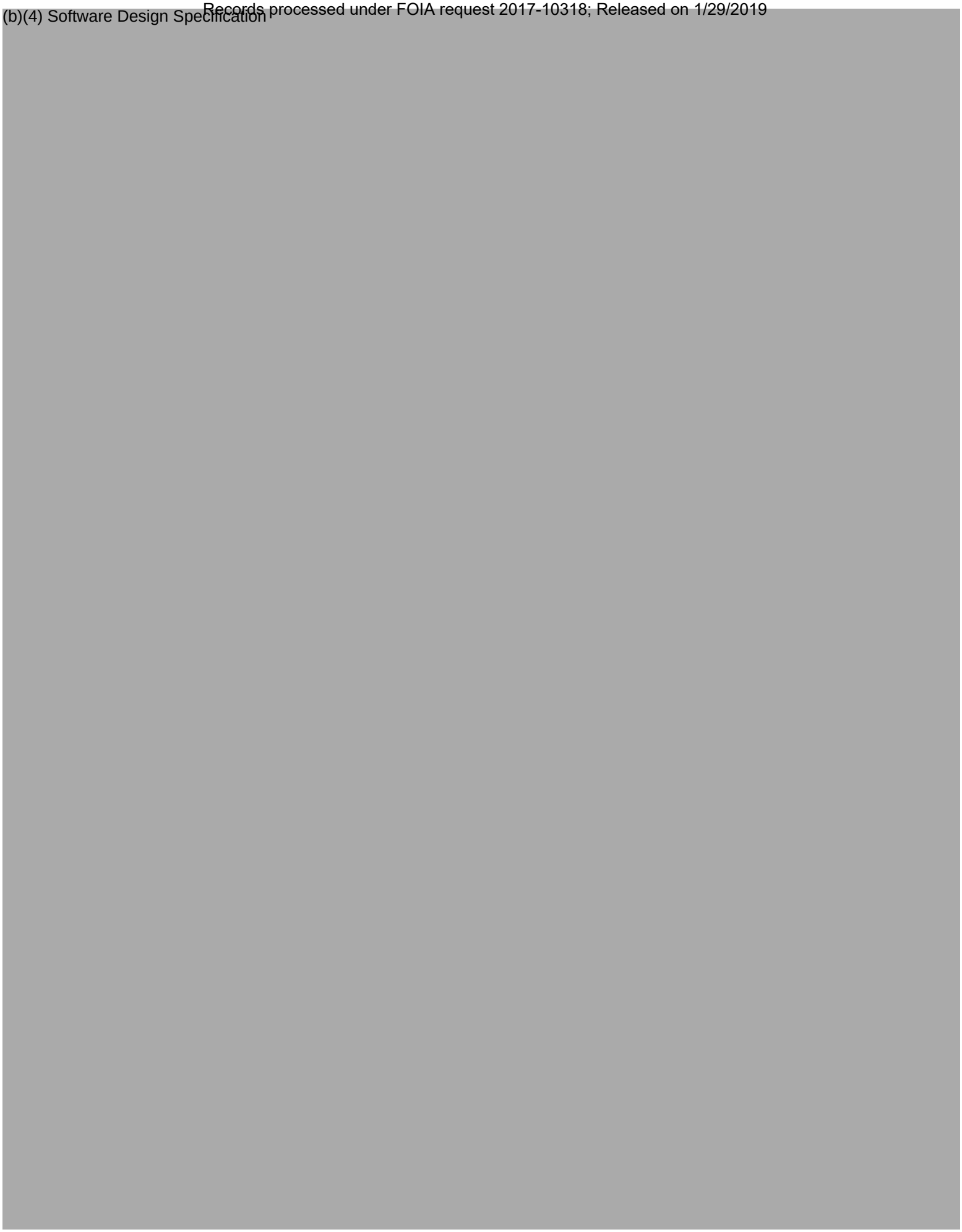

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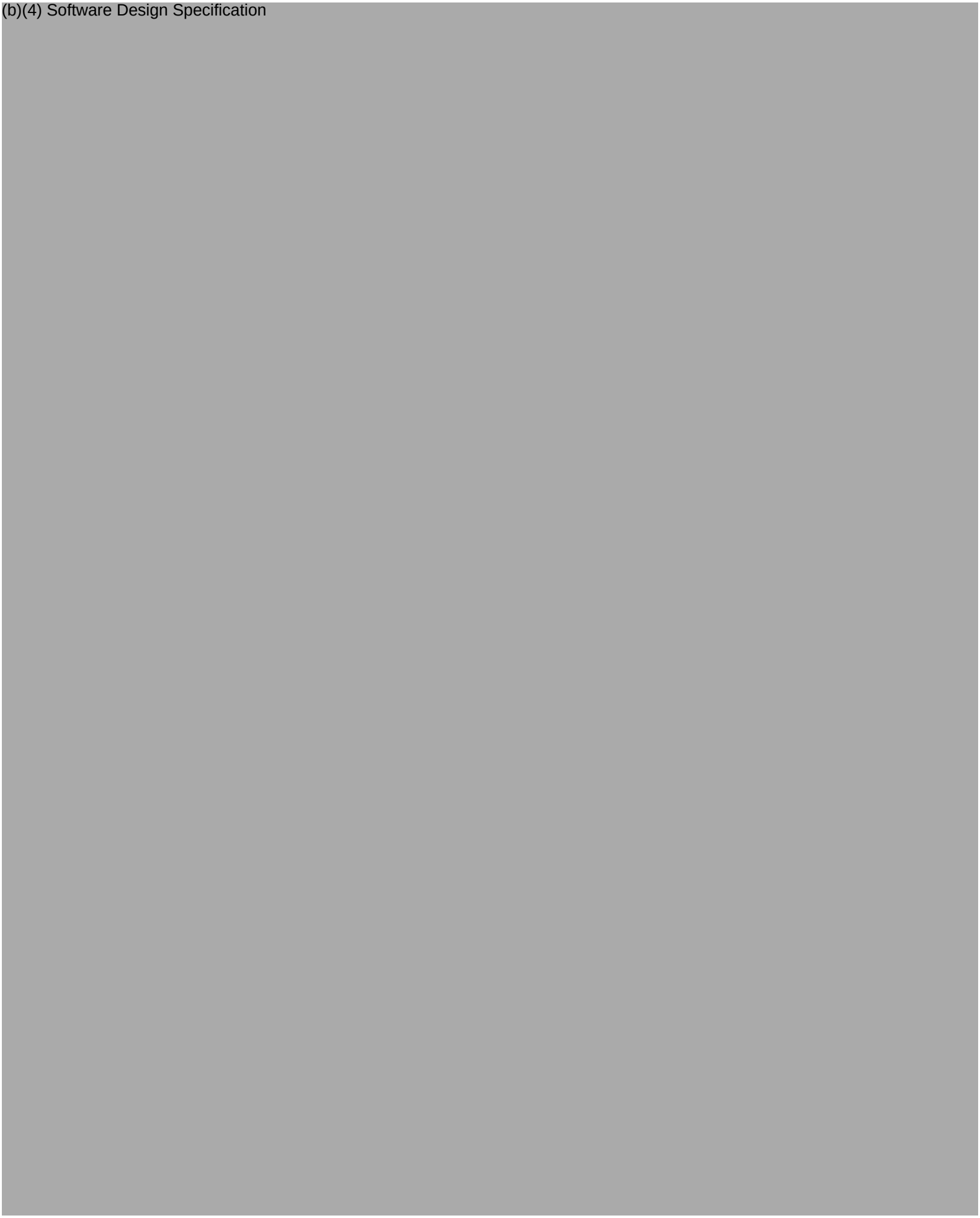

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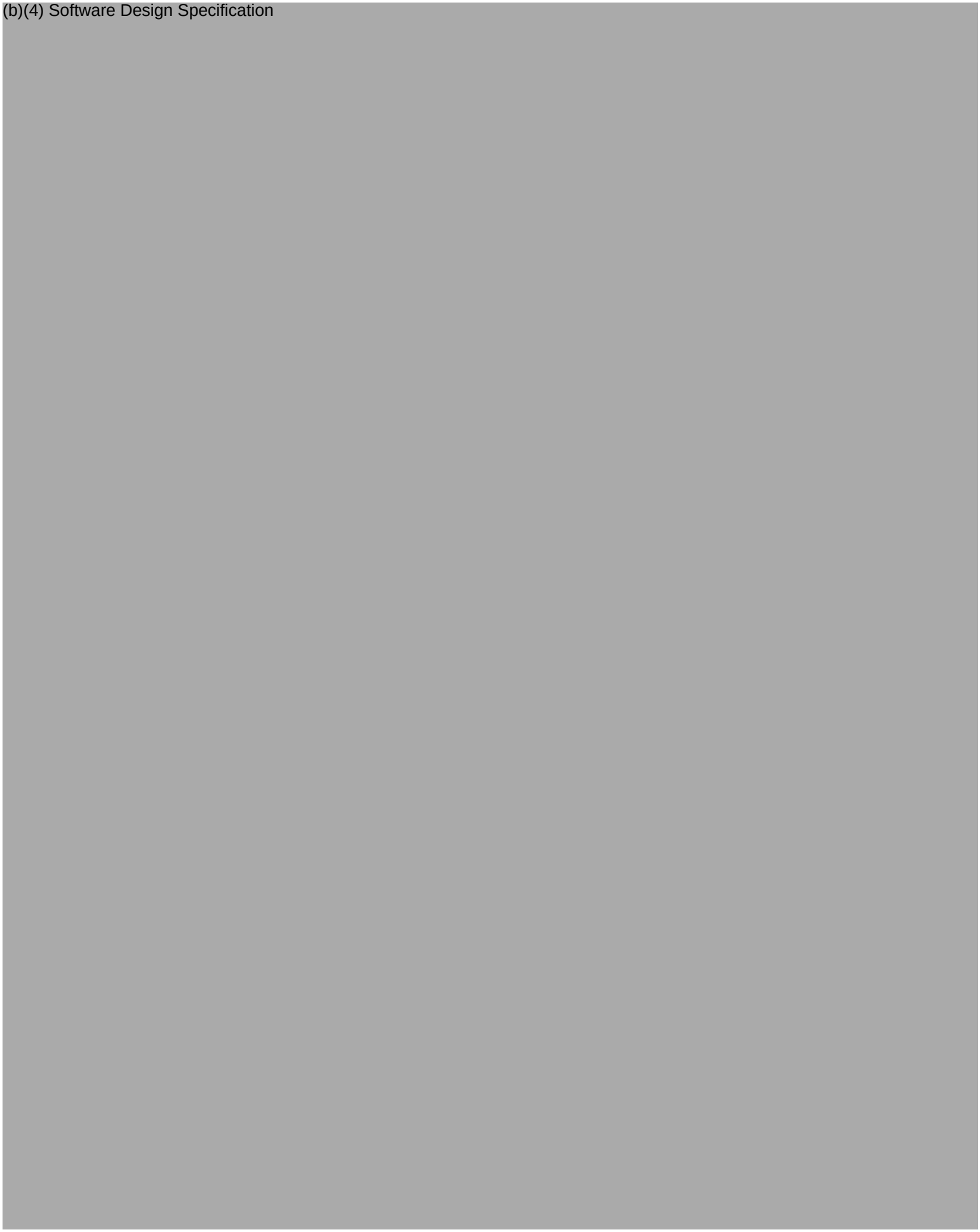

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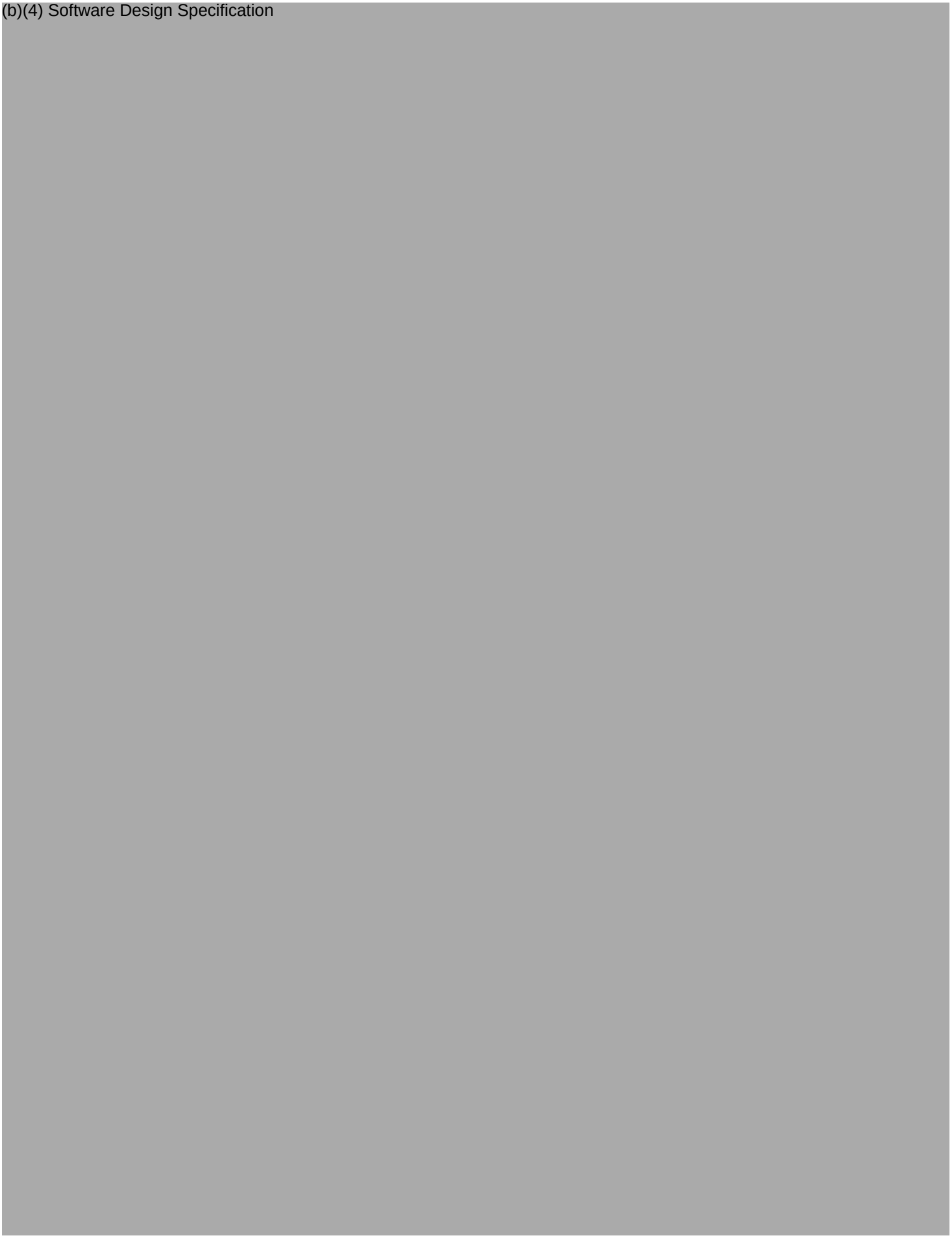

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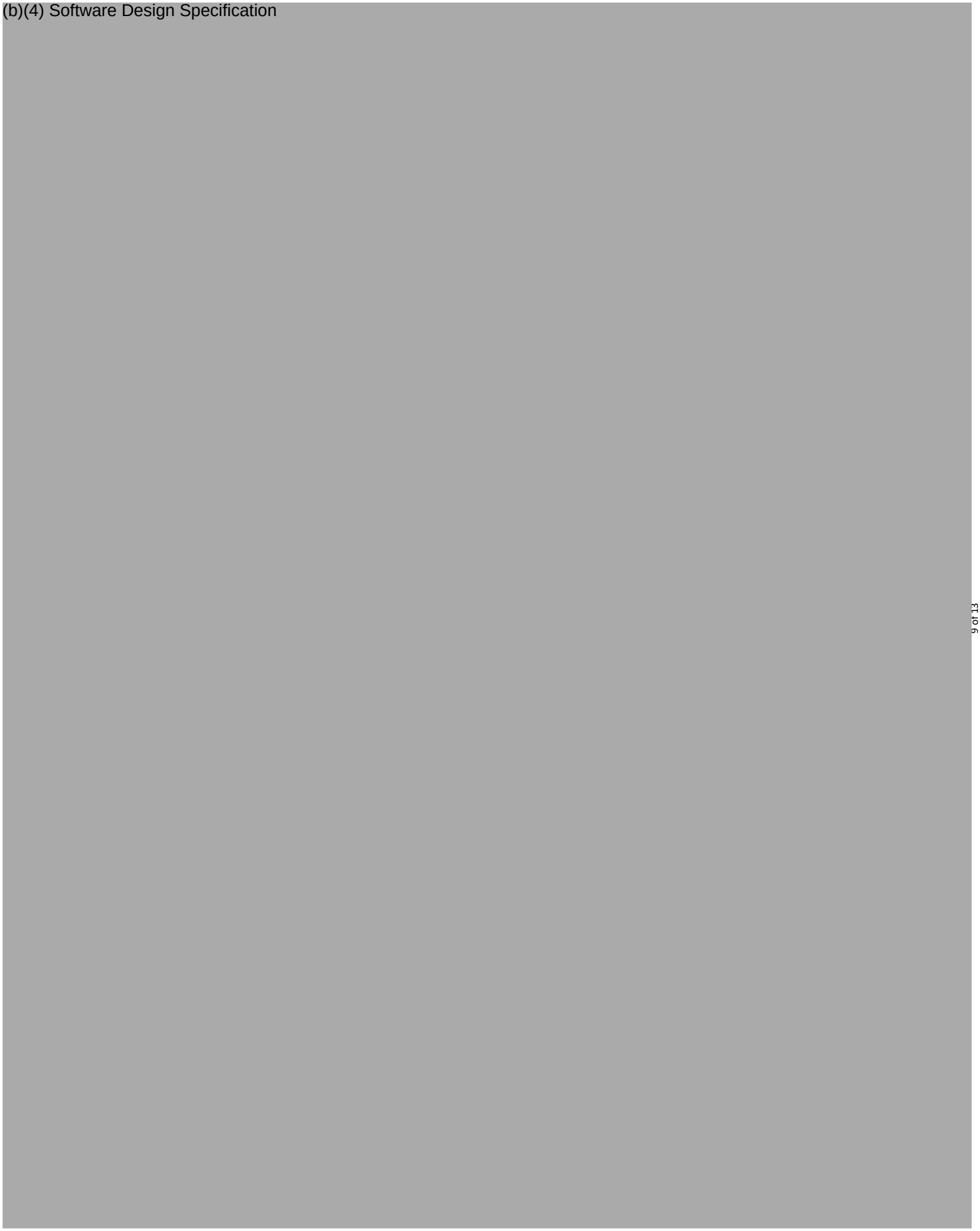

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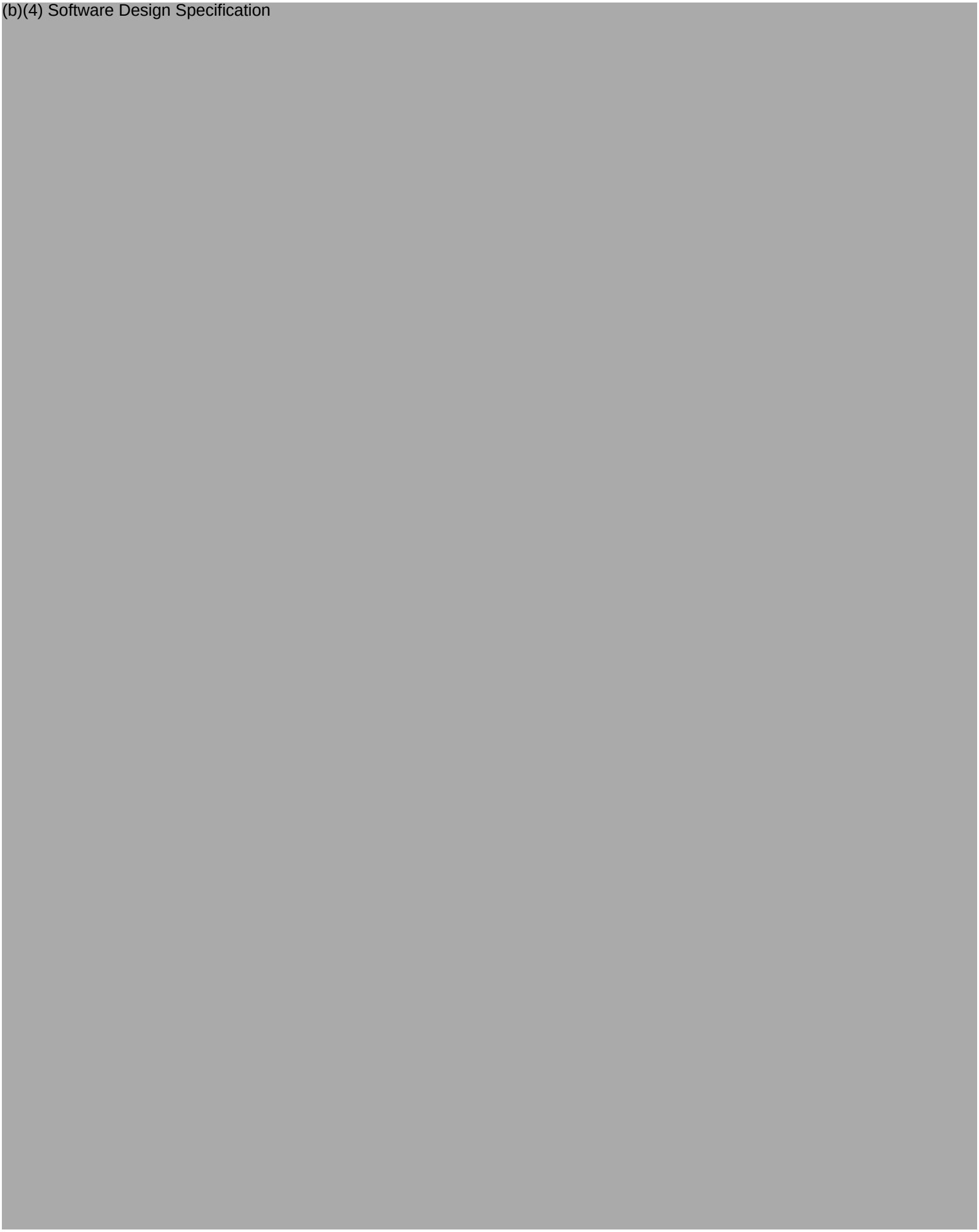

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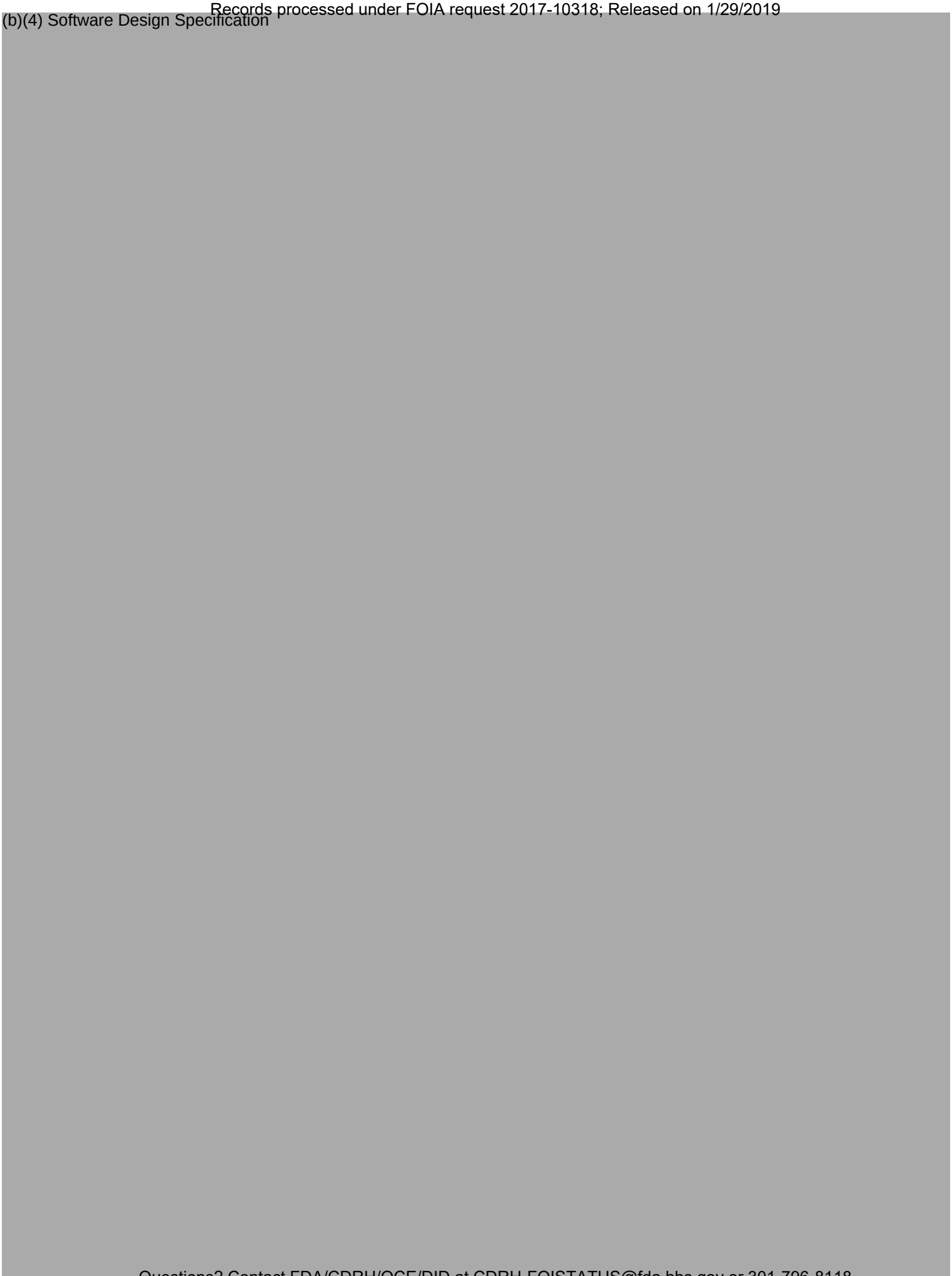

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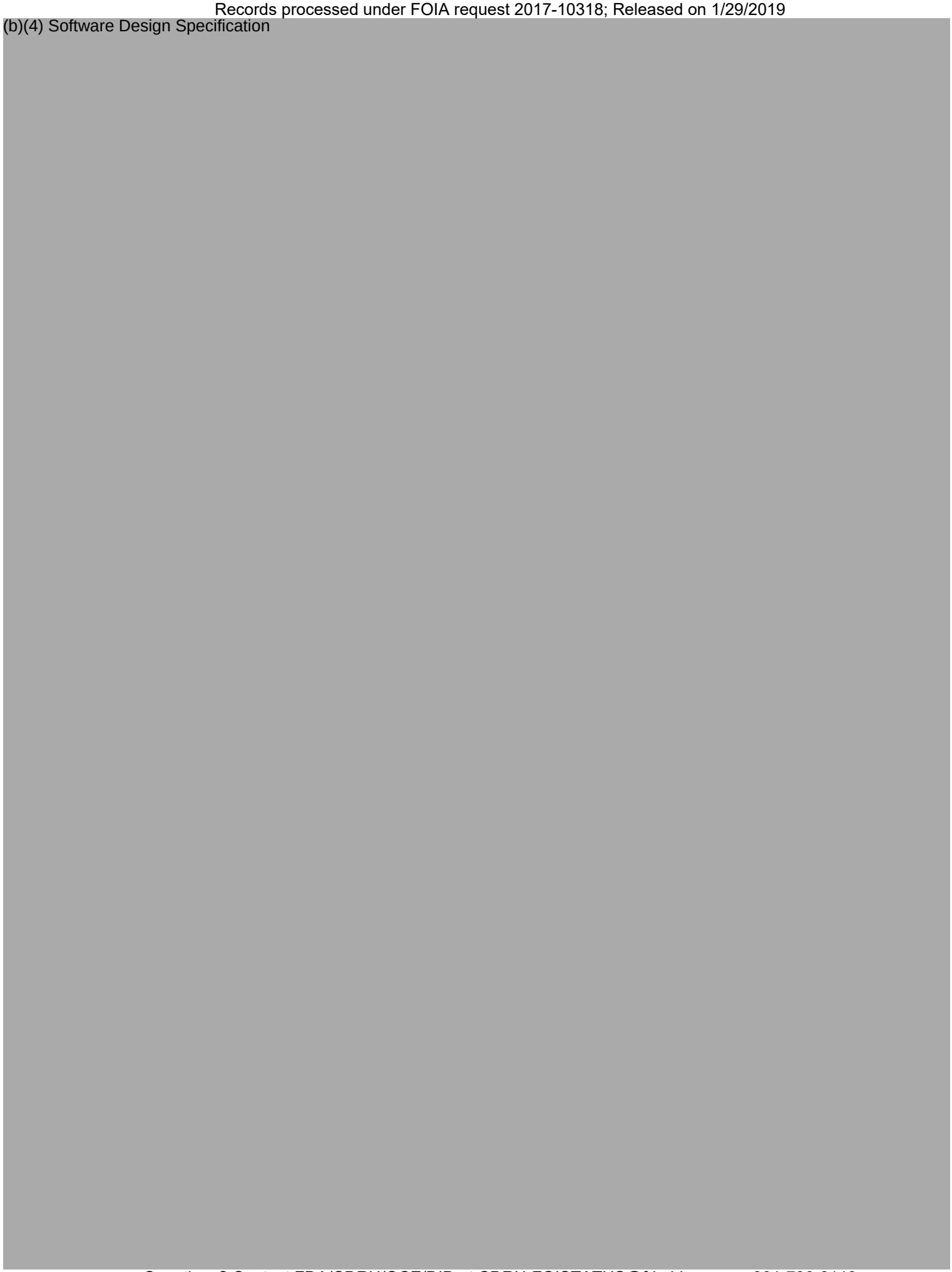

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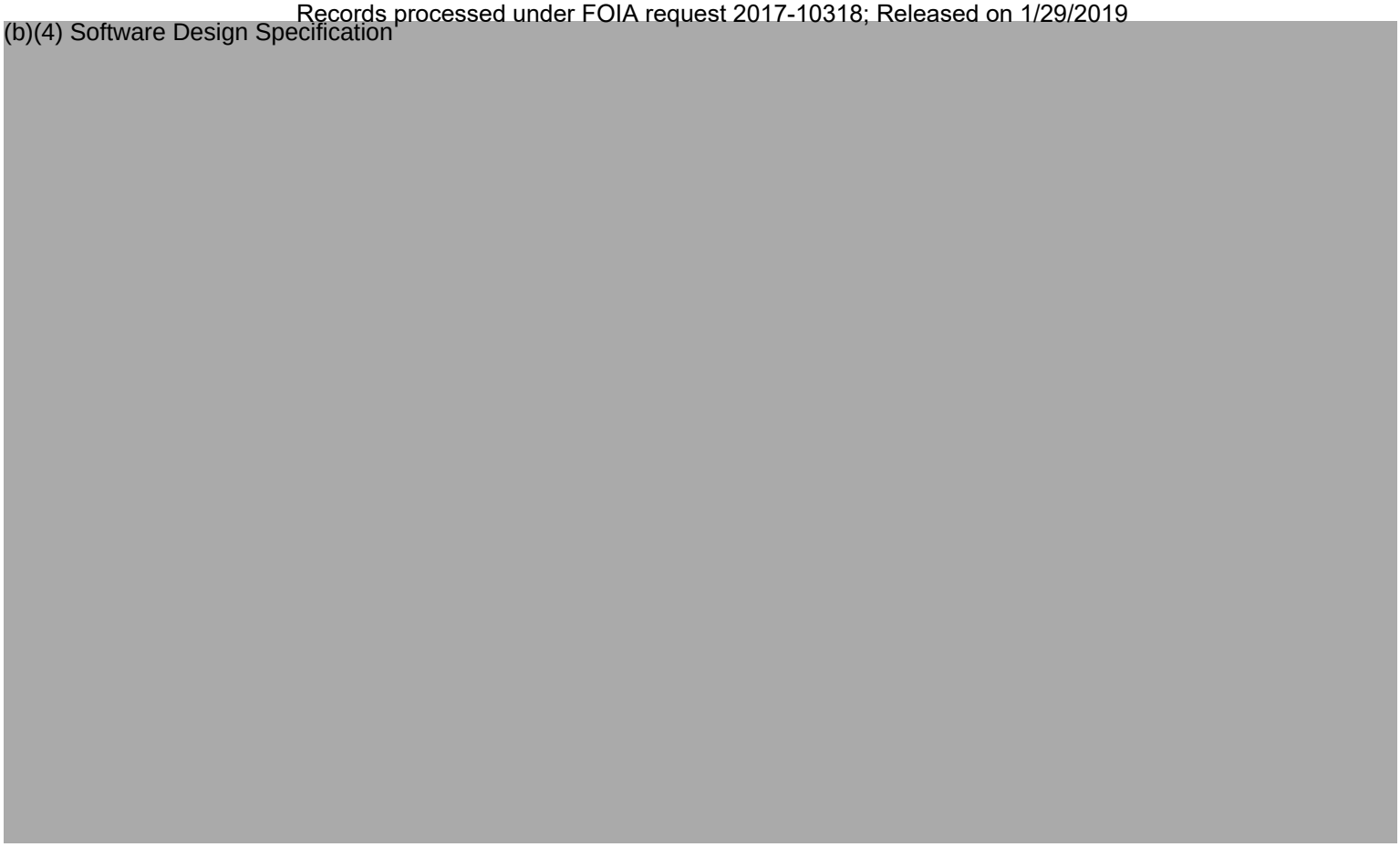

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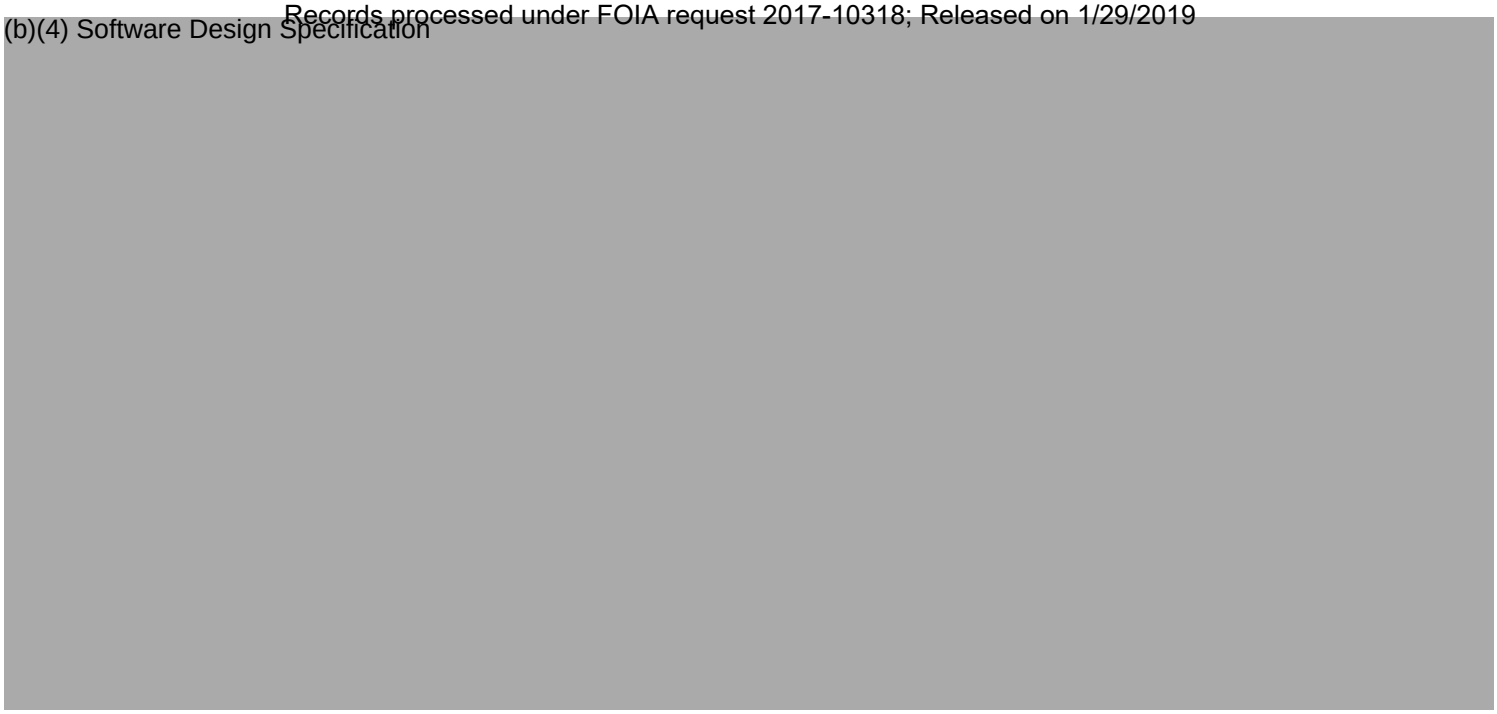

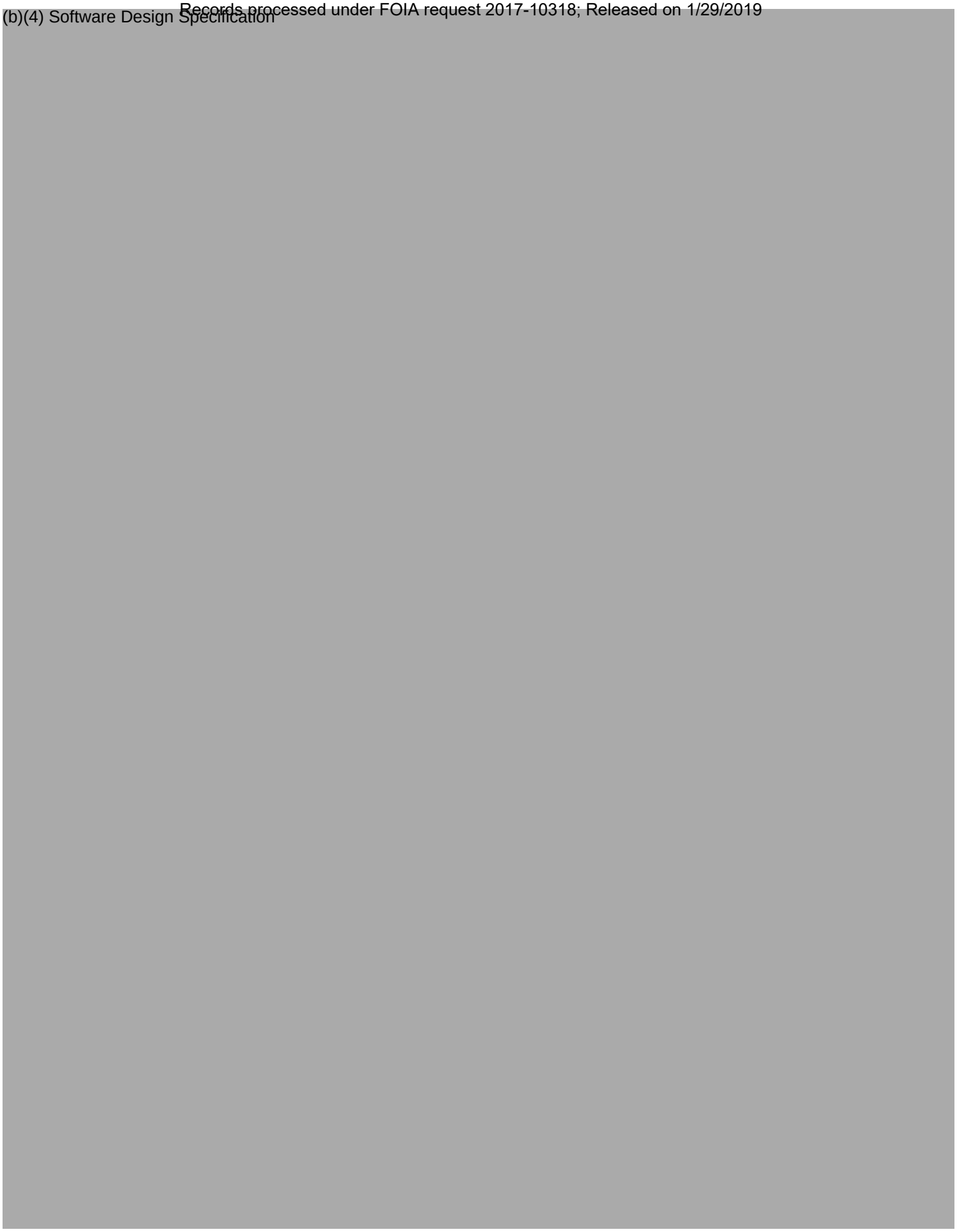

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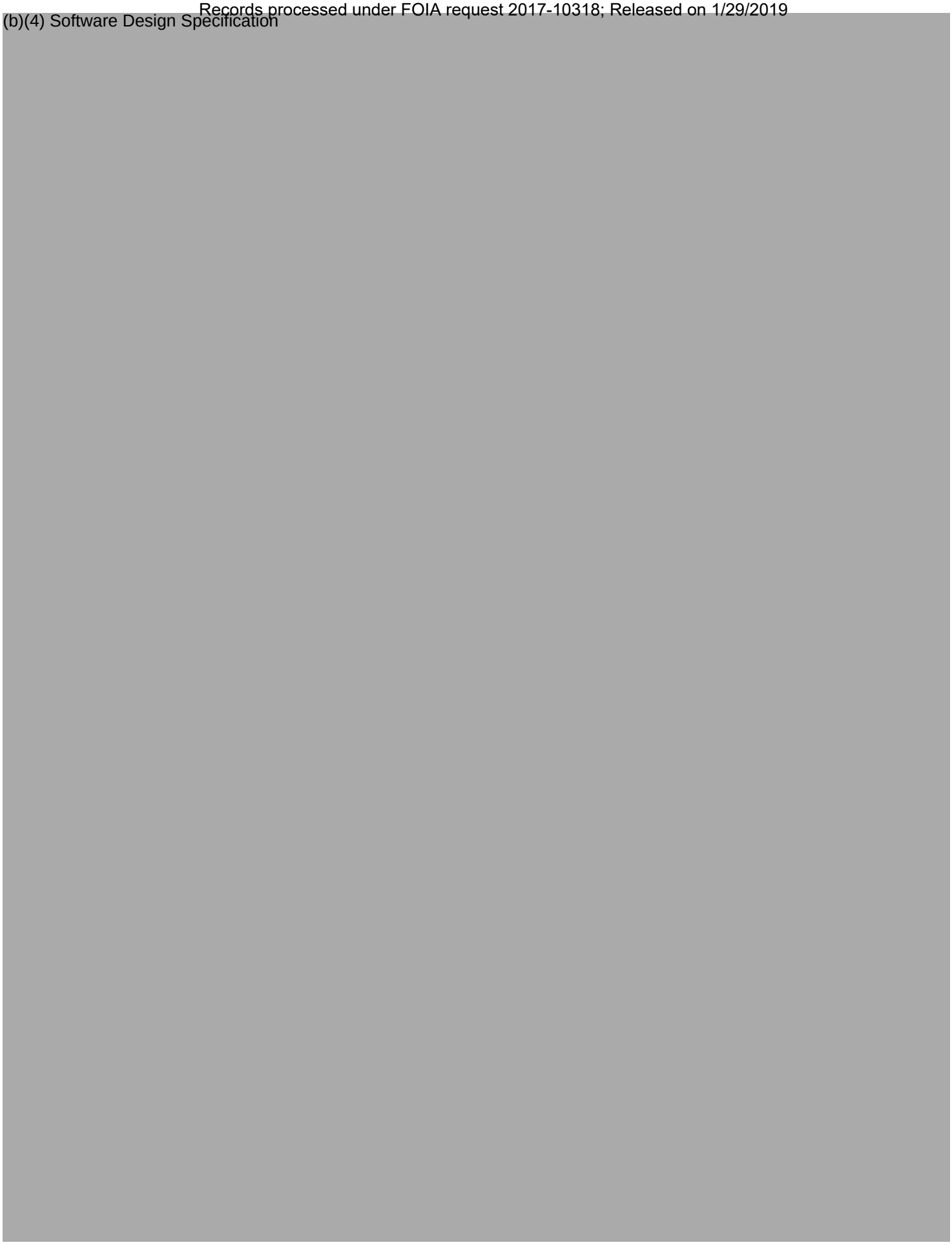

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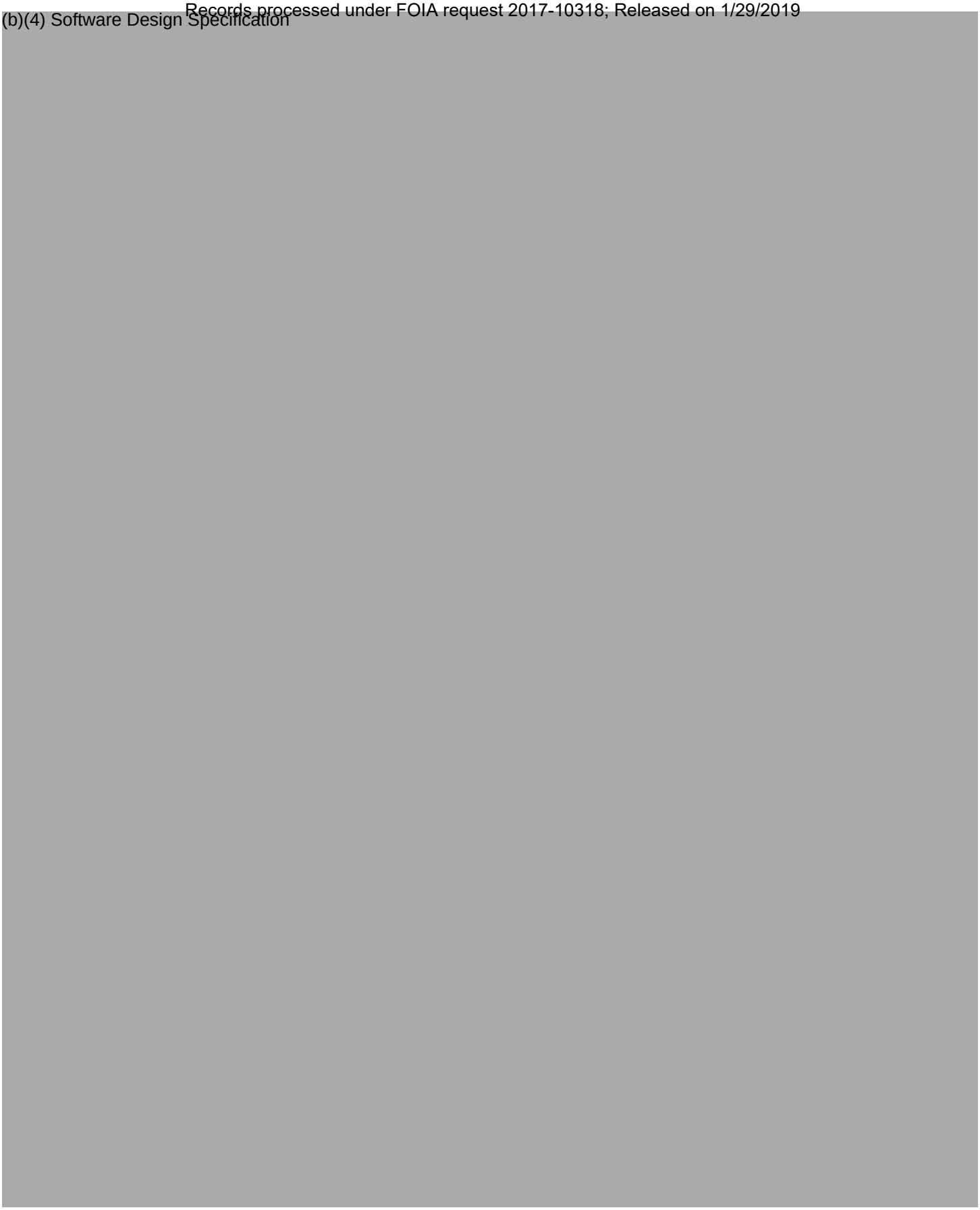

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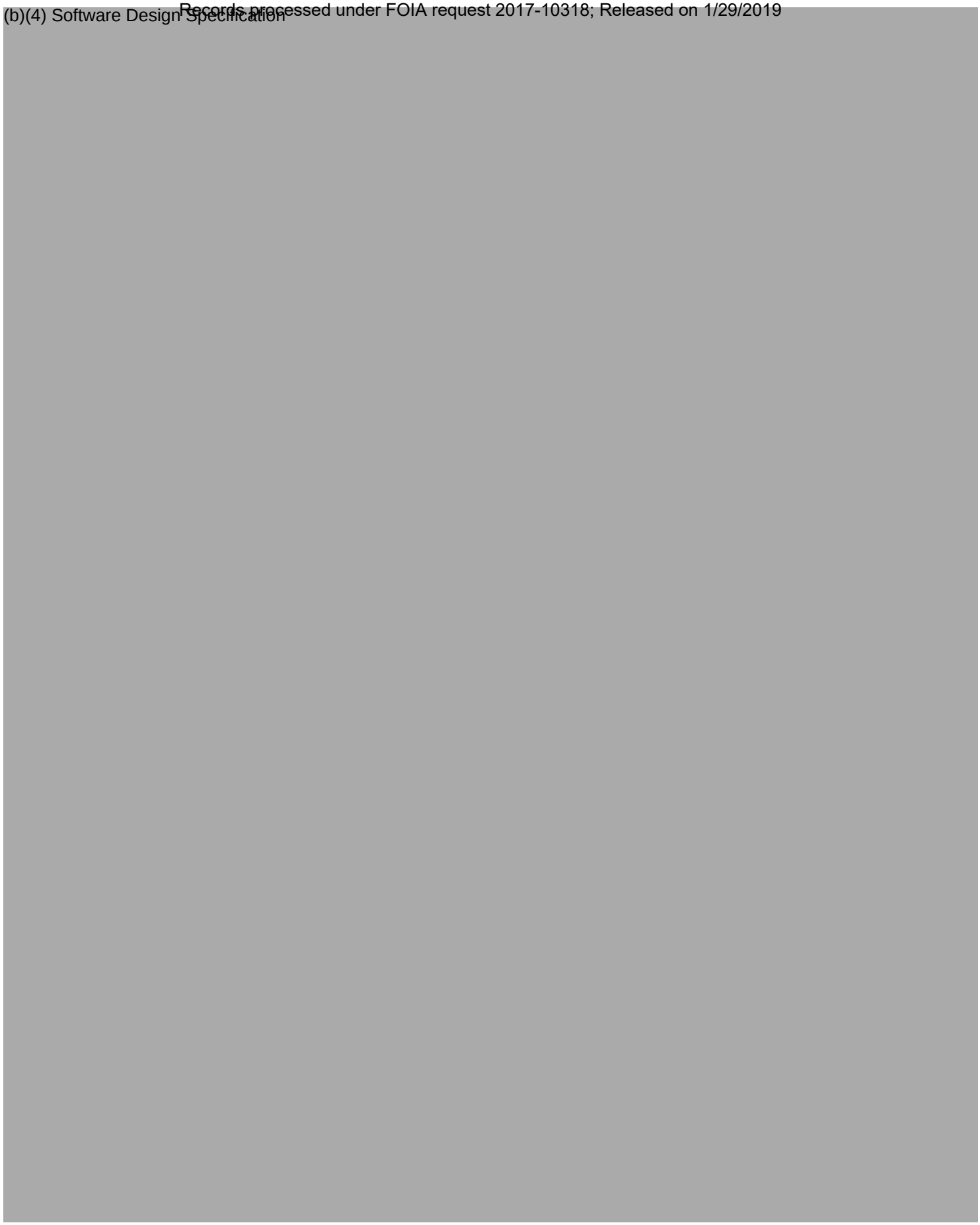

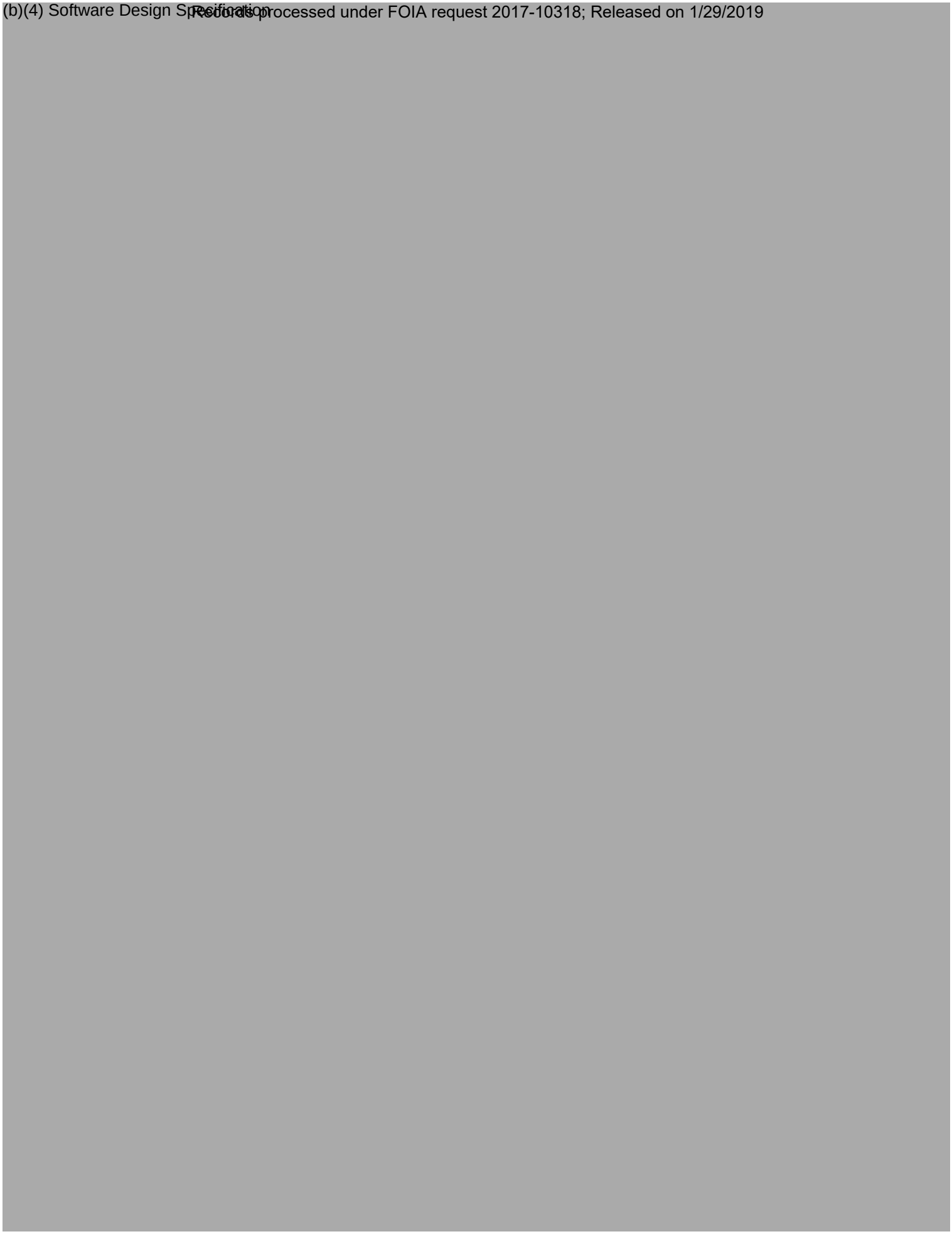

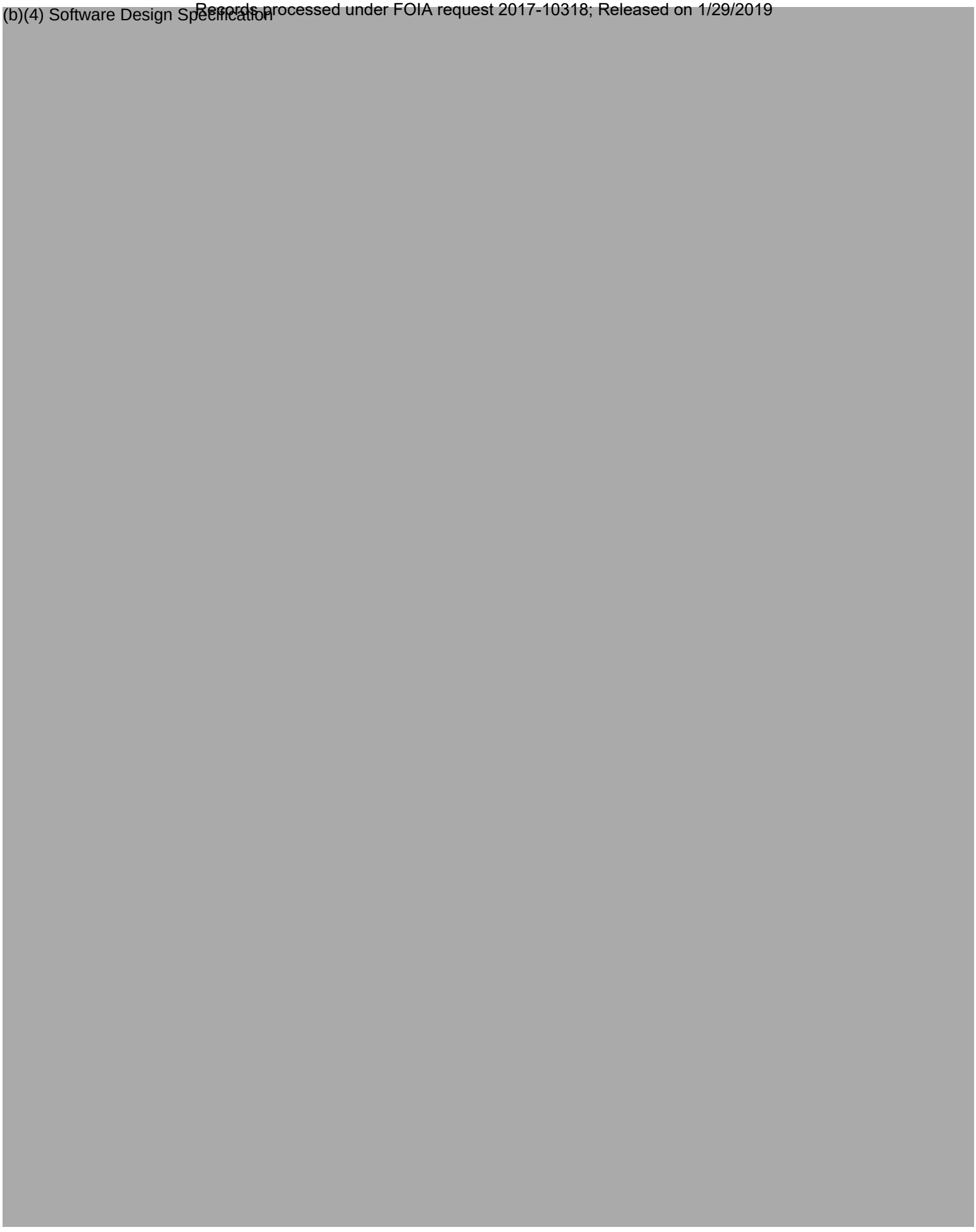

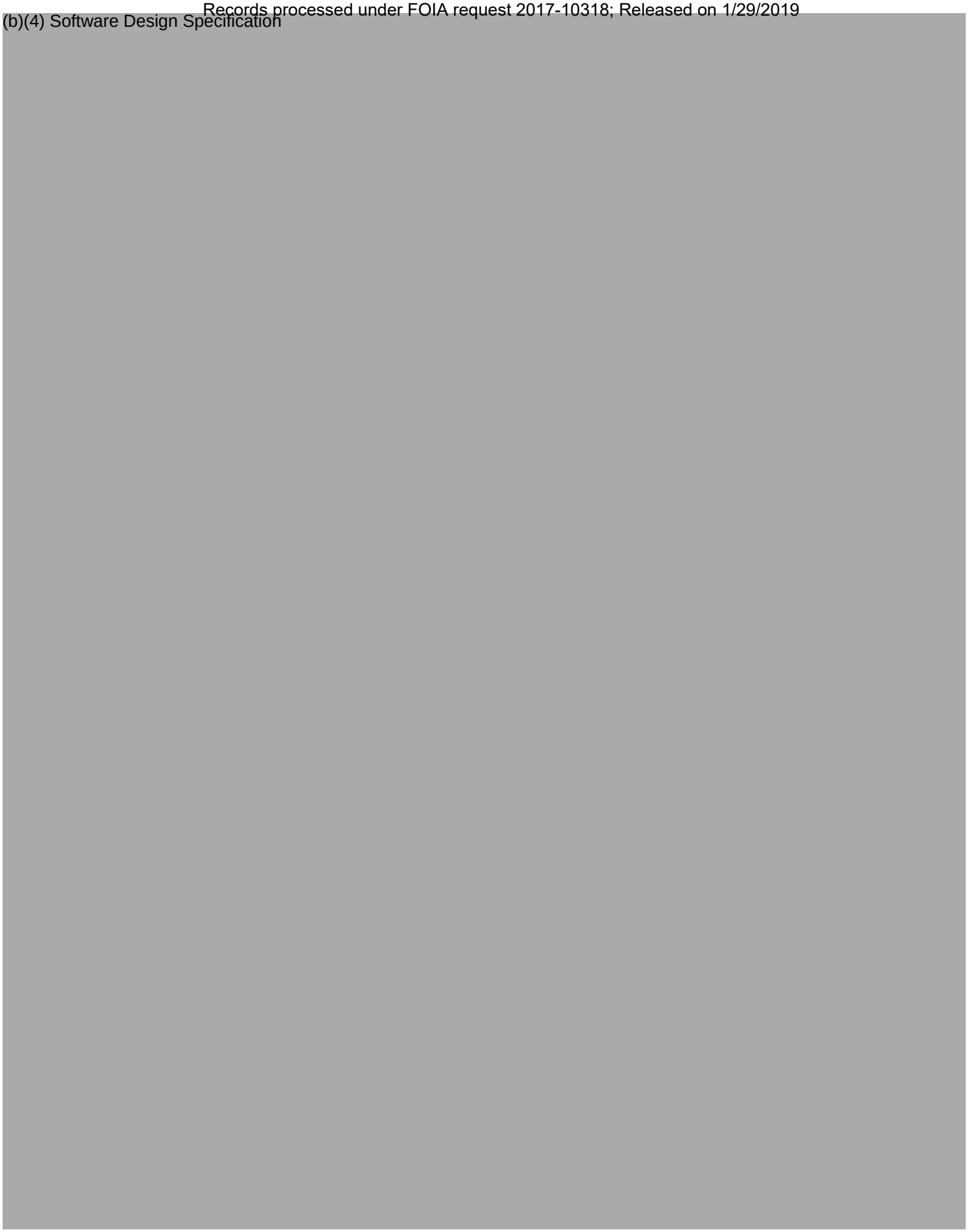

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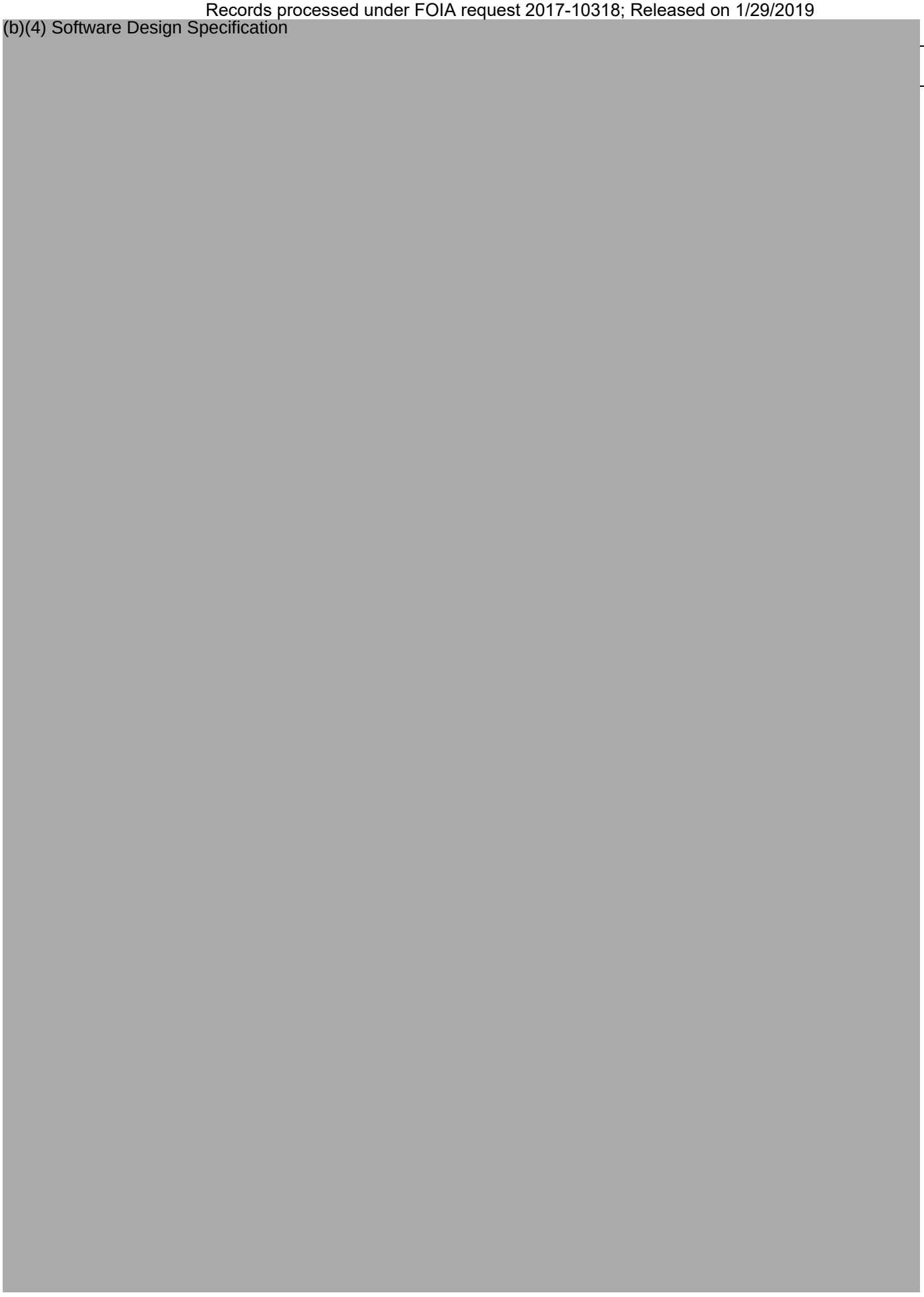

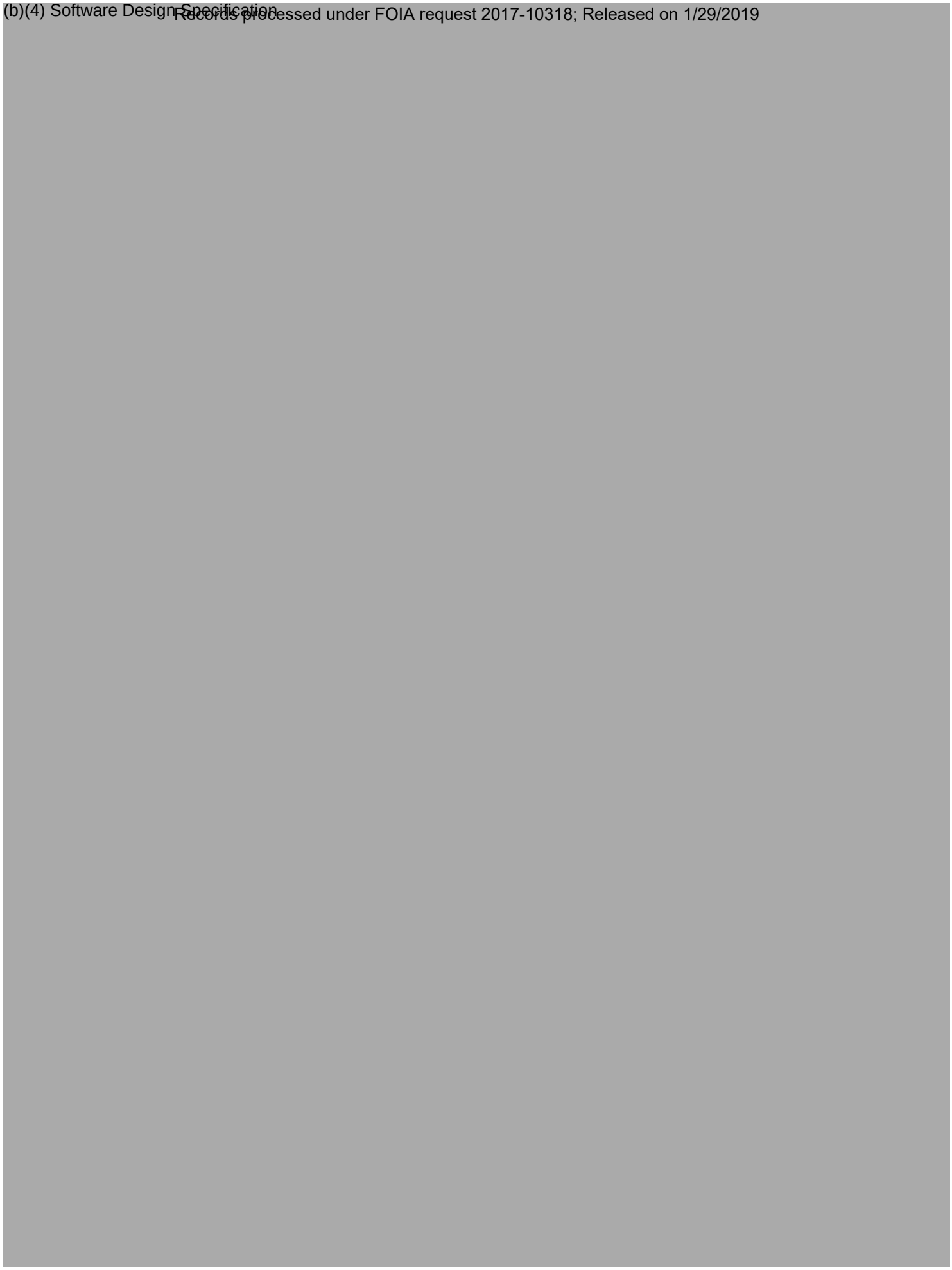

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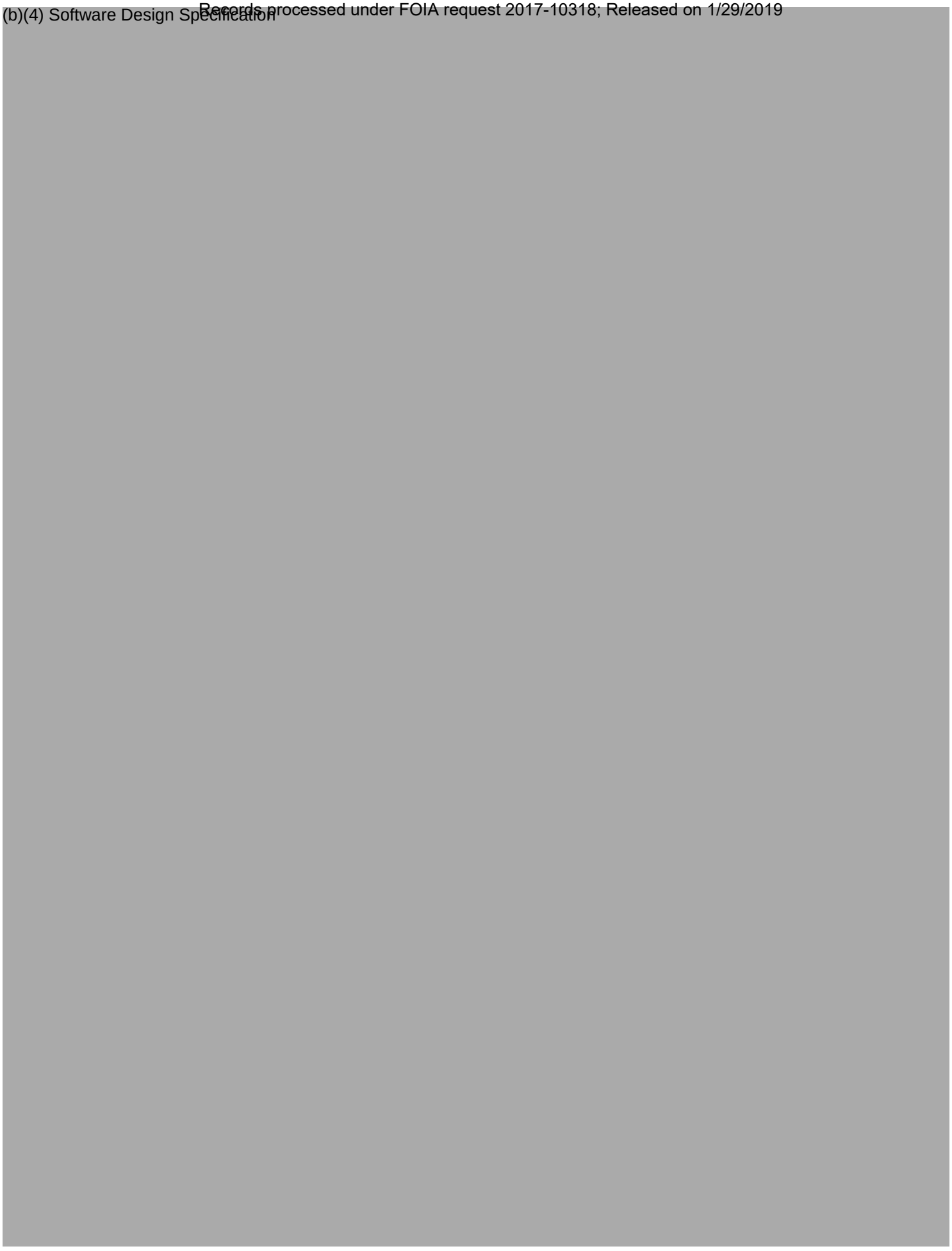

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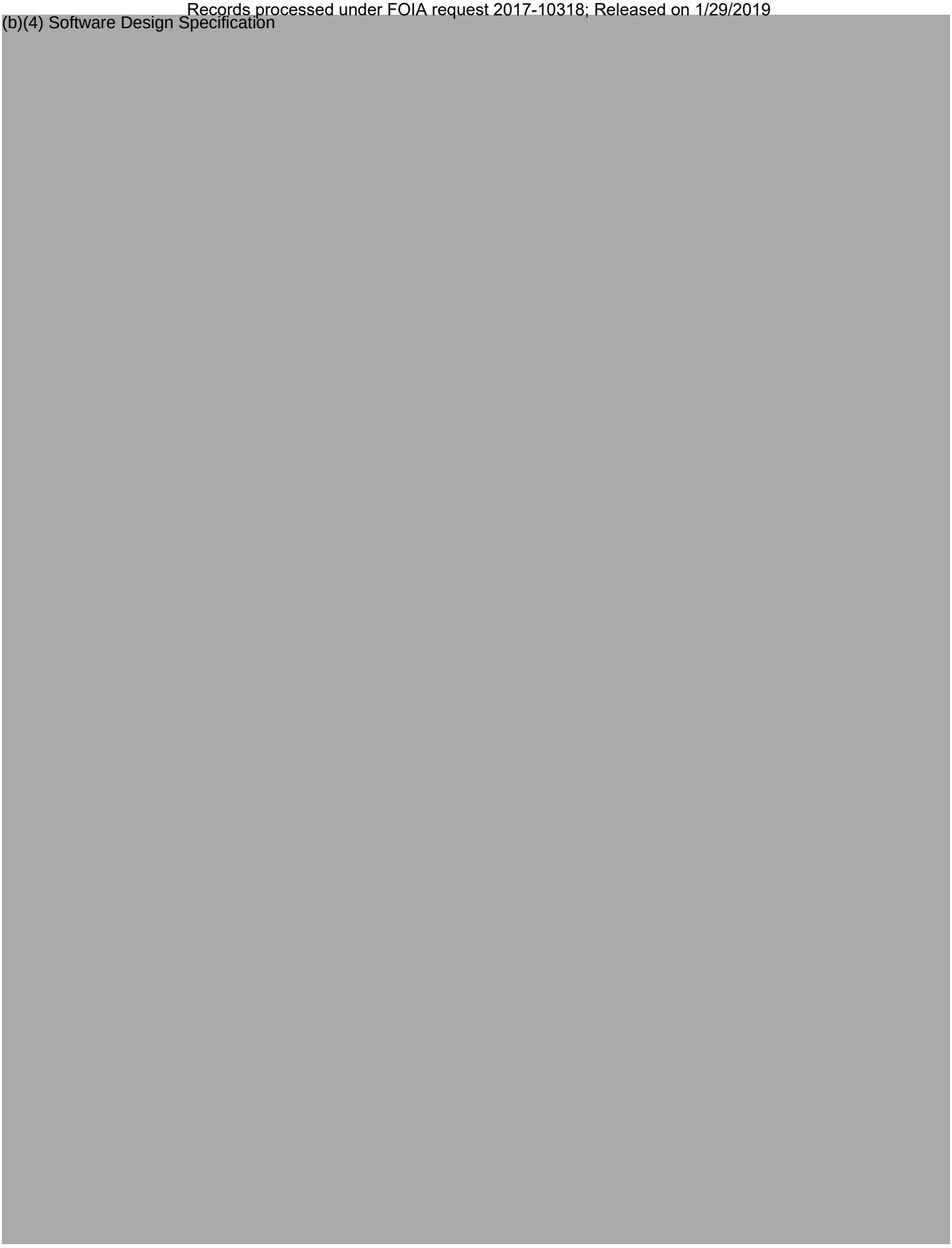

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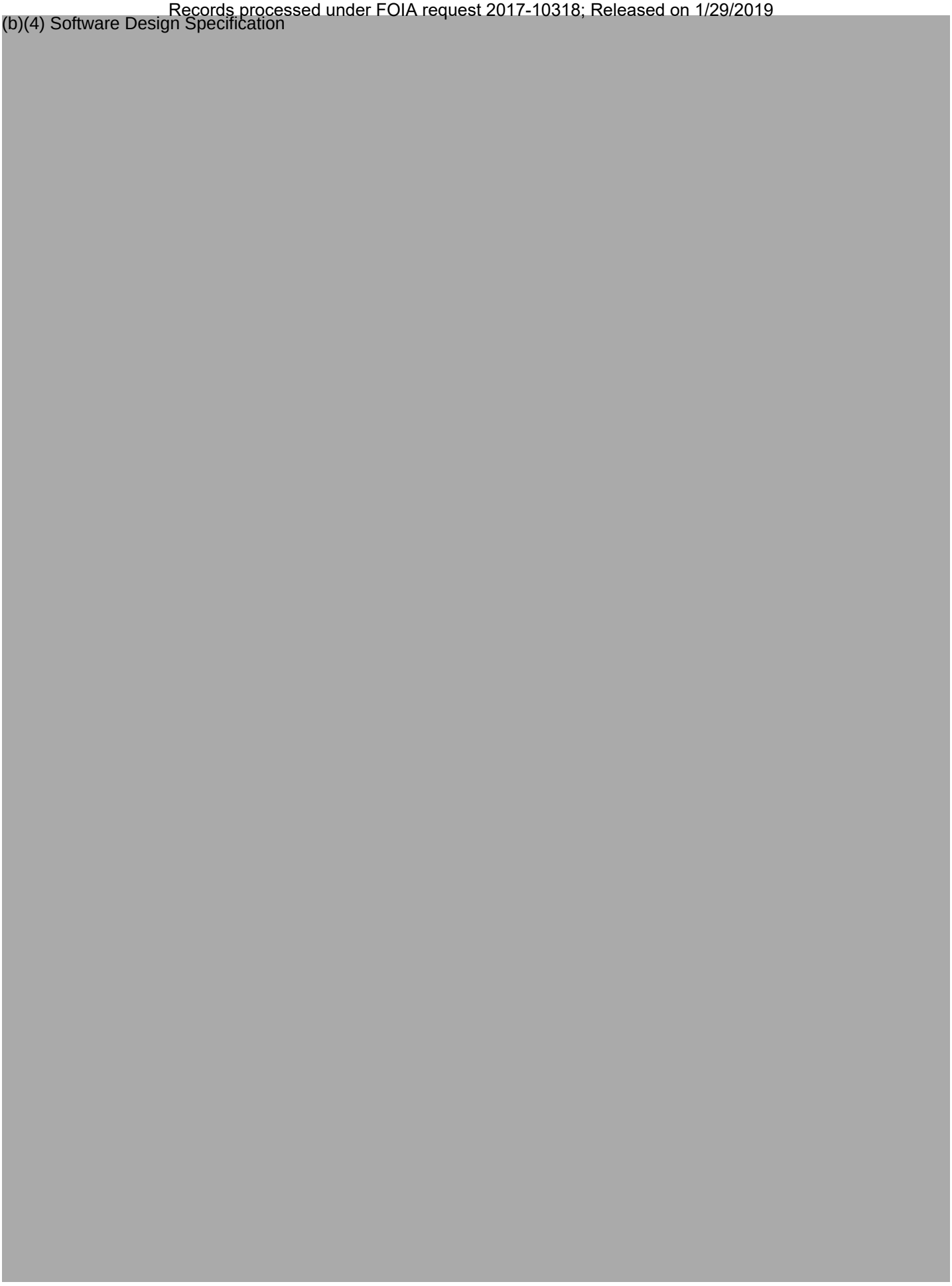
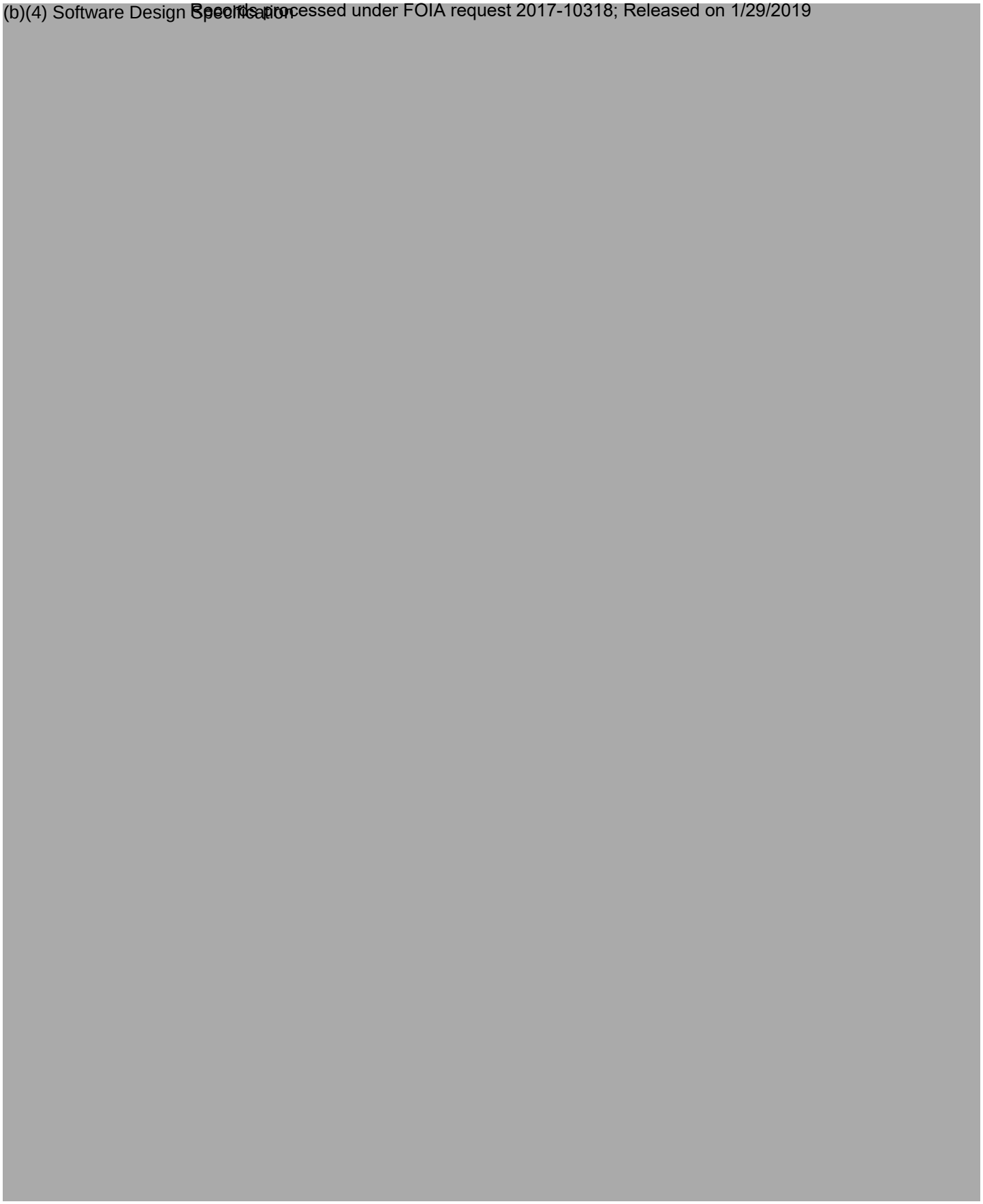


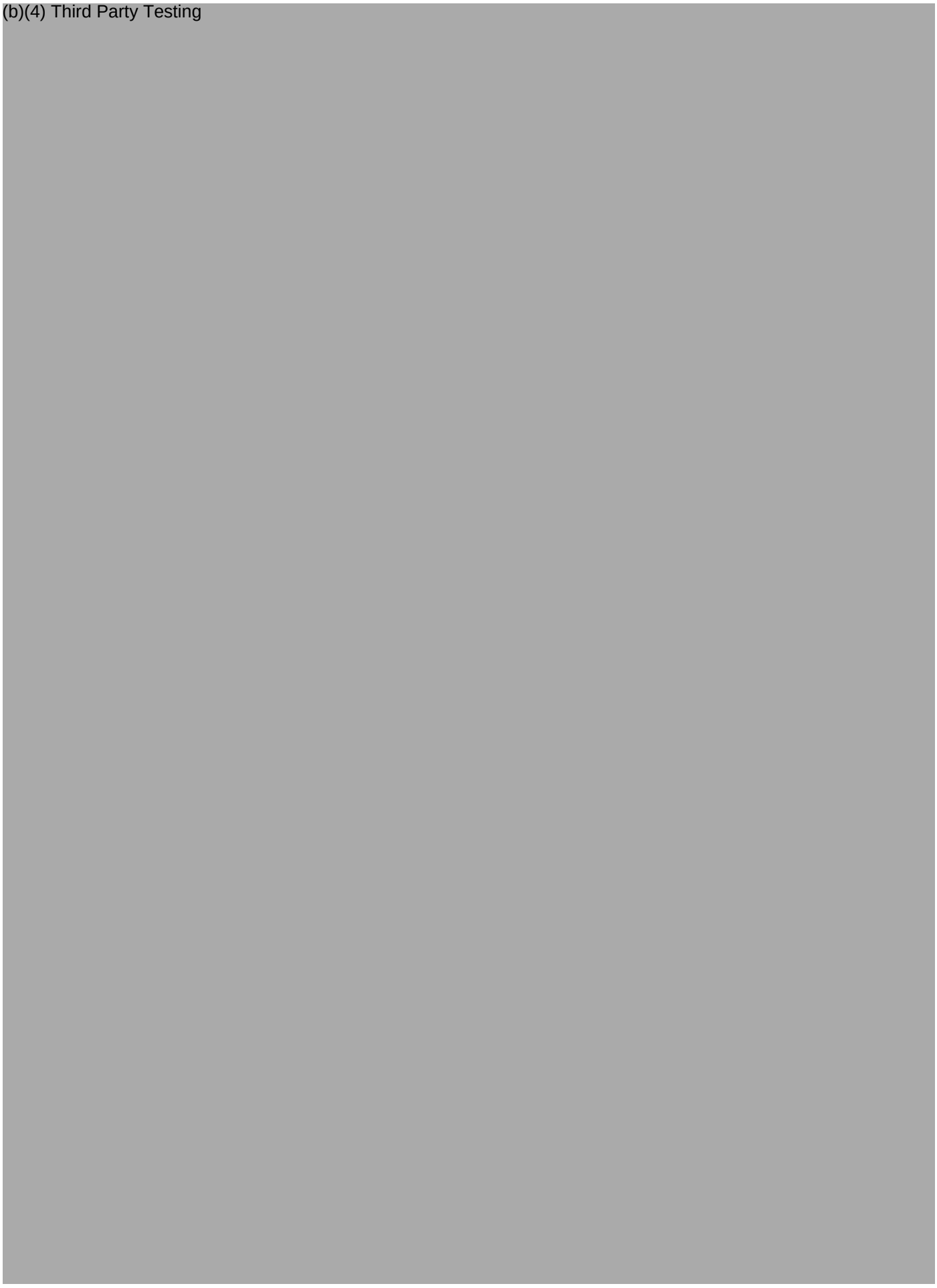


APPENDIX 7
ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

Provided in this appendix are the following test reports discussed within this 510(k) submission:

(b) (4)

(b)(4) Third Party Testing



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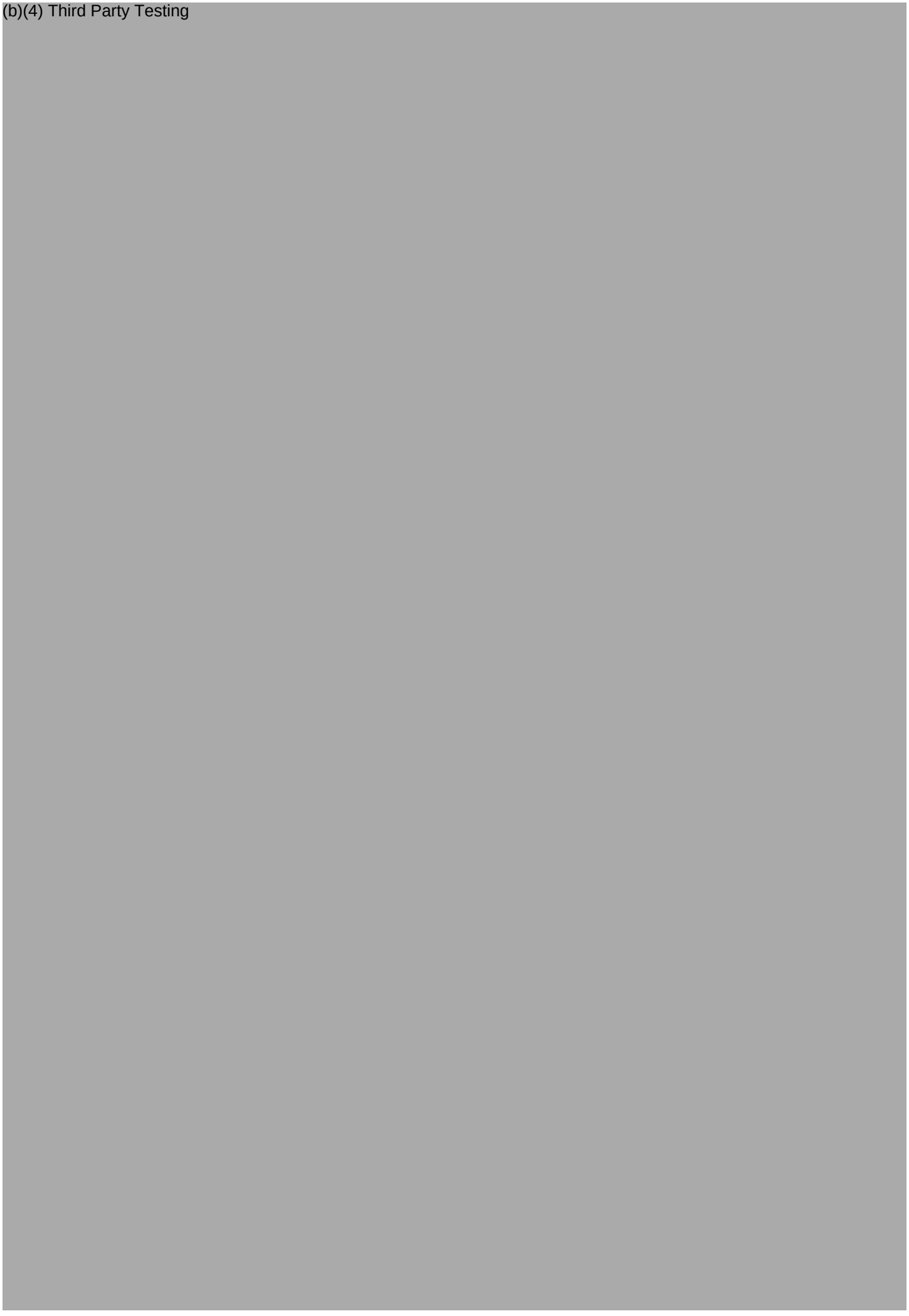

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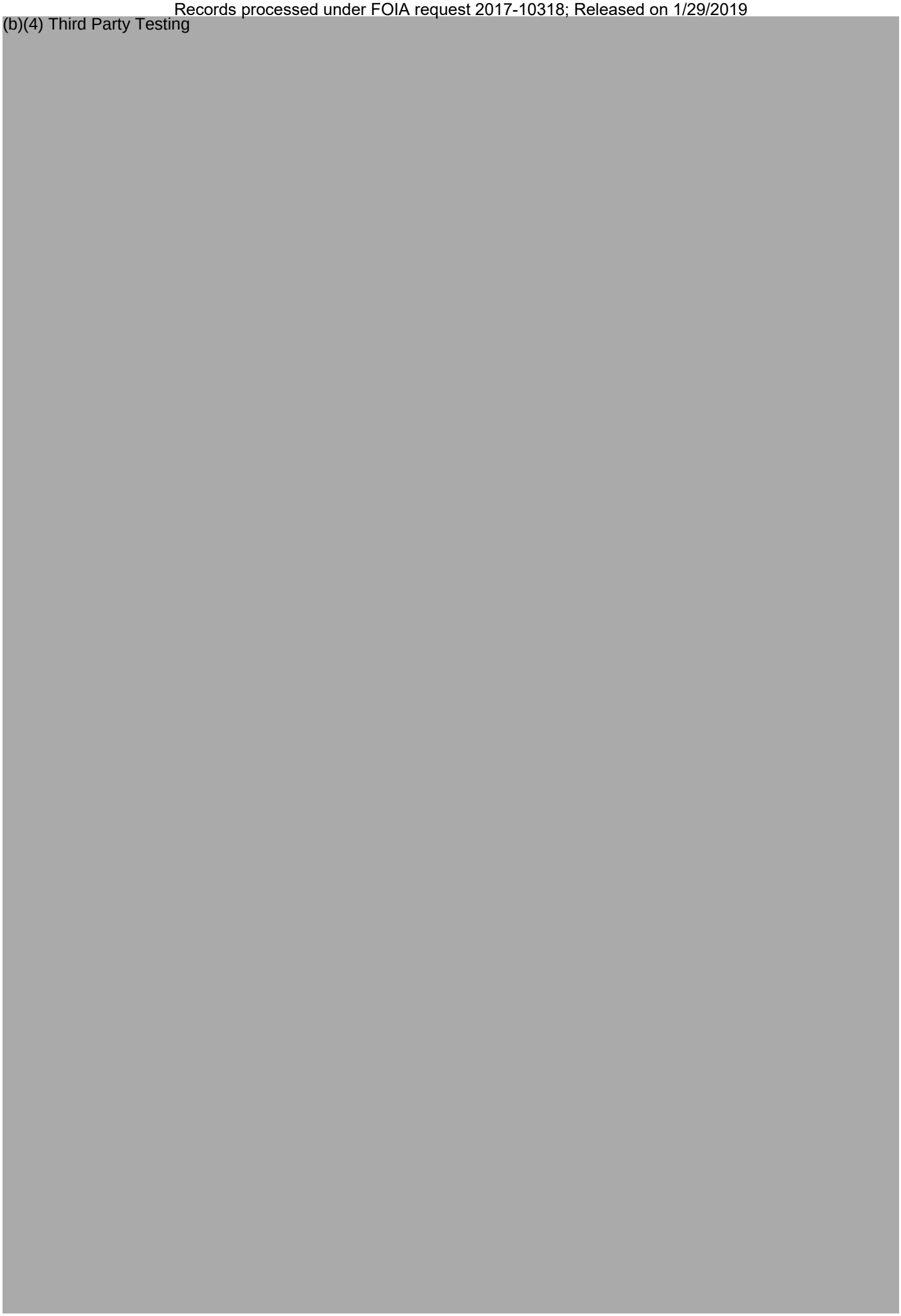

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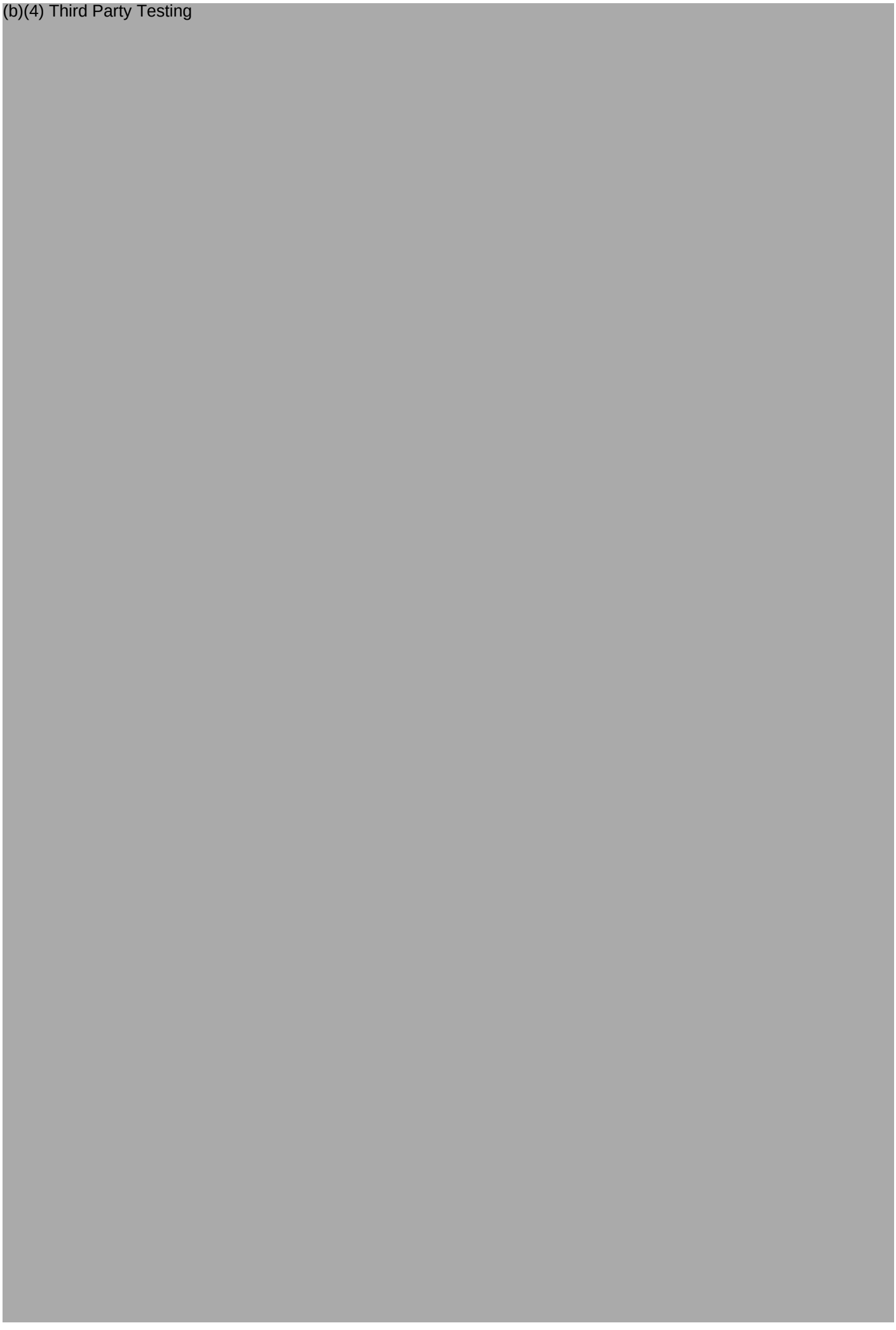

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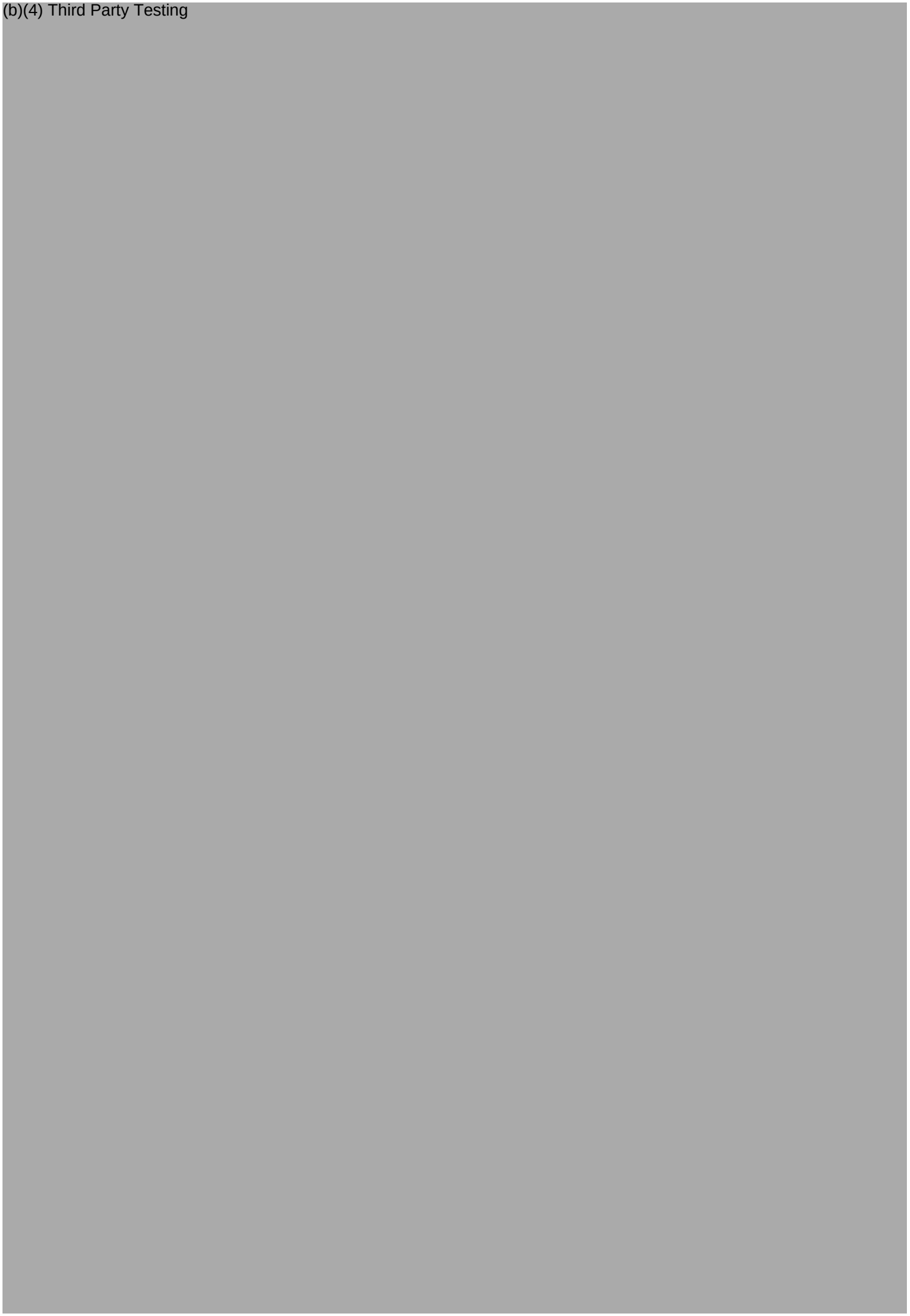

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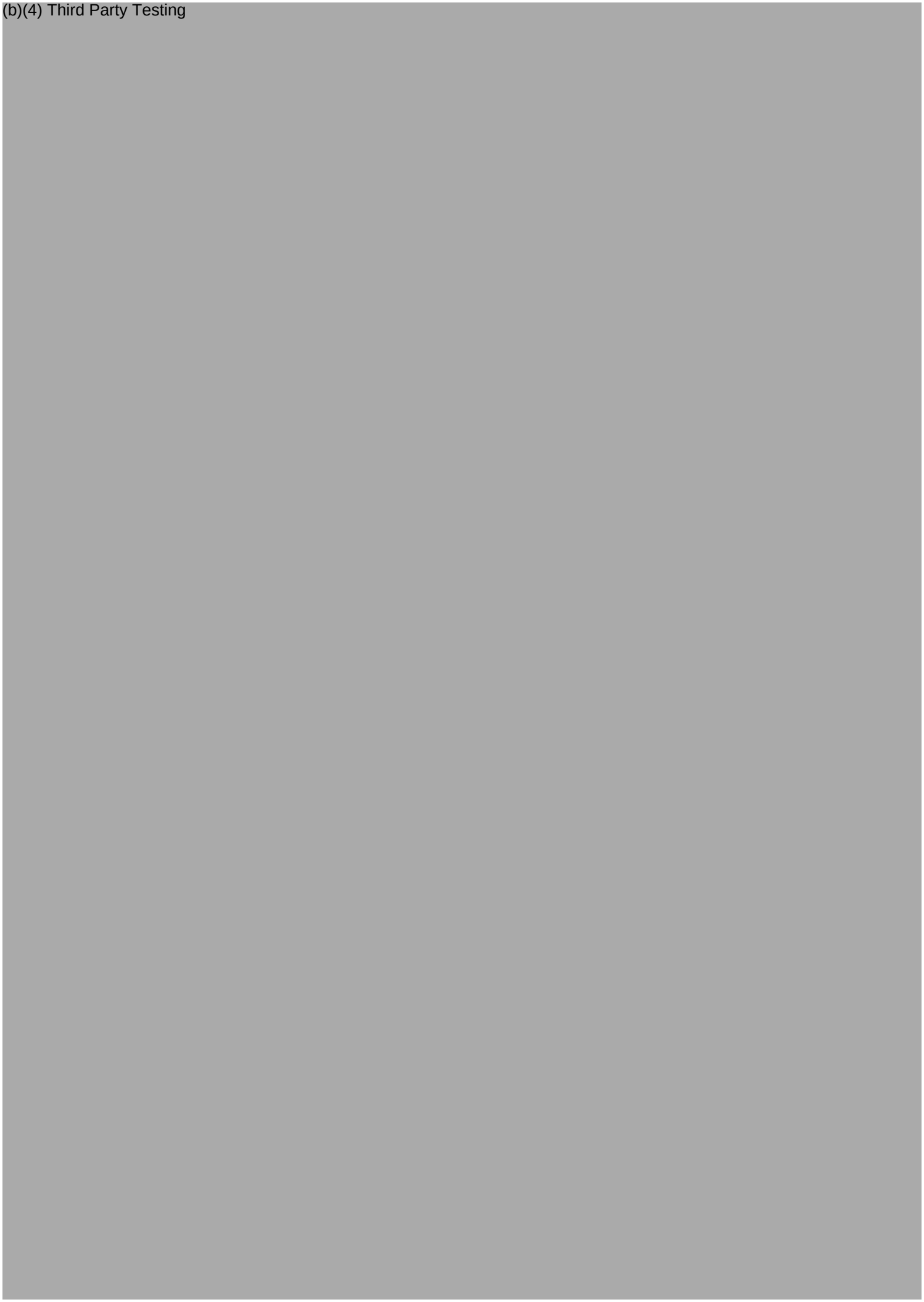

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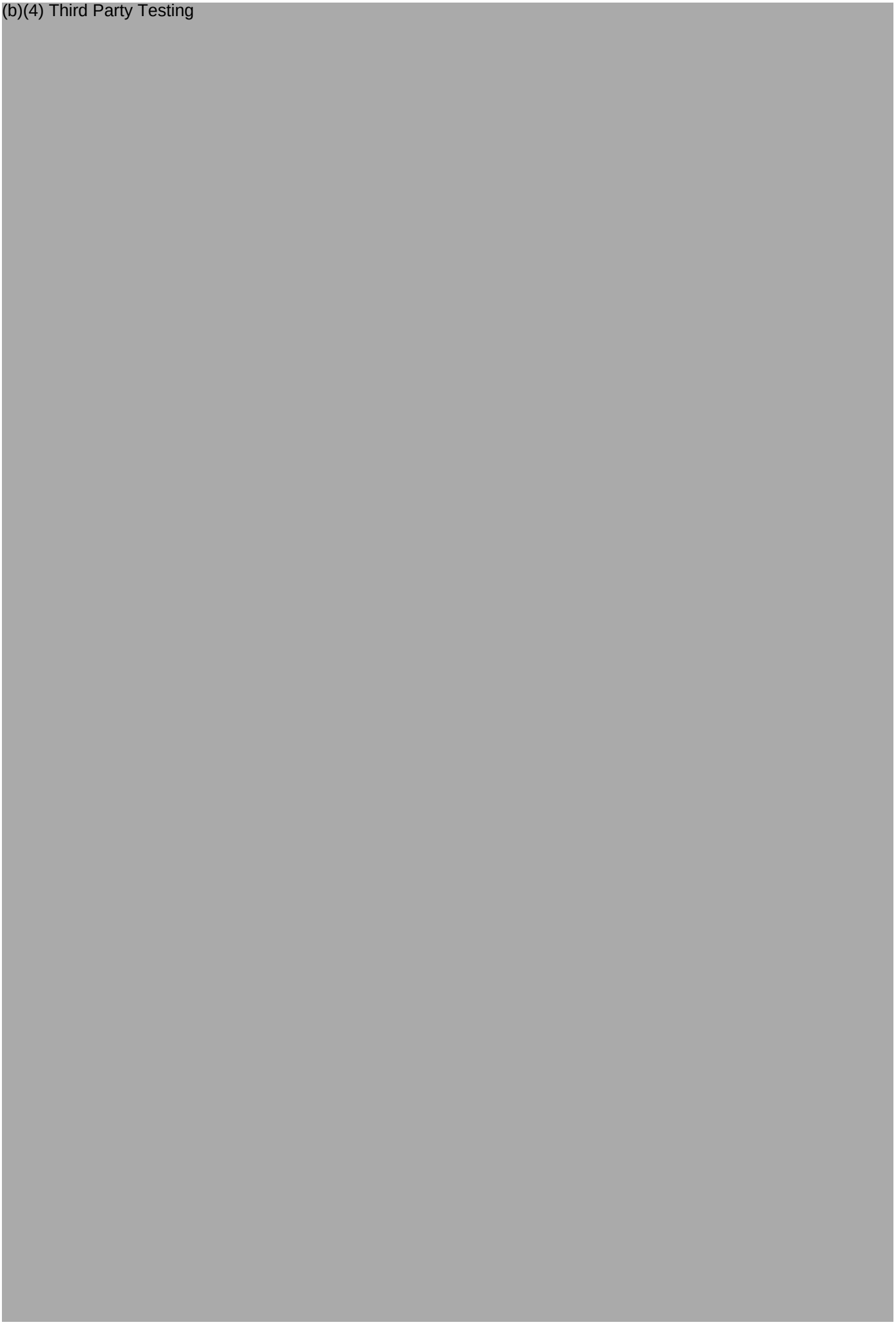

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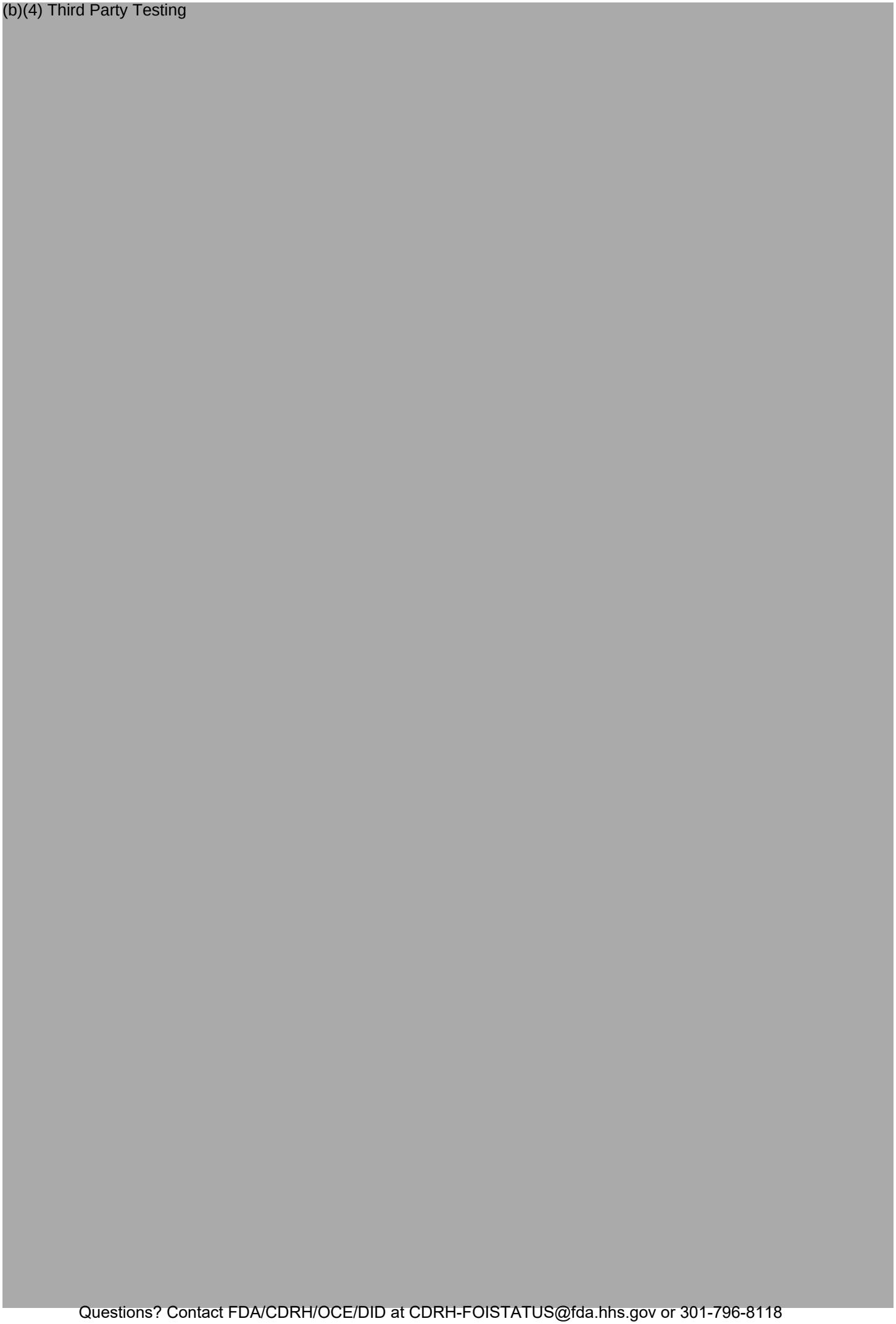

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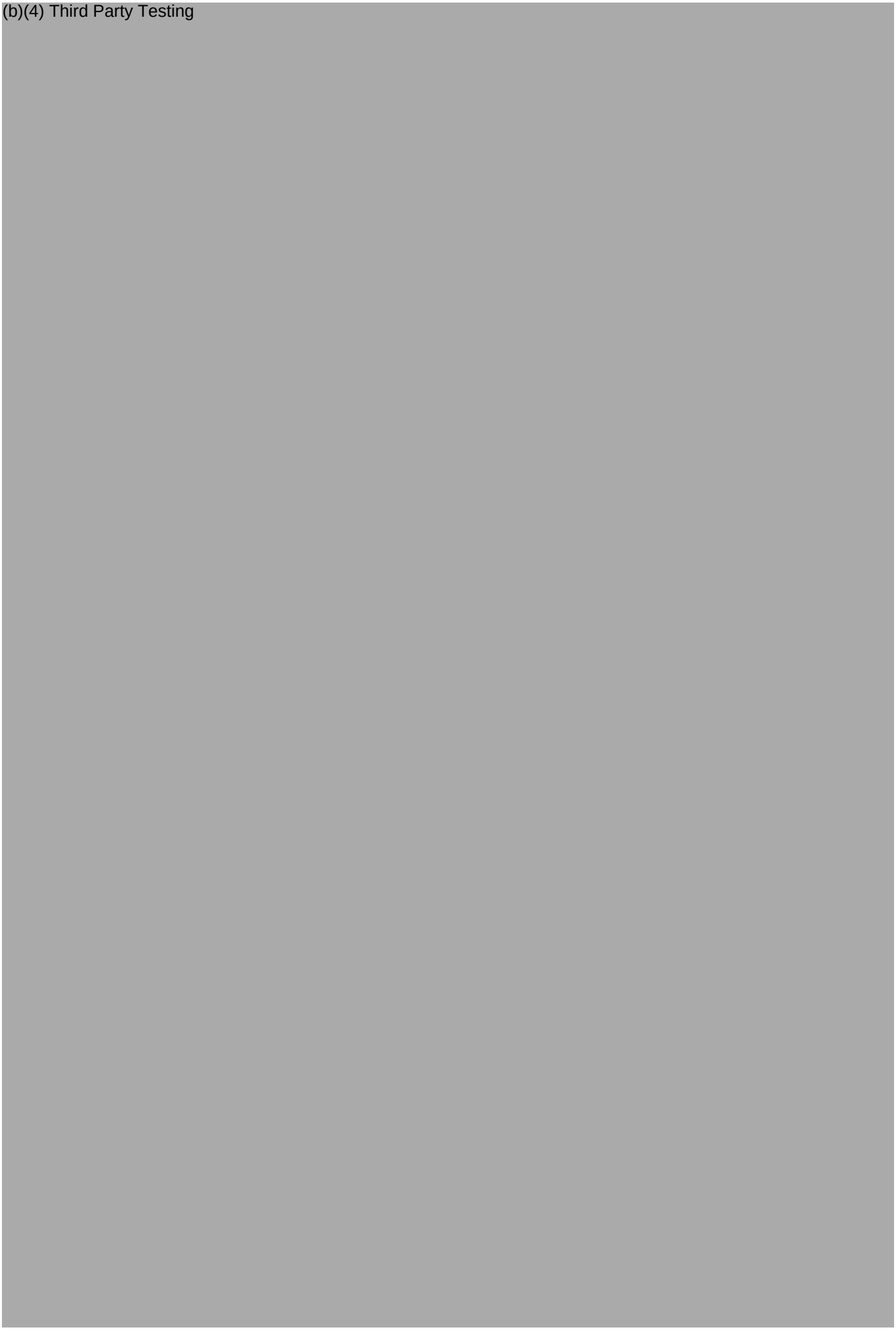

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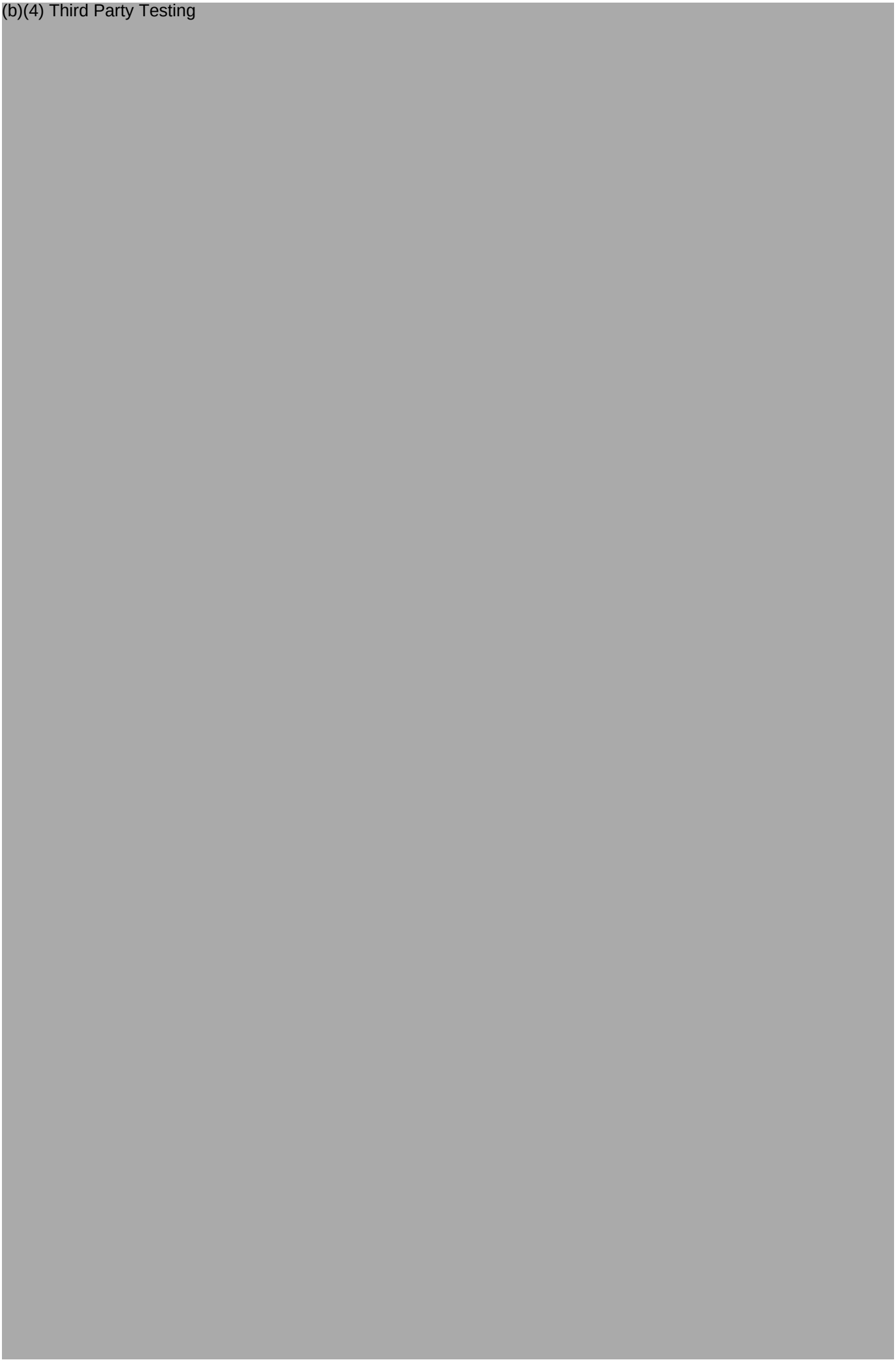

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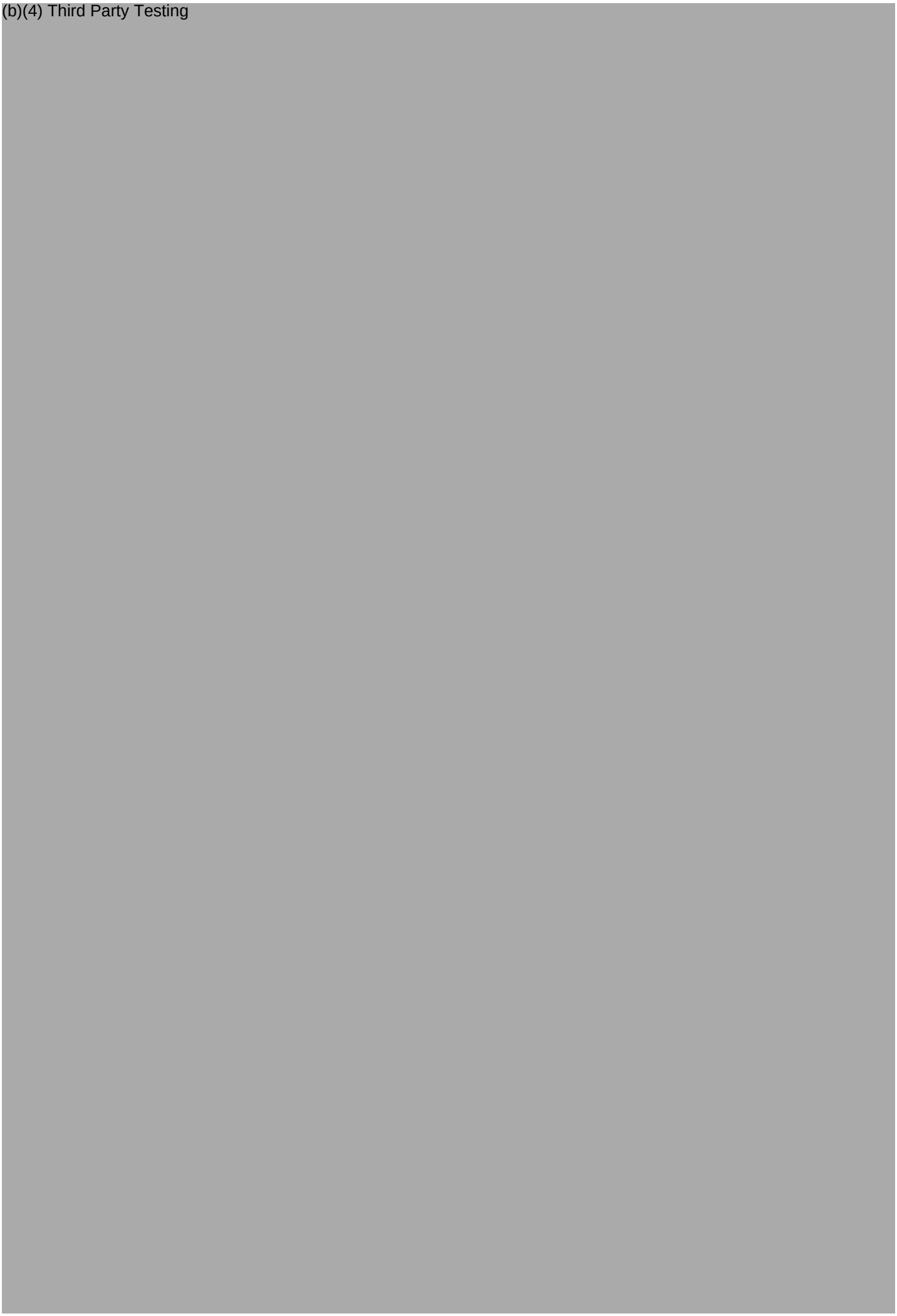

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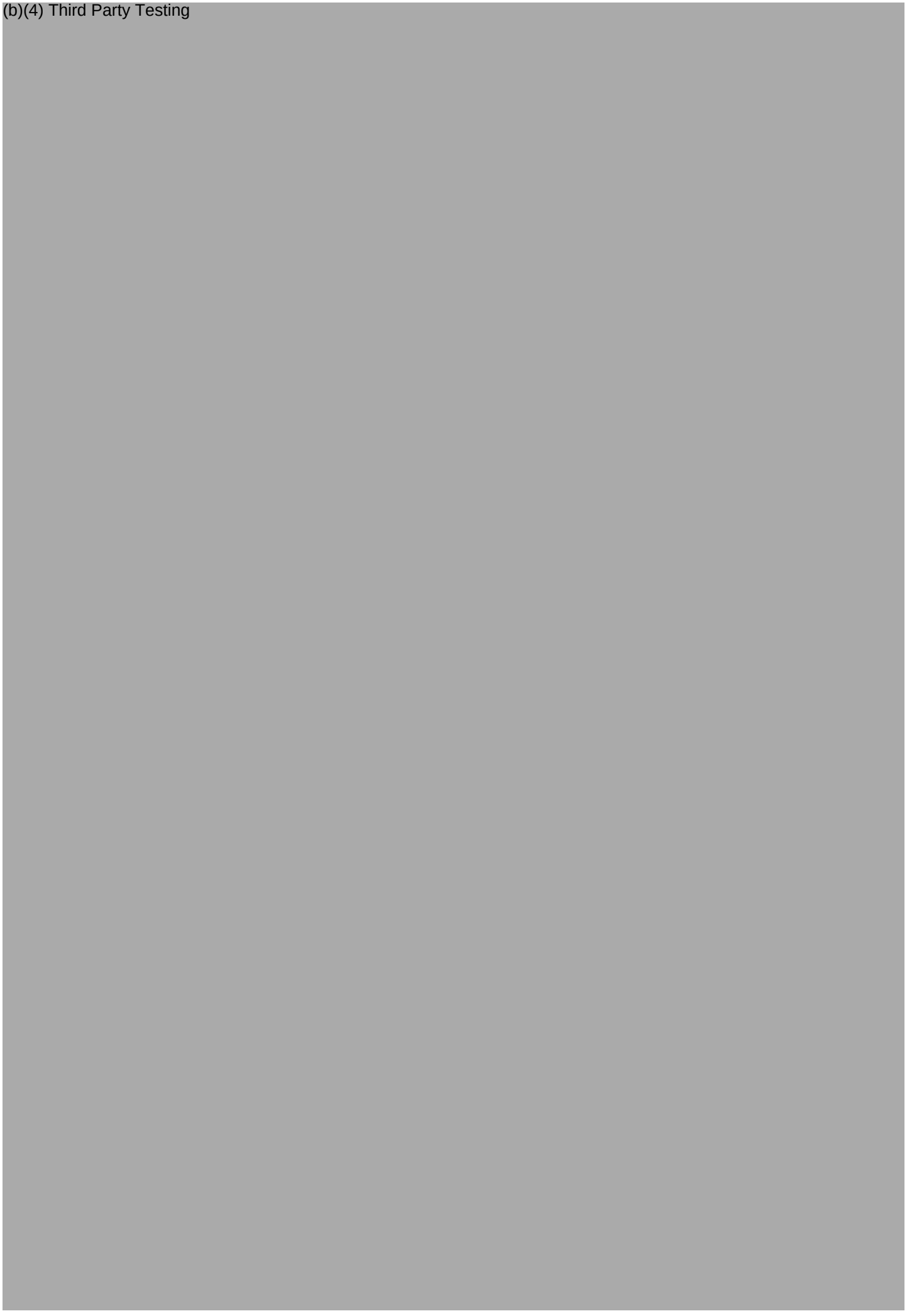

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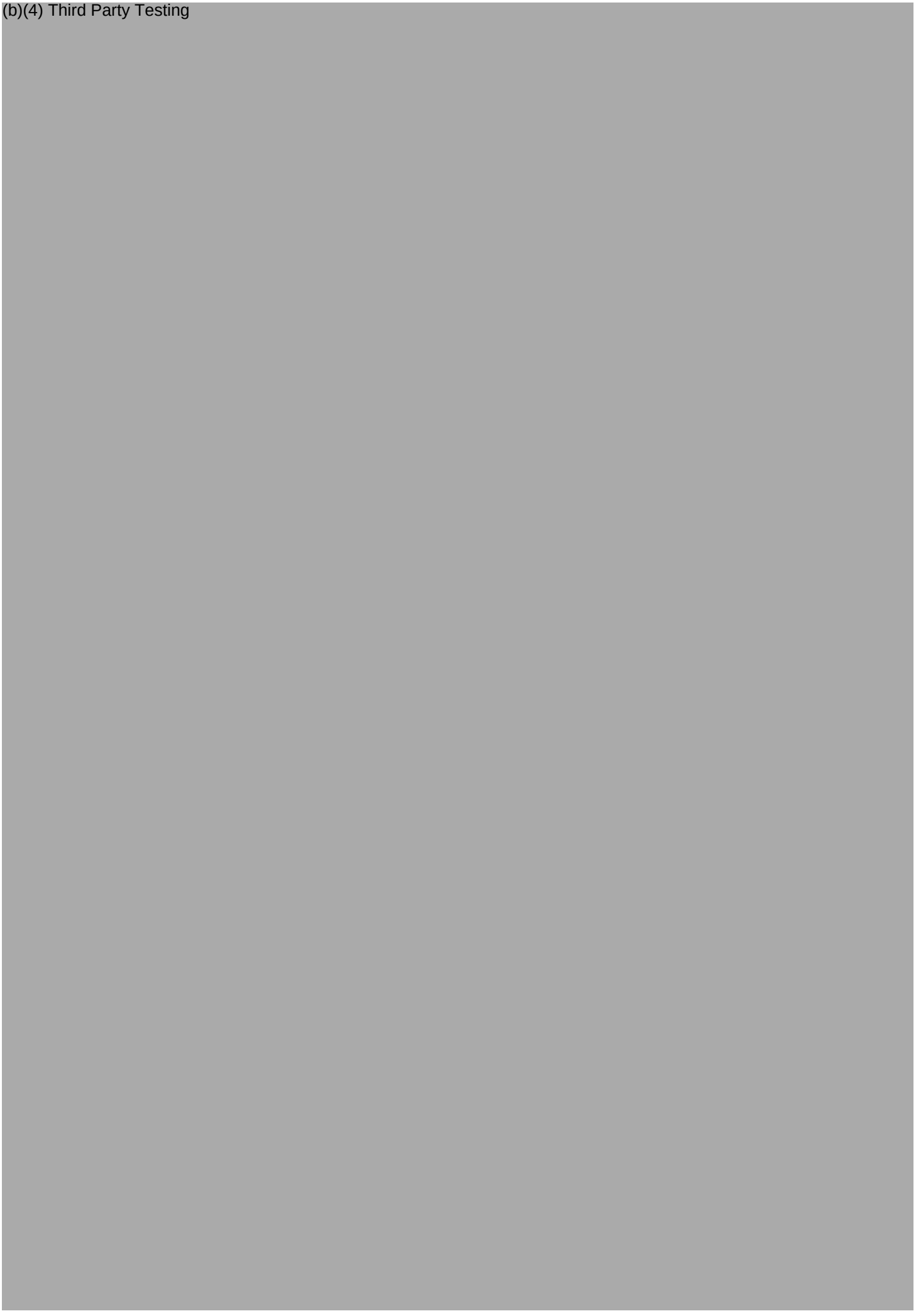

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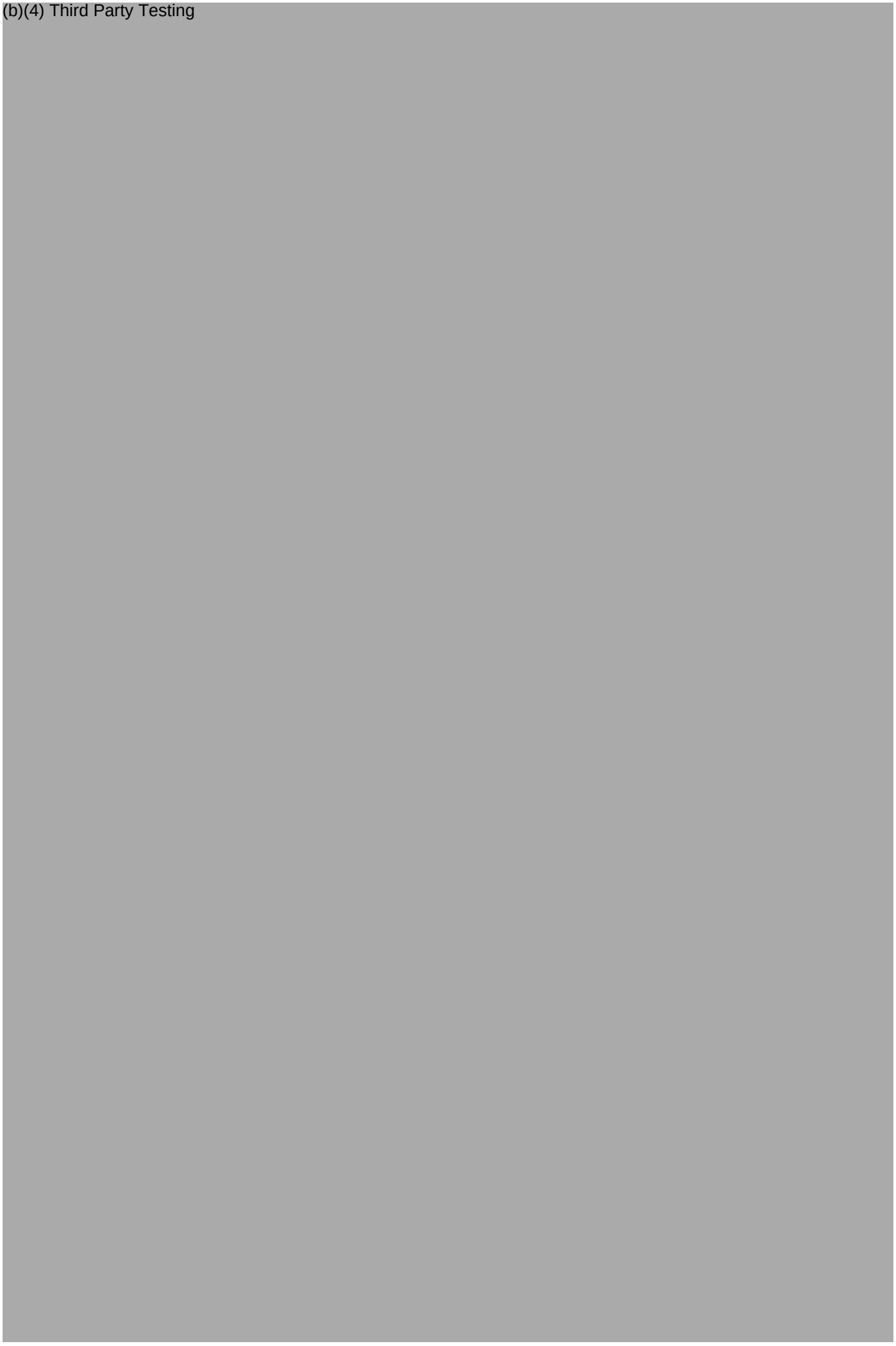

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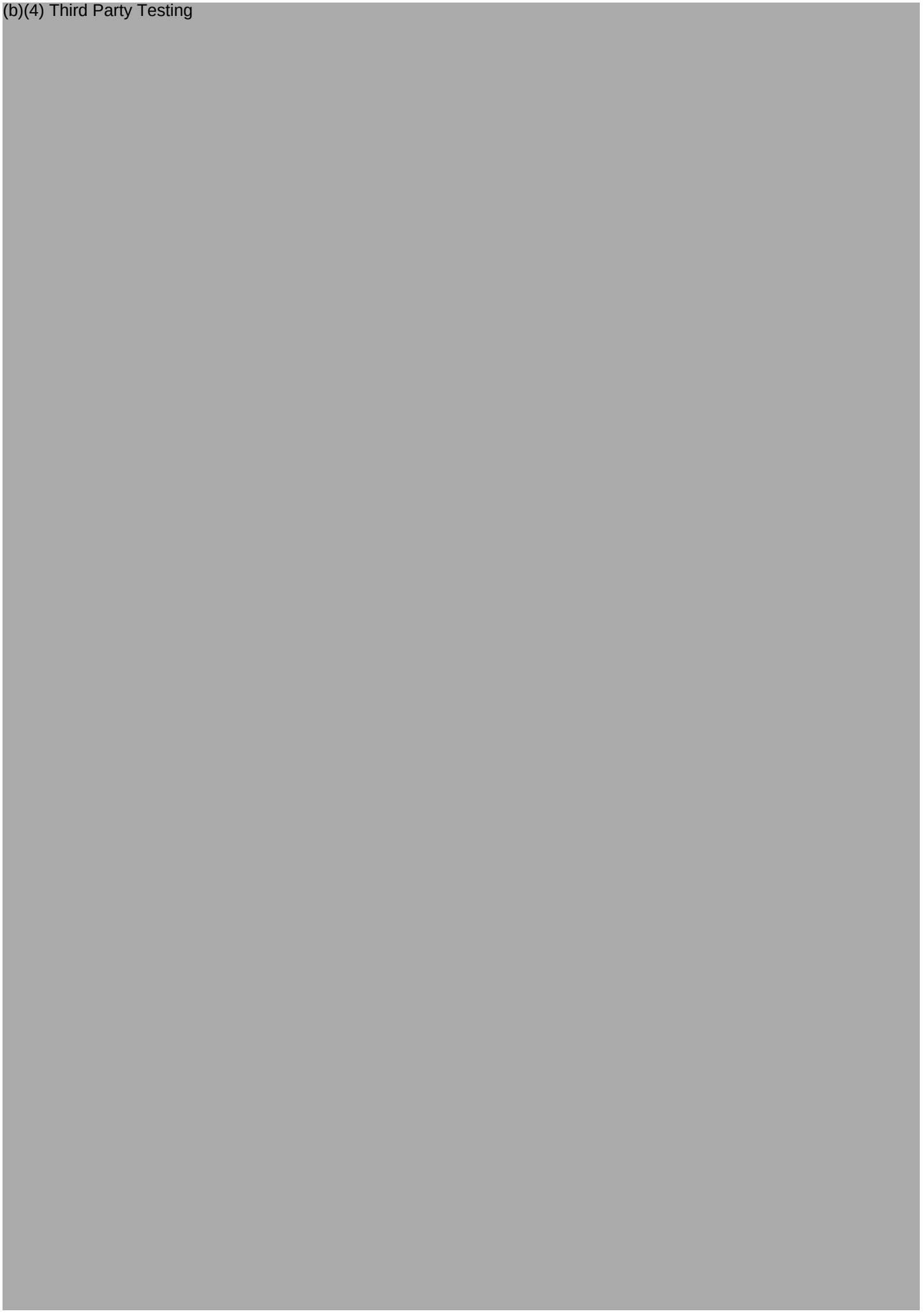

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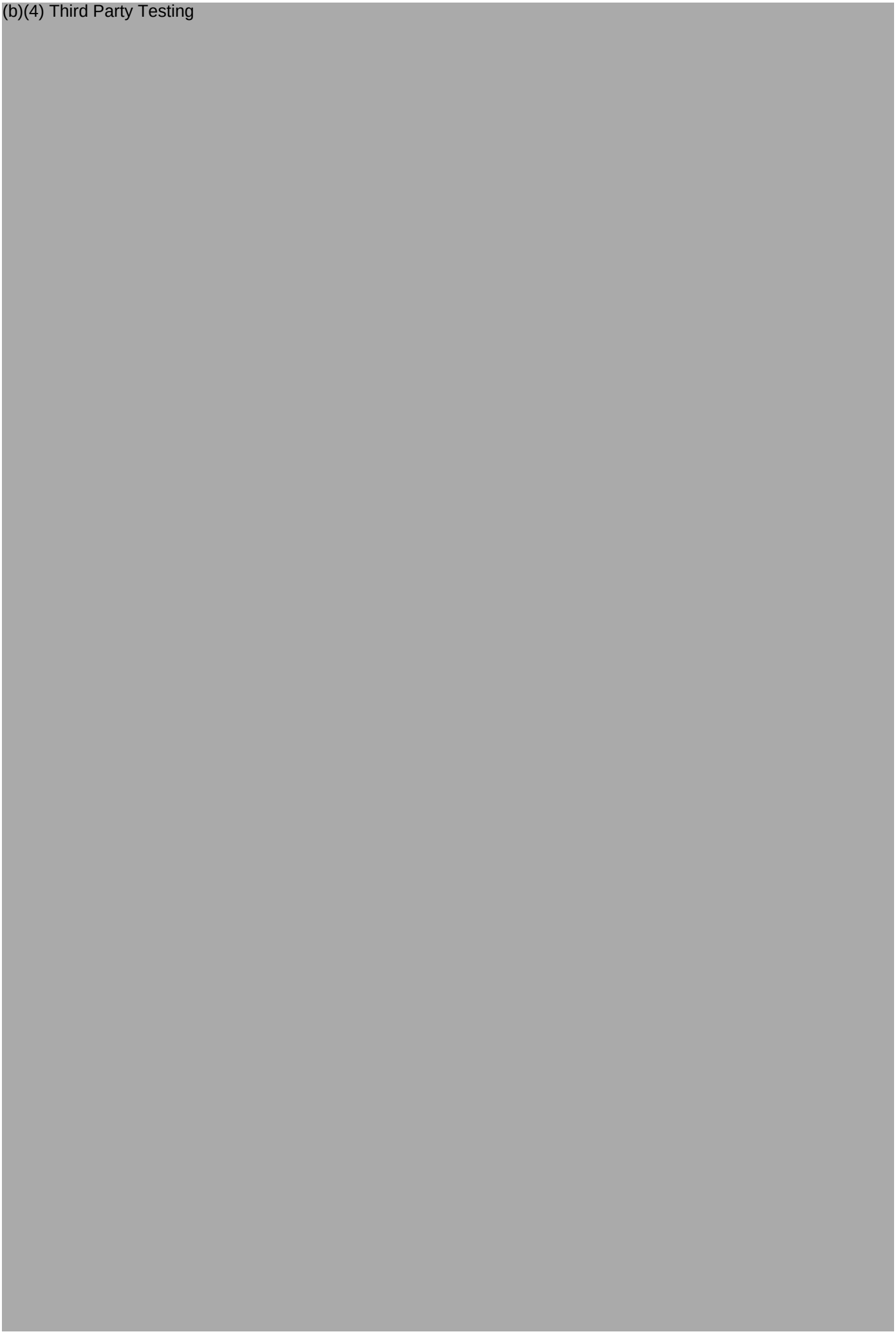

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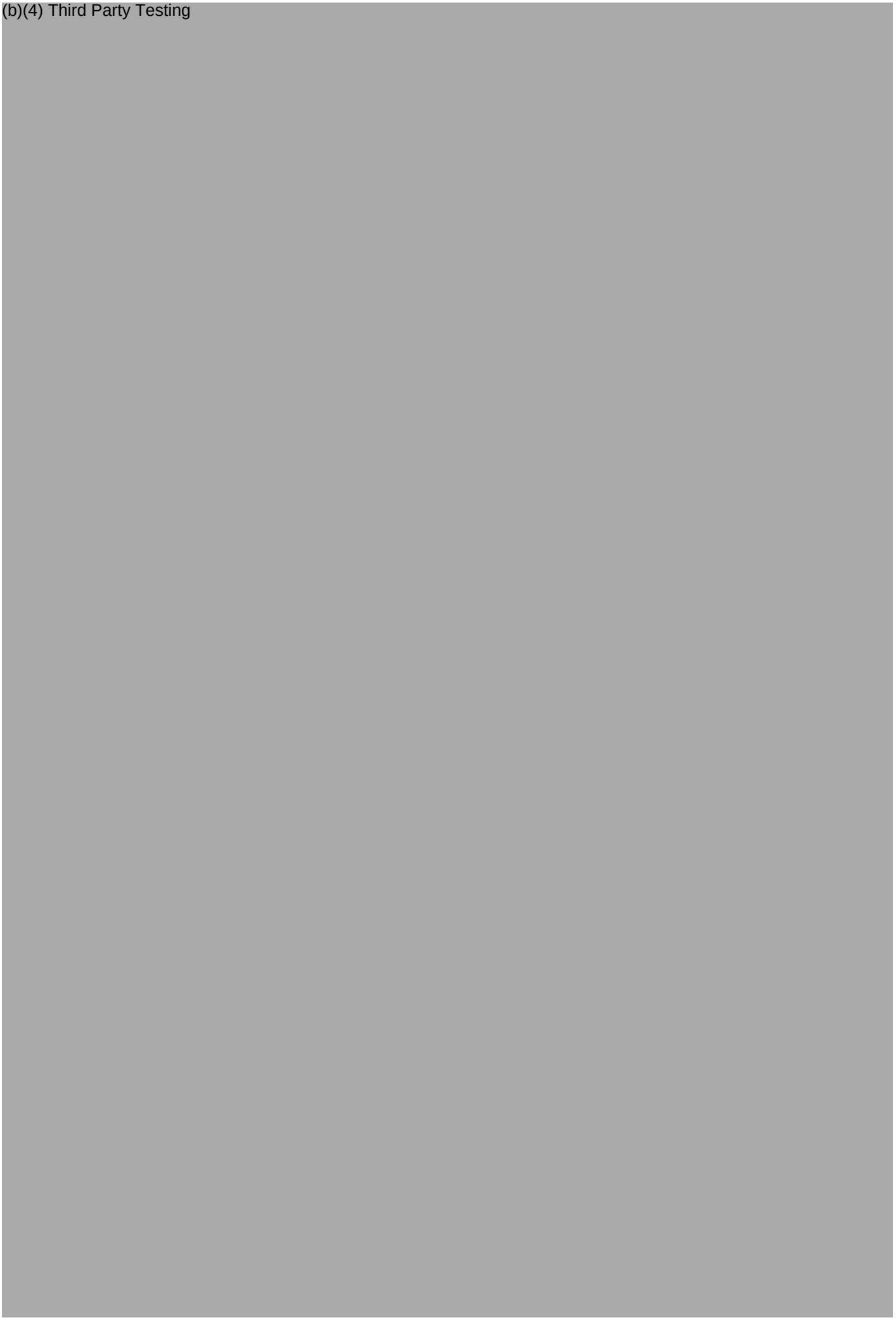

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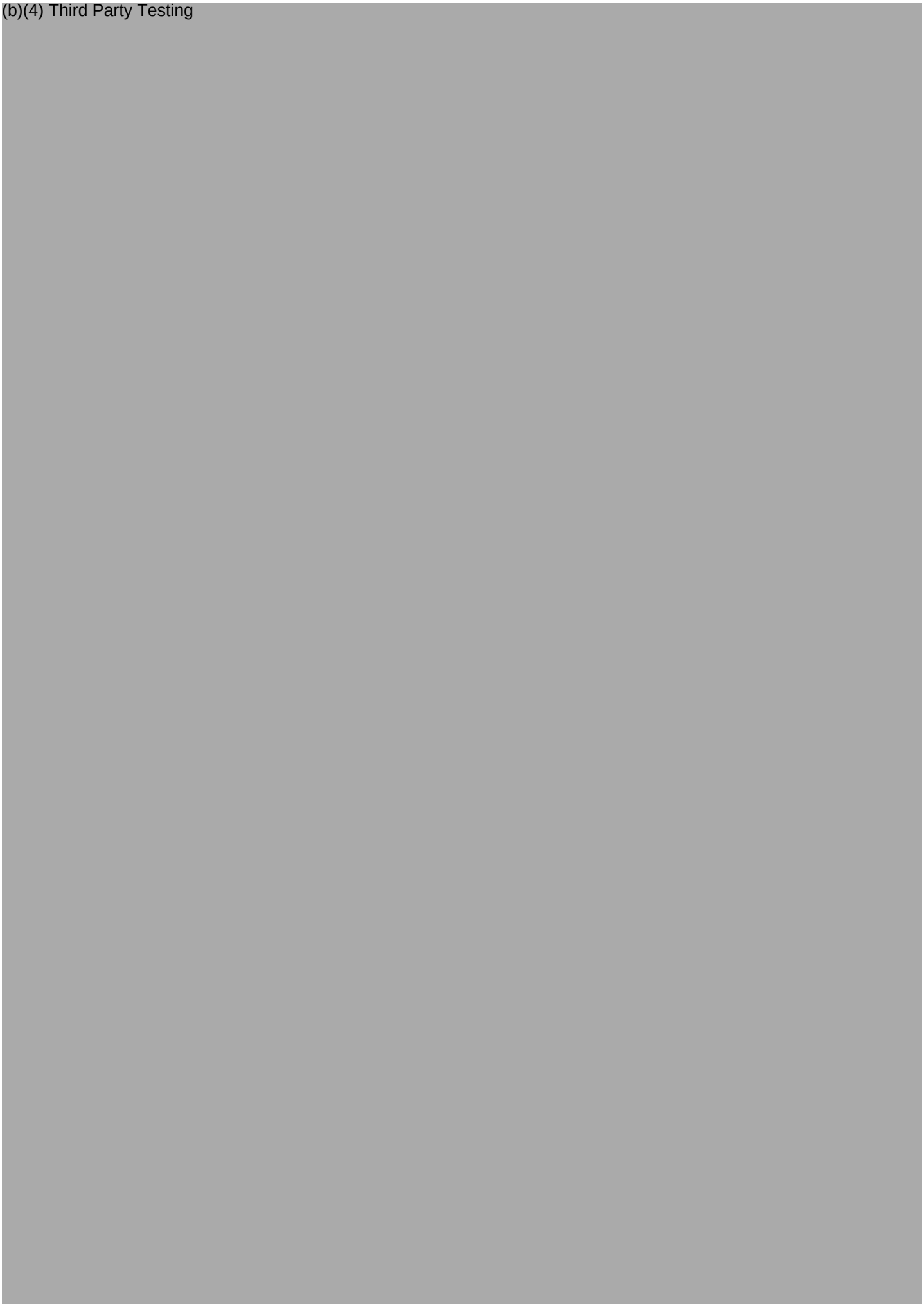

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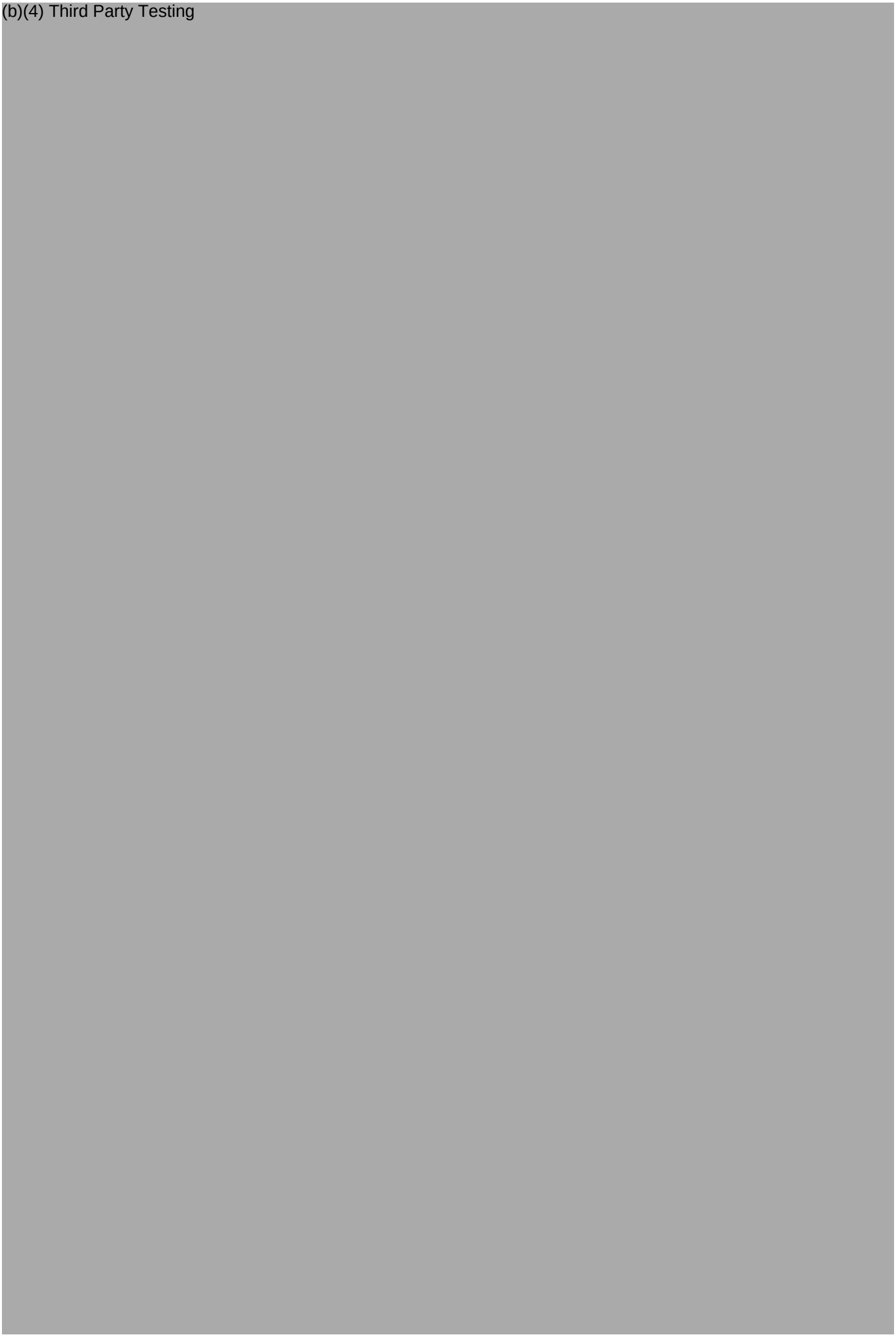

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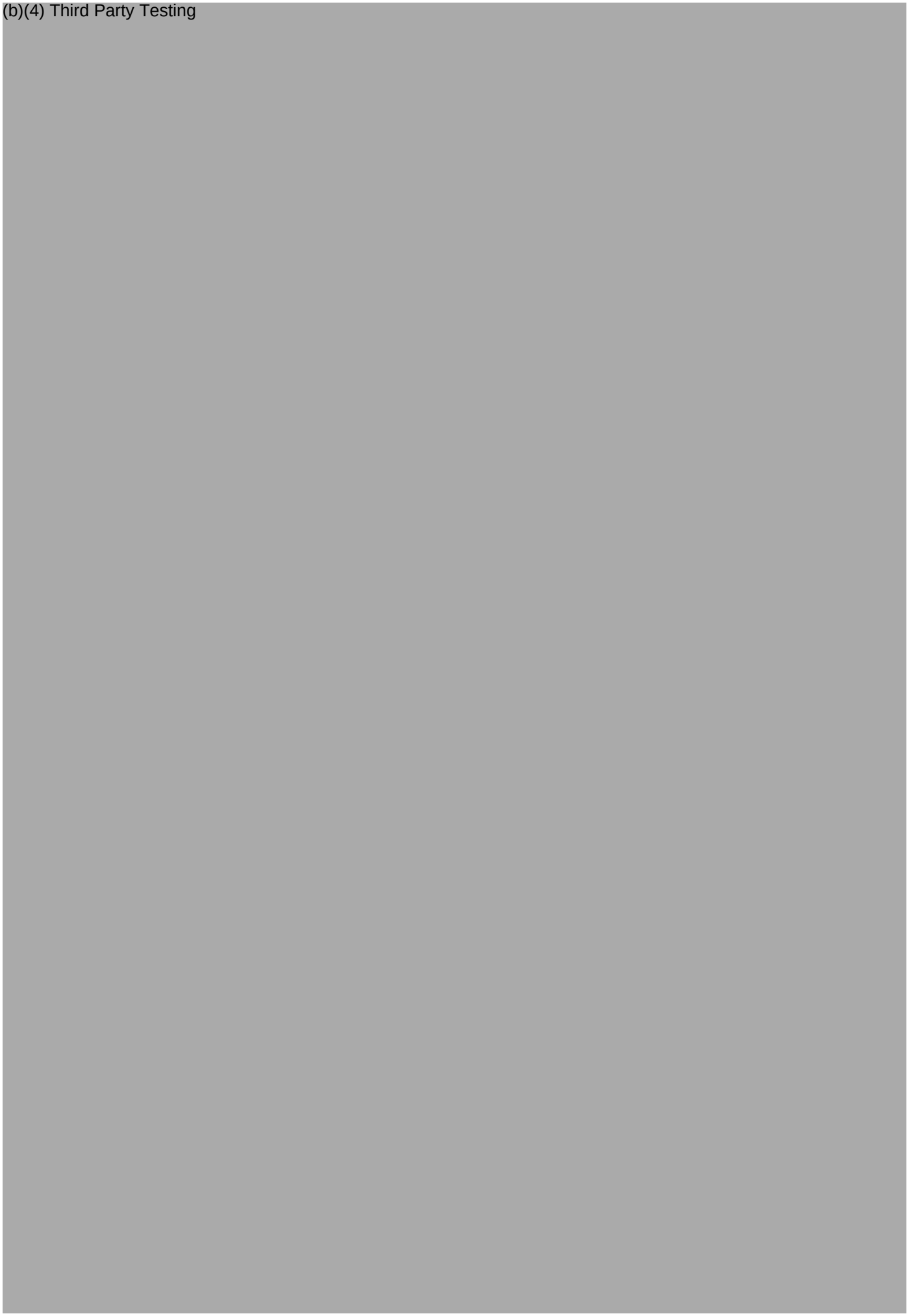

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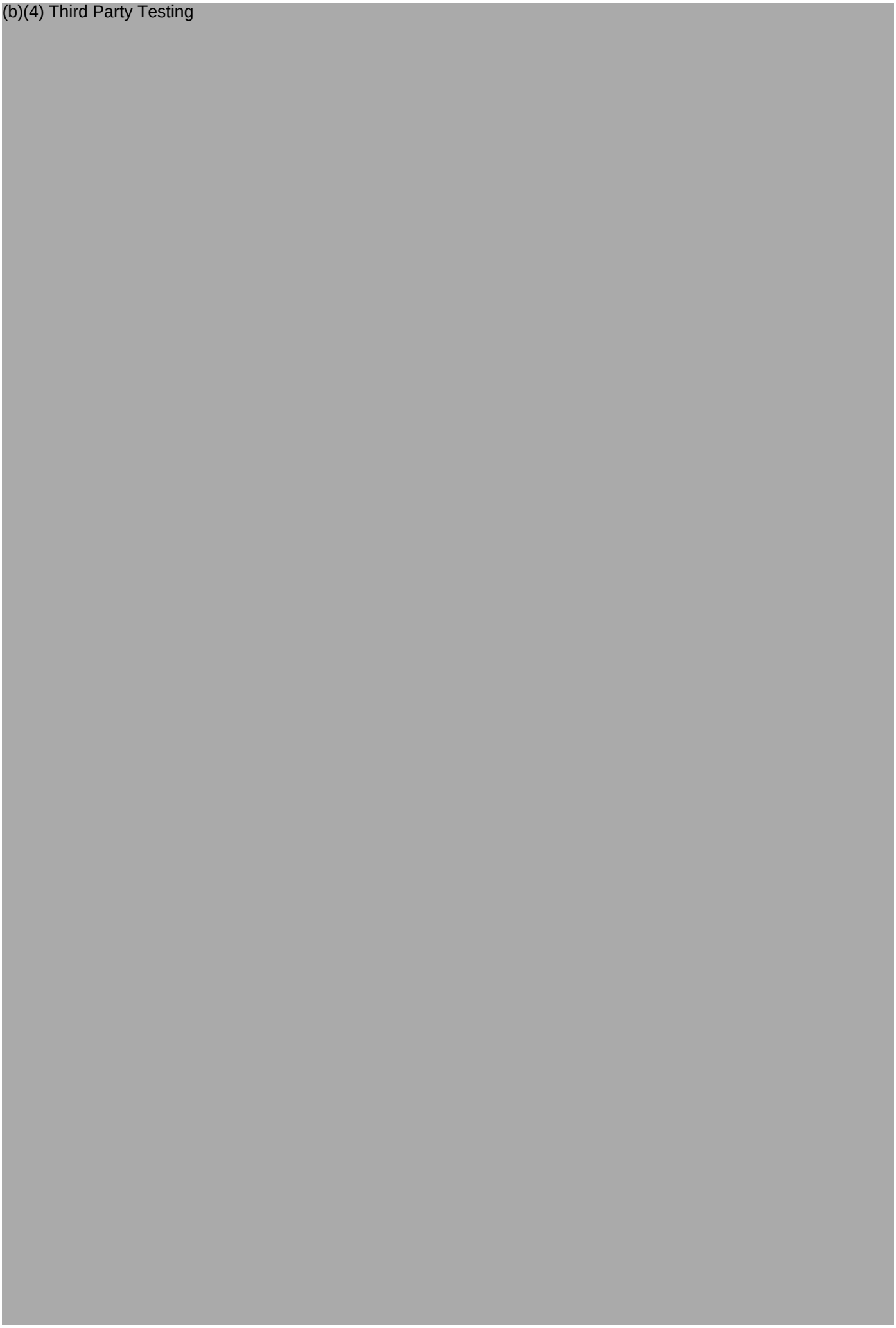

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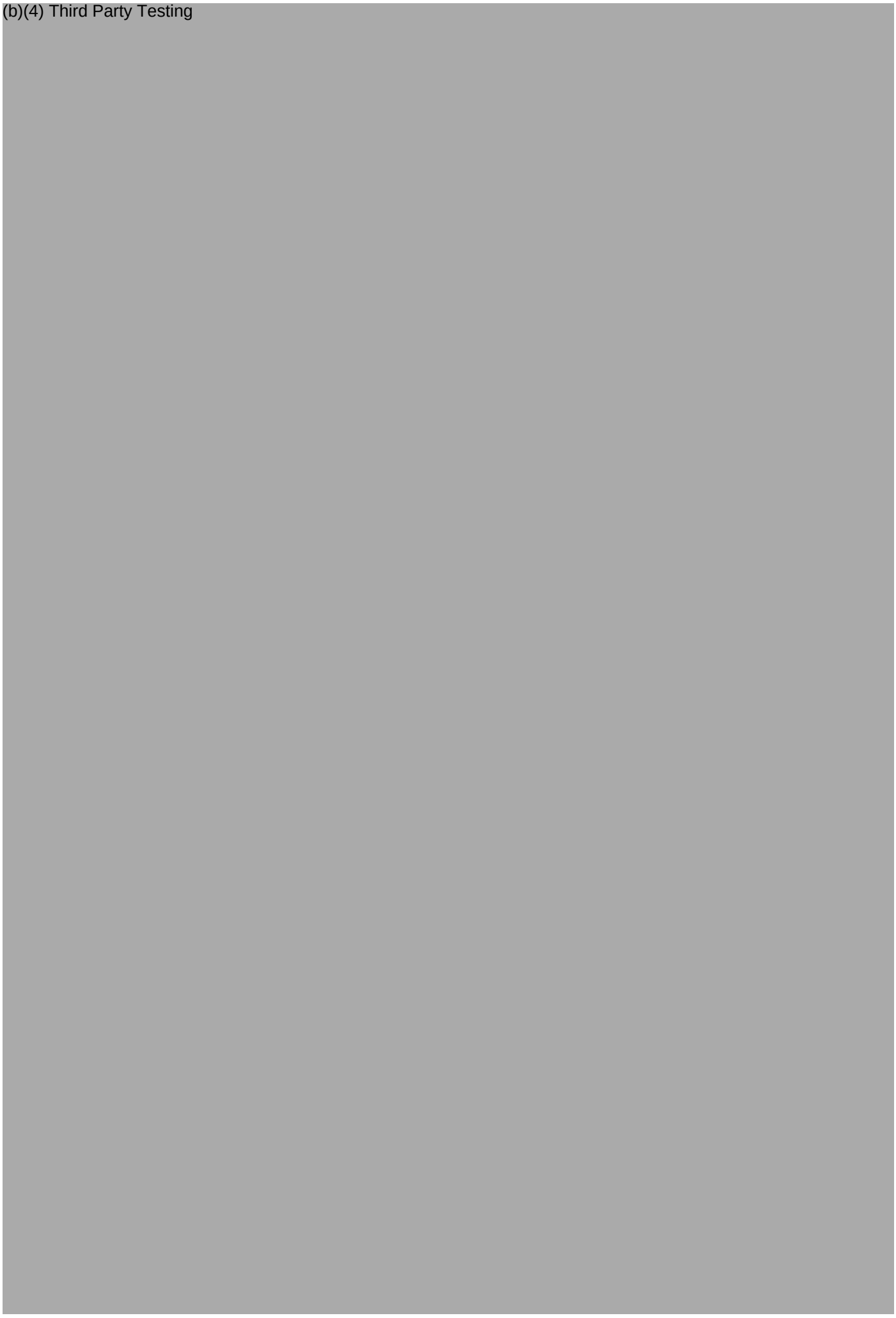

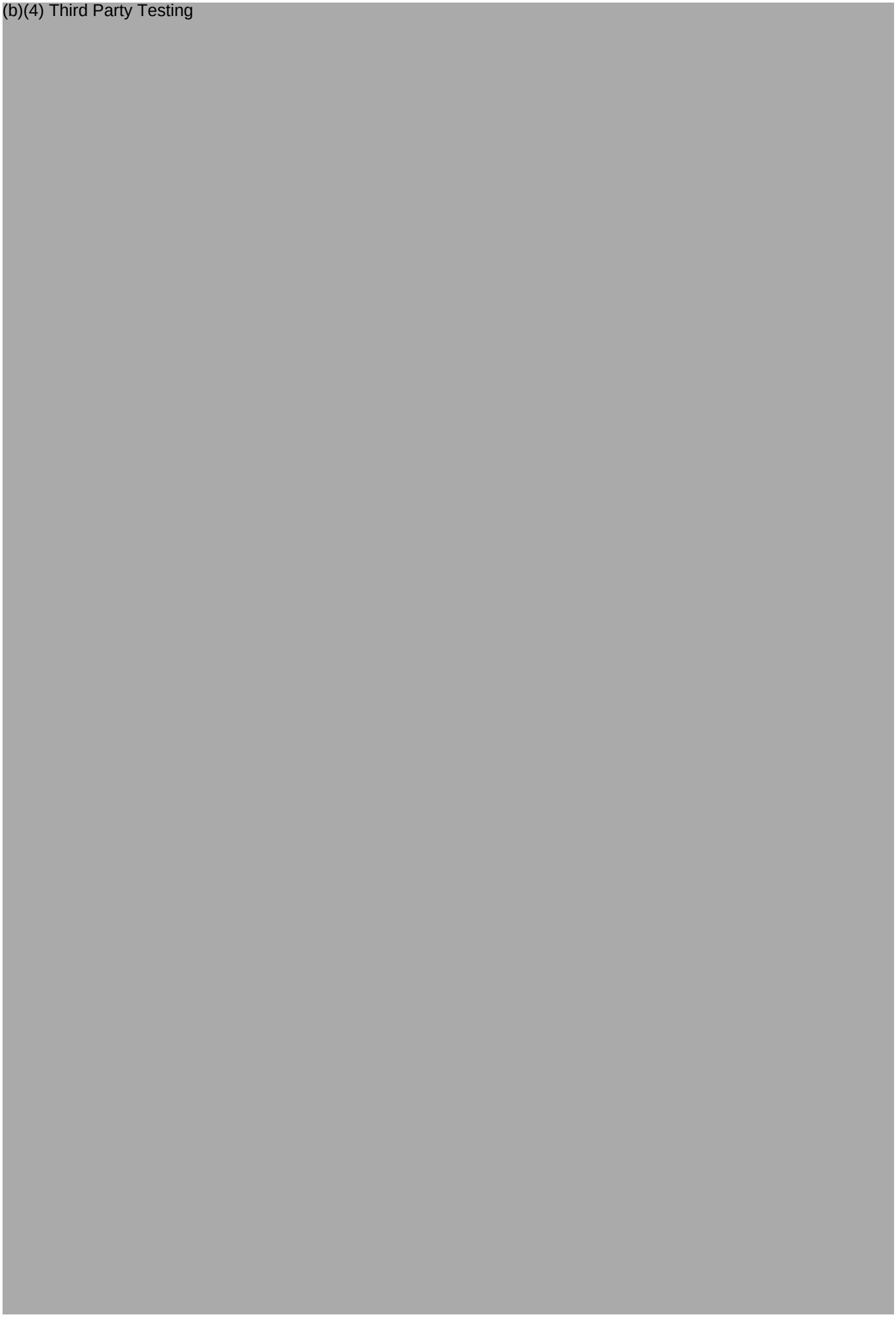

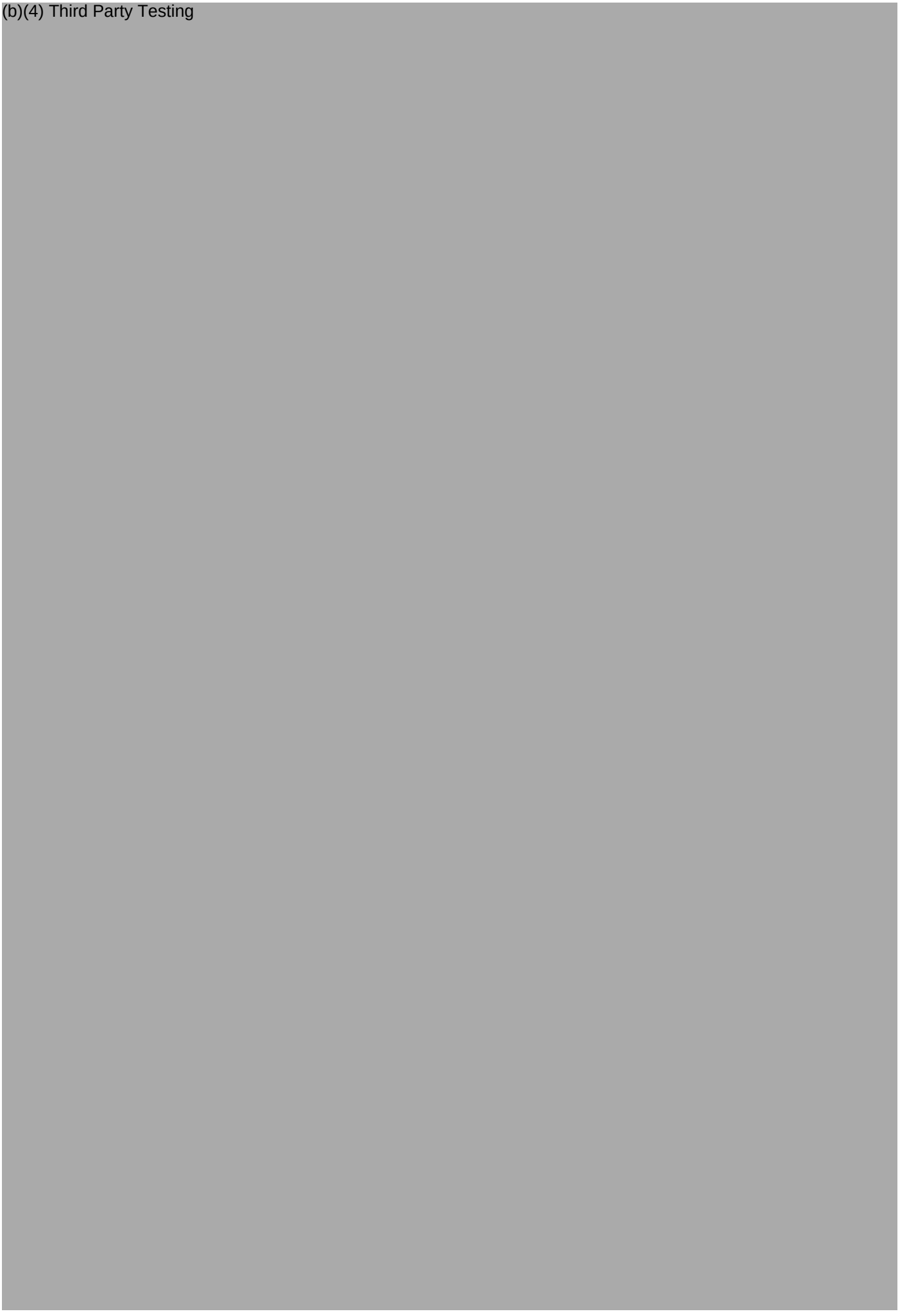

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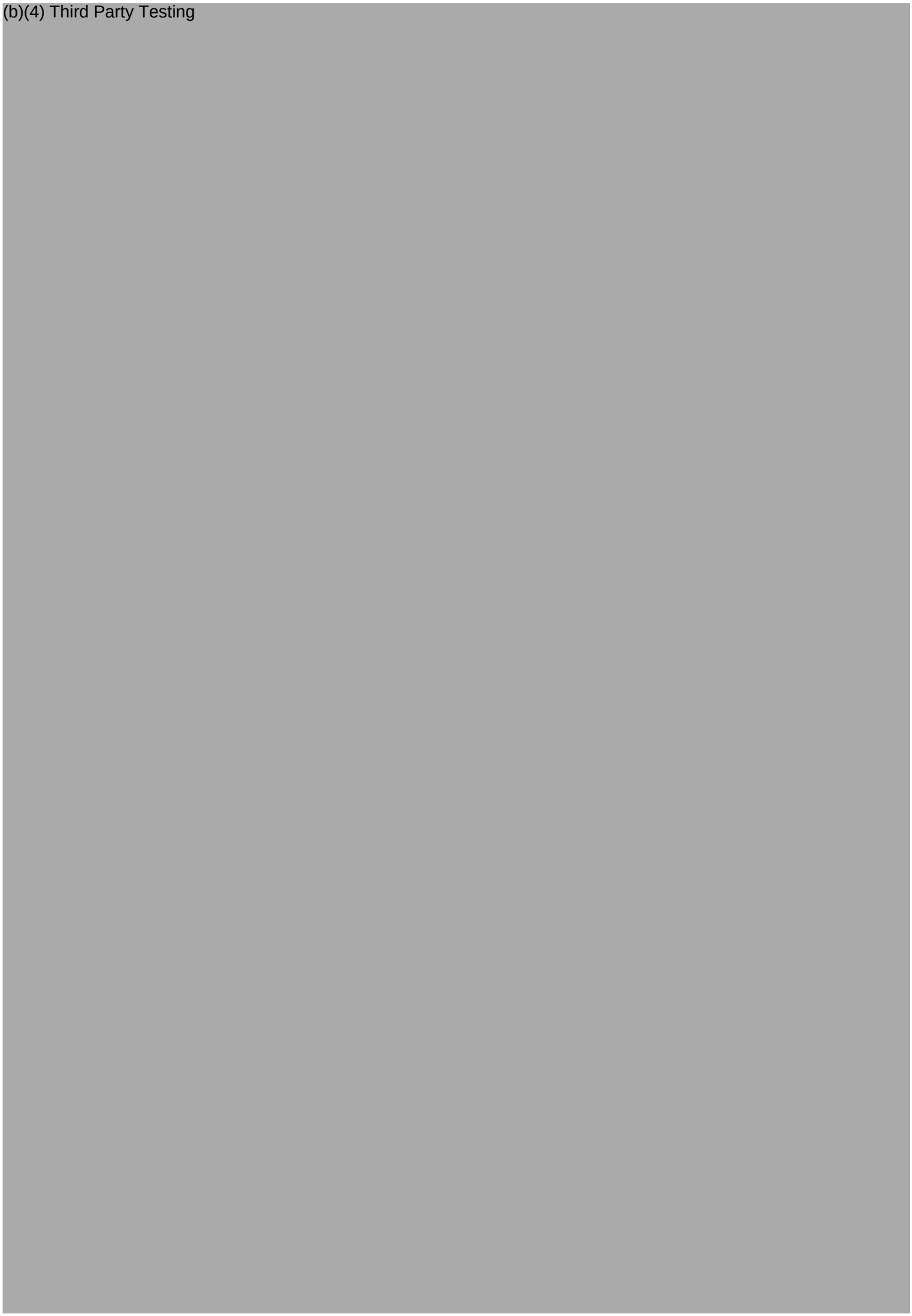

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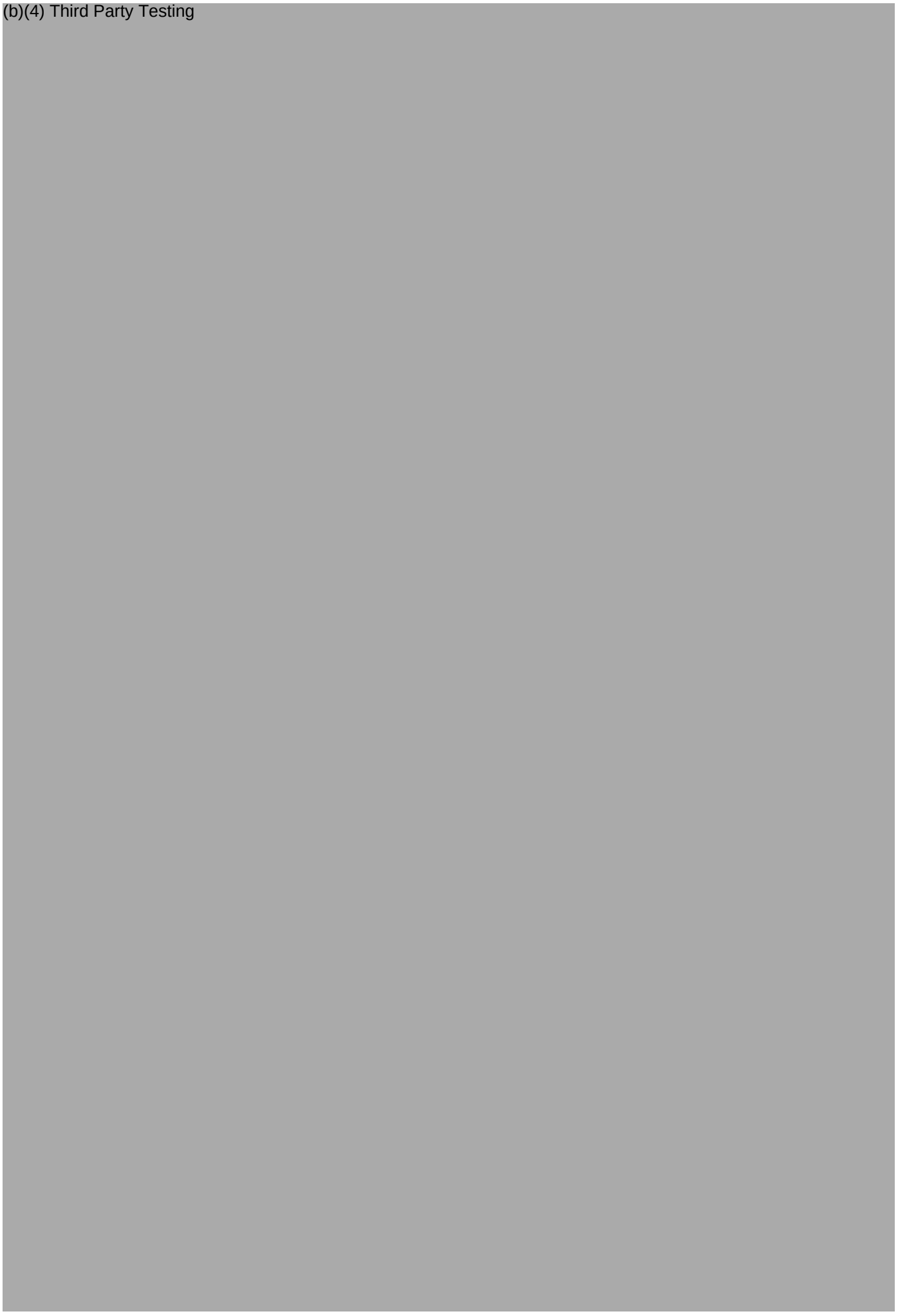

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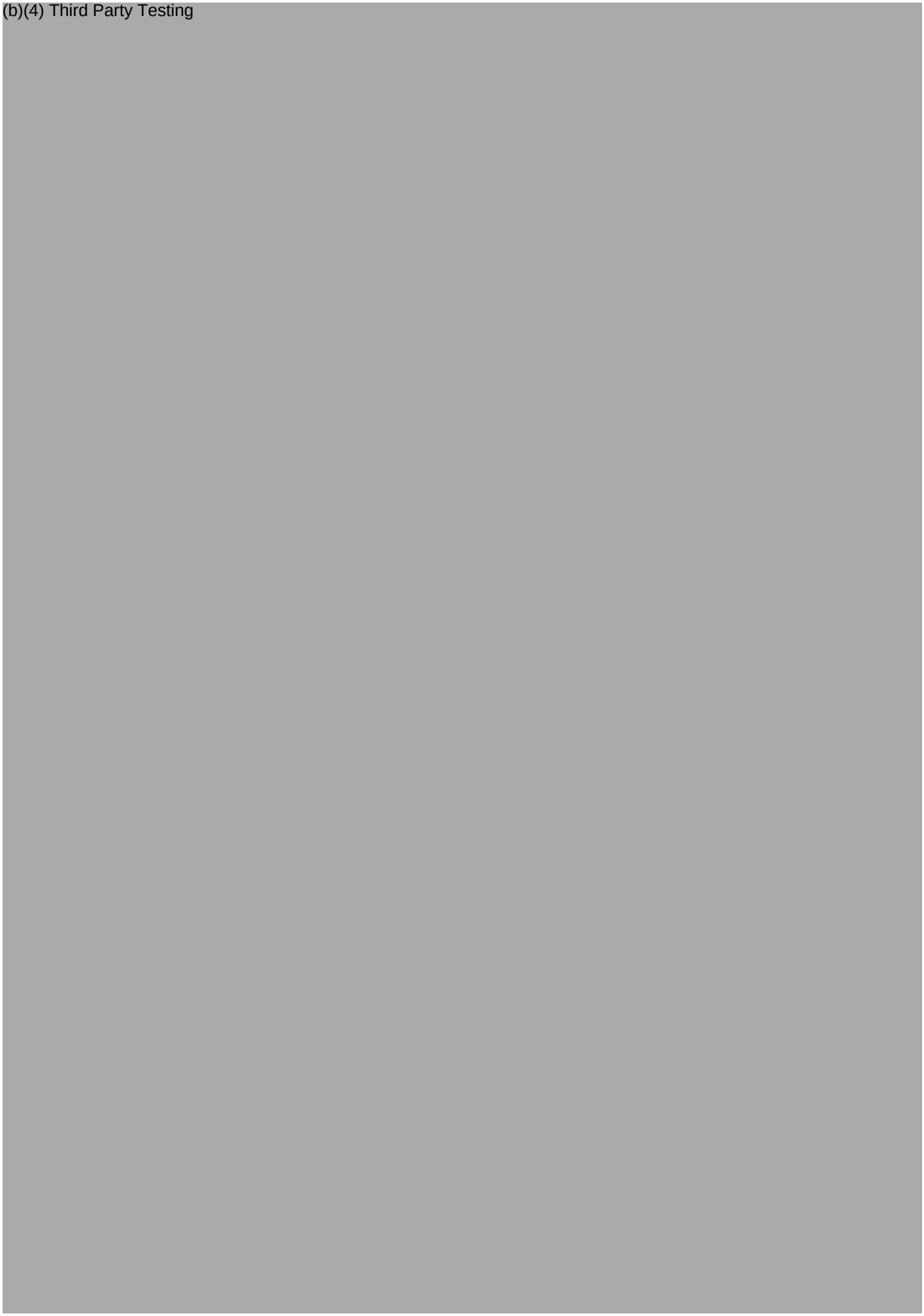

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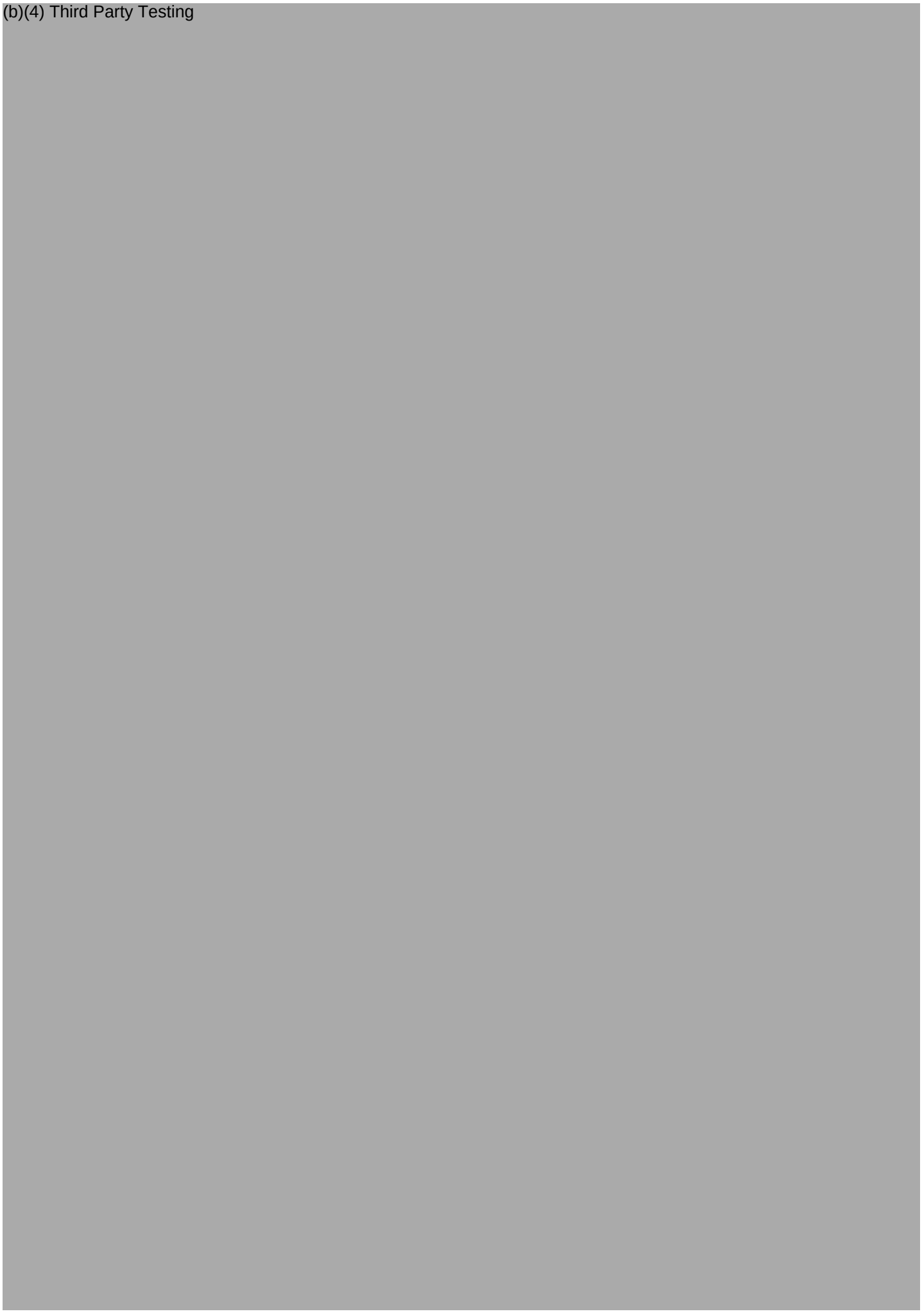

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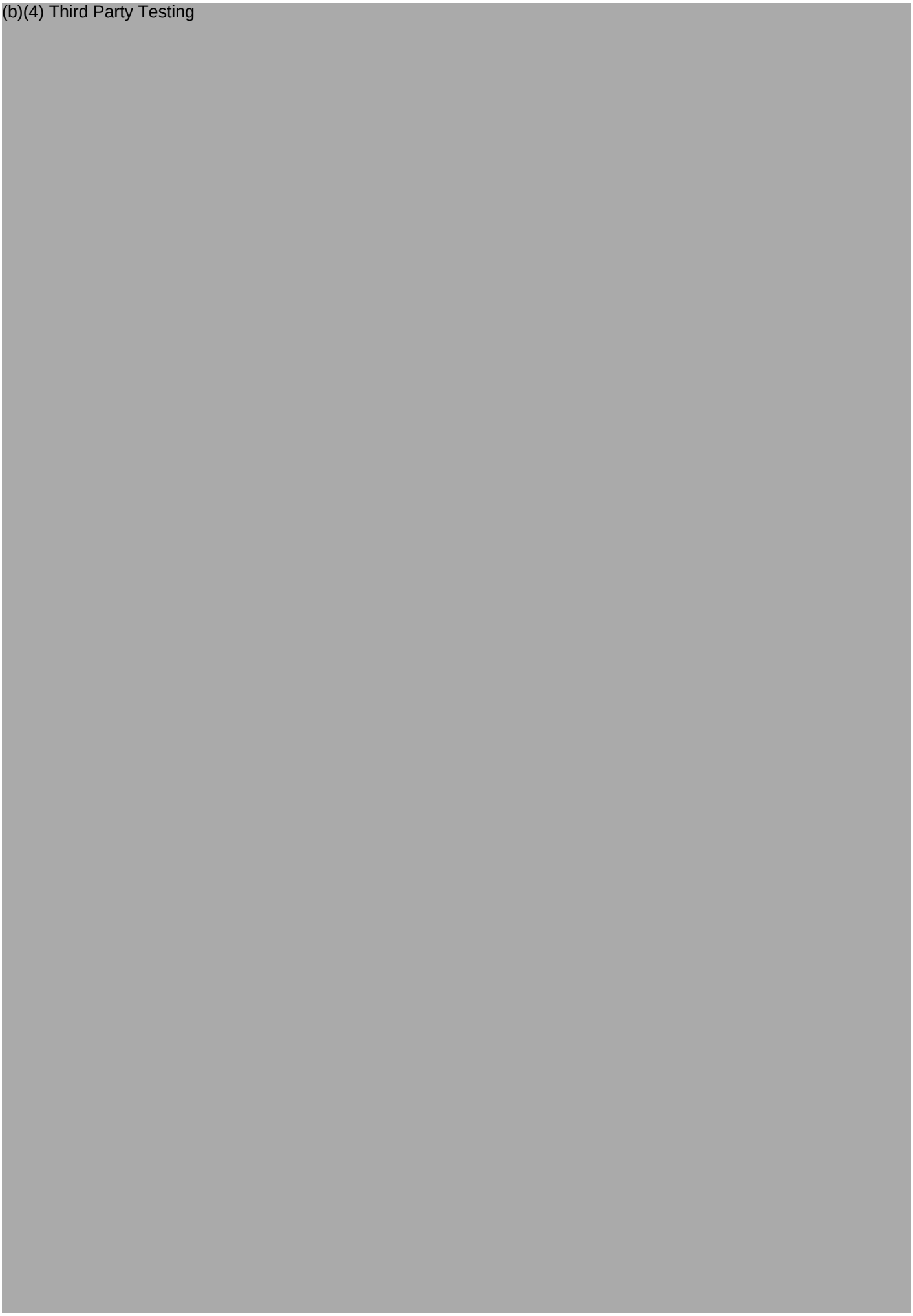

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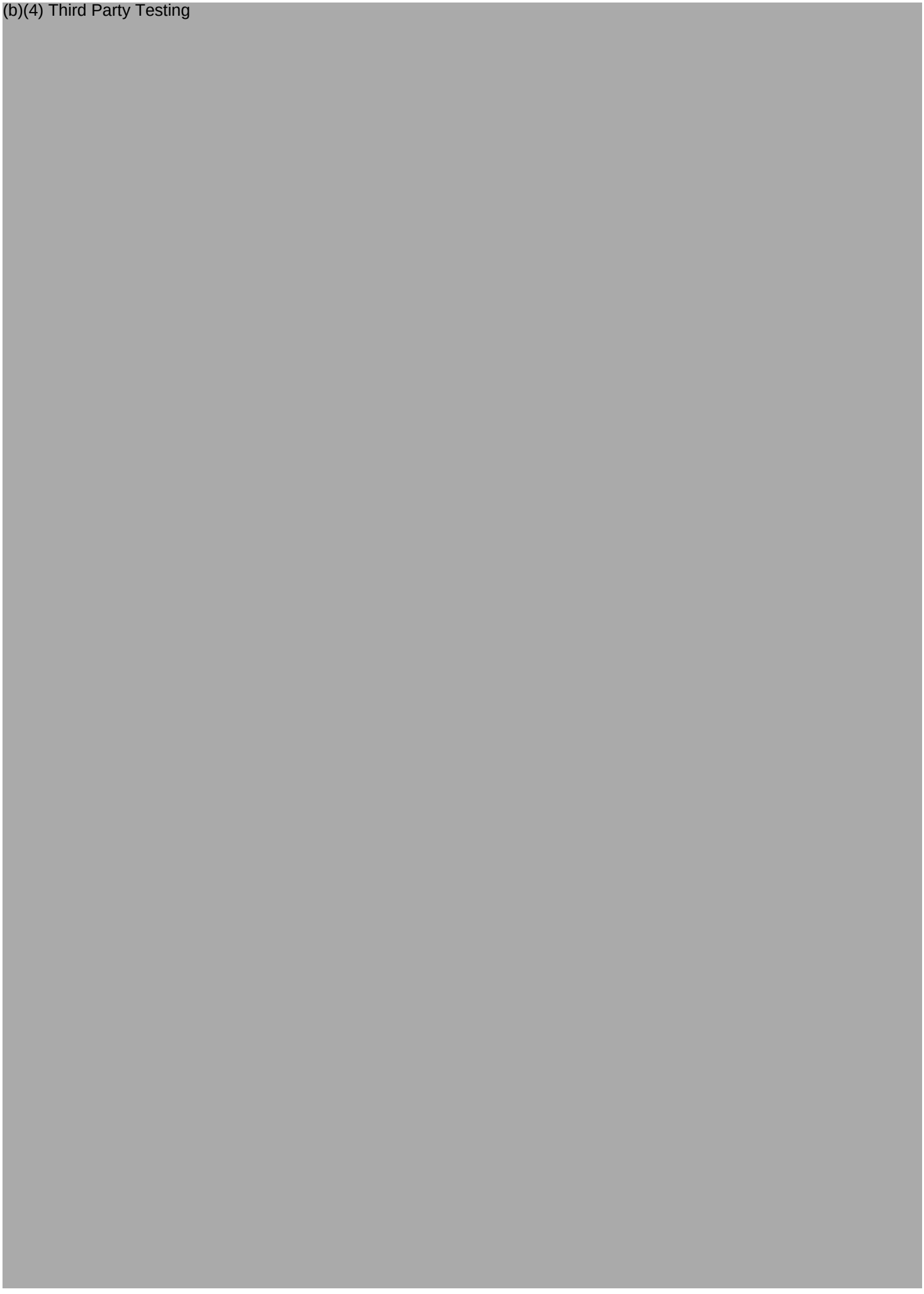

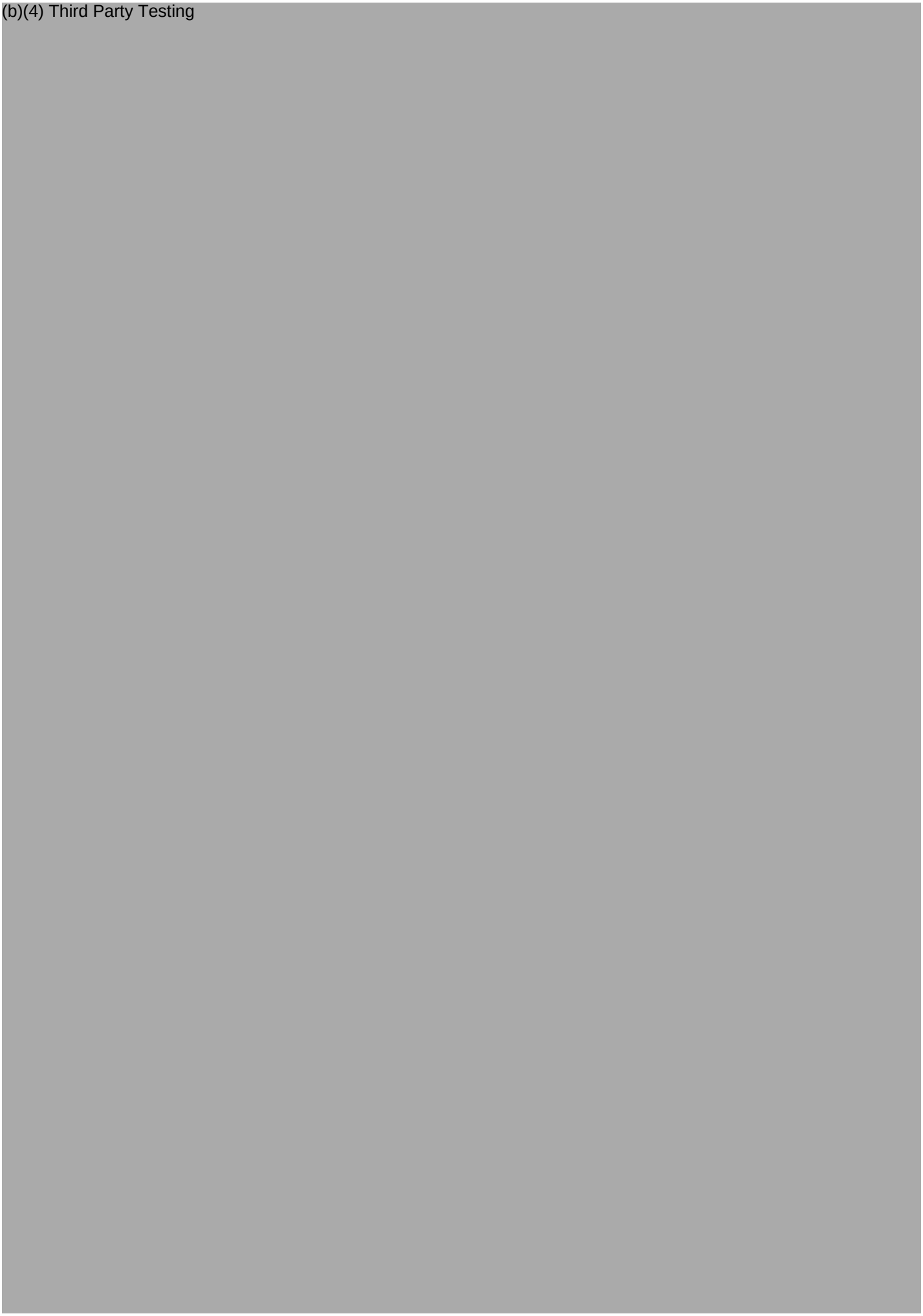

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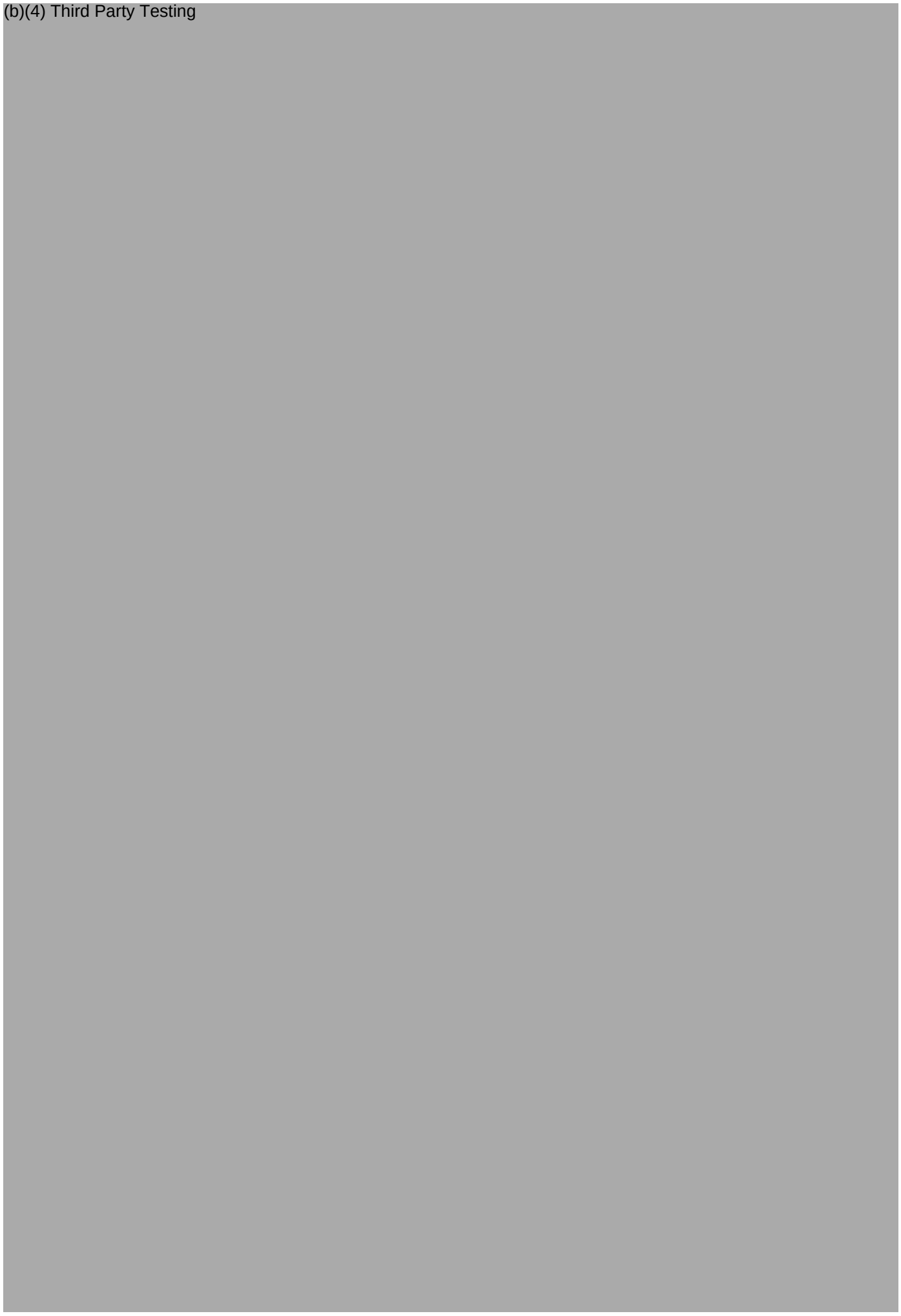

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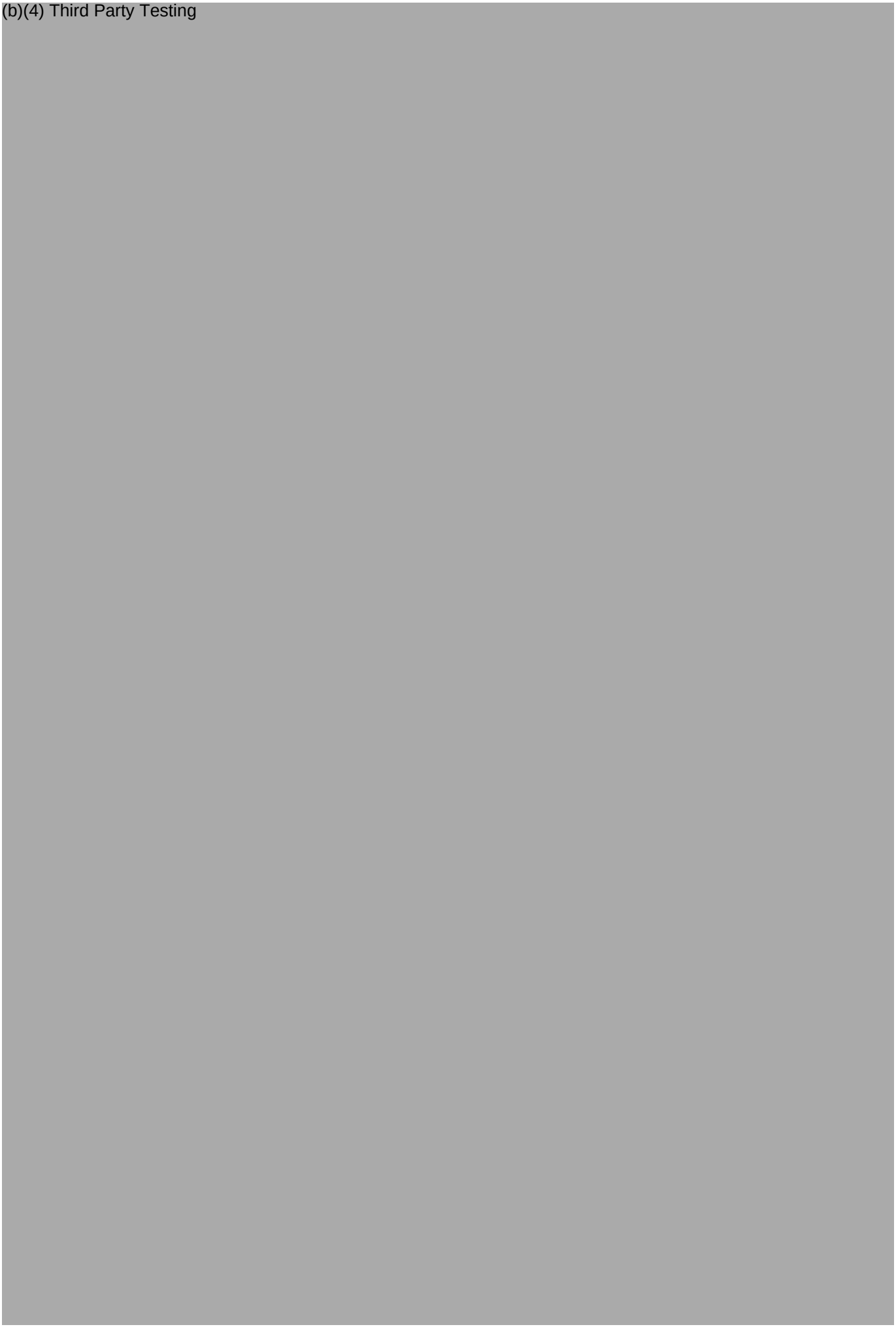

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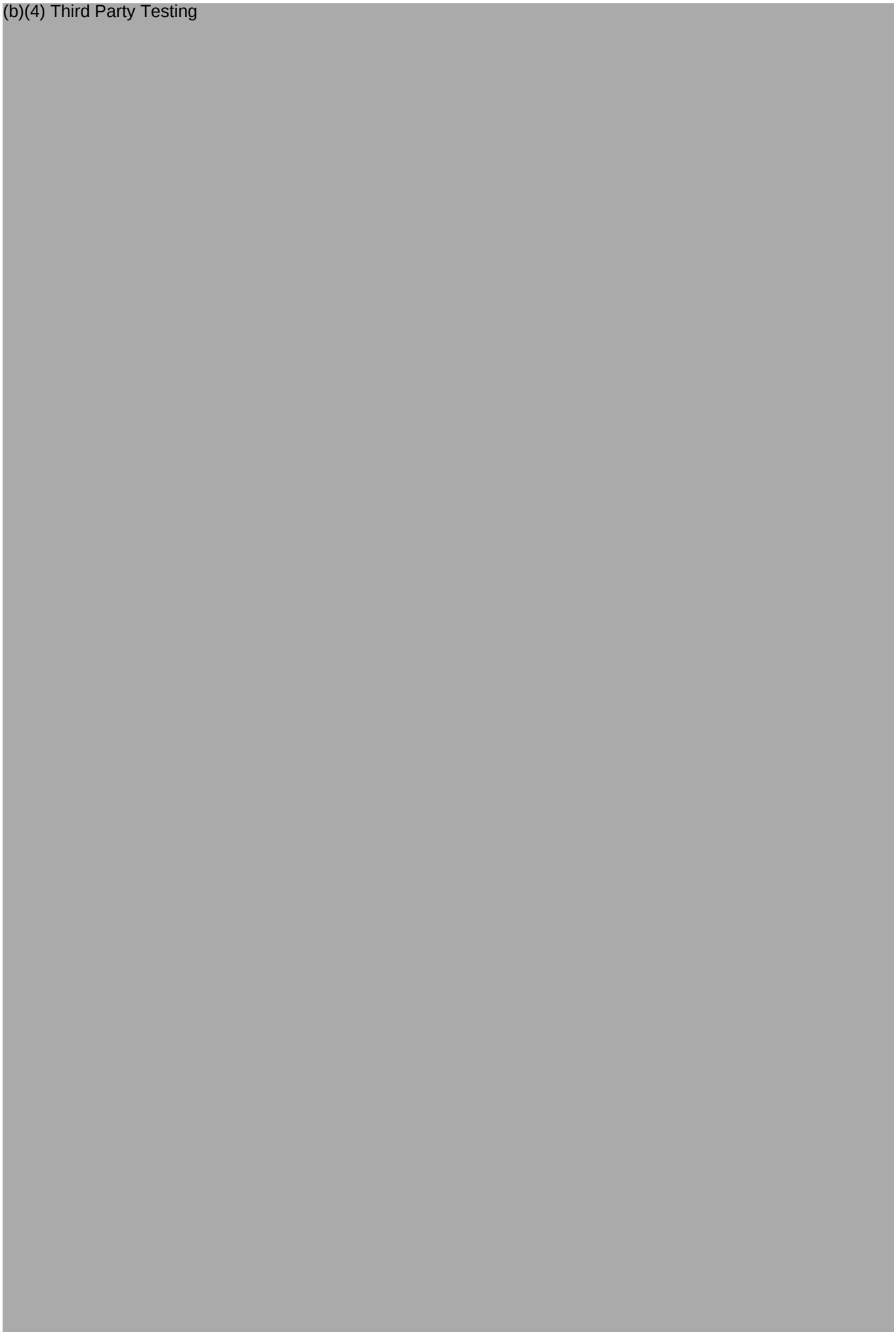

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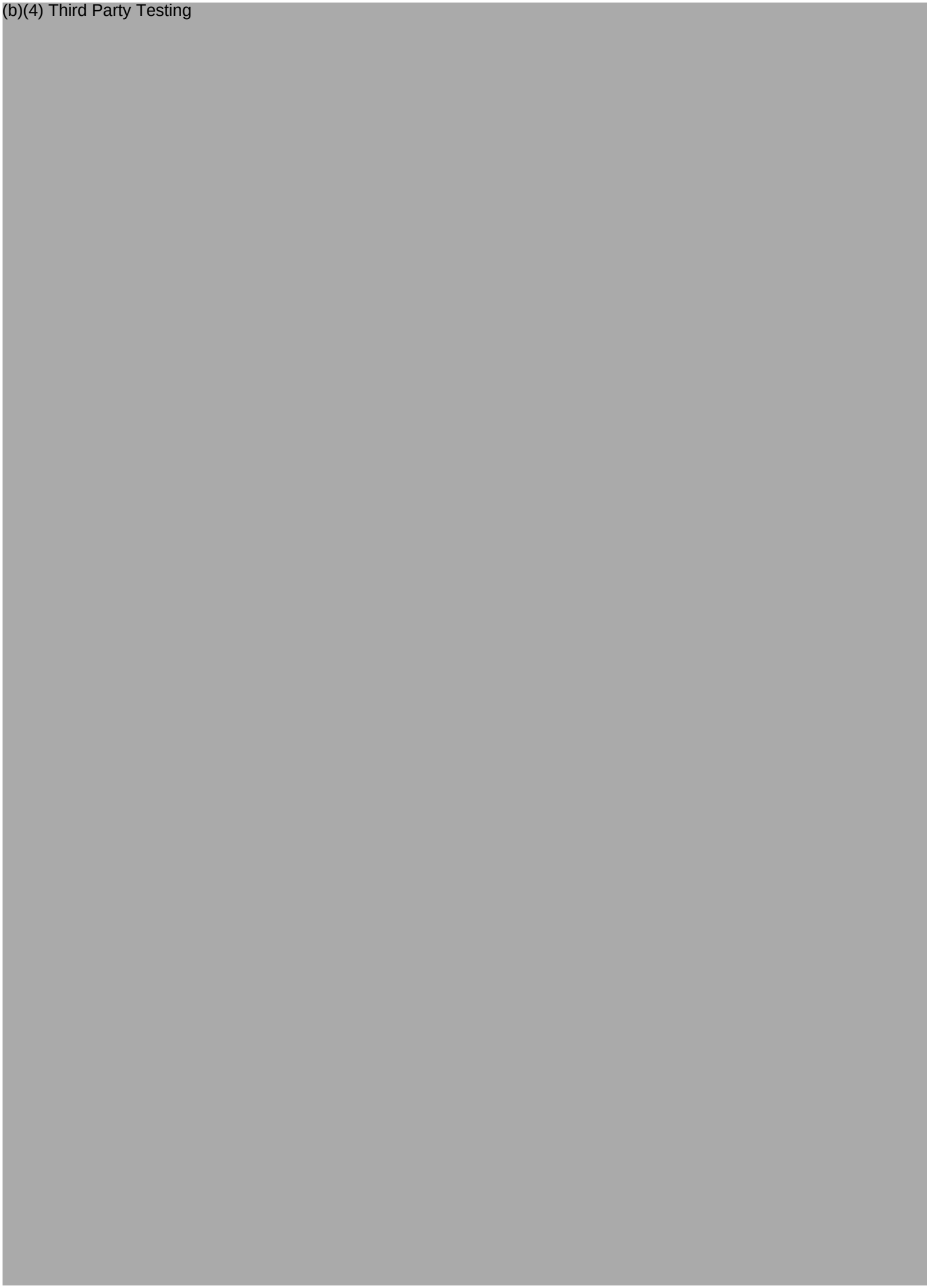

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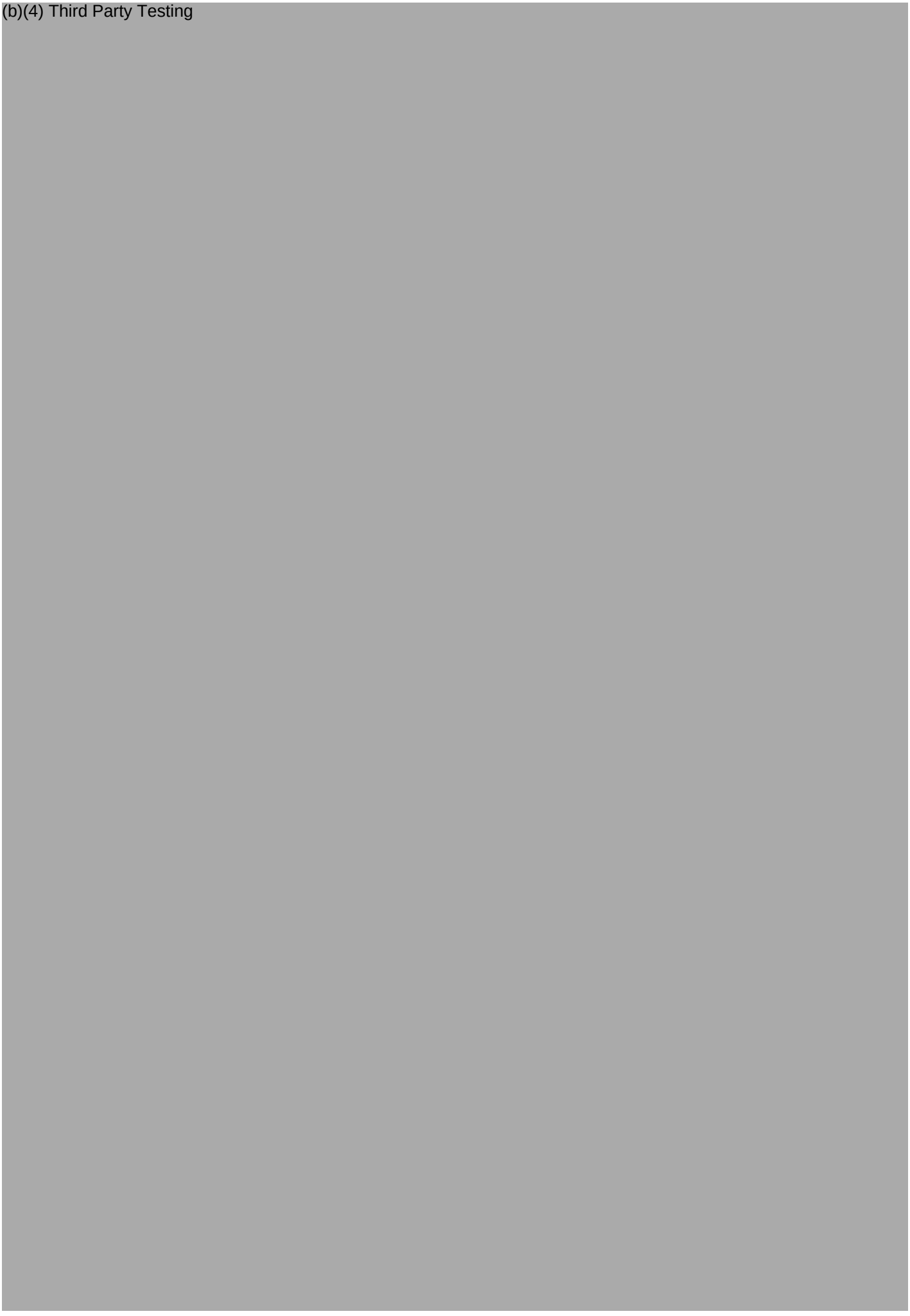

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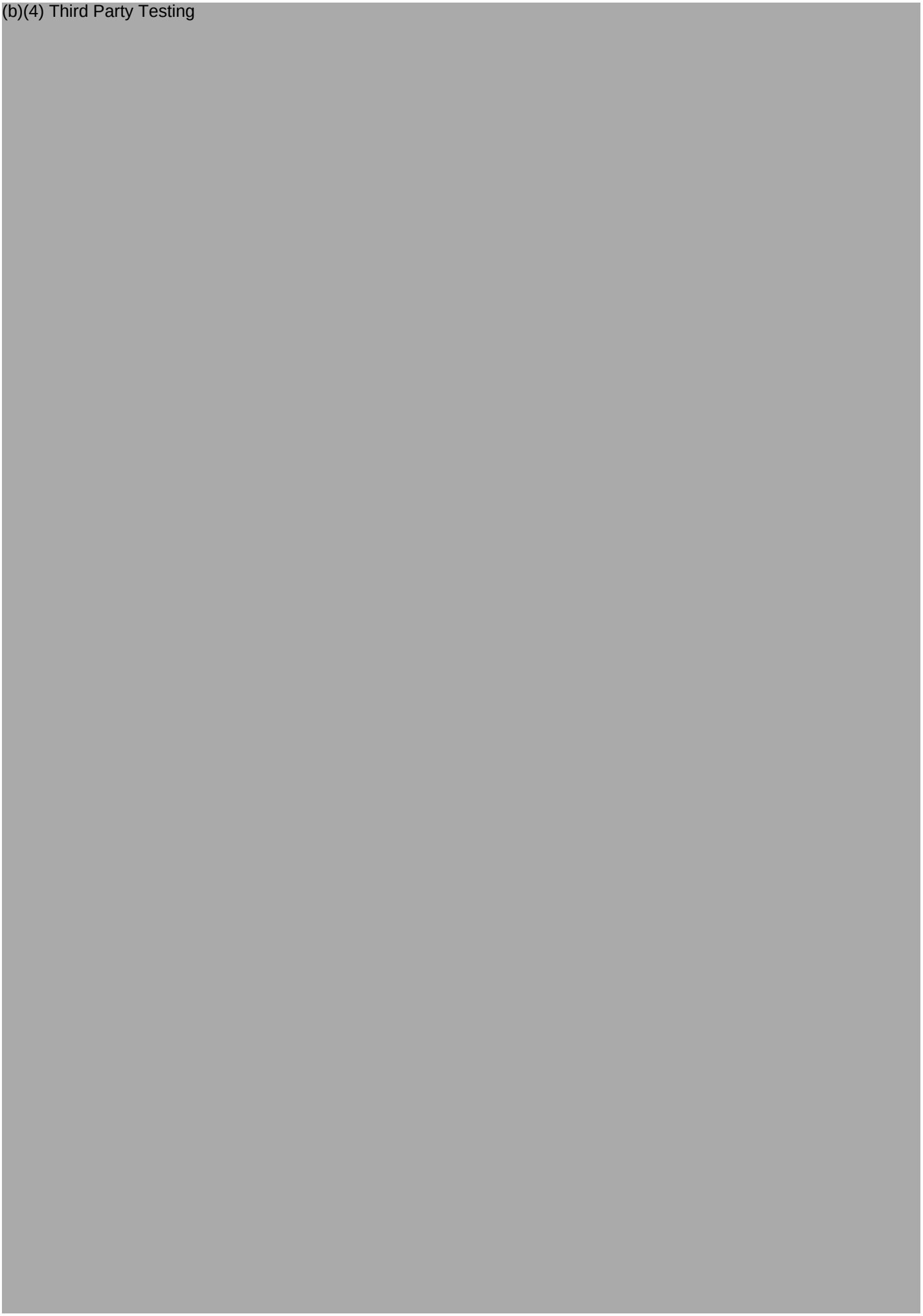

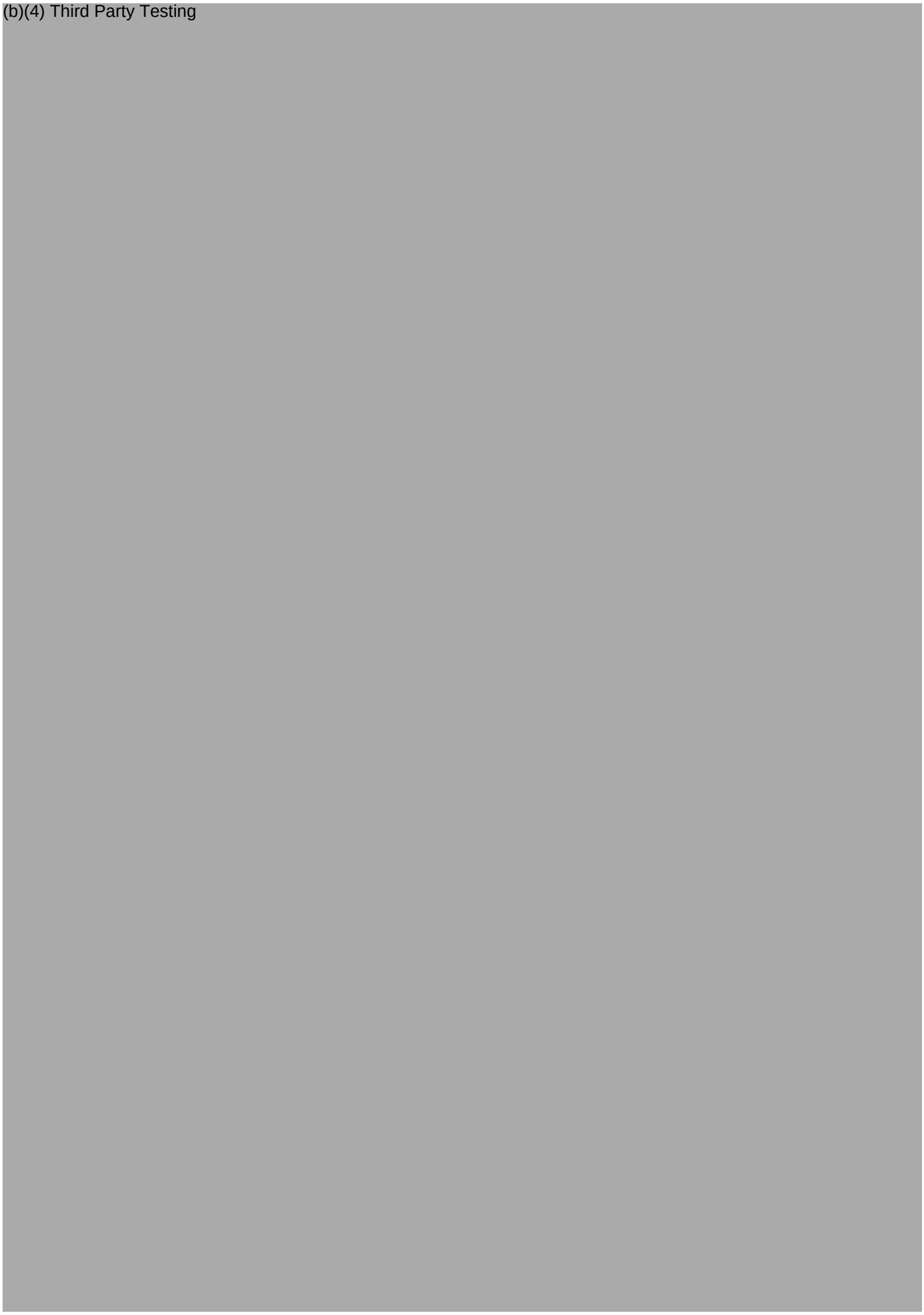

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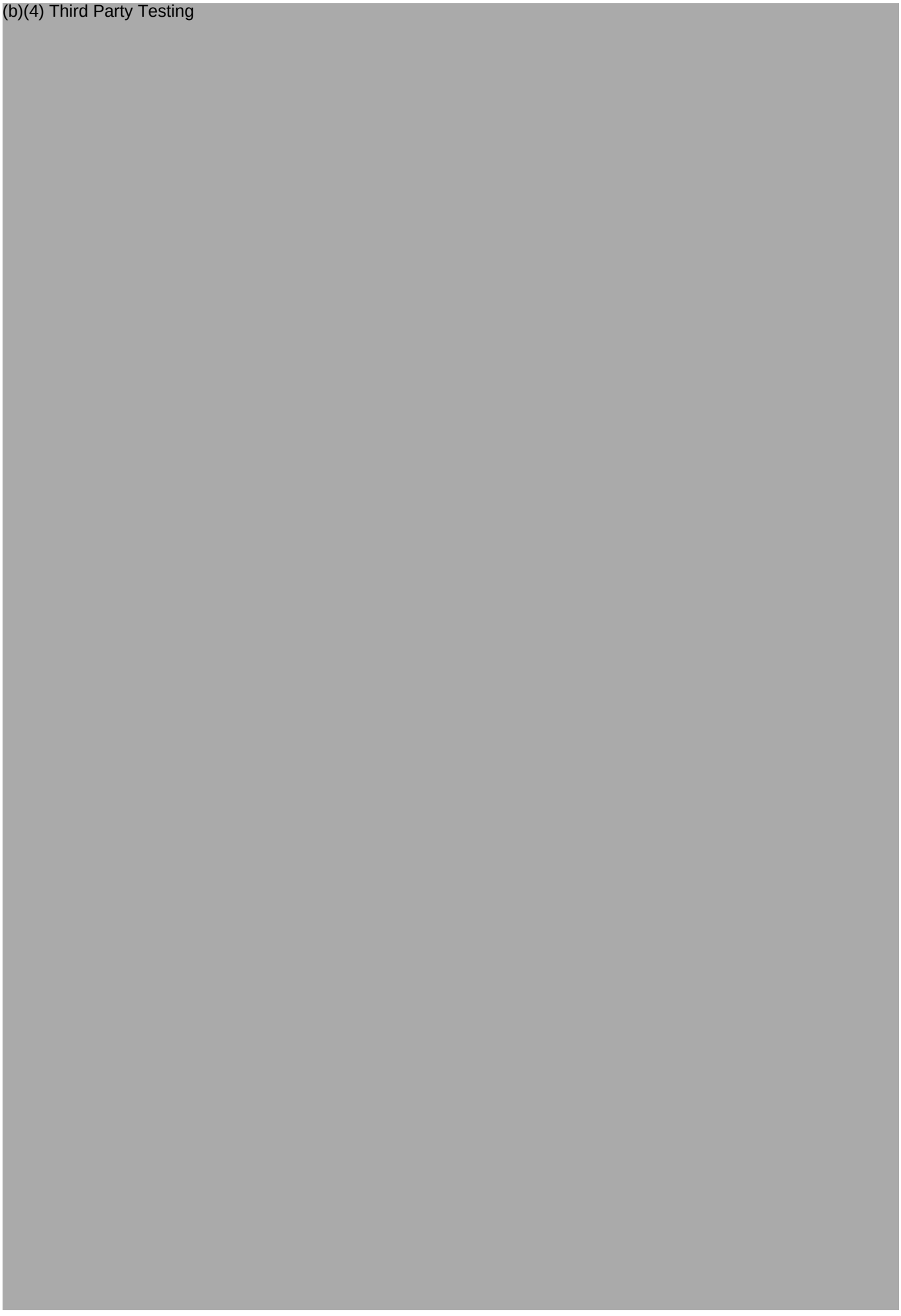

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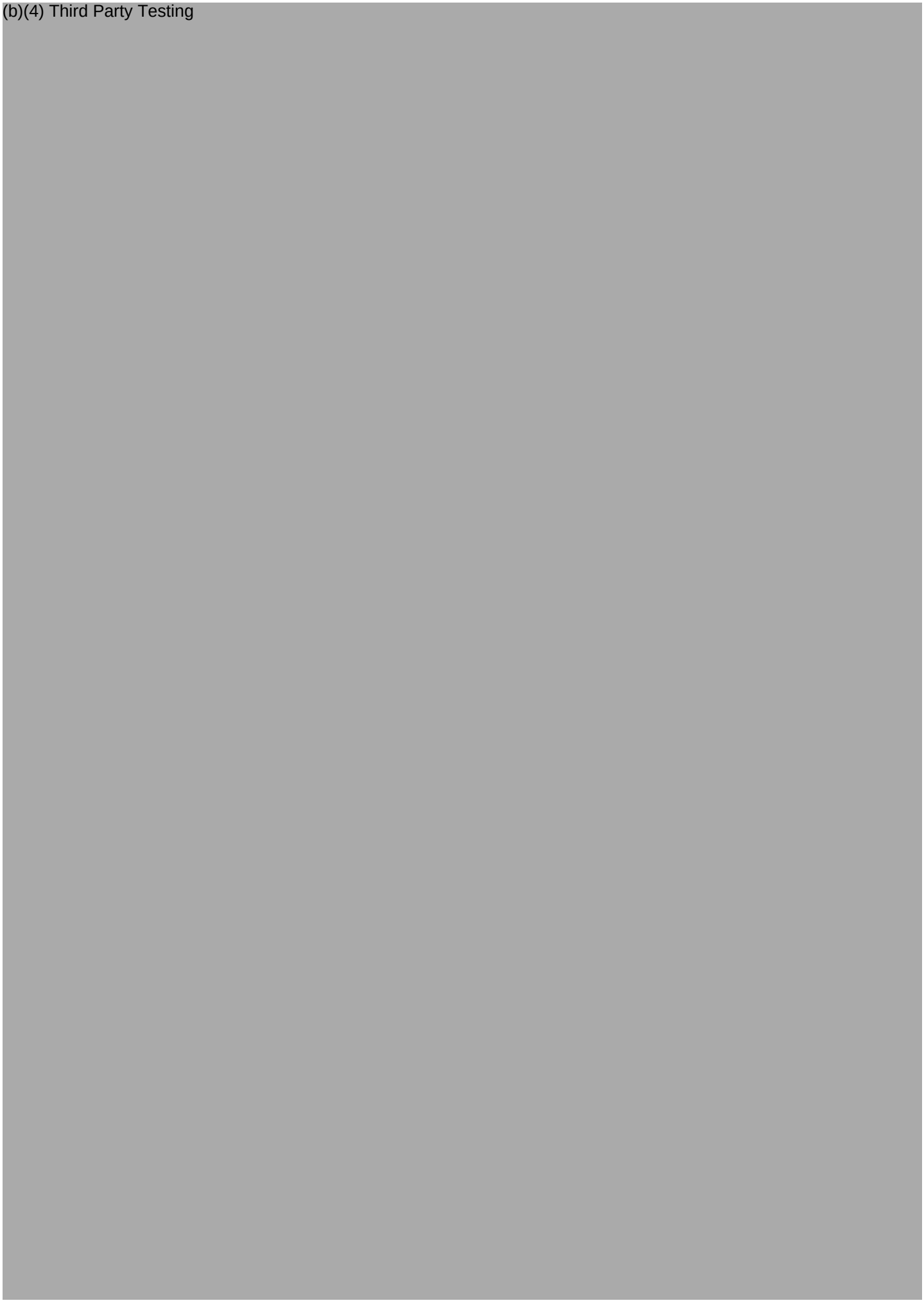

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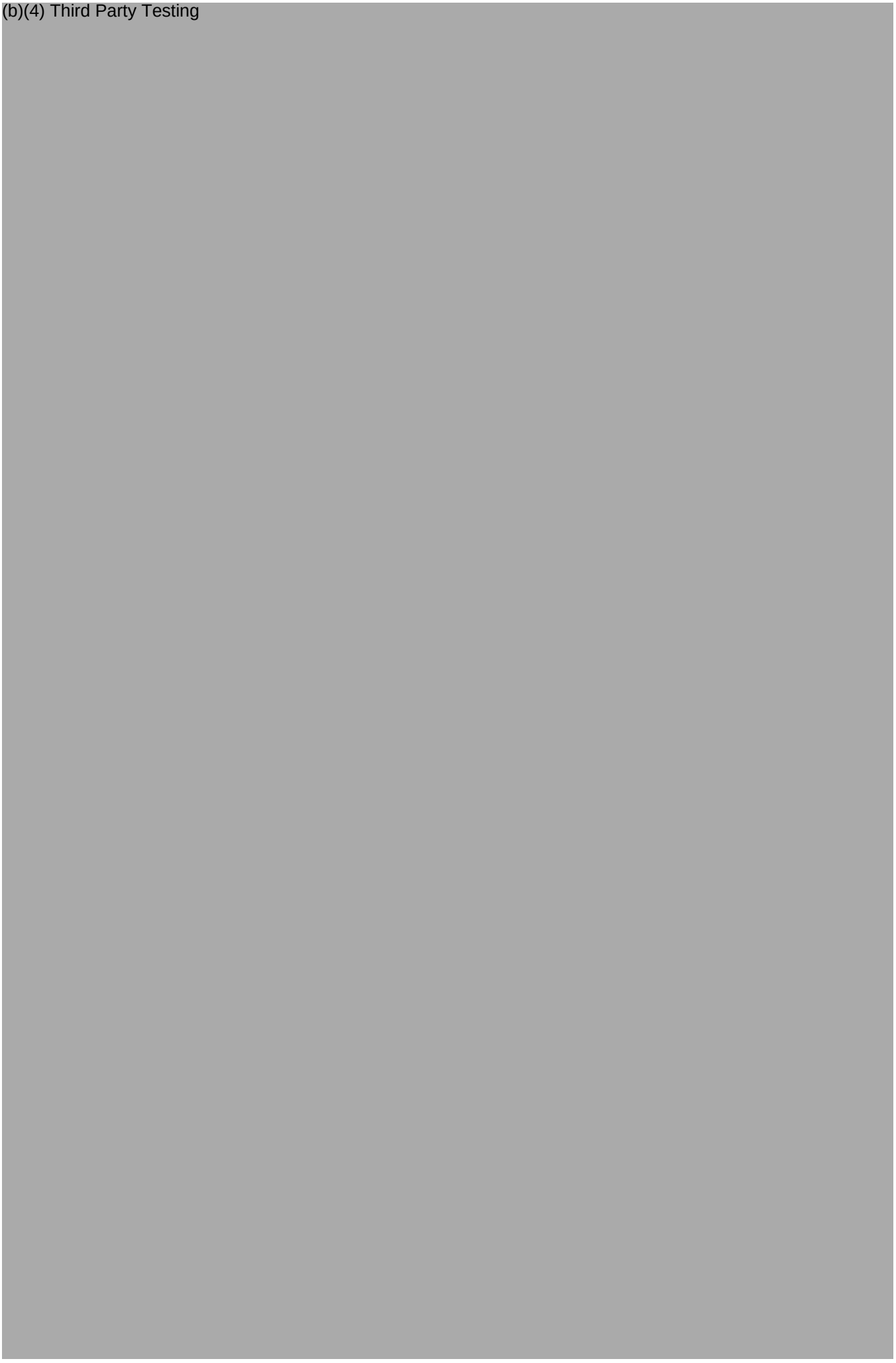

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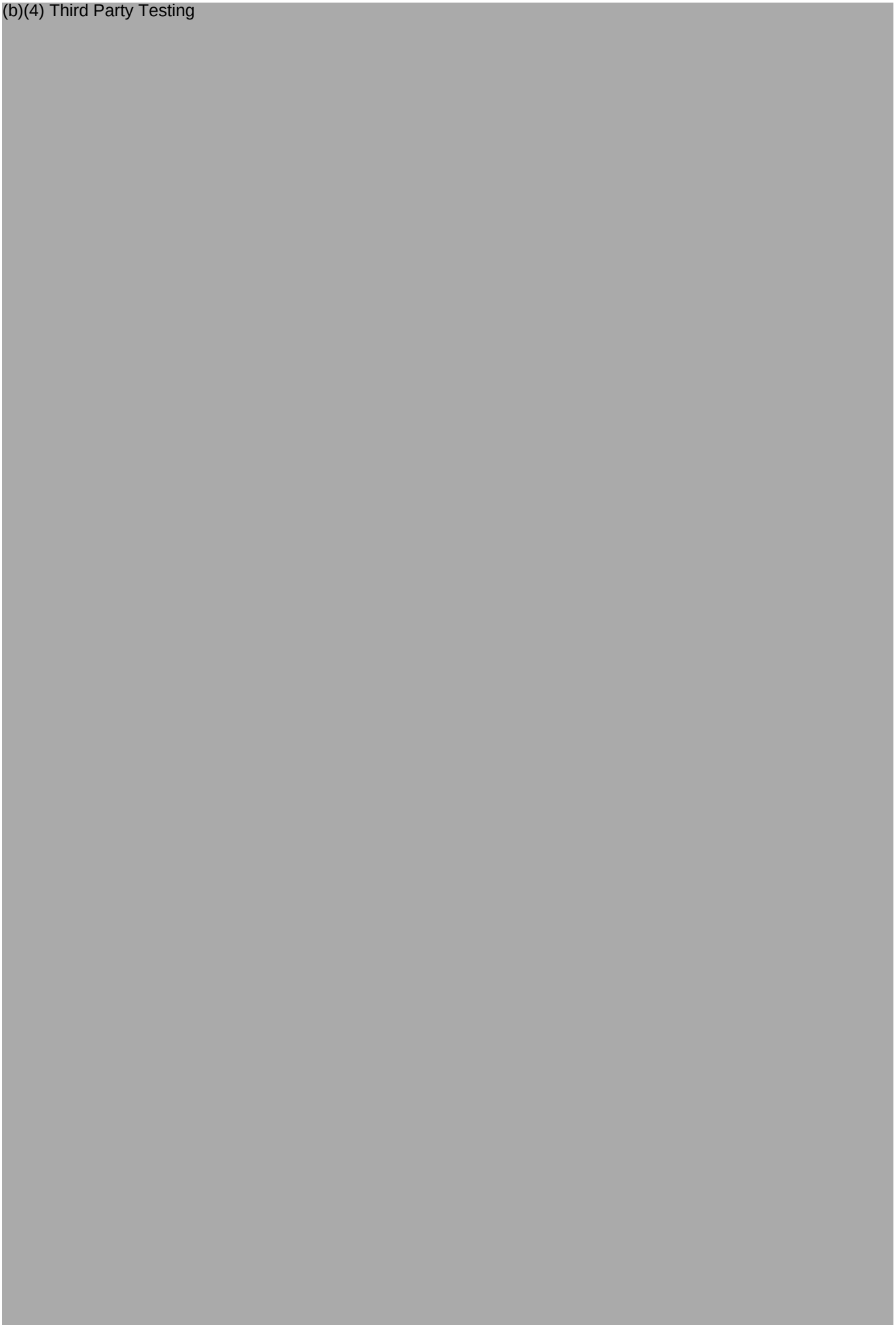

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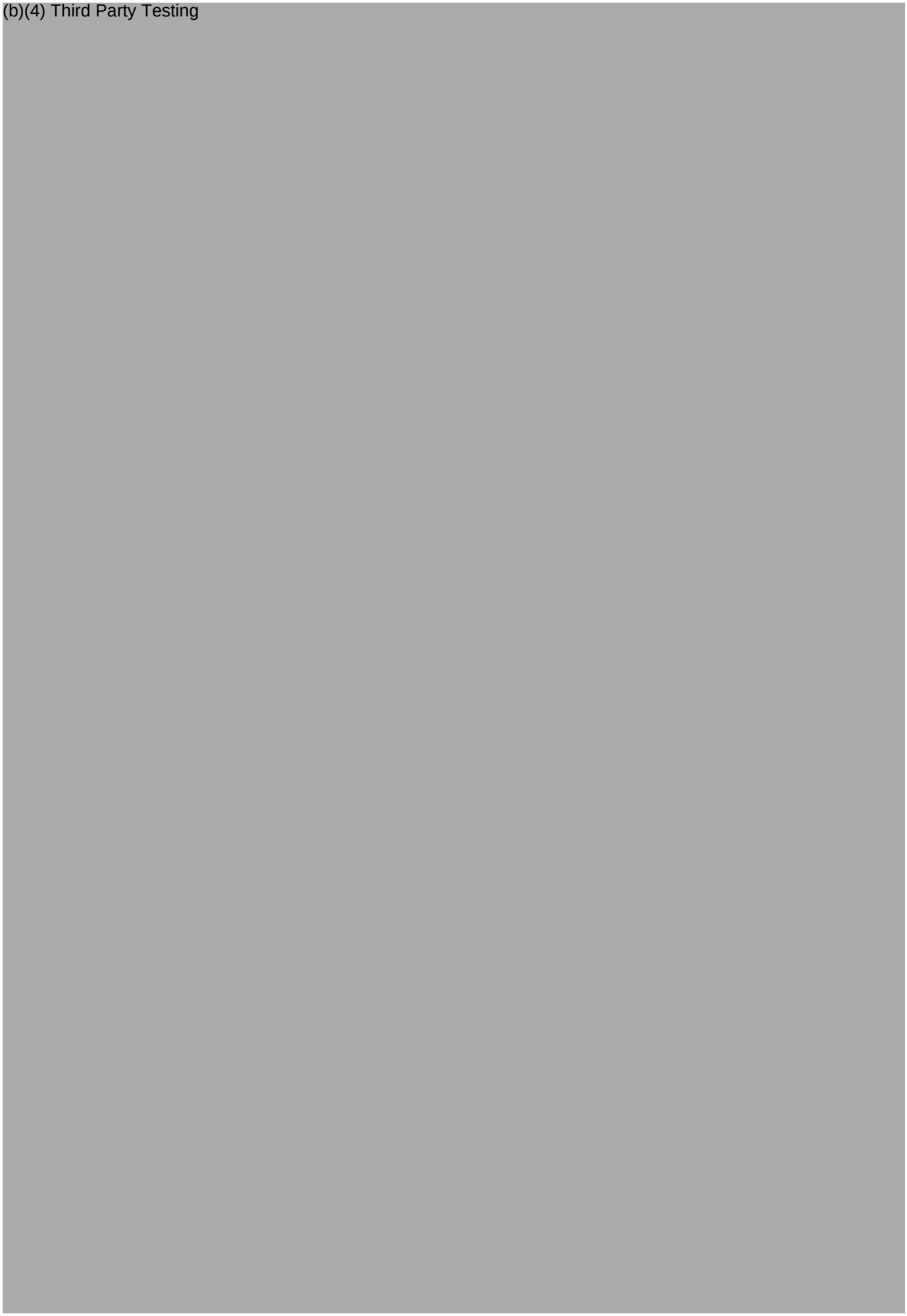

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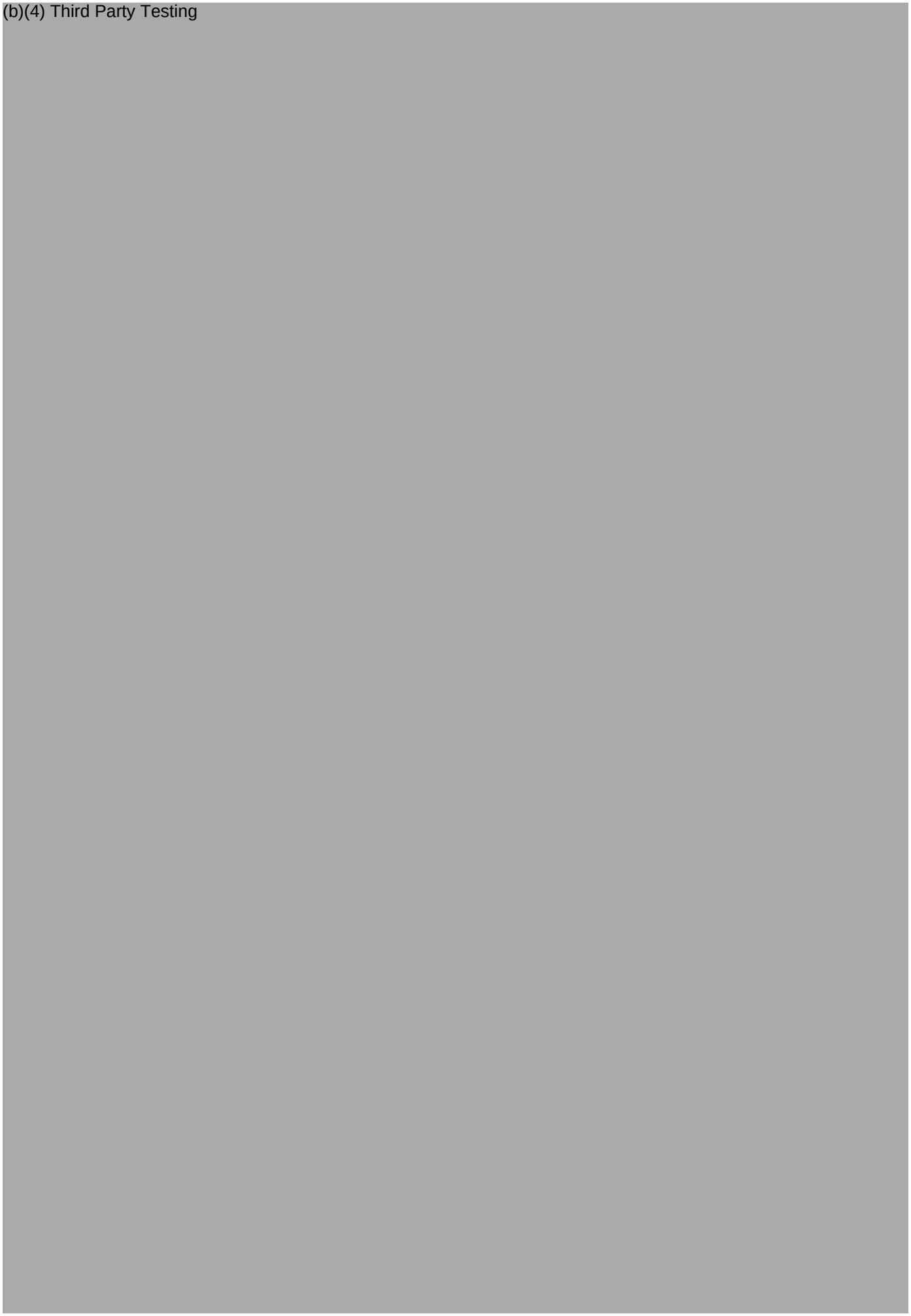

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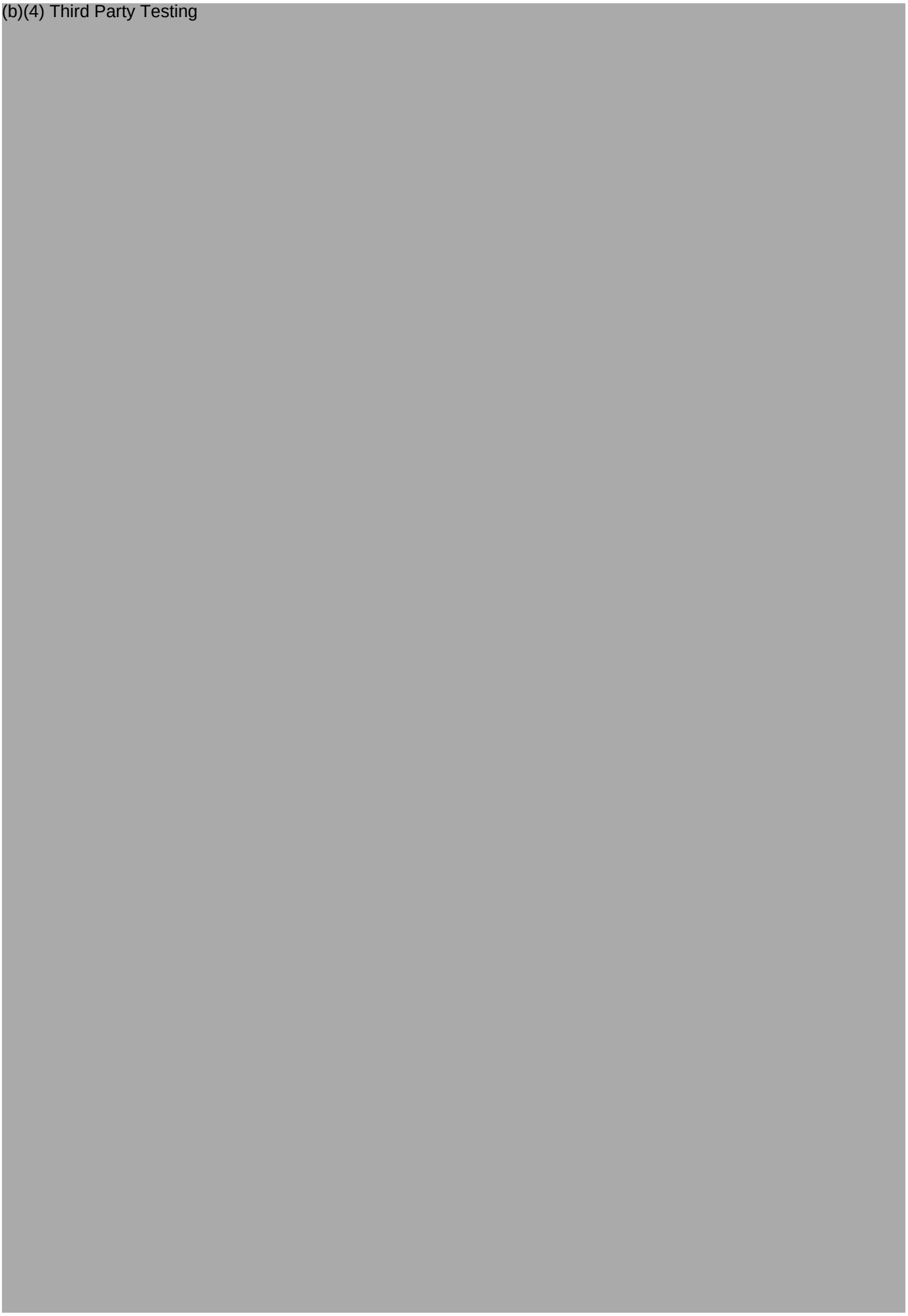

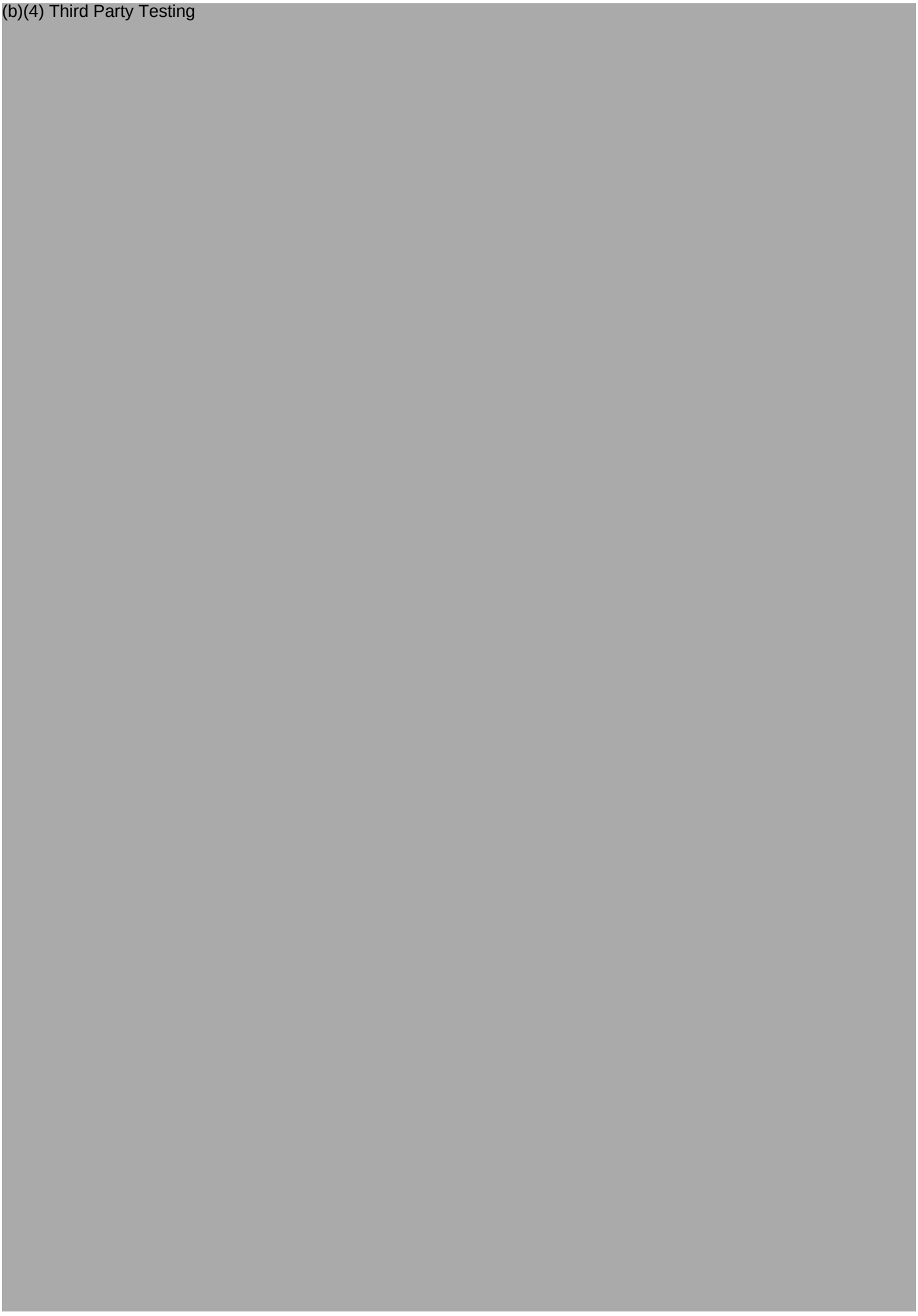

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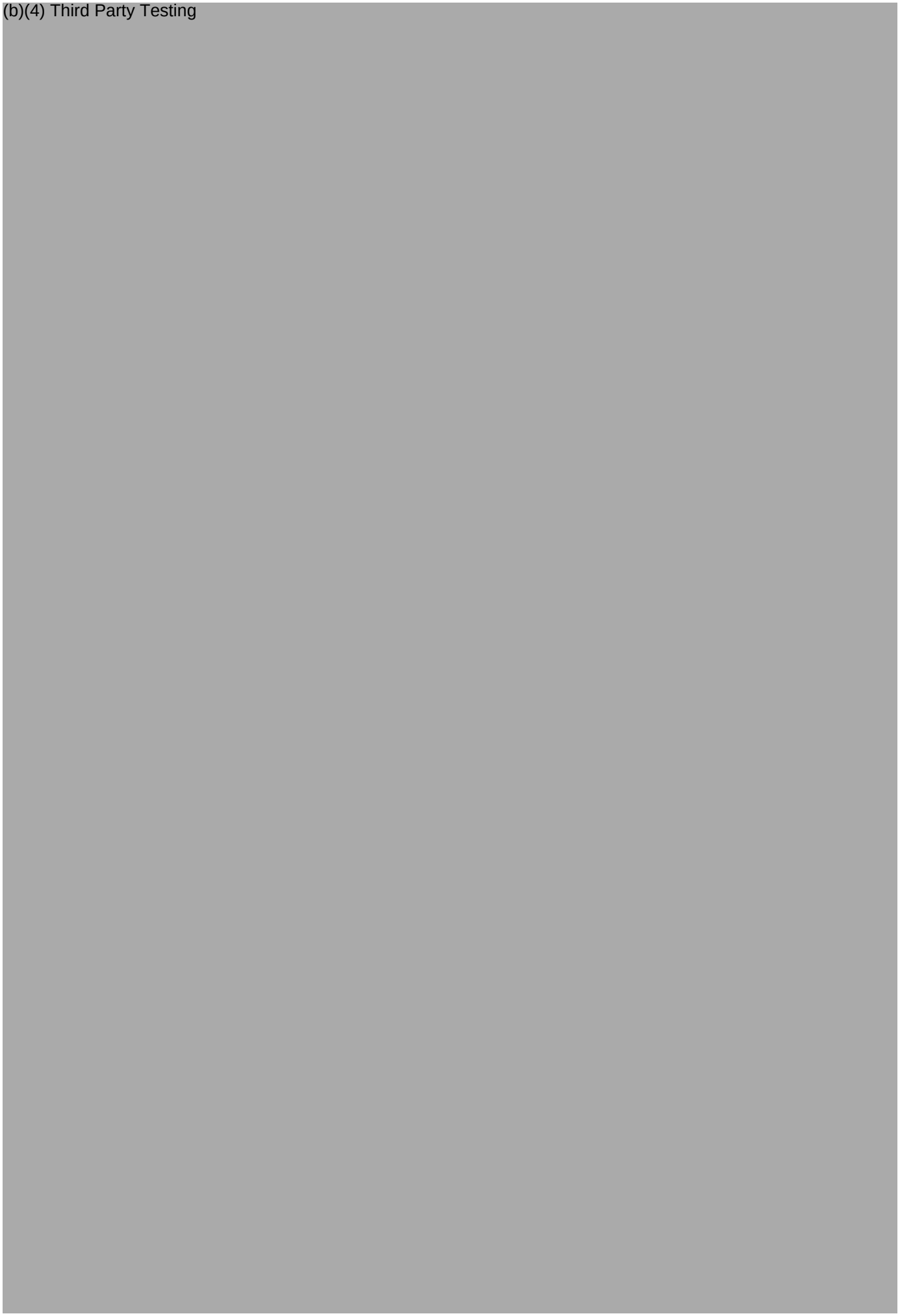

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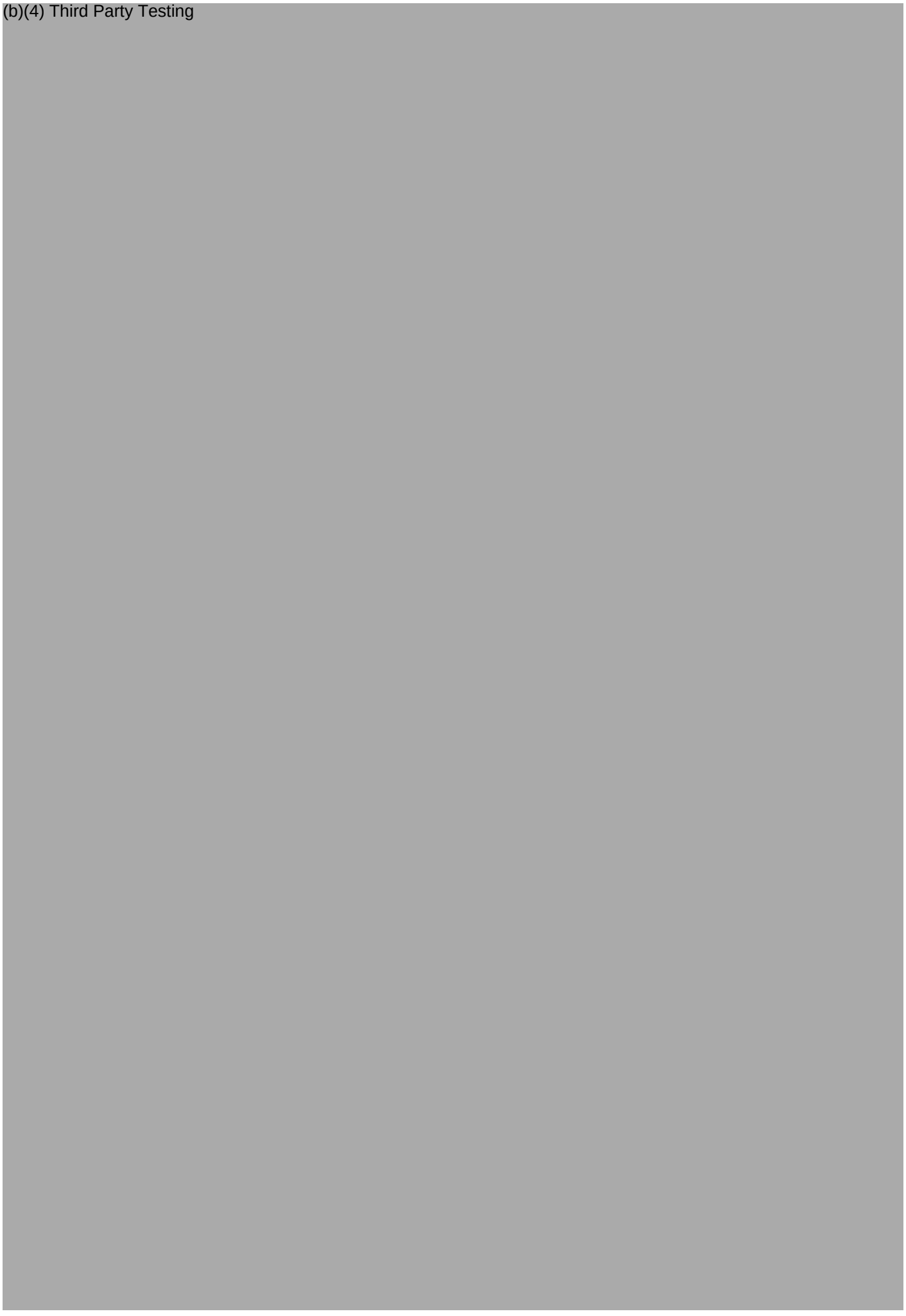

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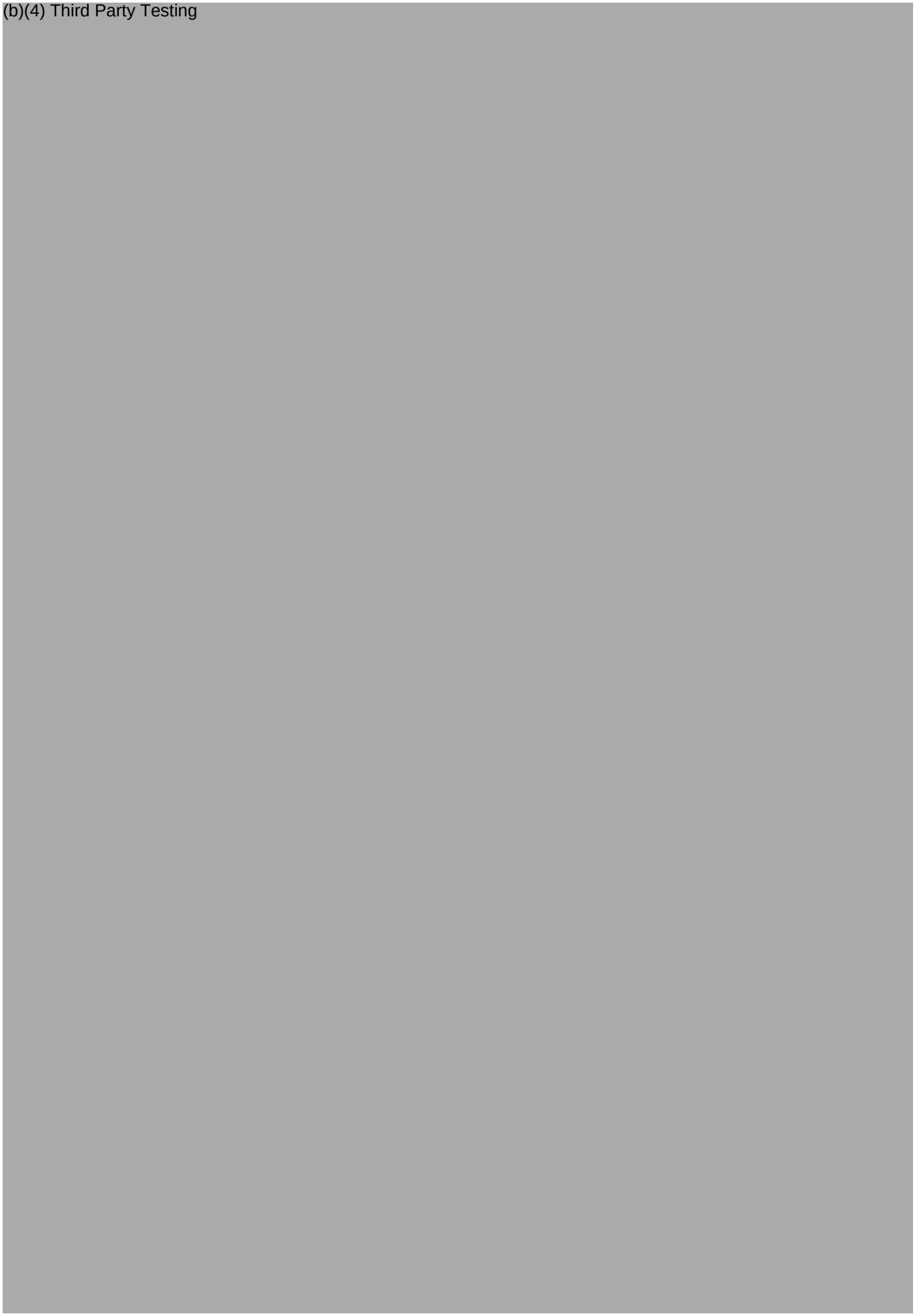

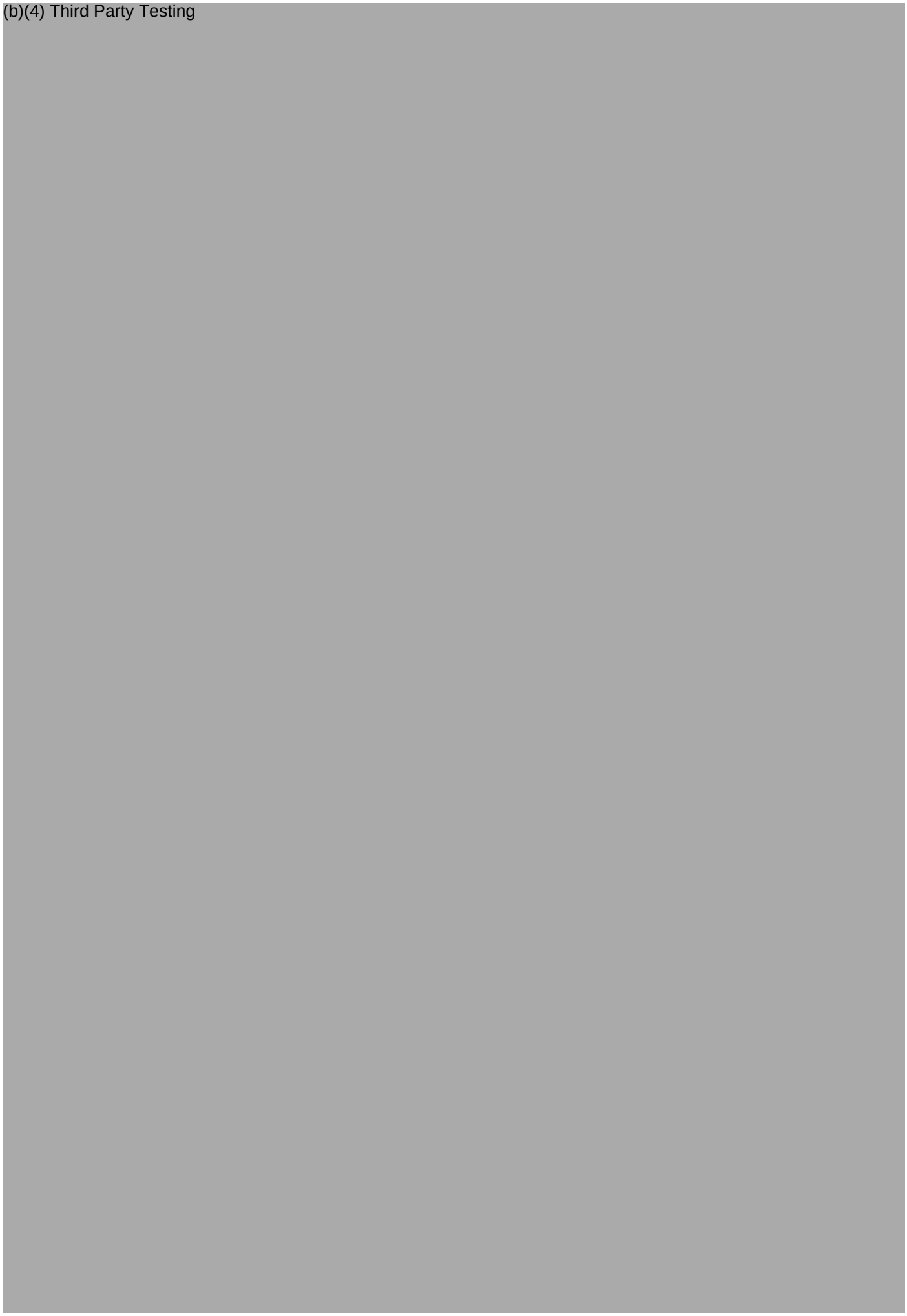

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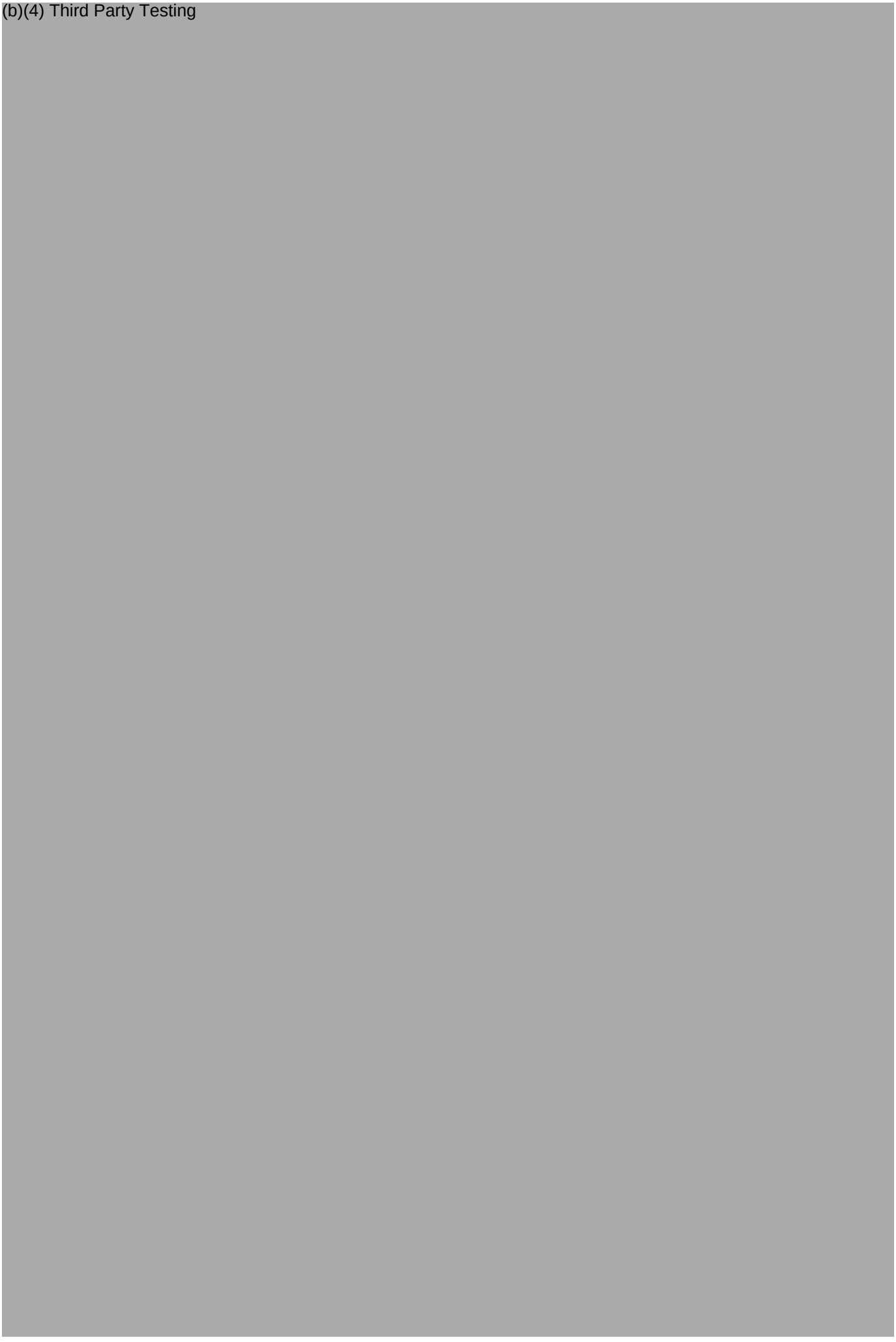

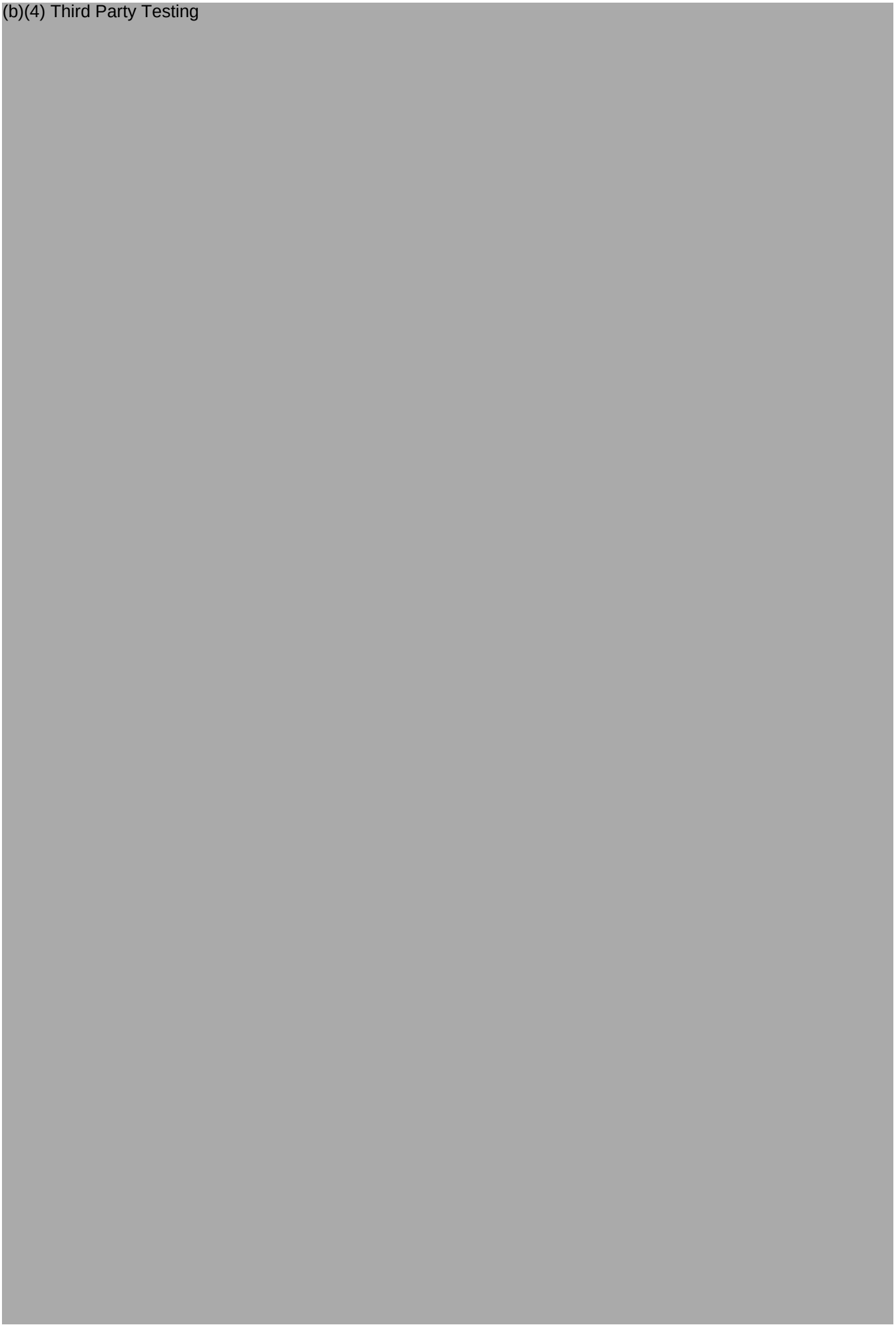

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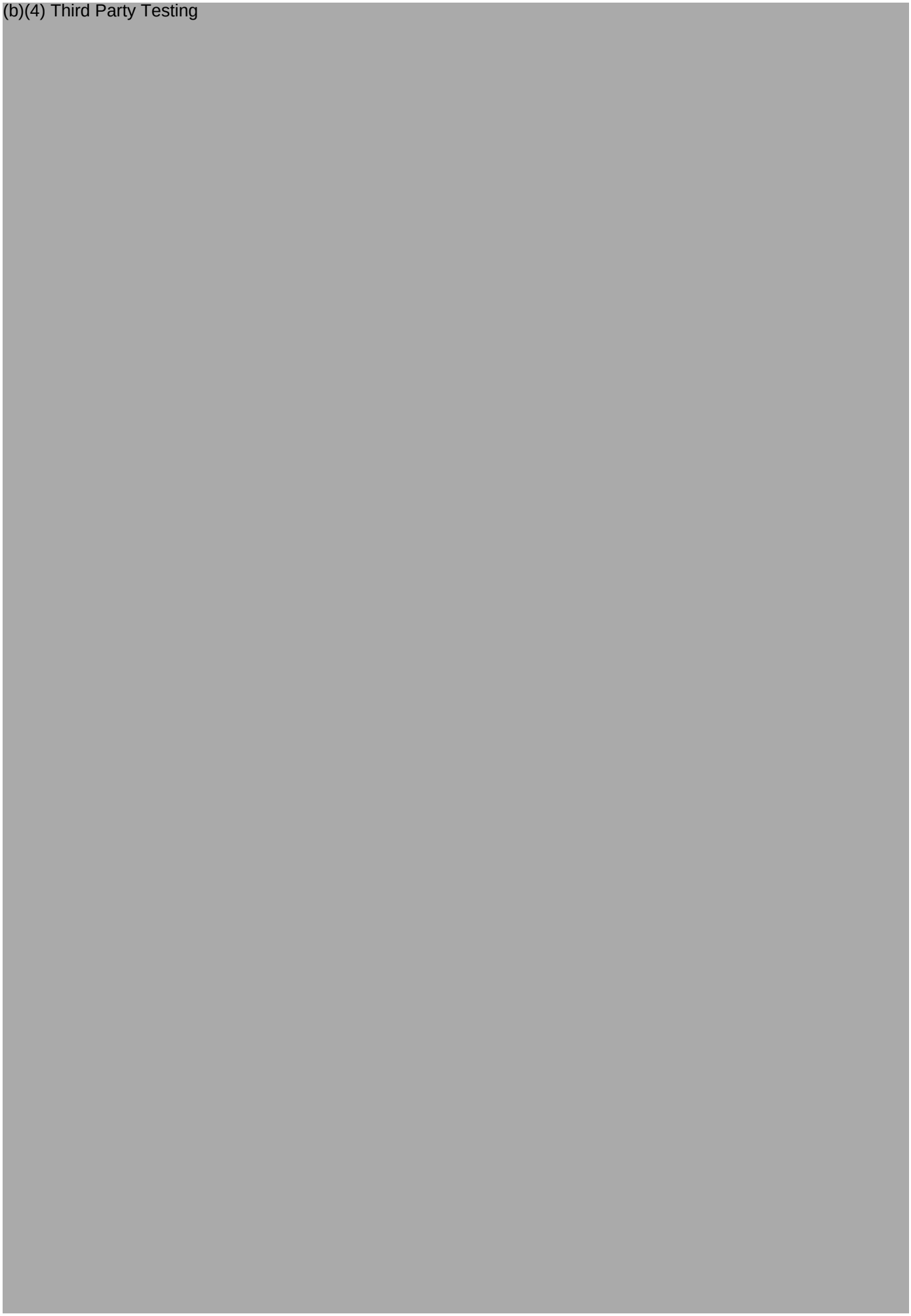

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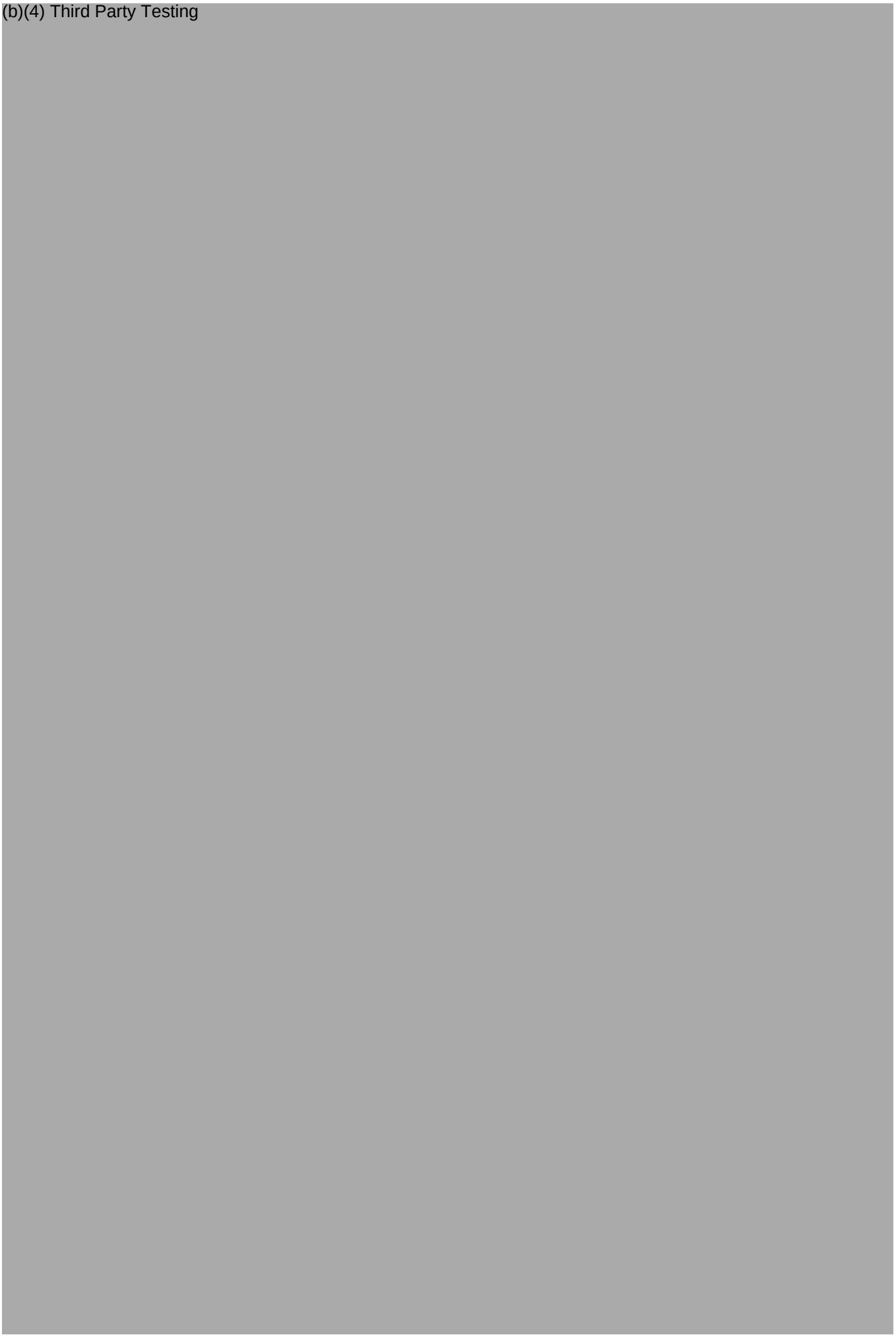

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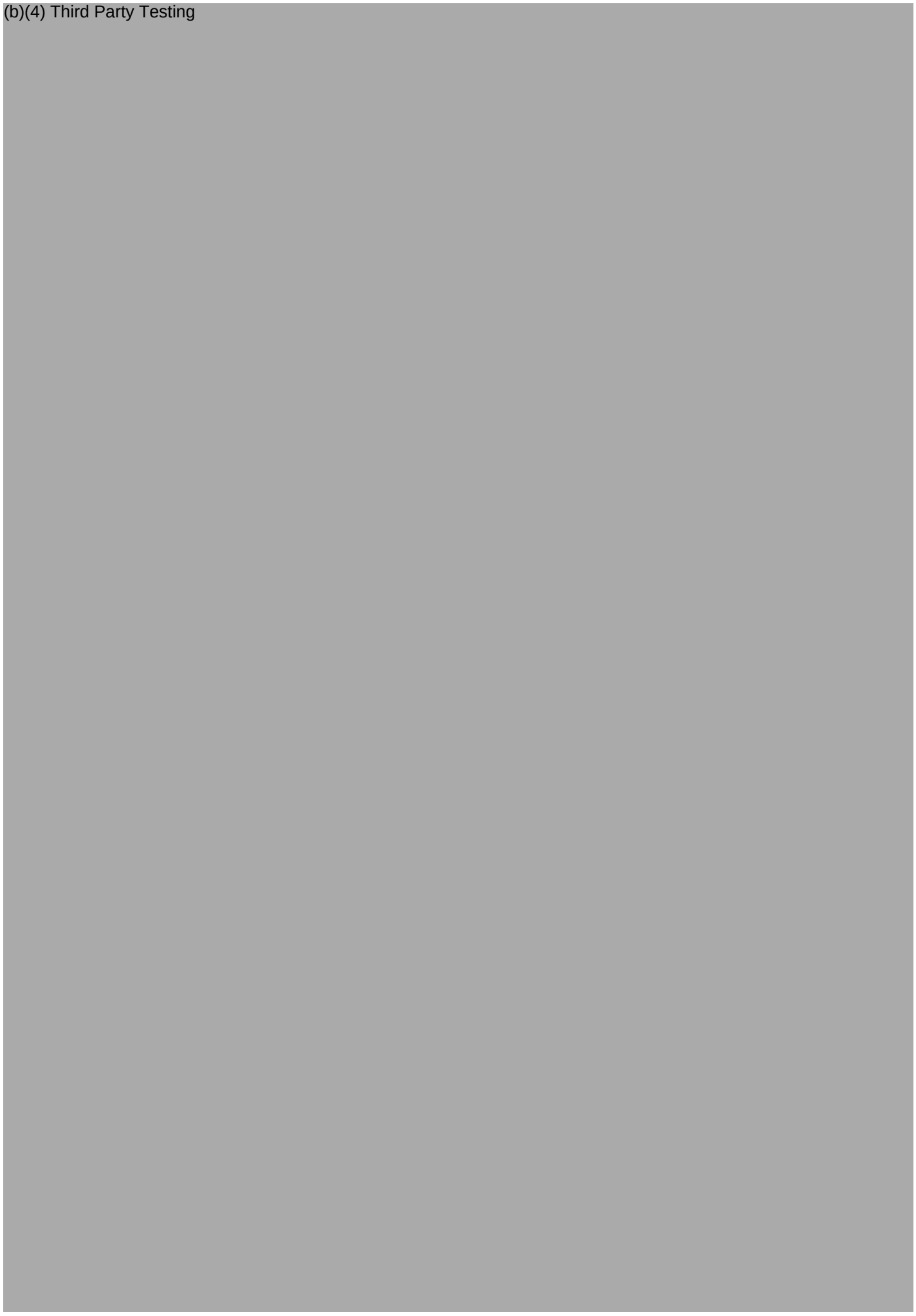

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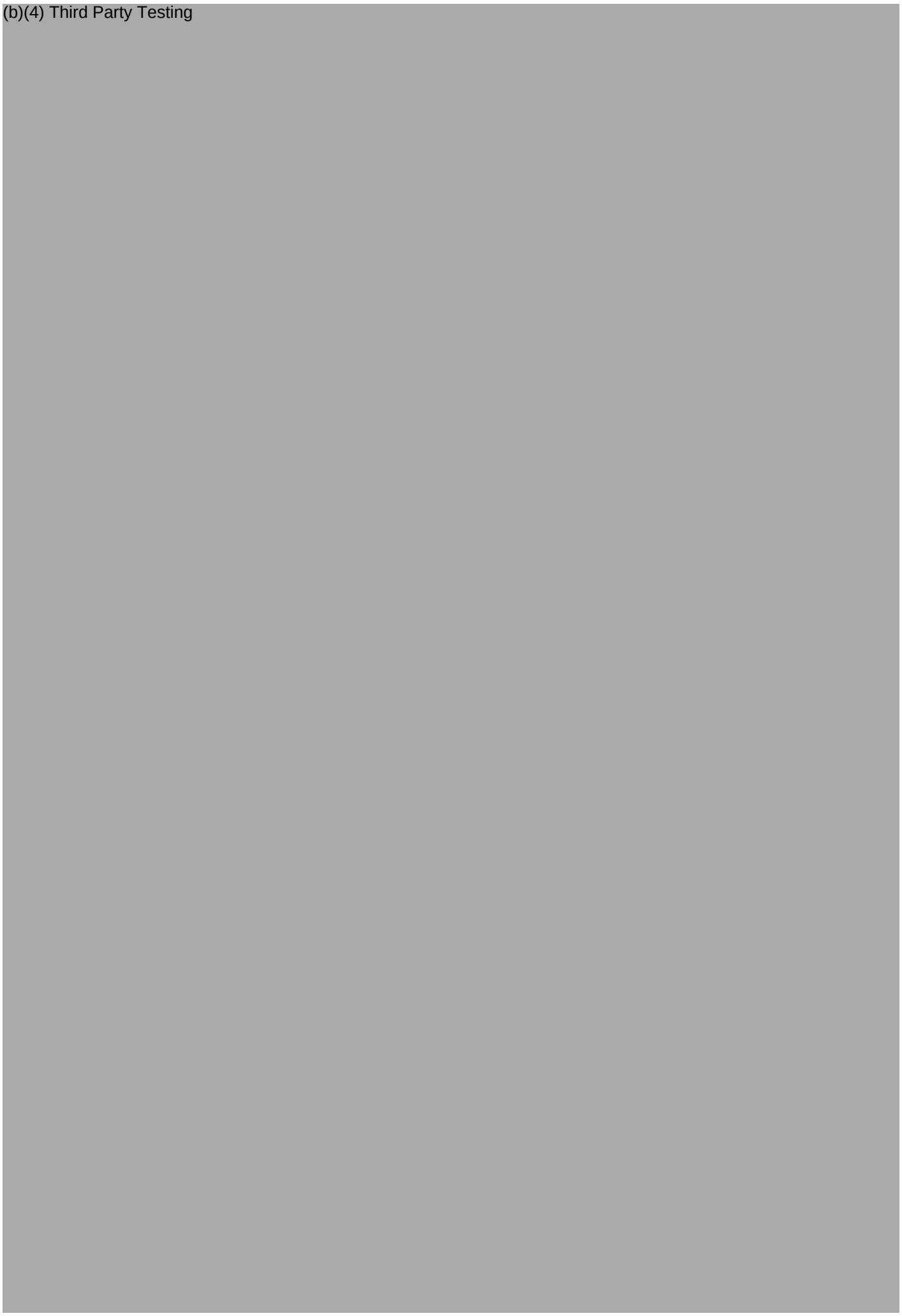

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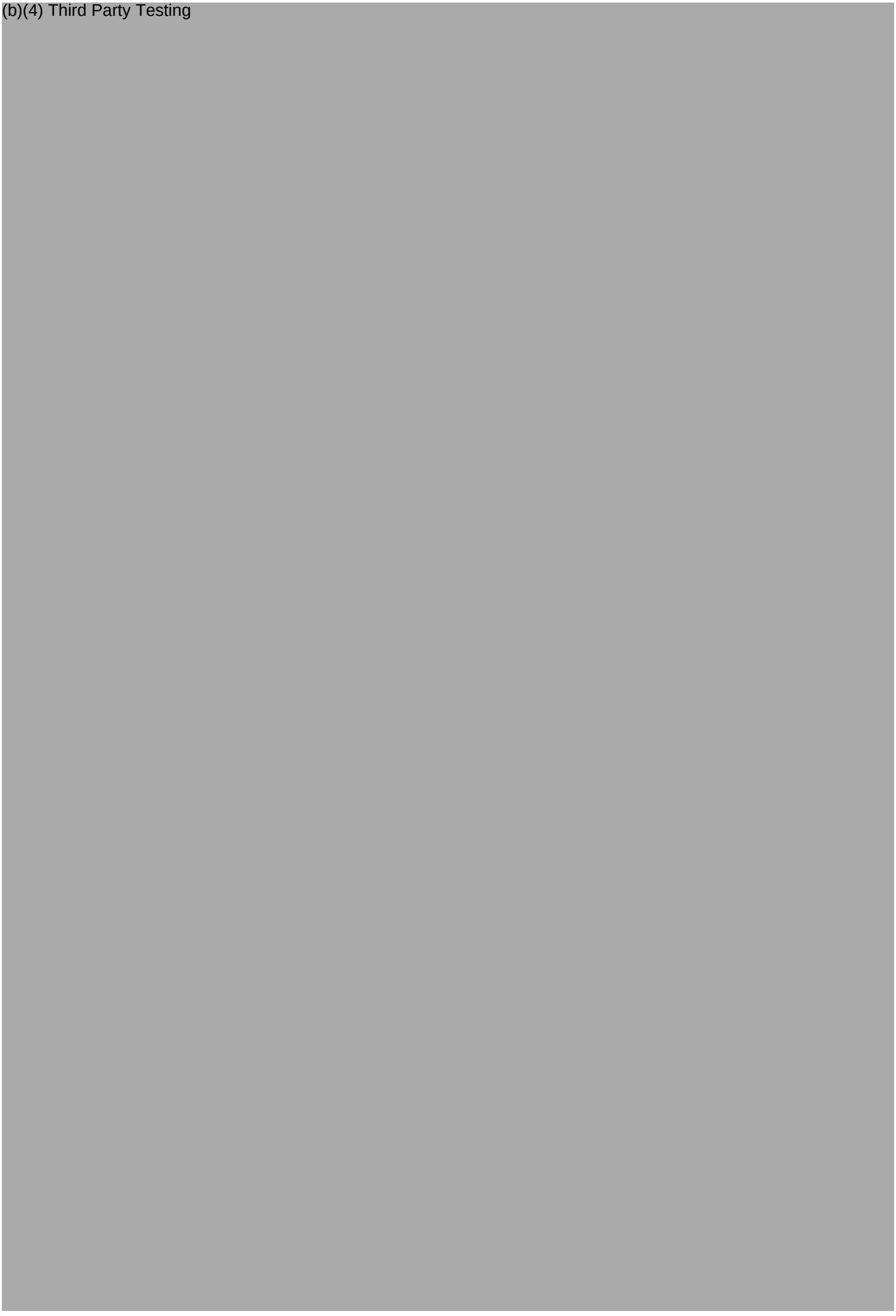

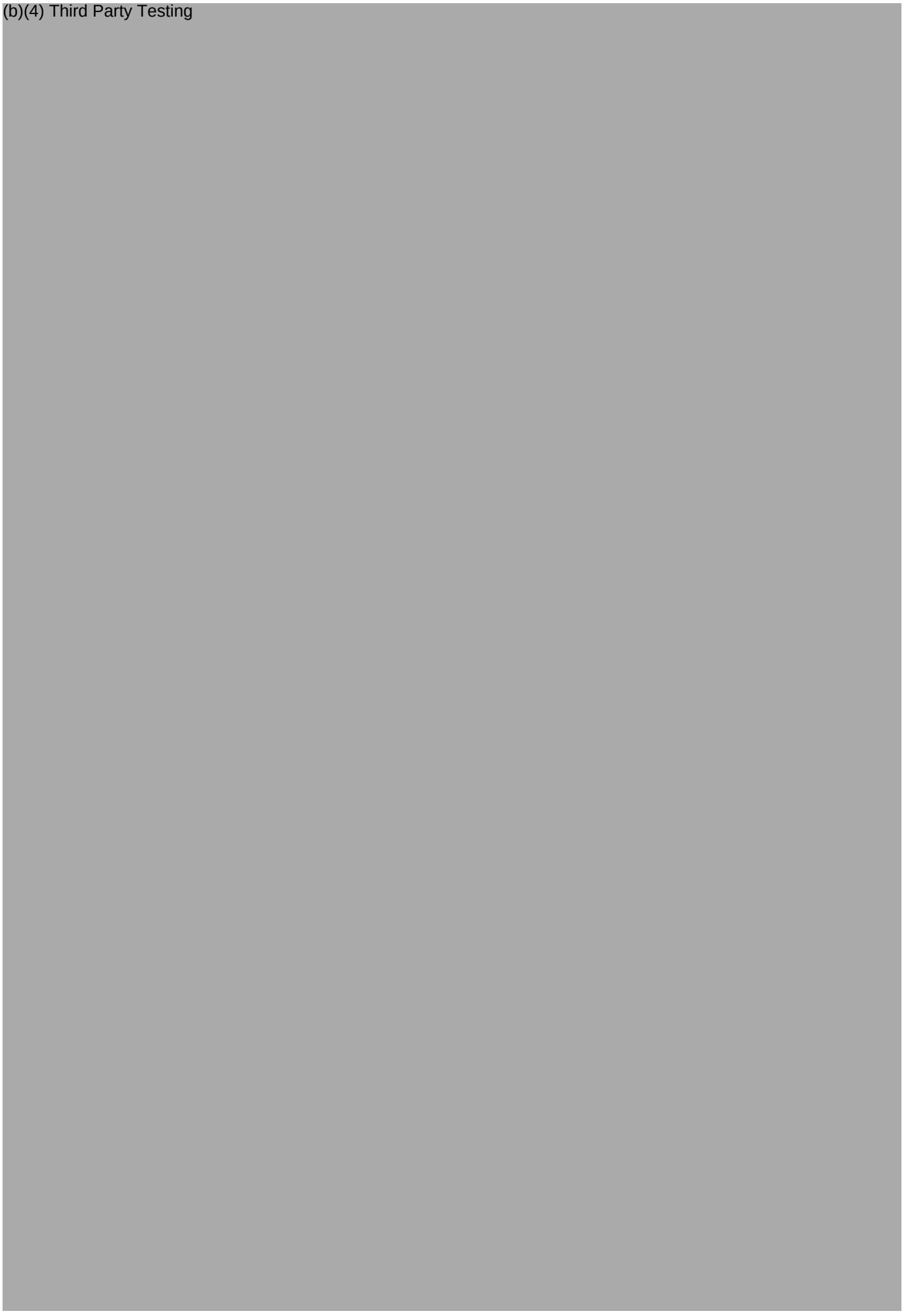

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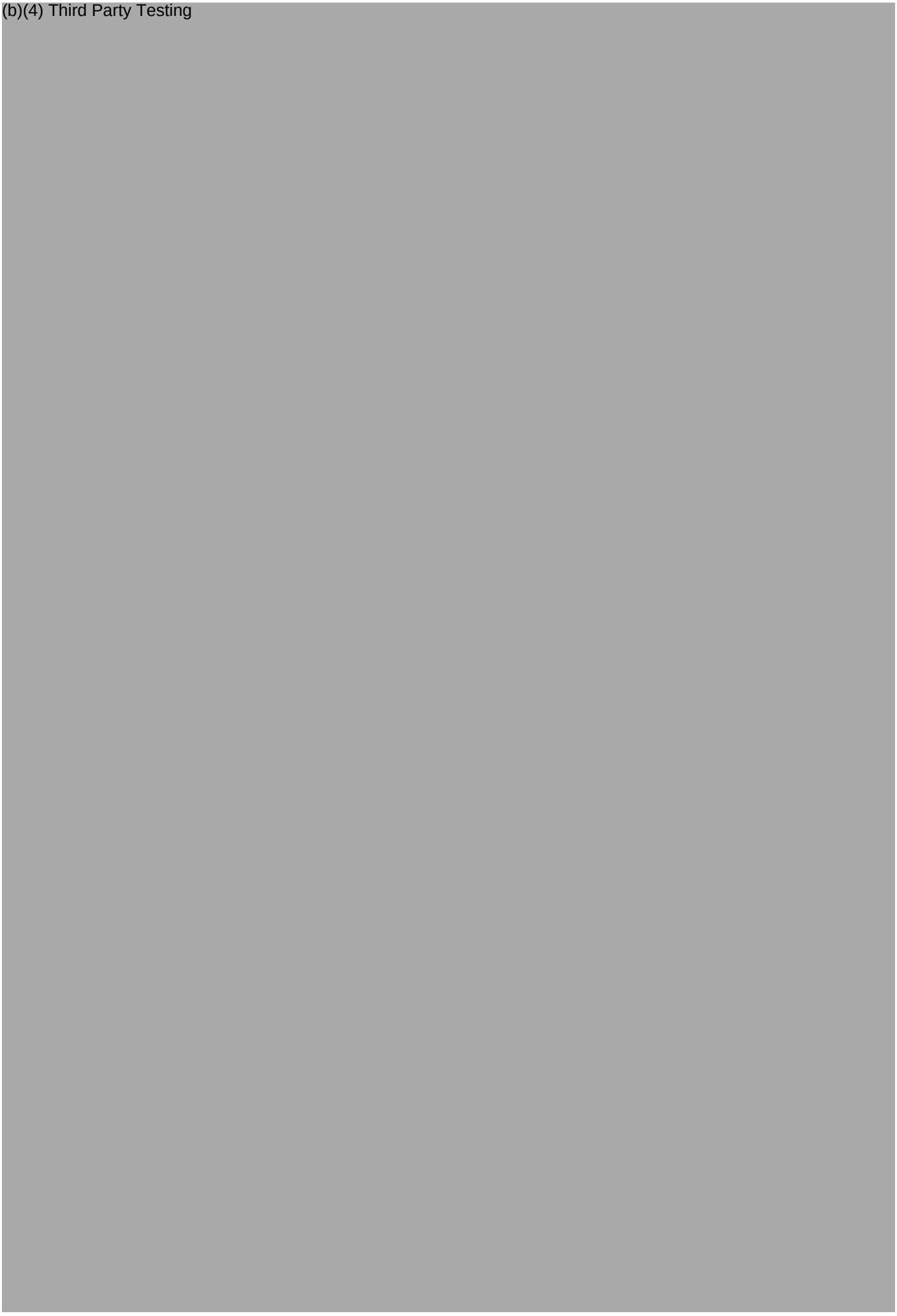

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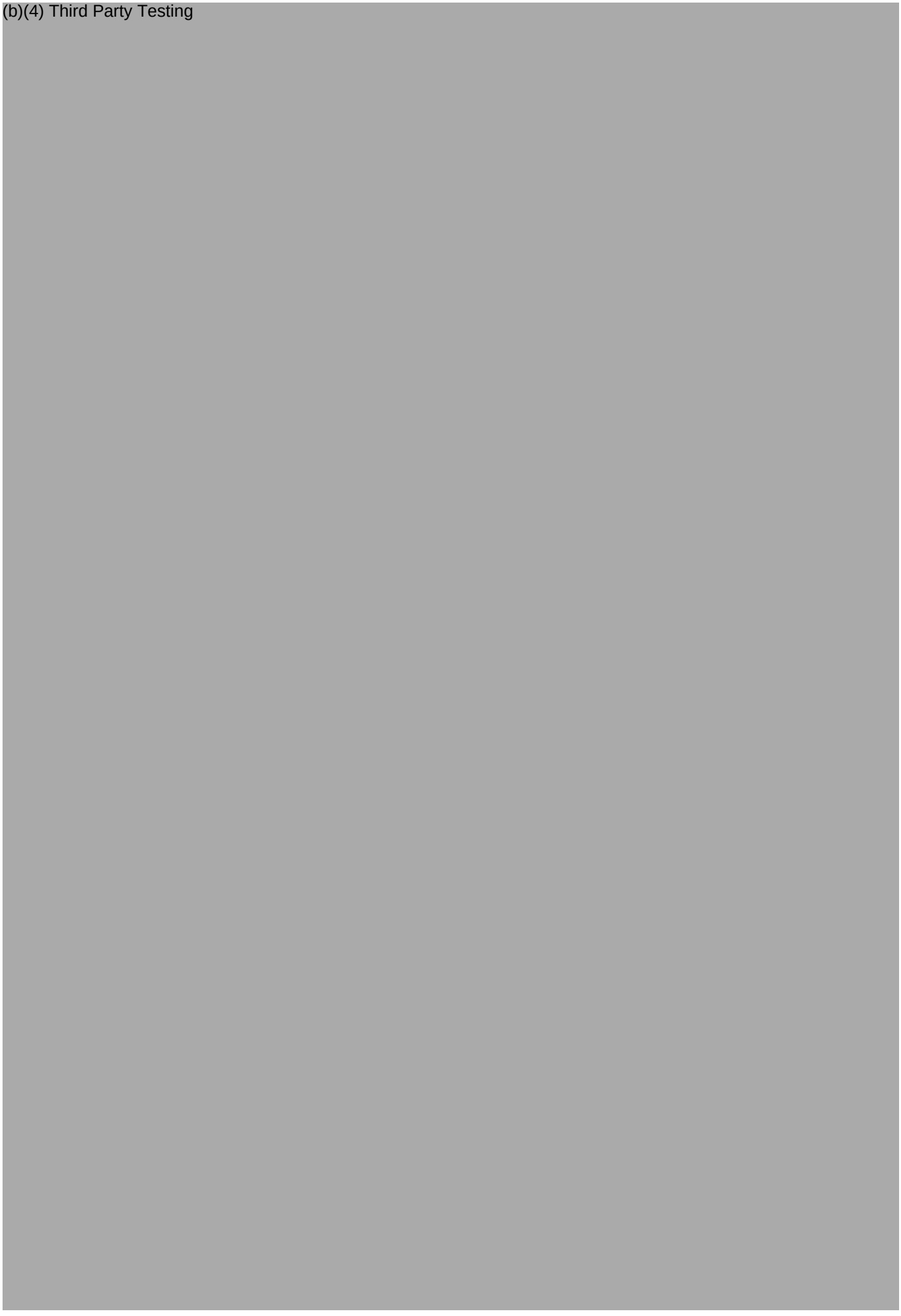

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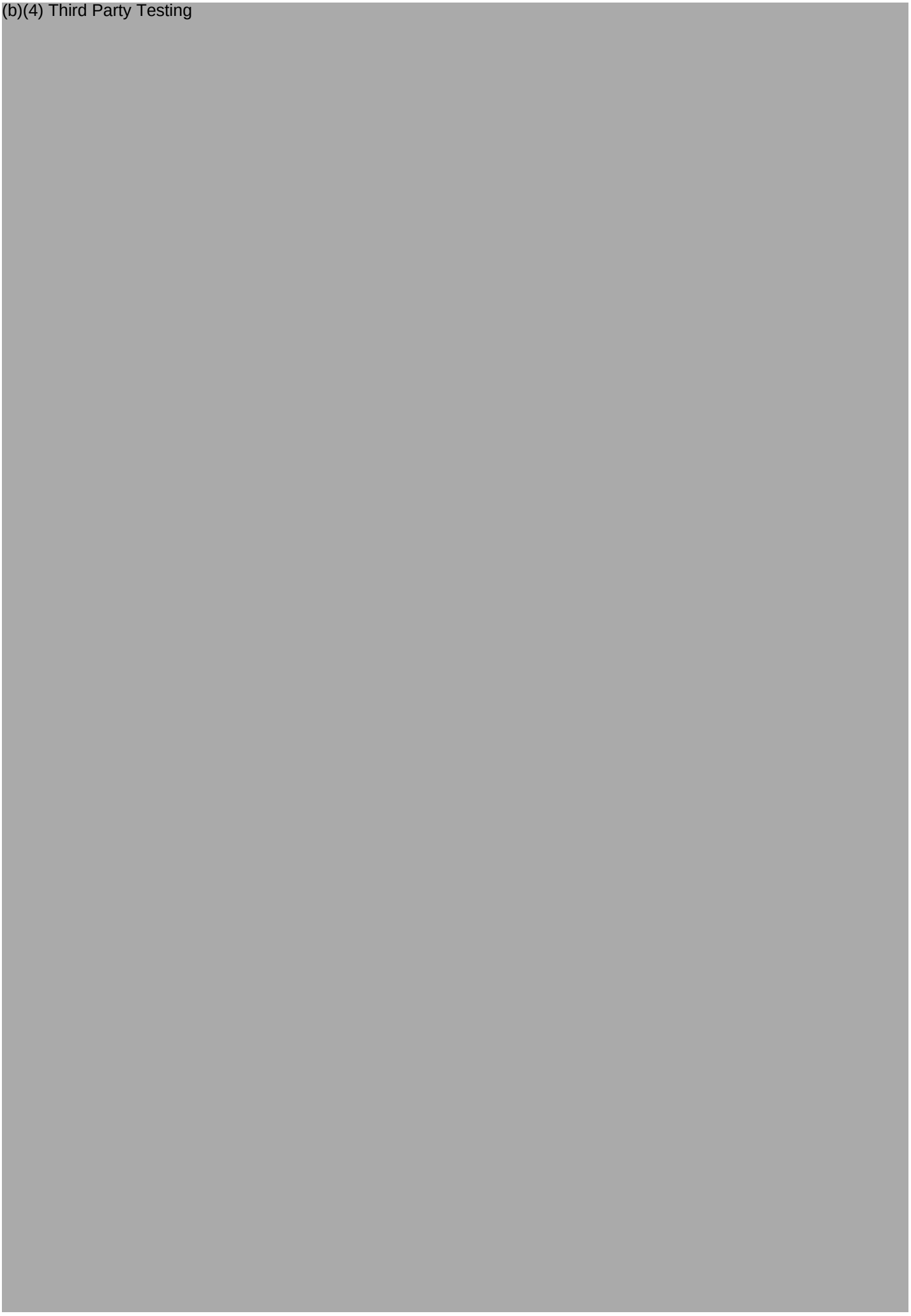

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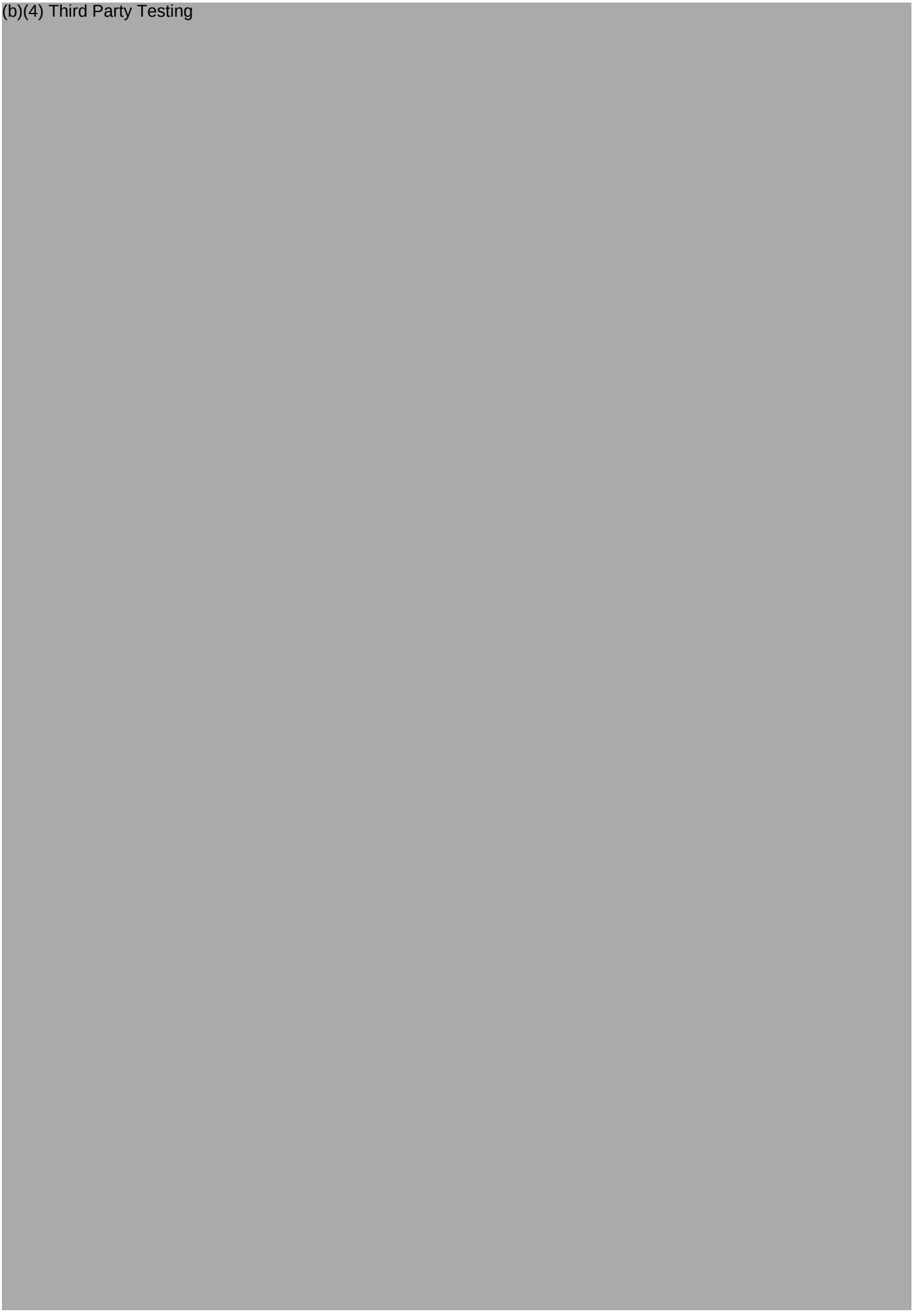

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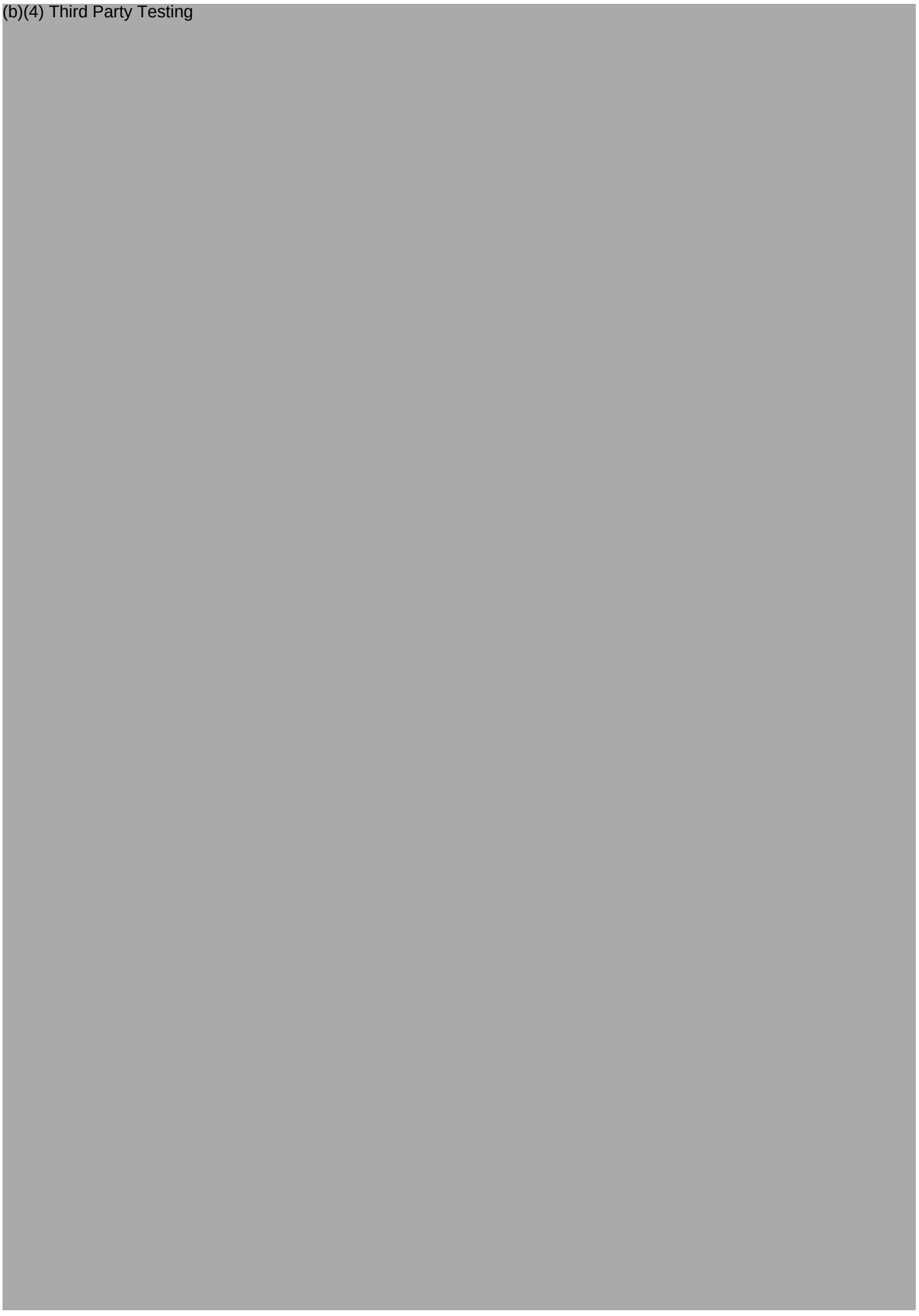

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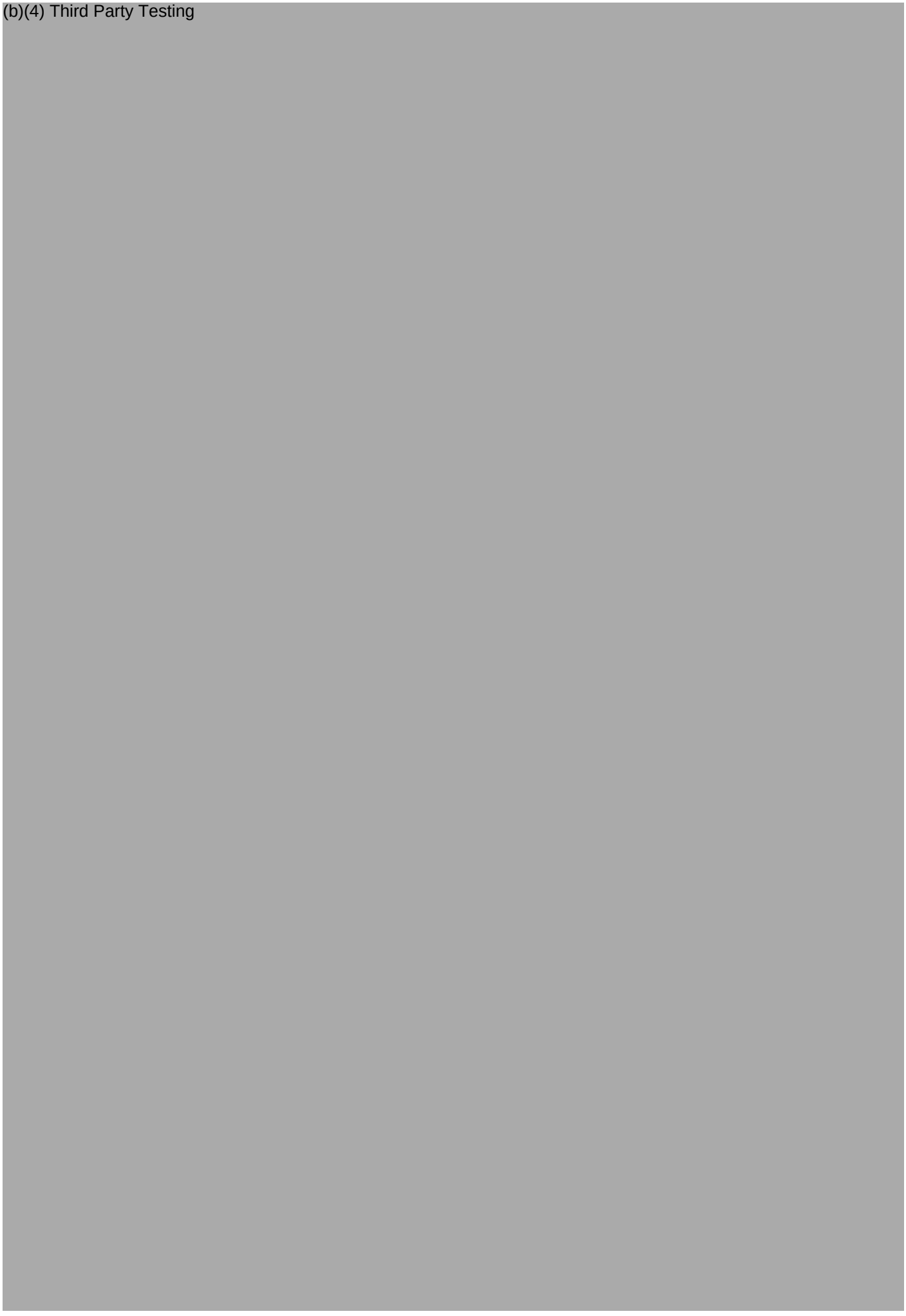

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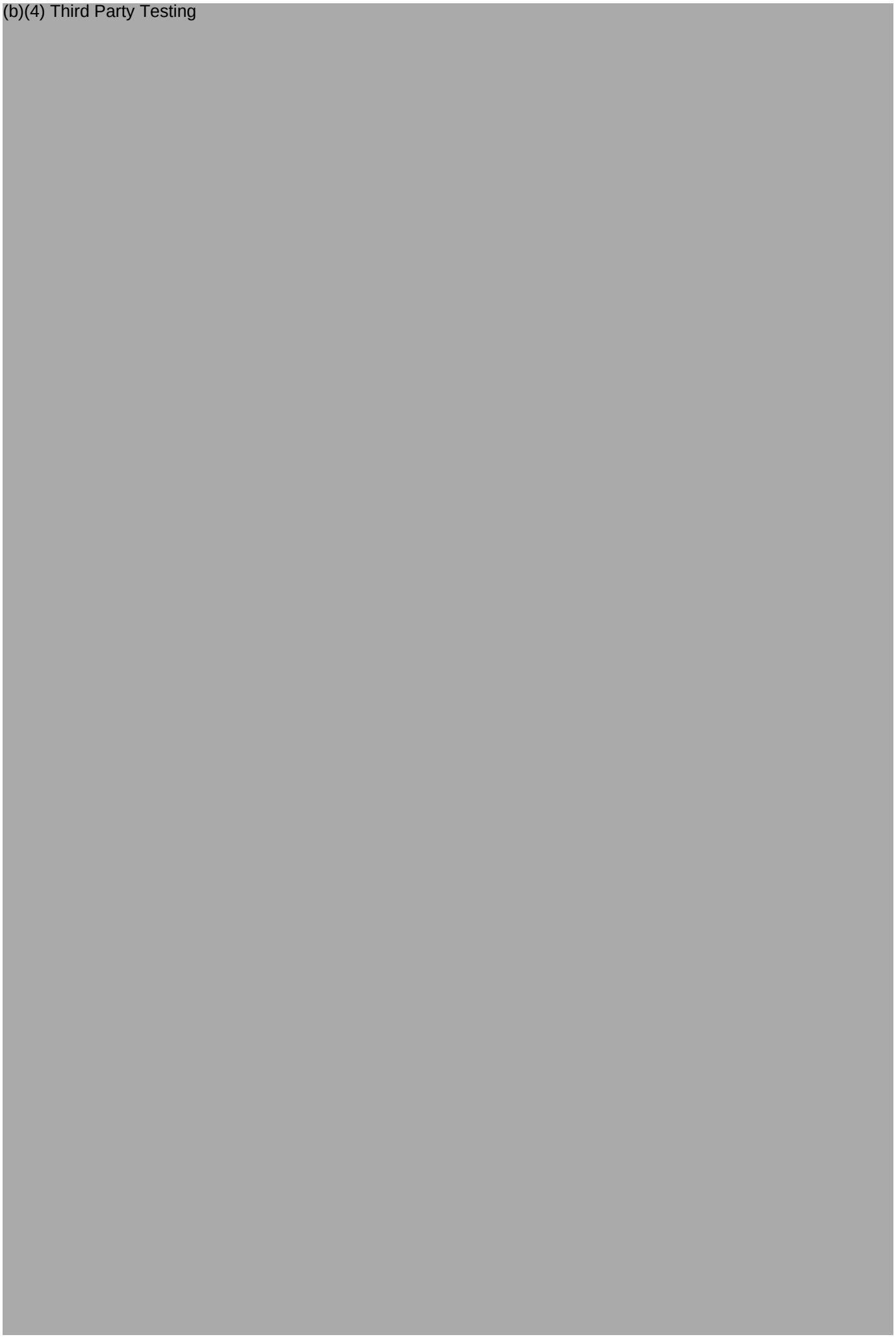

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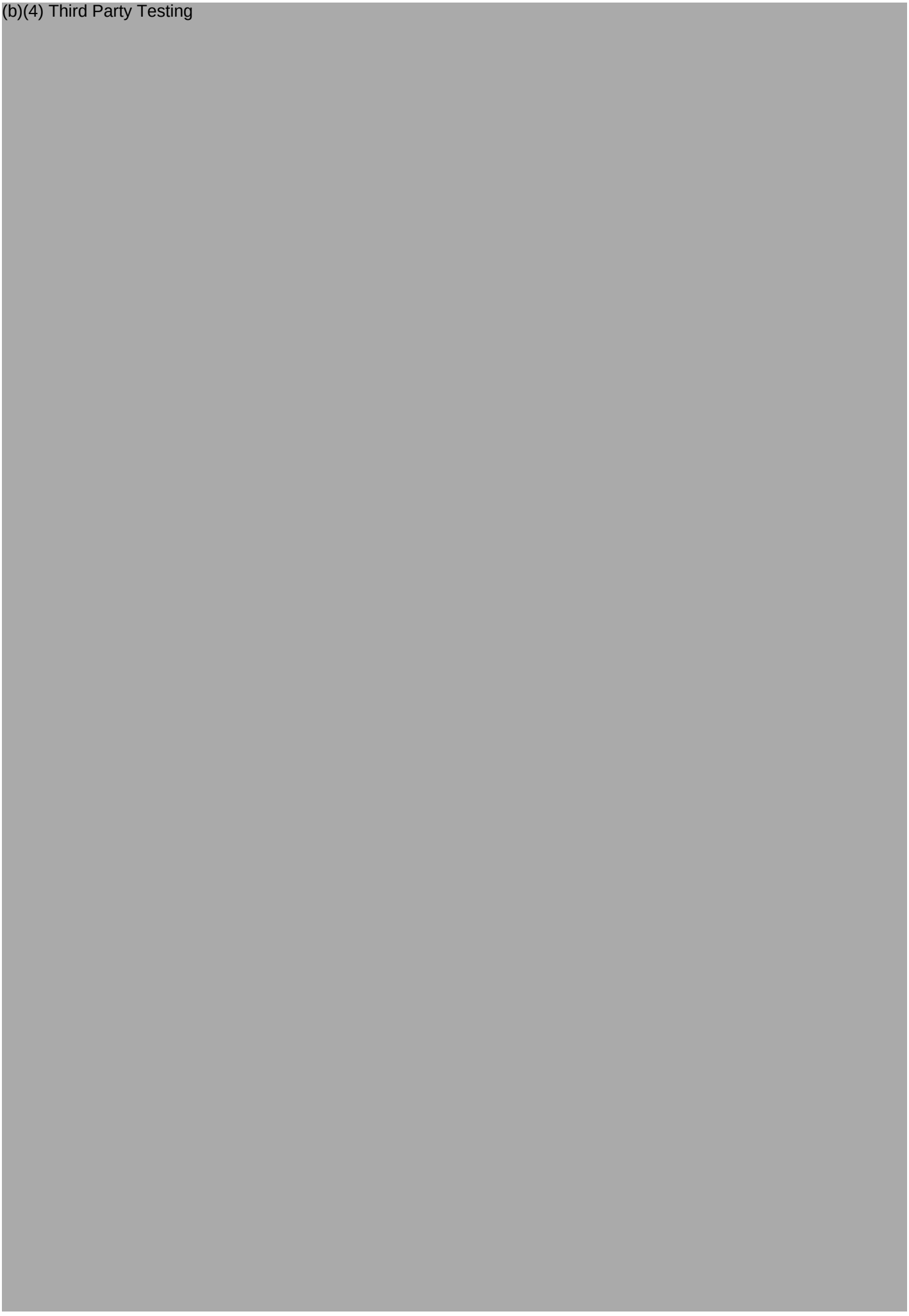

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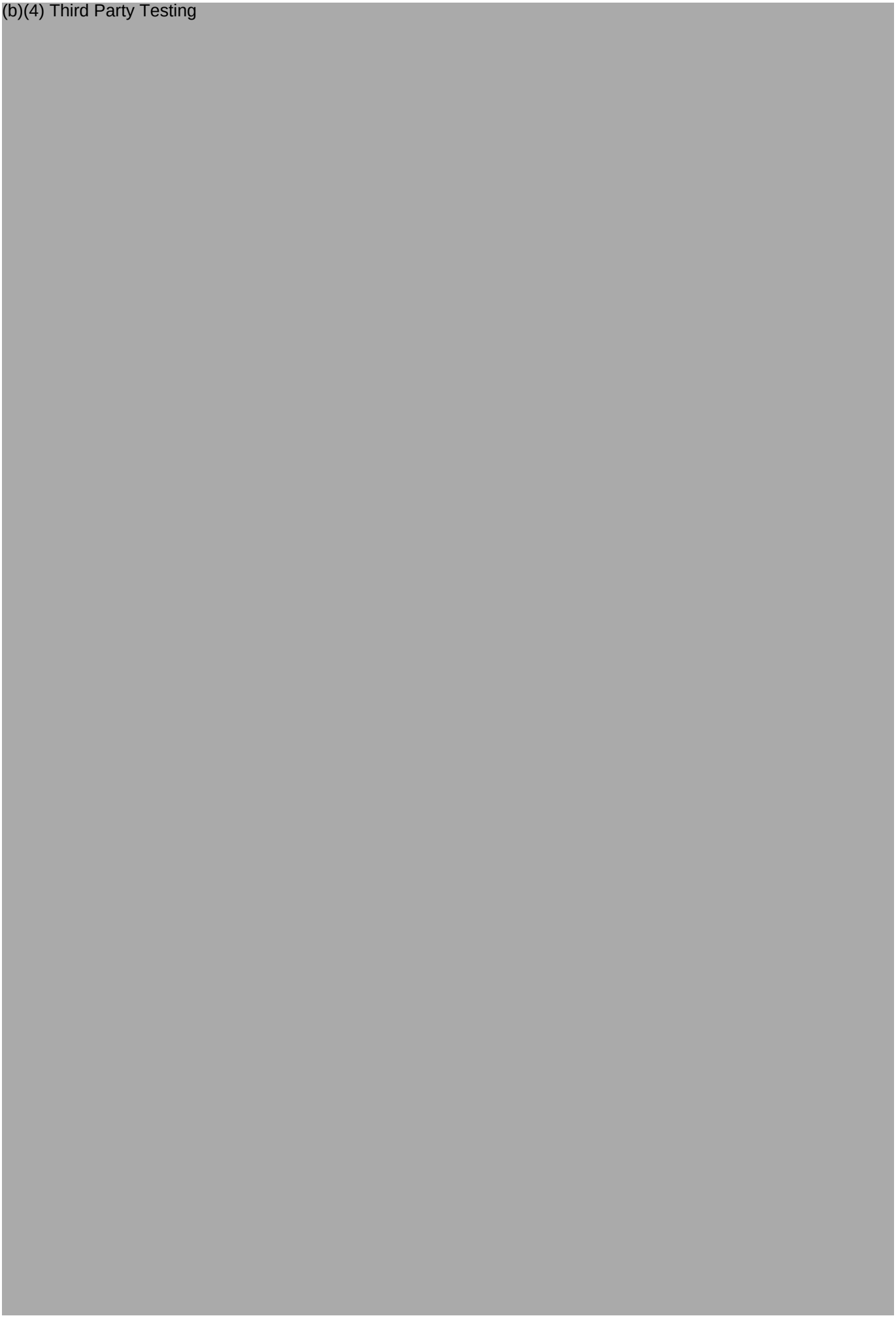

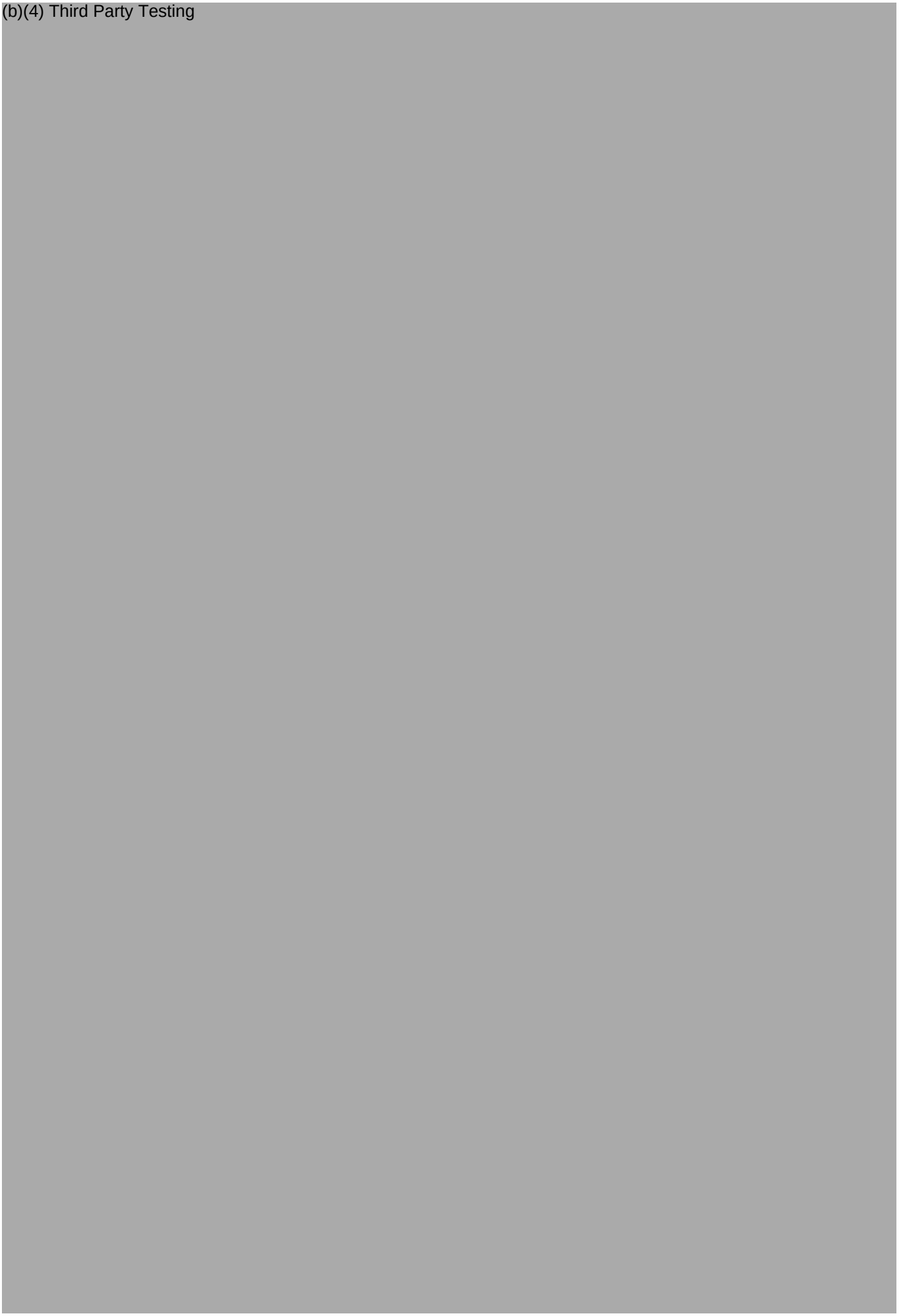

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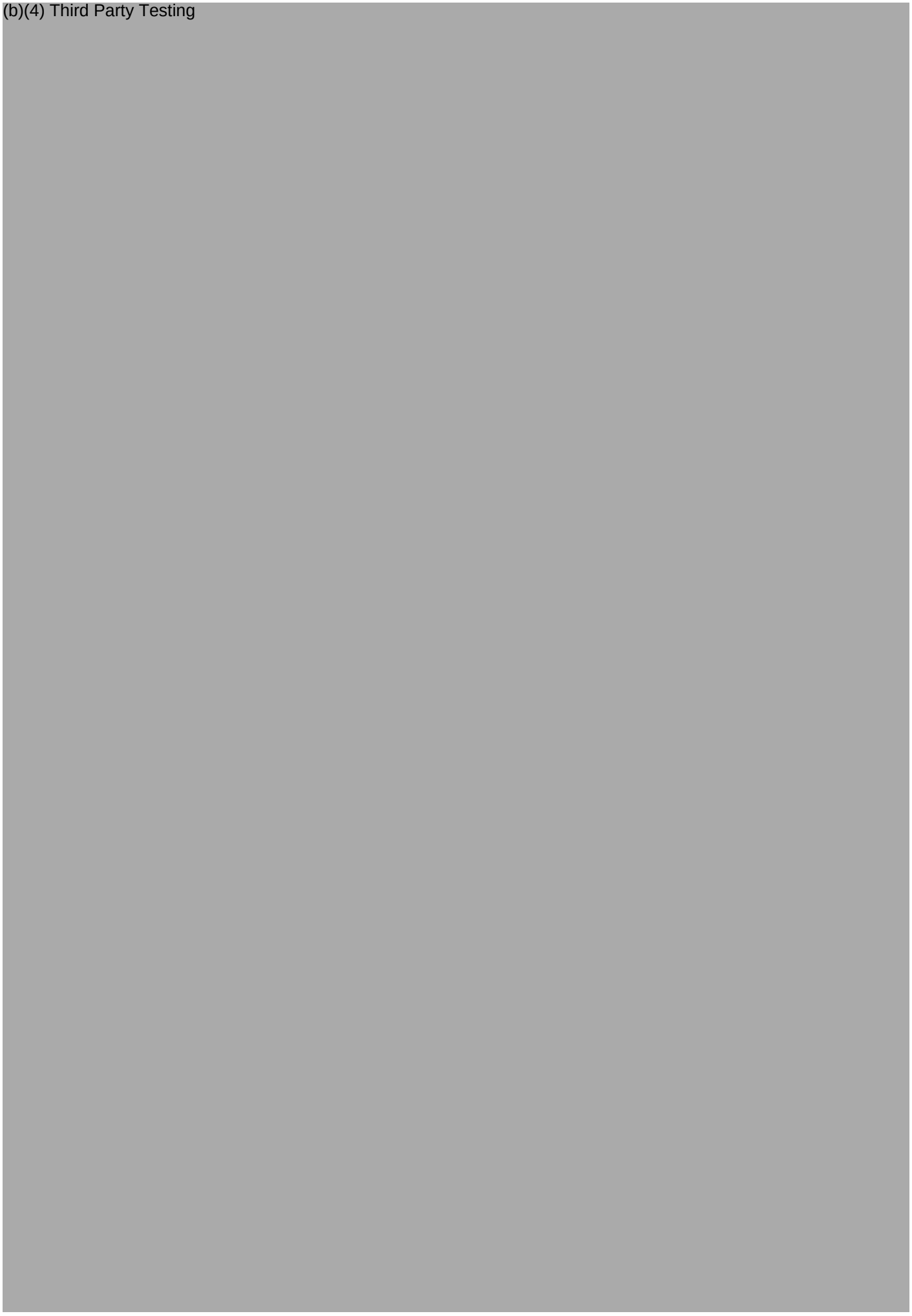

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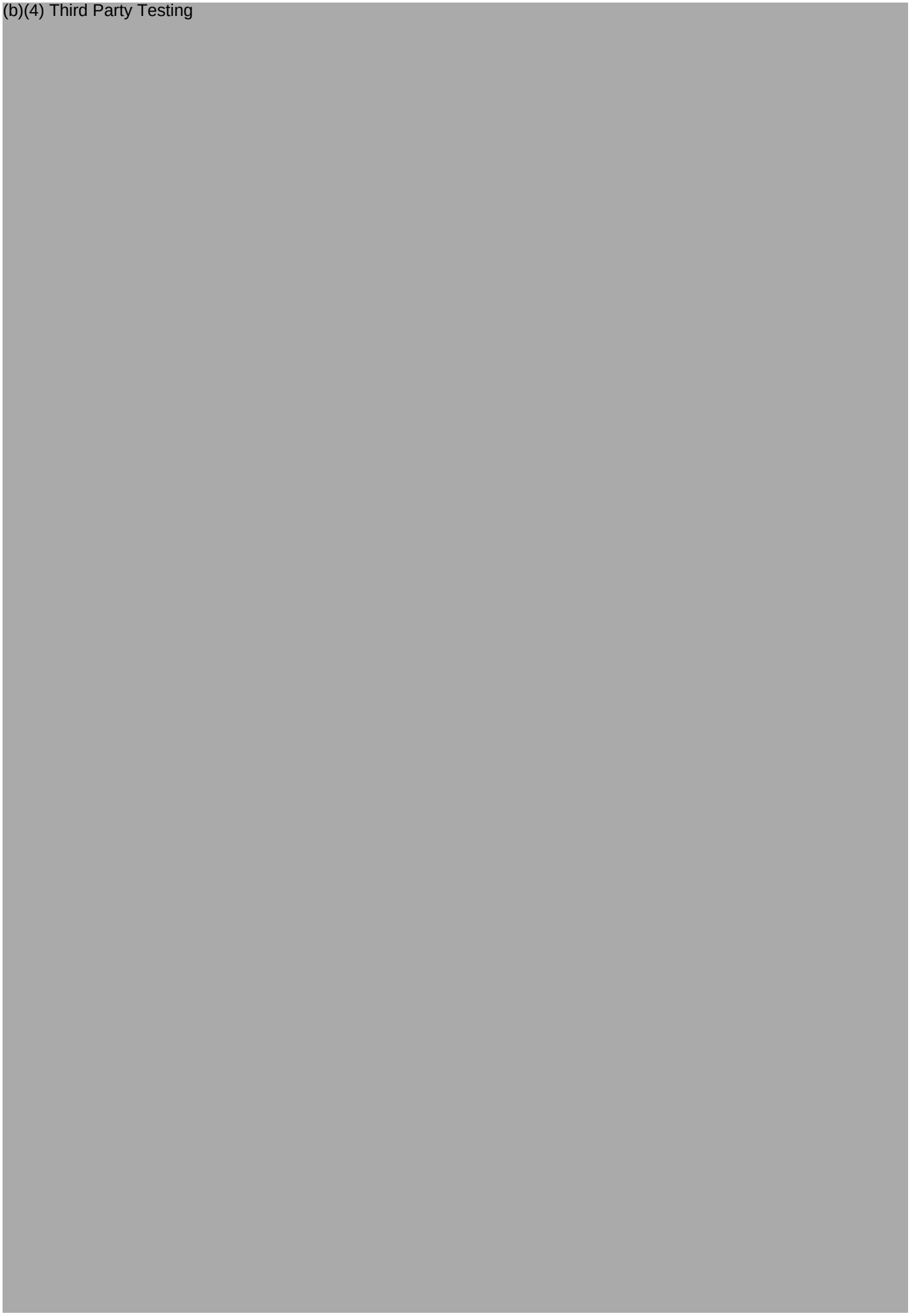

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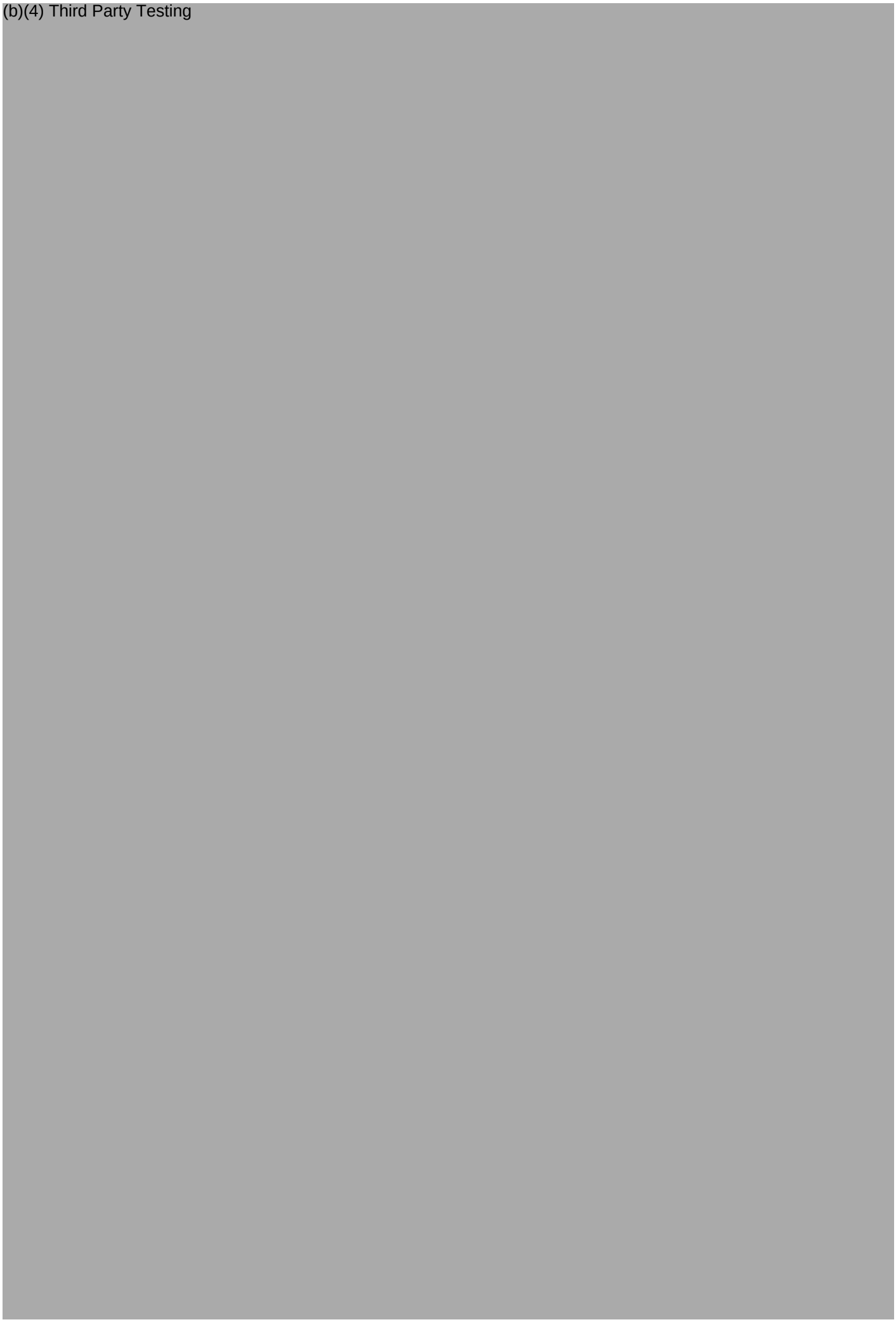

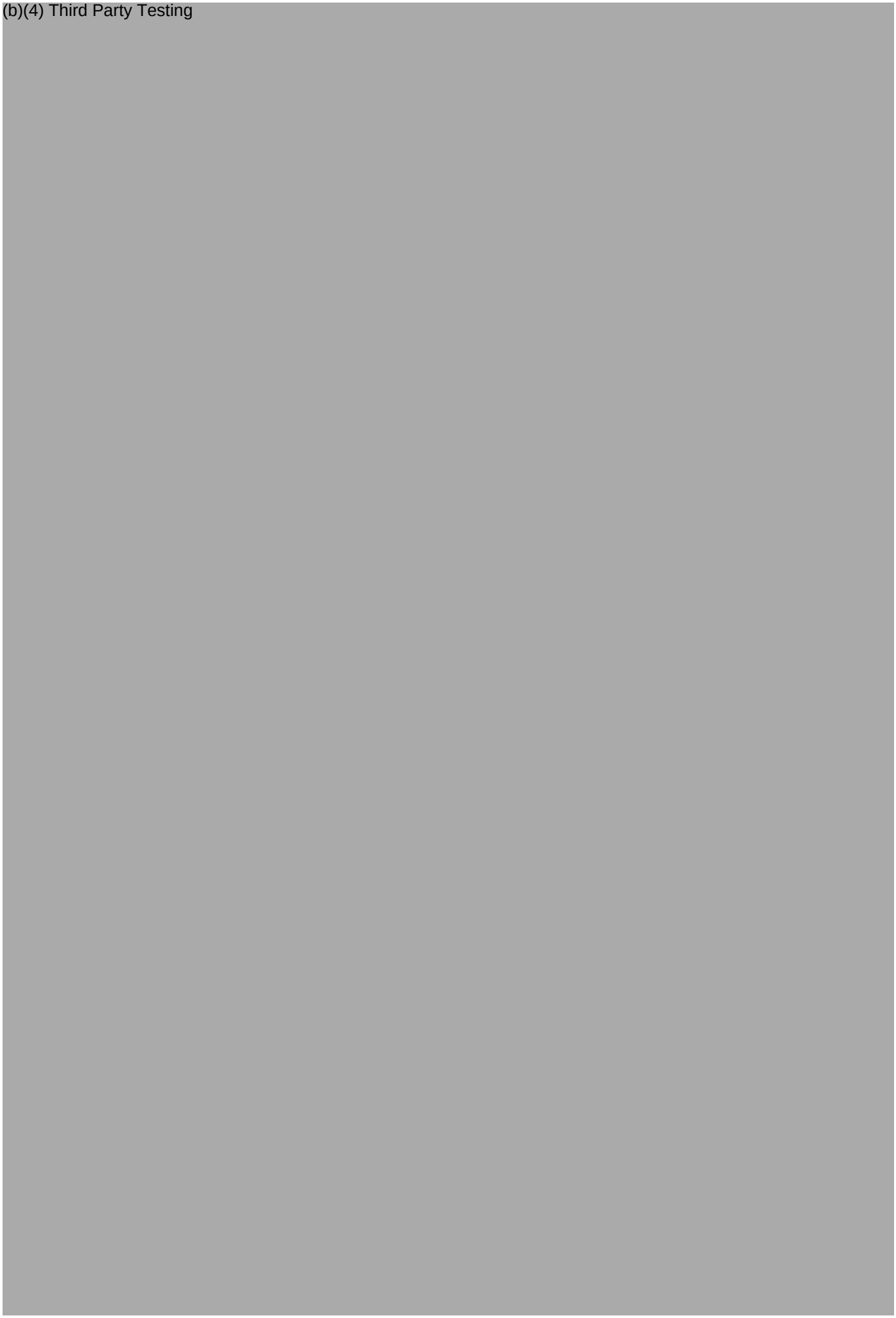

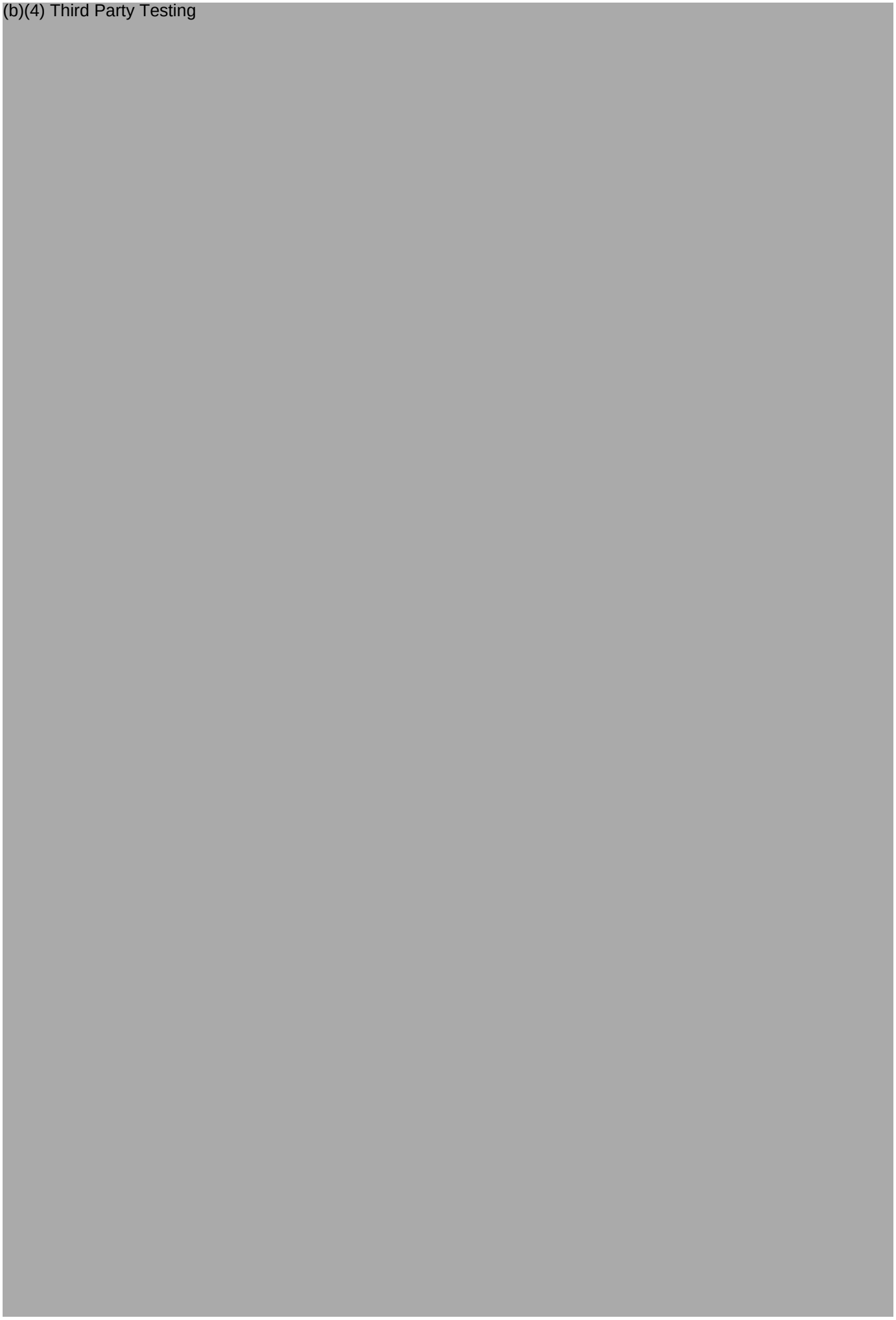

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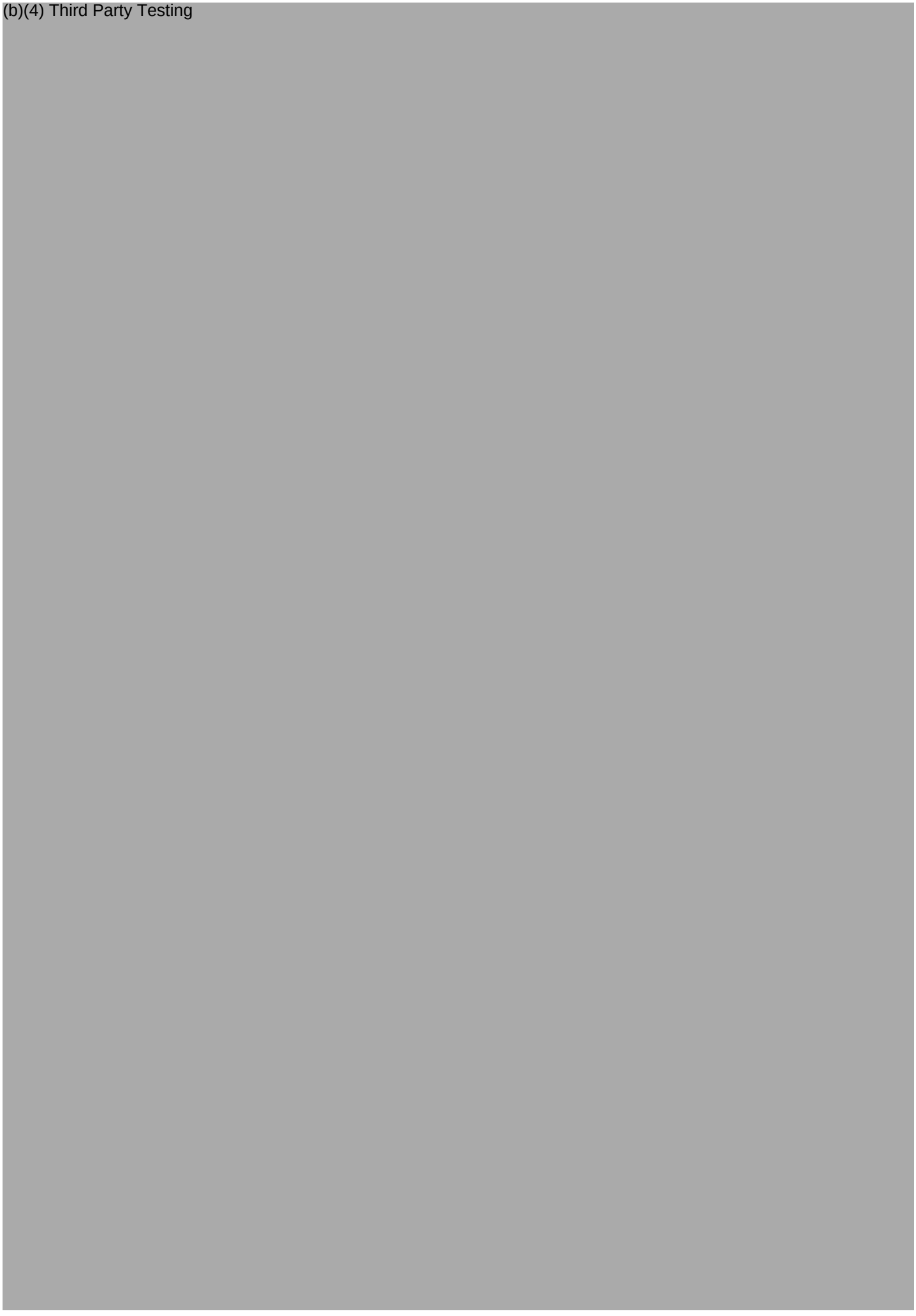

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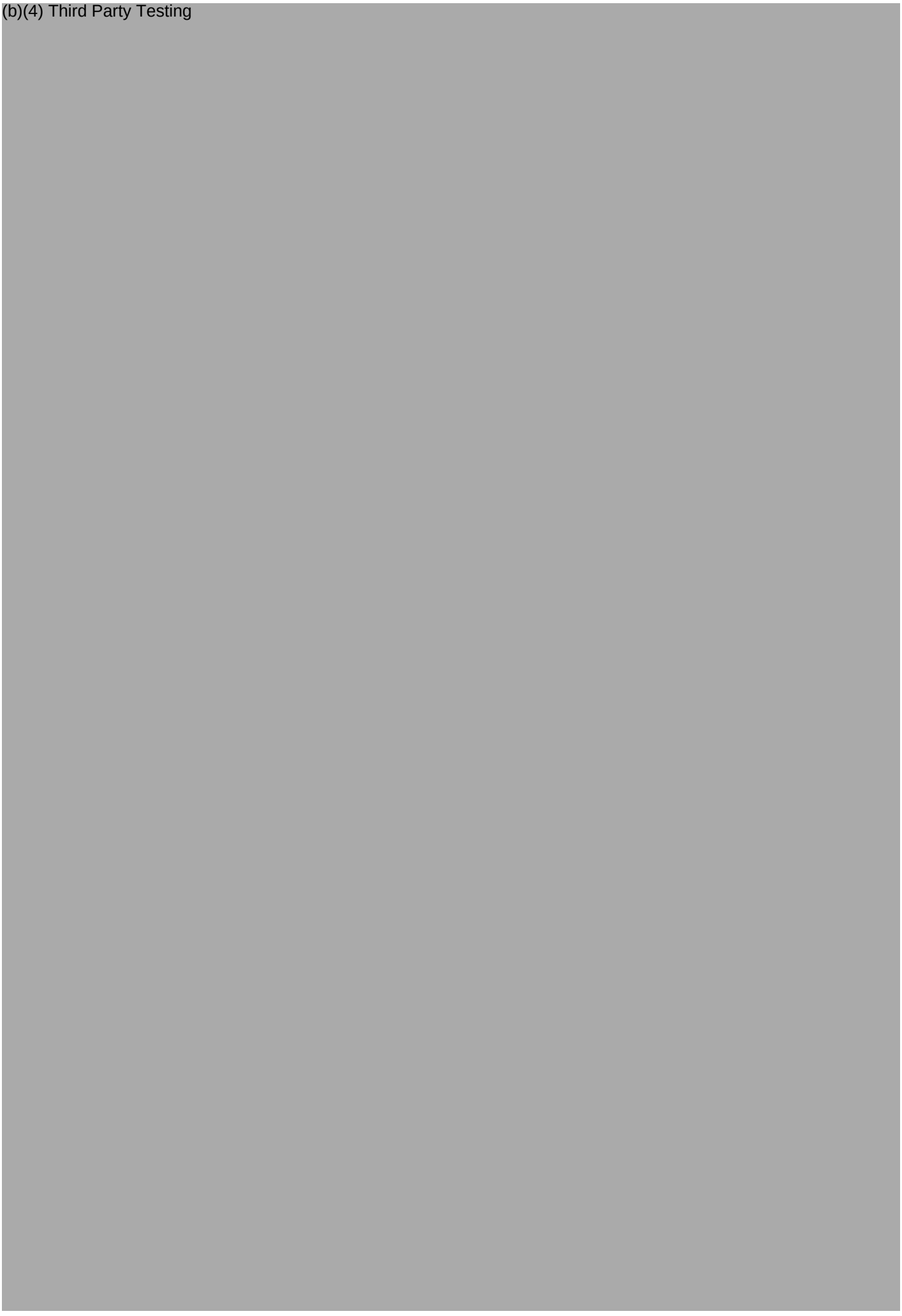

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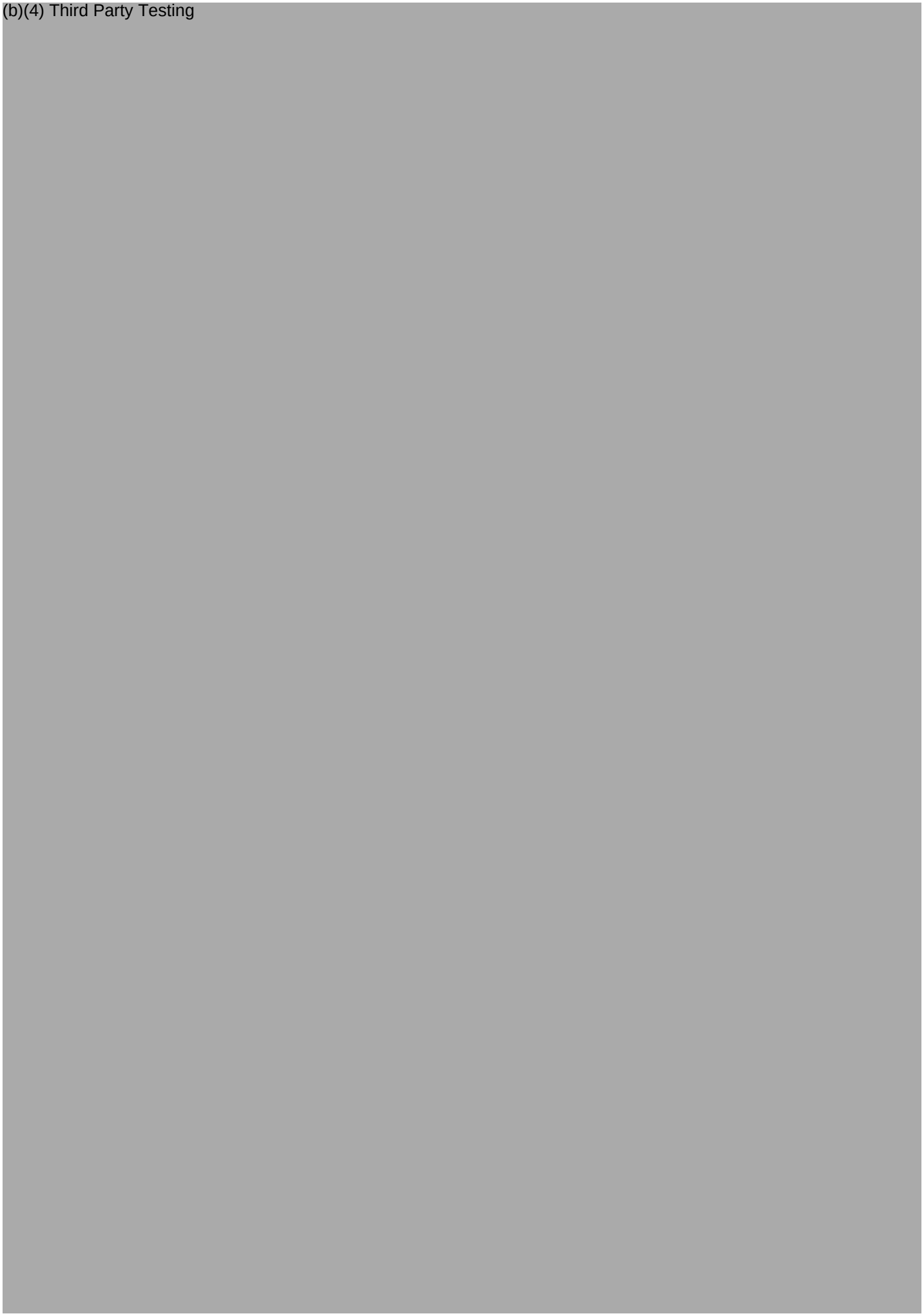

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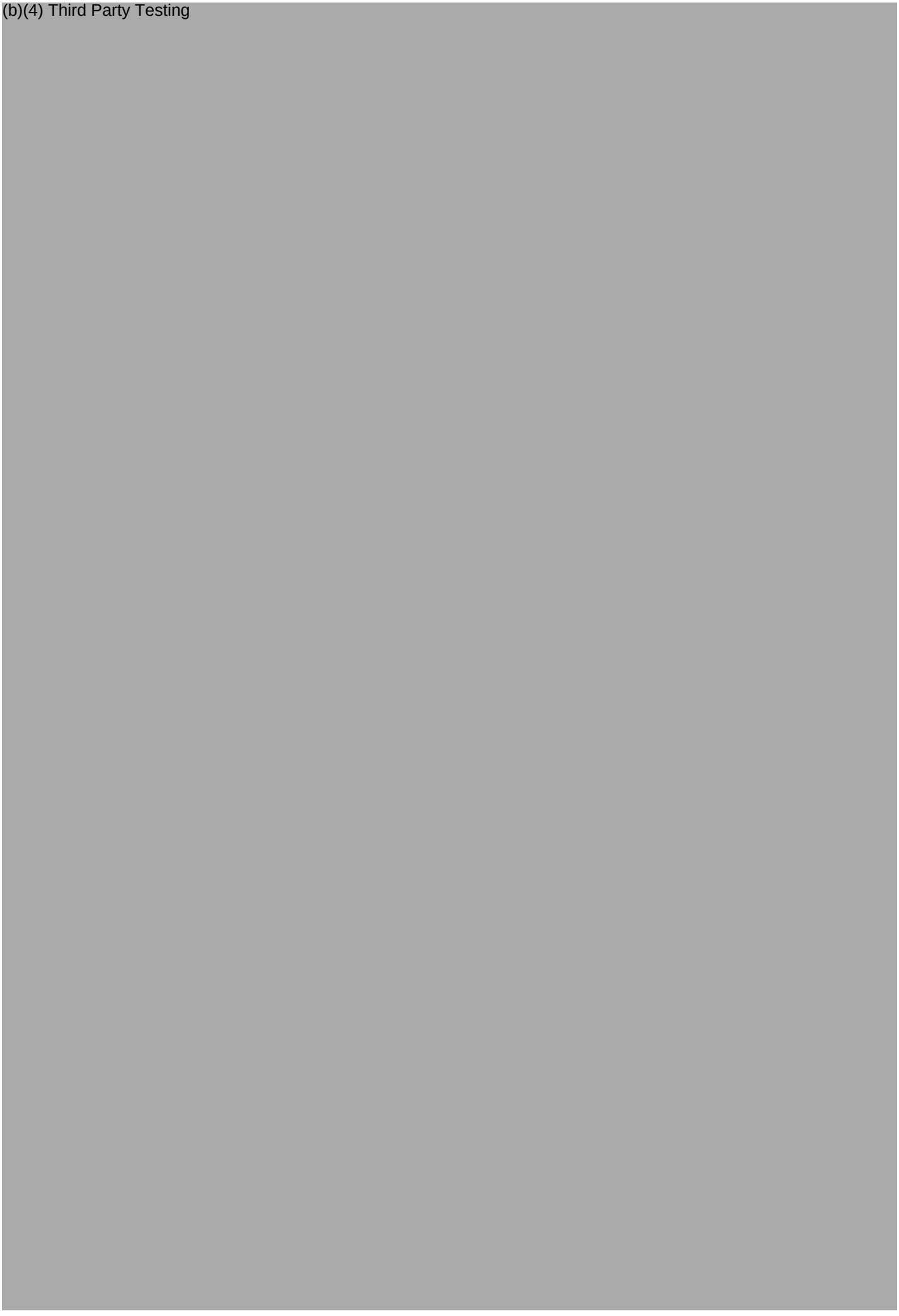

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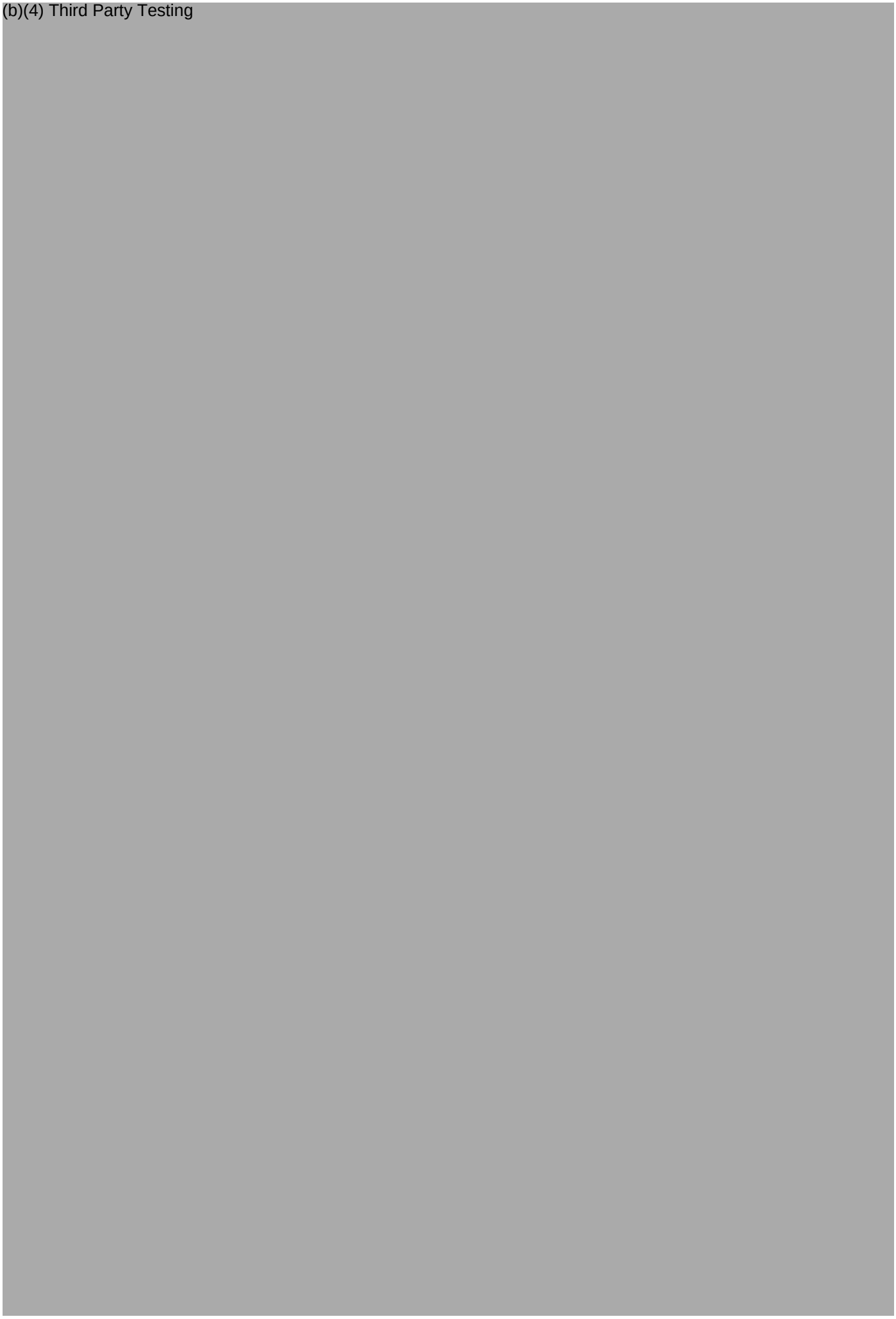

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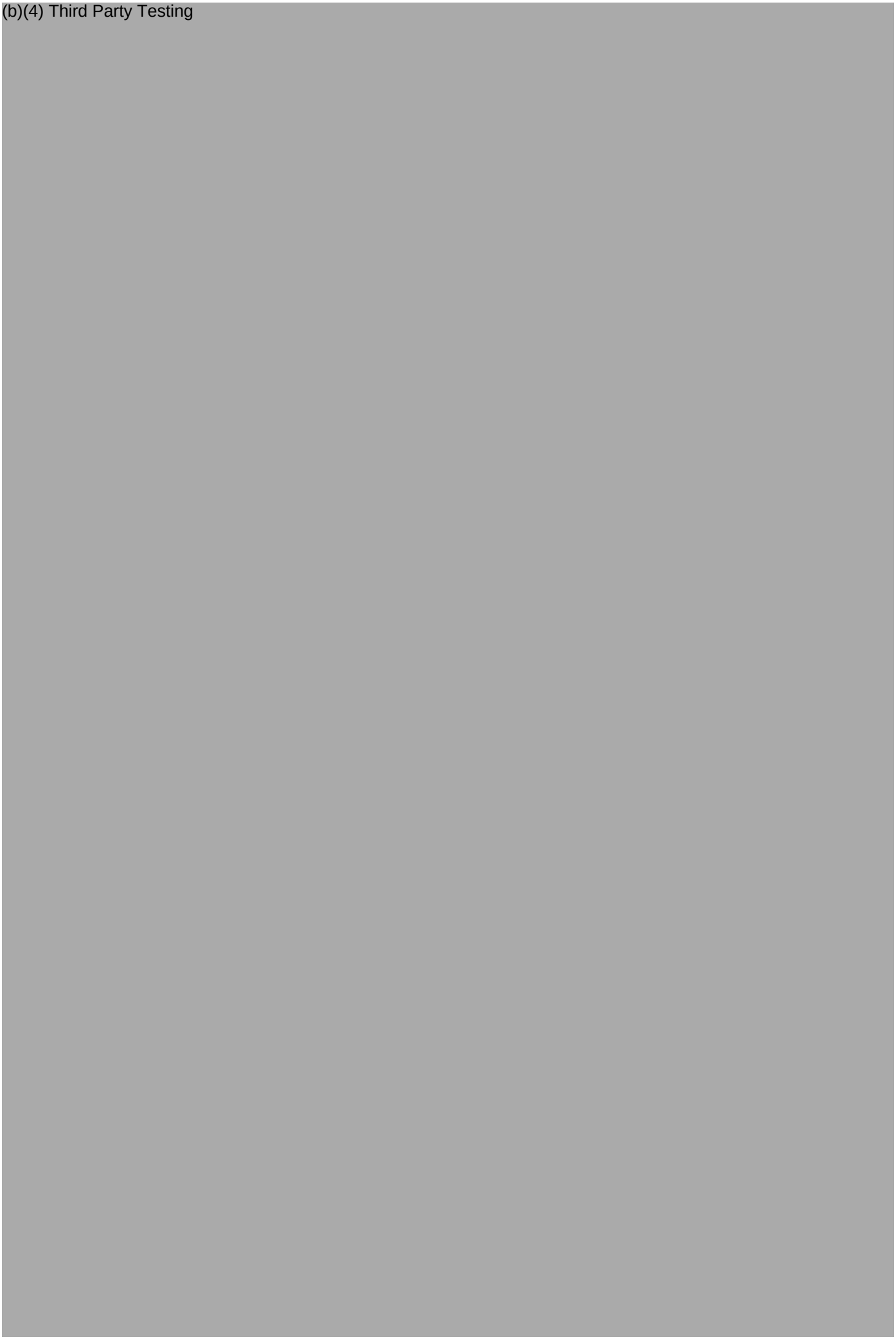

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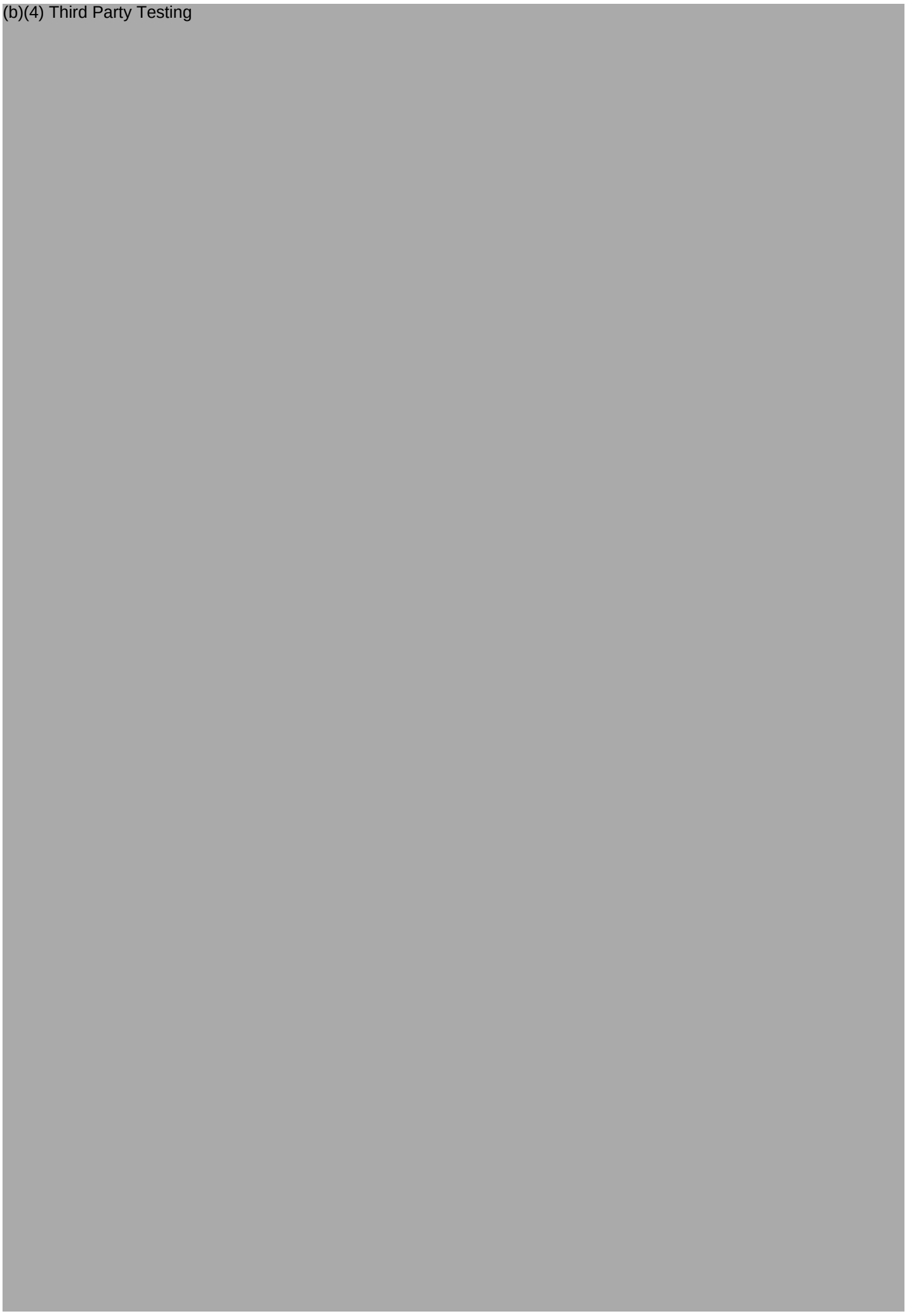

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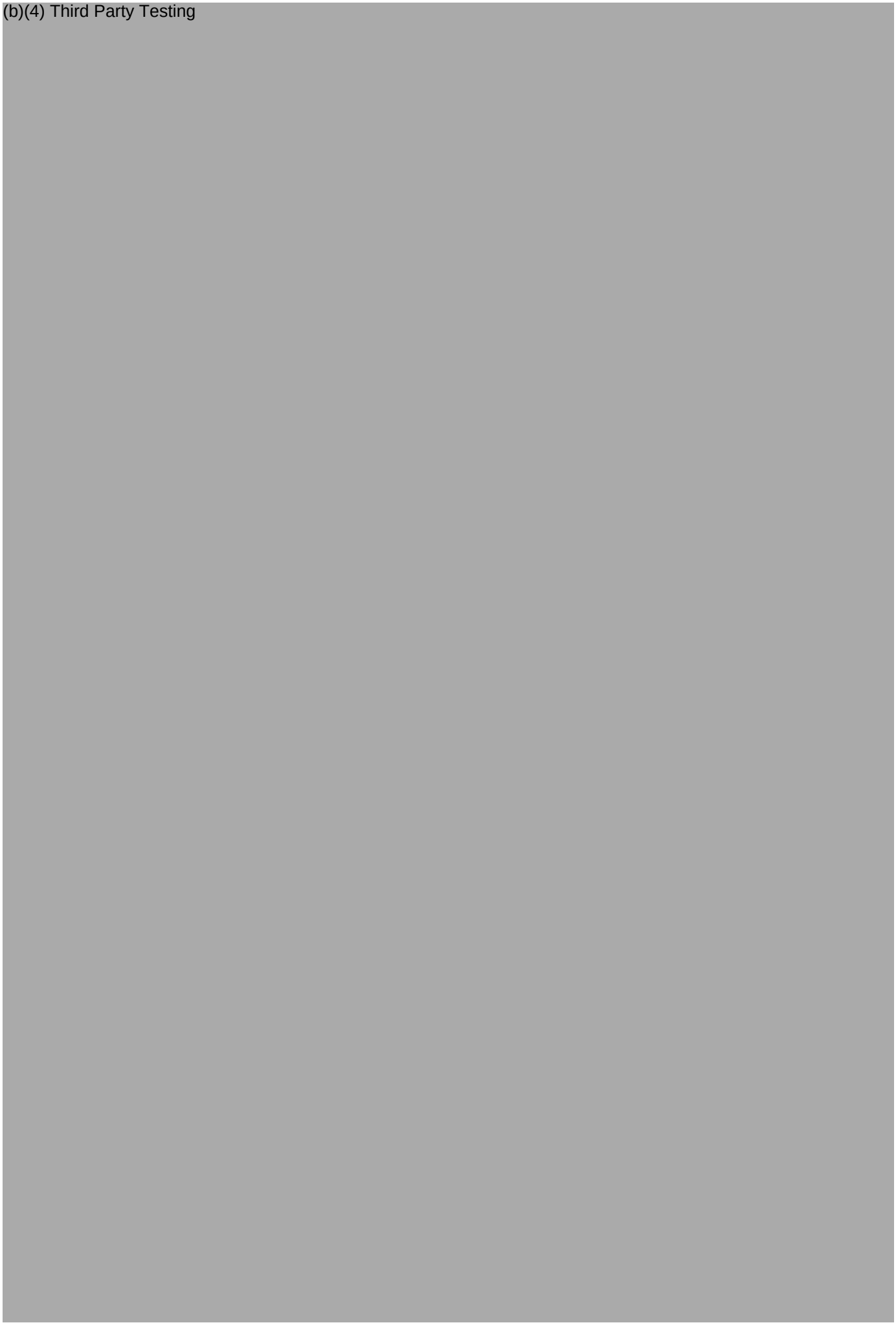

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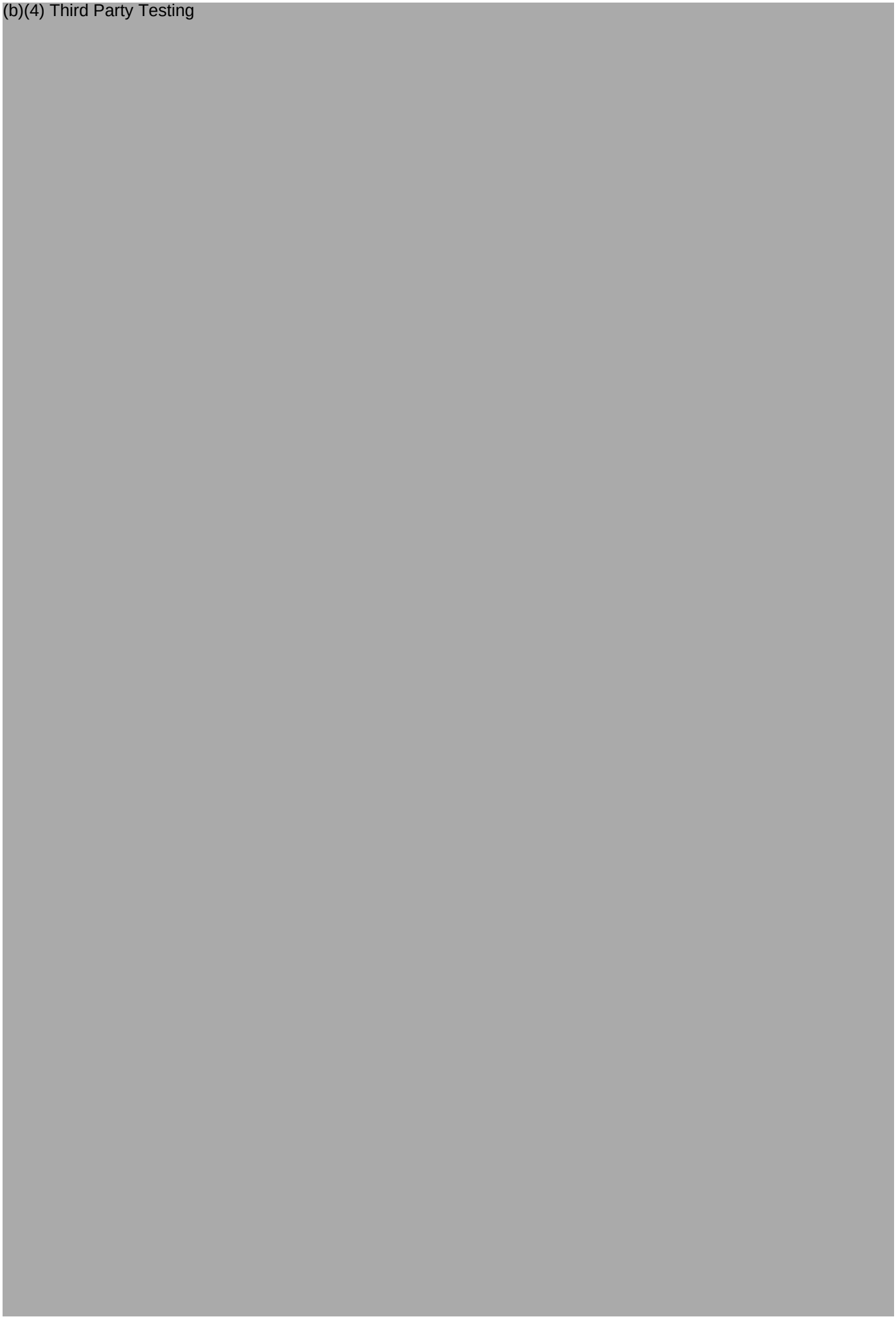

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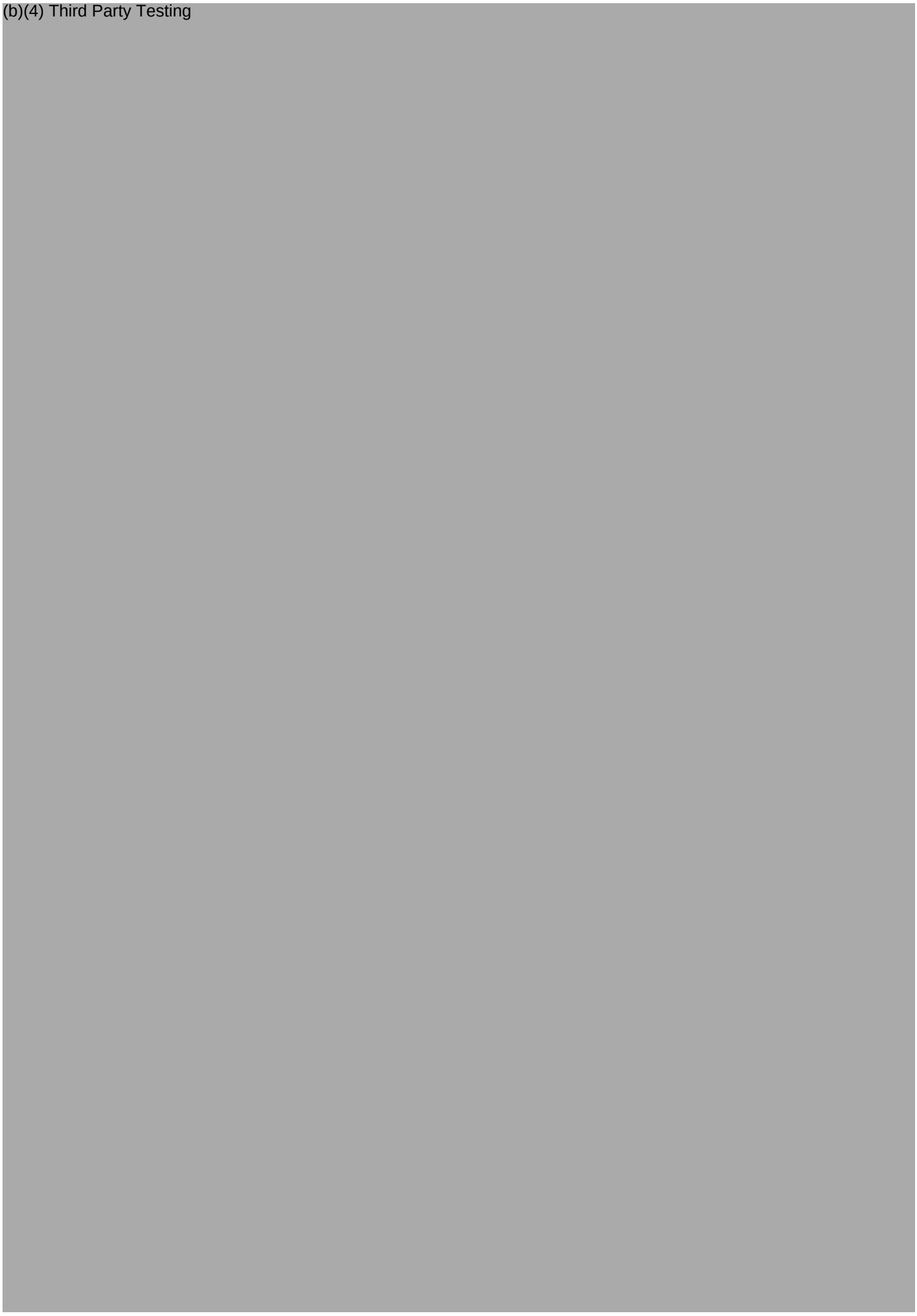

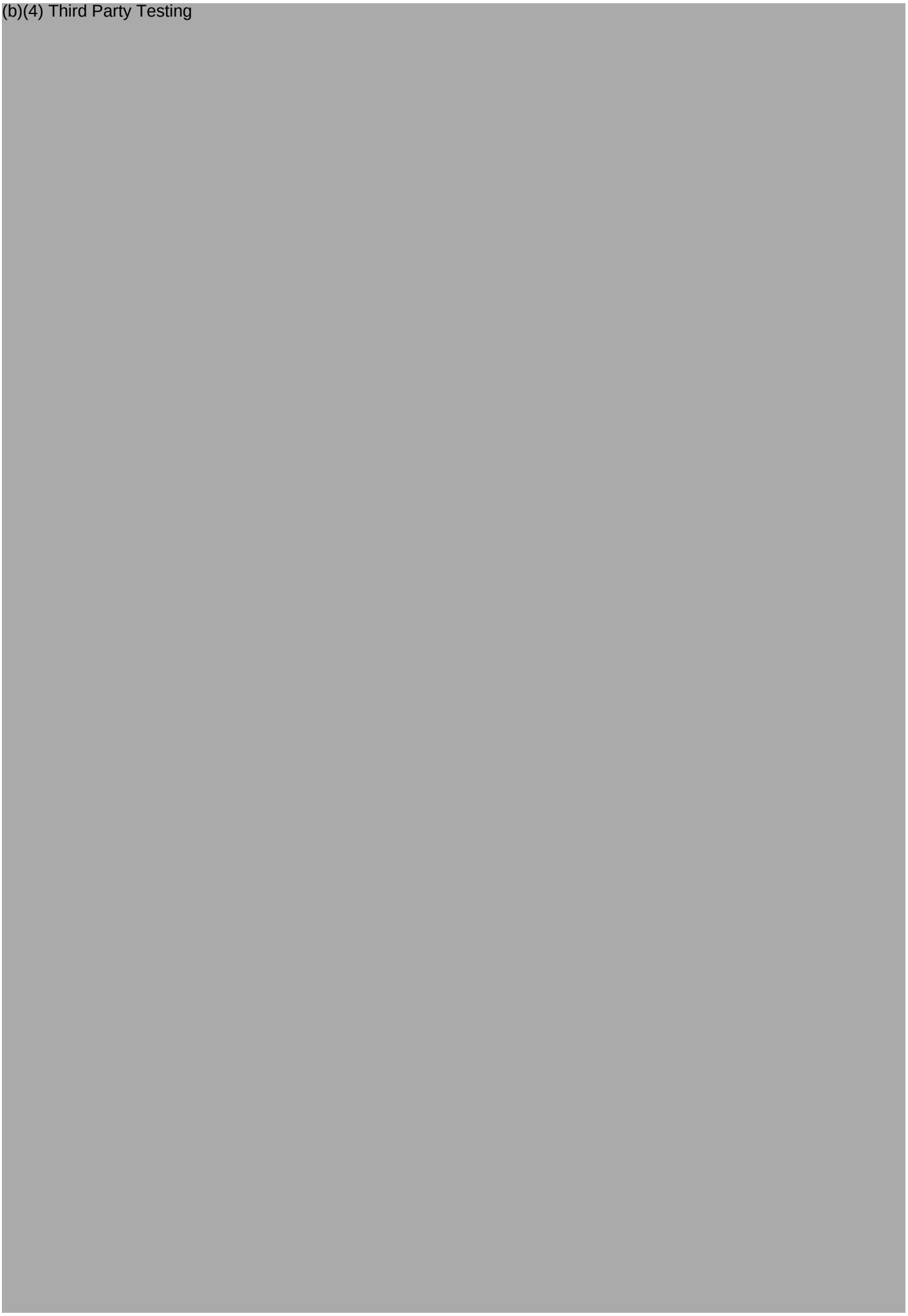

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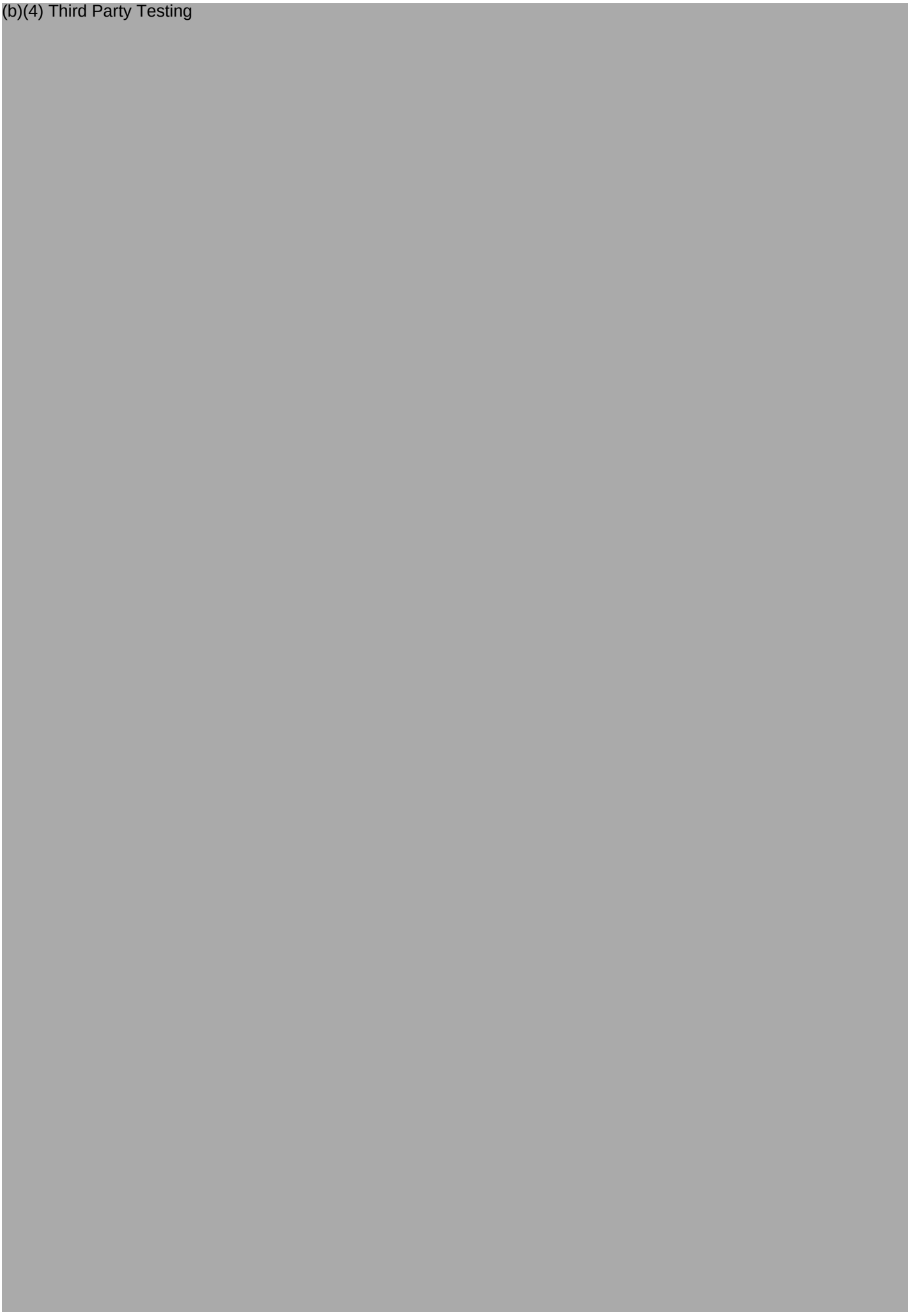

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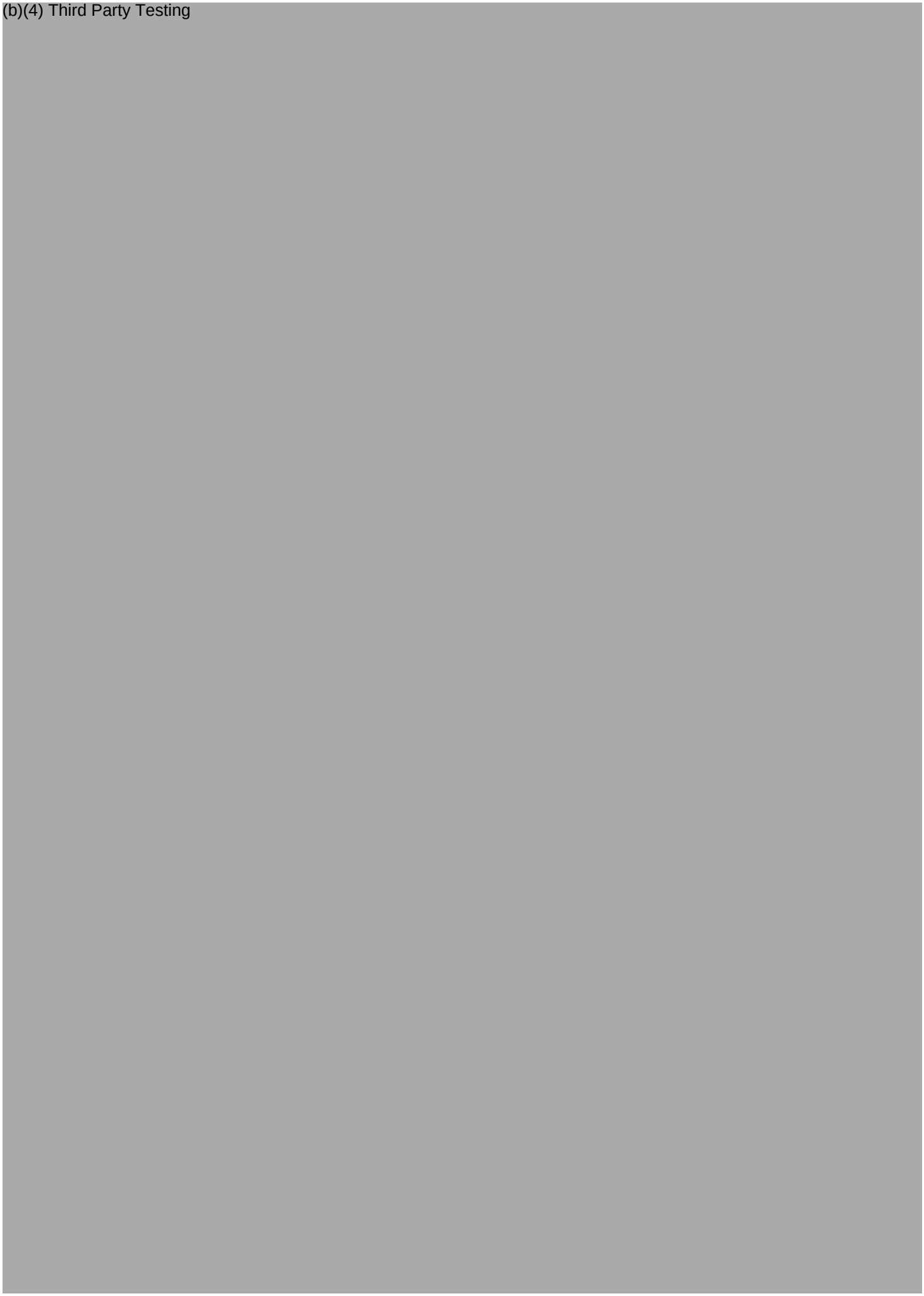

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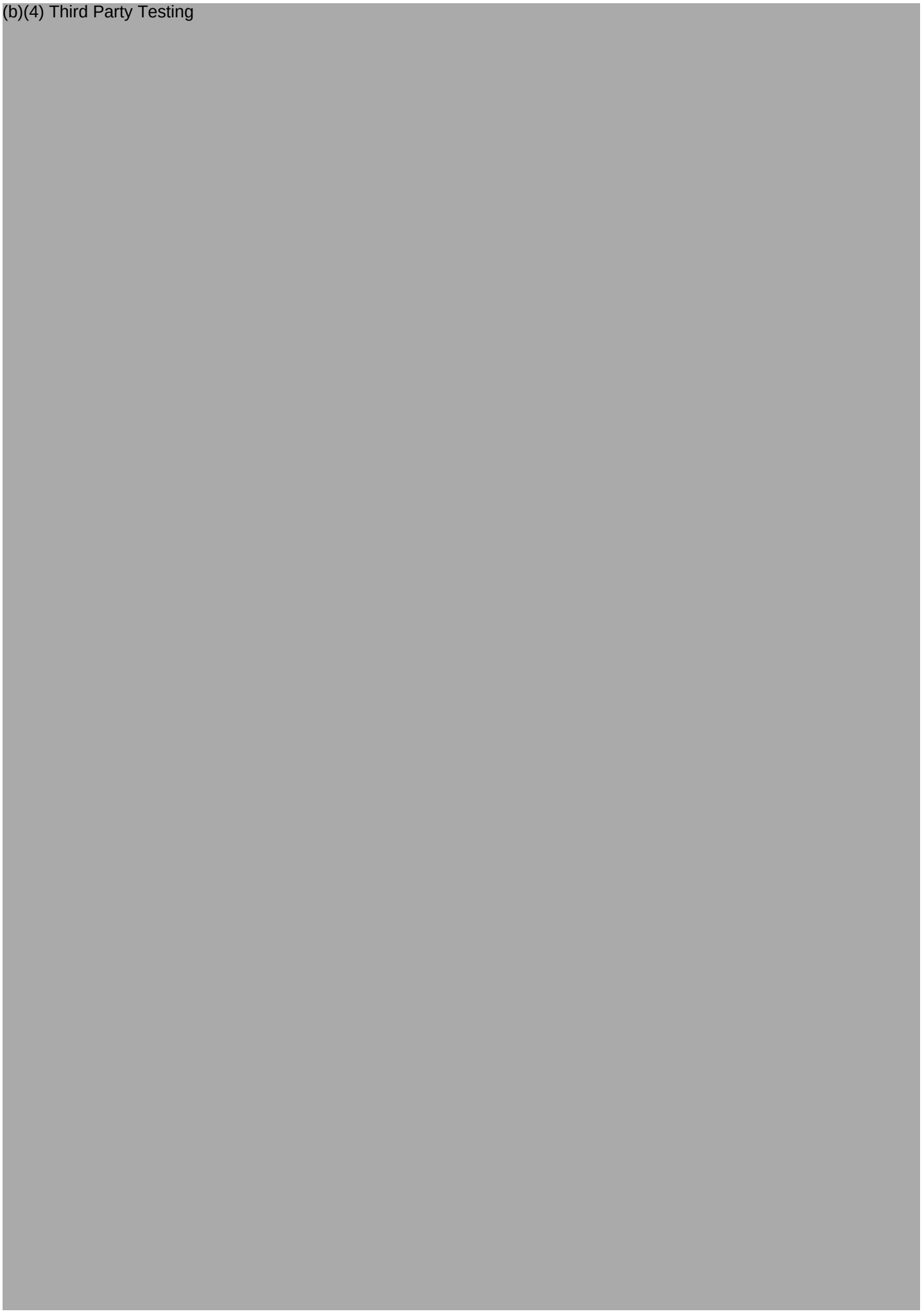

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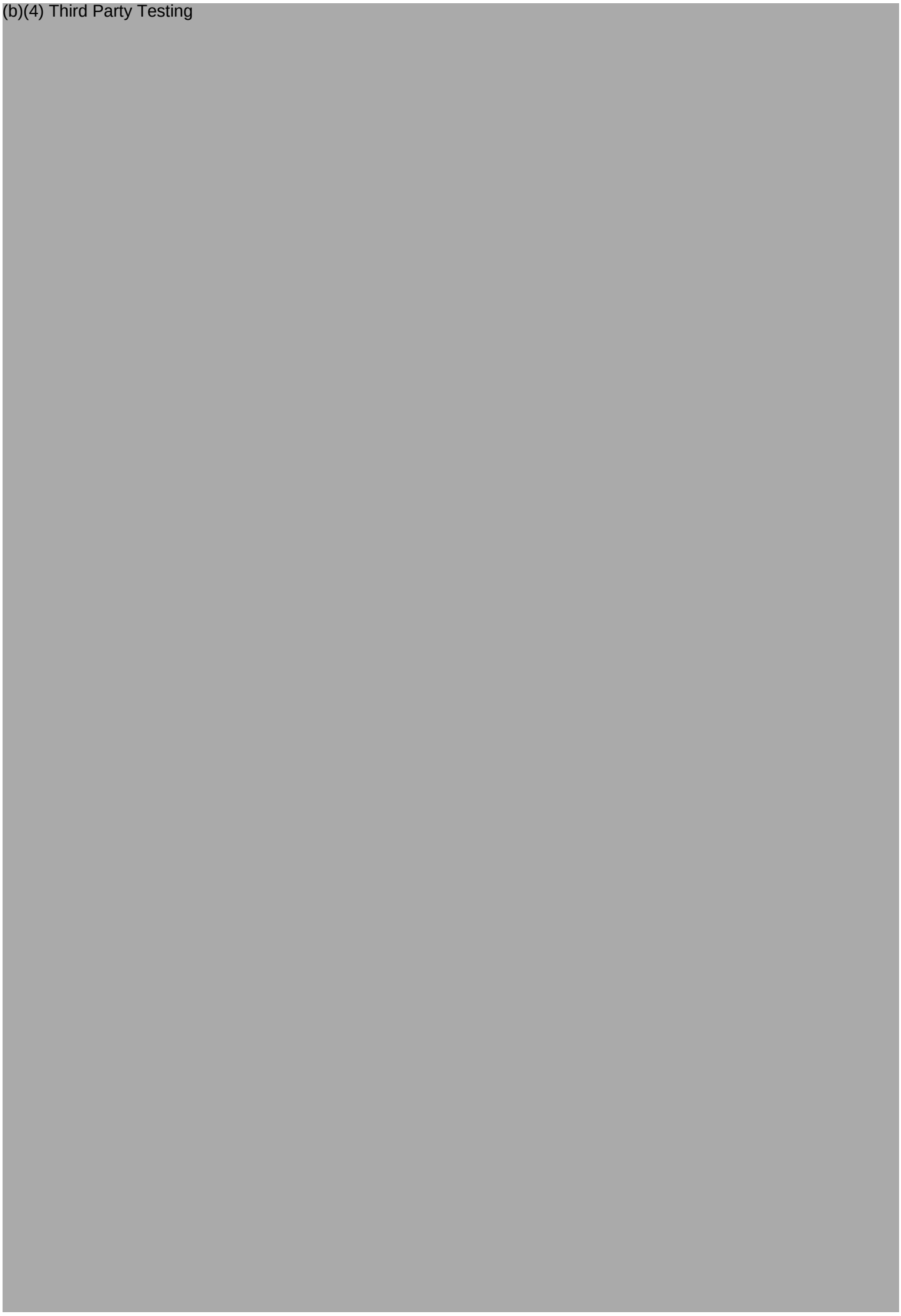

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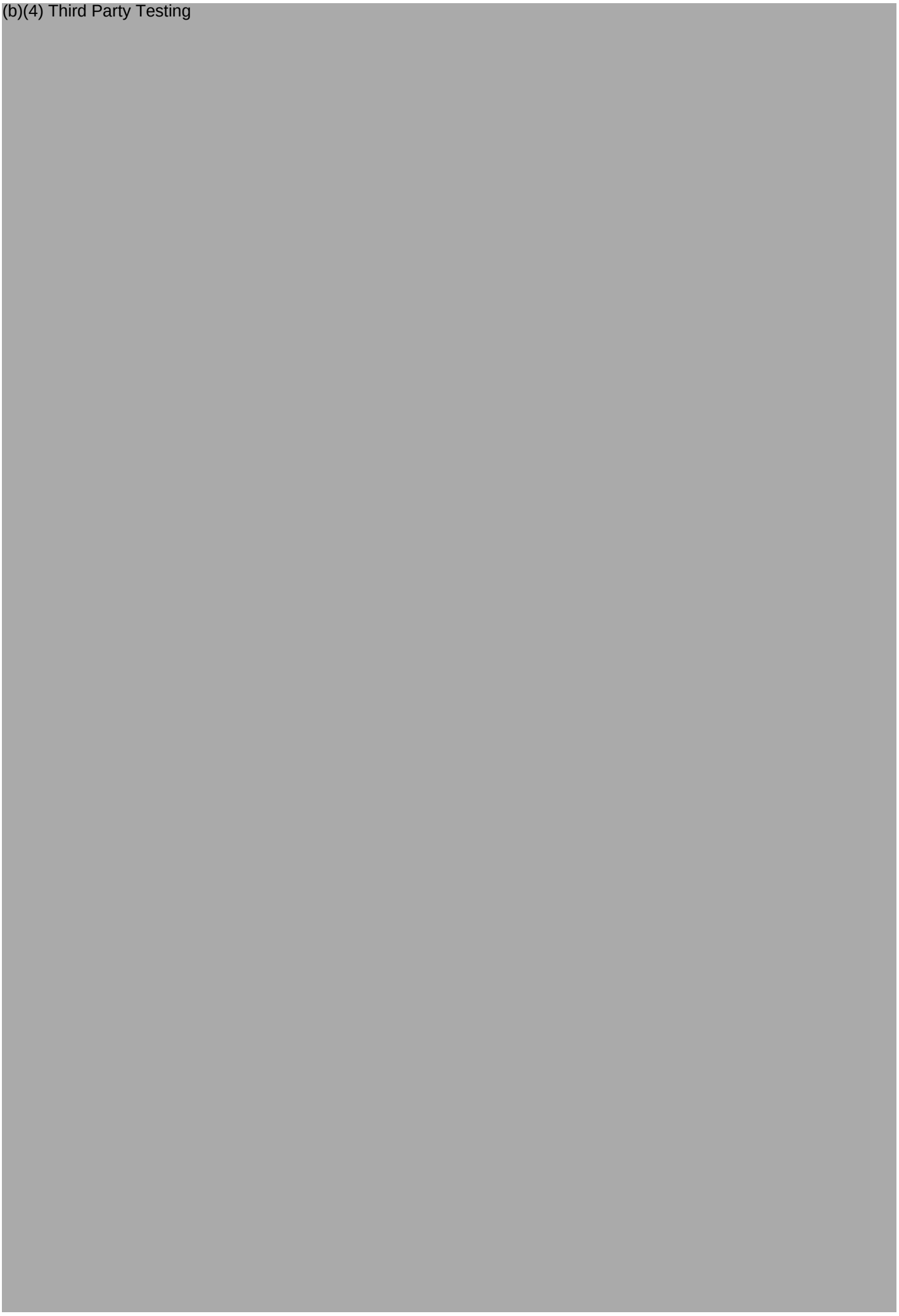

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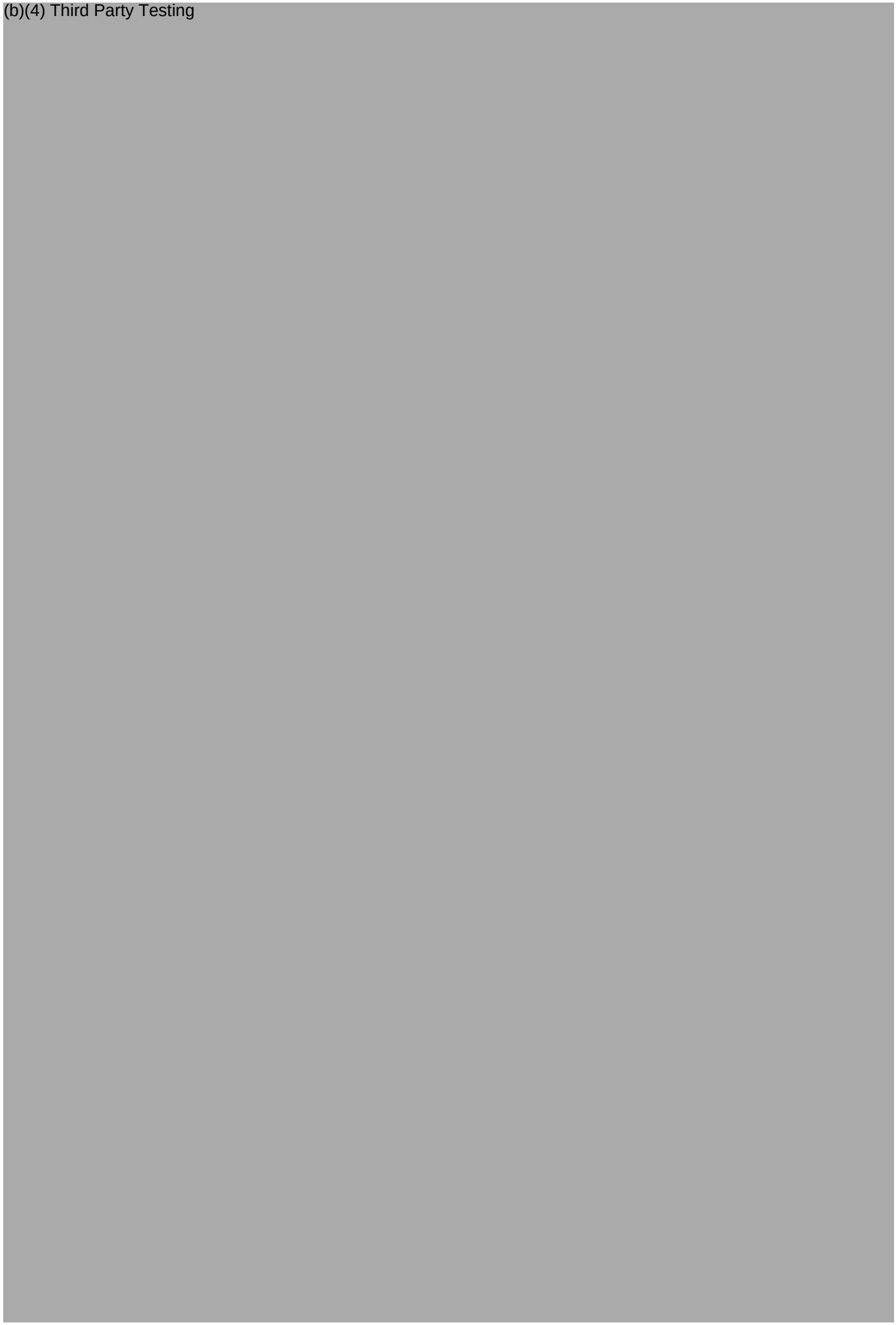

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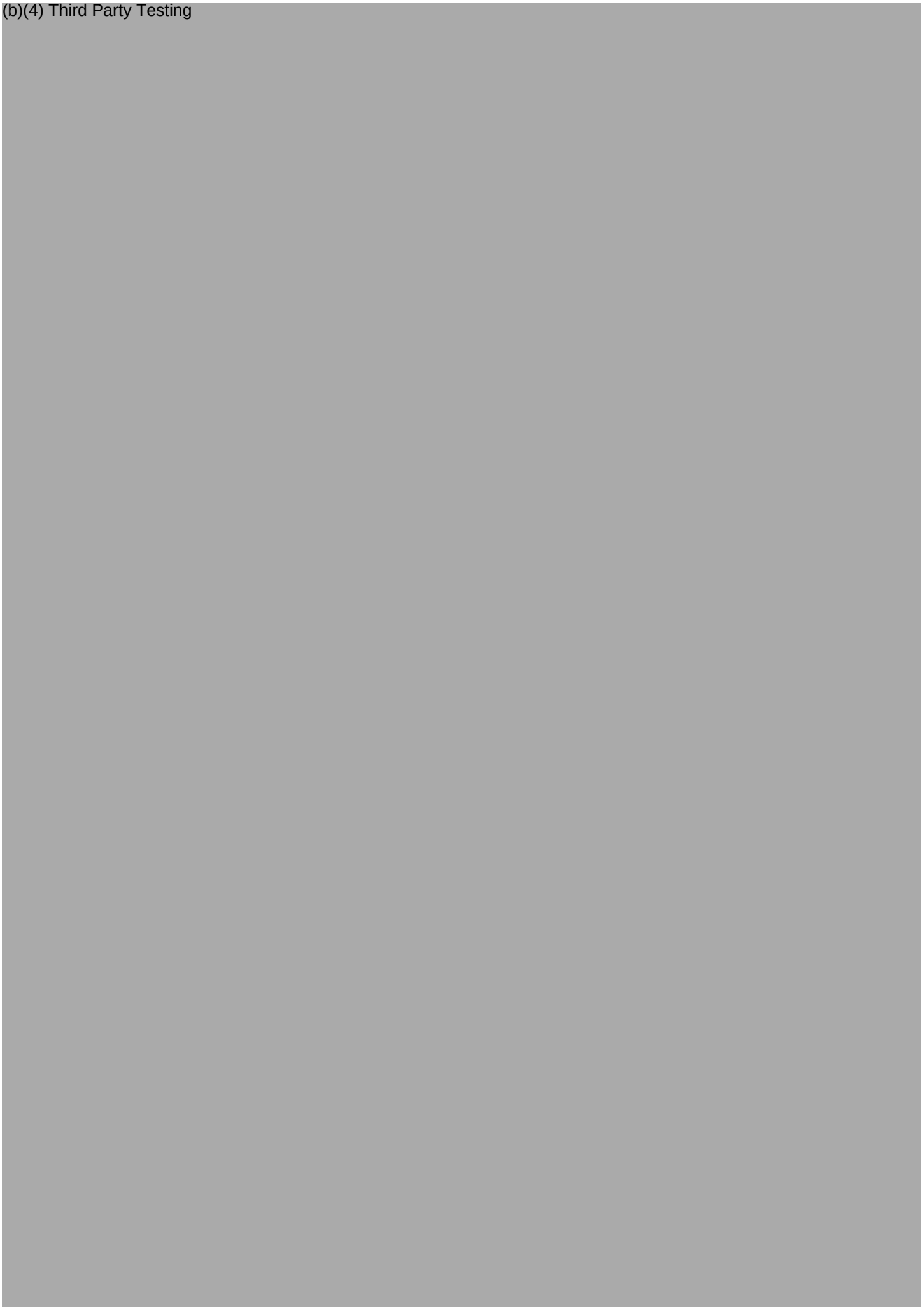

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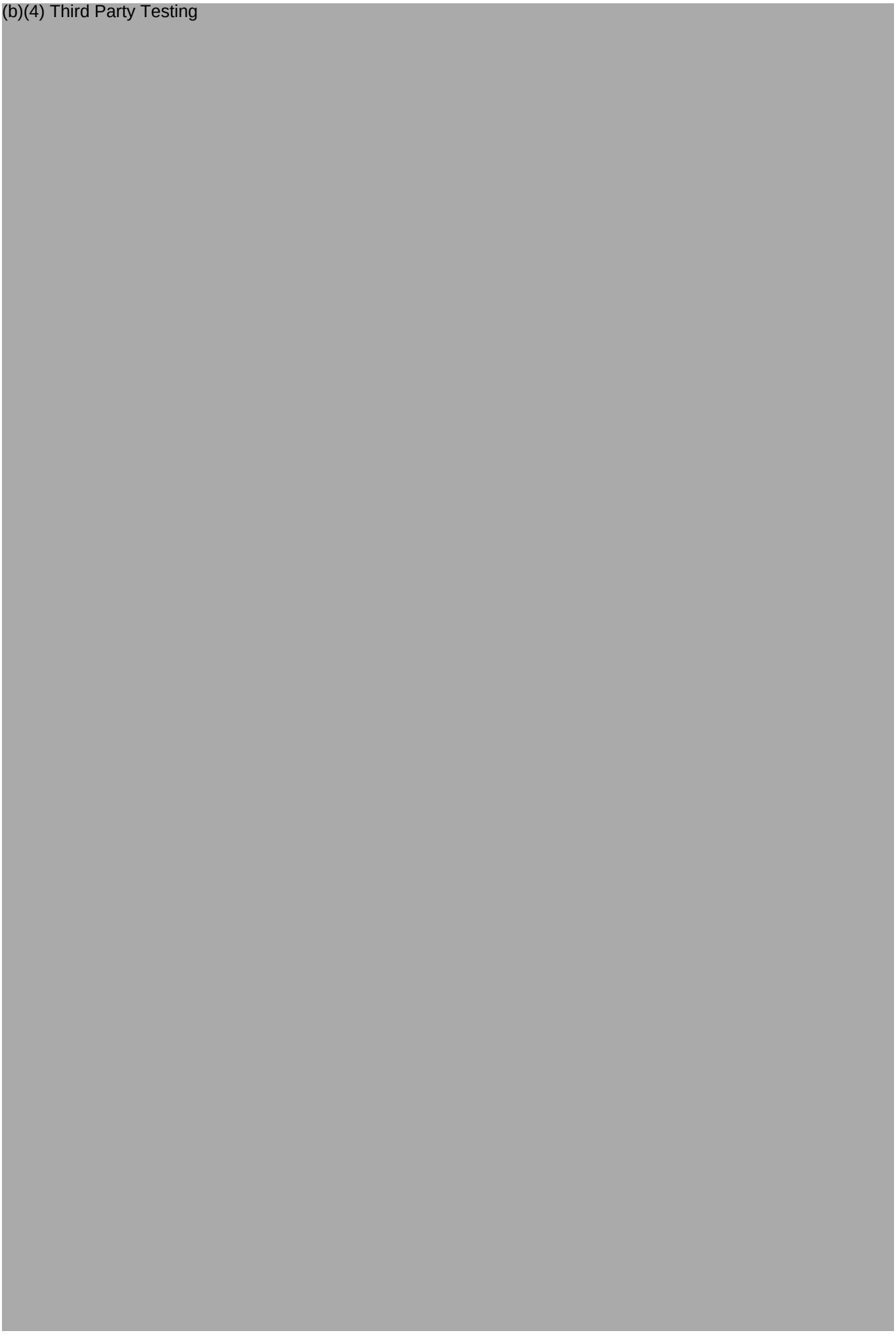

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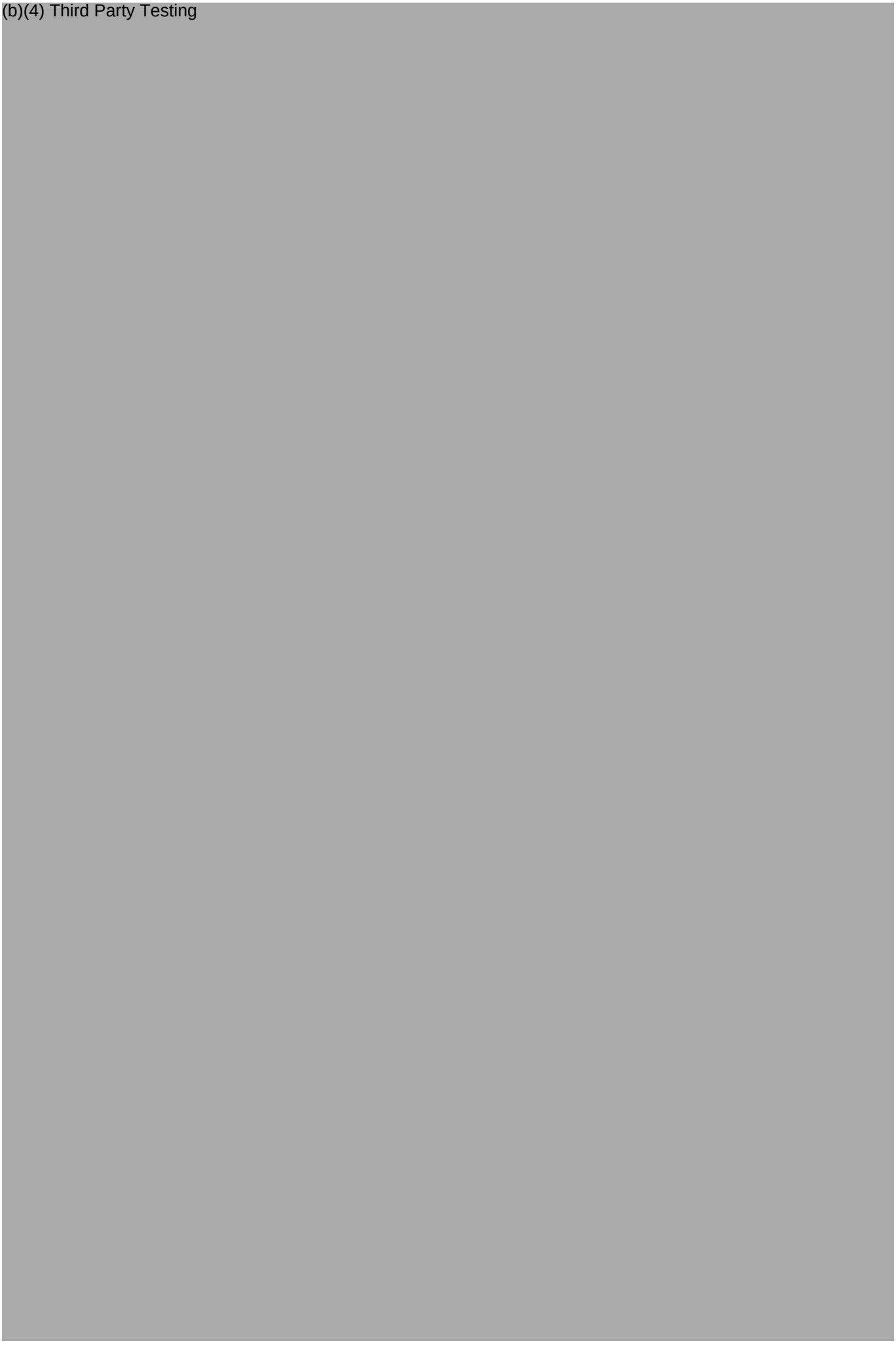

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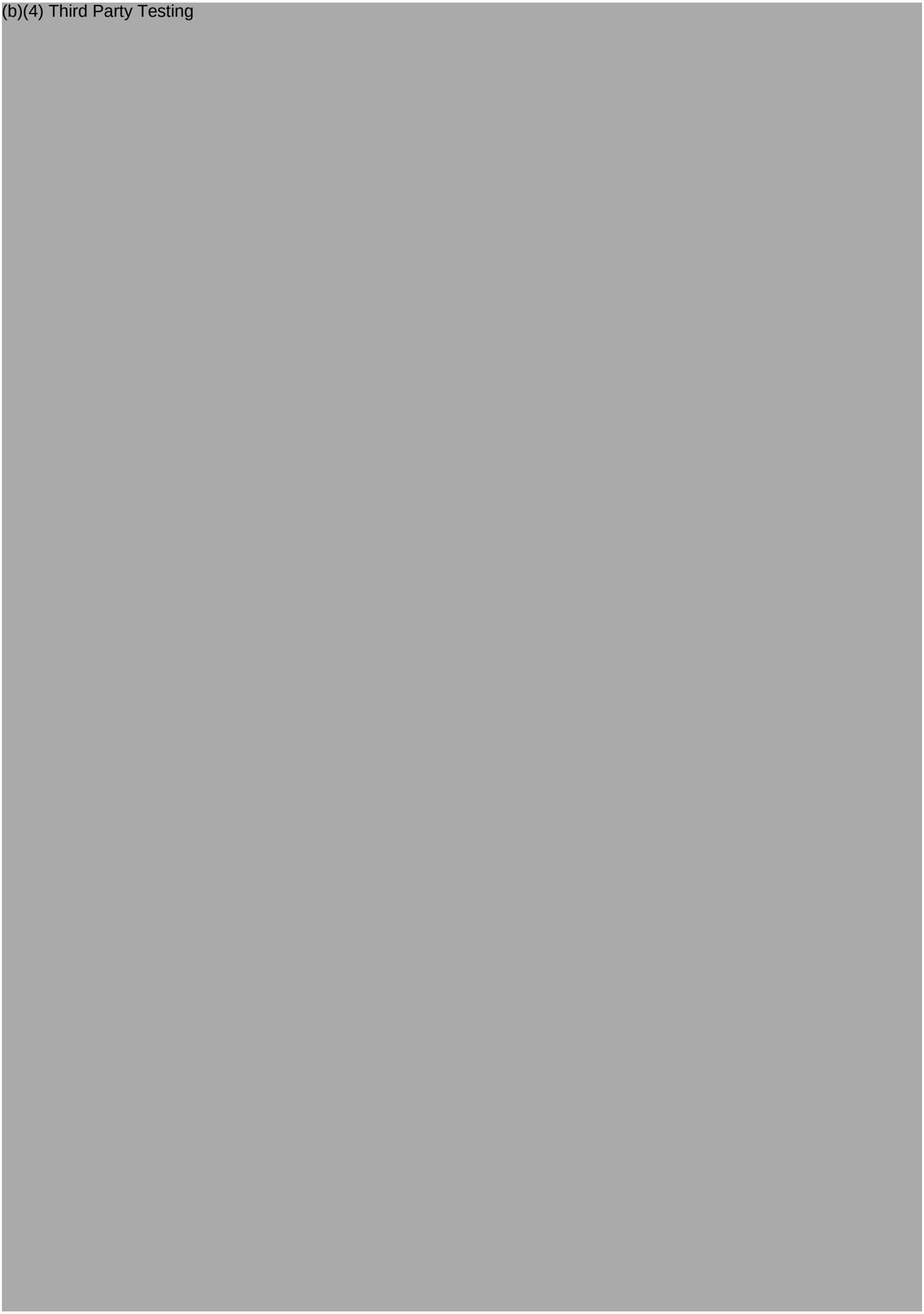

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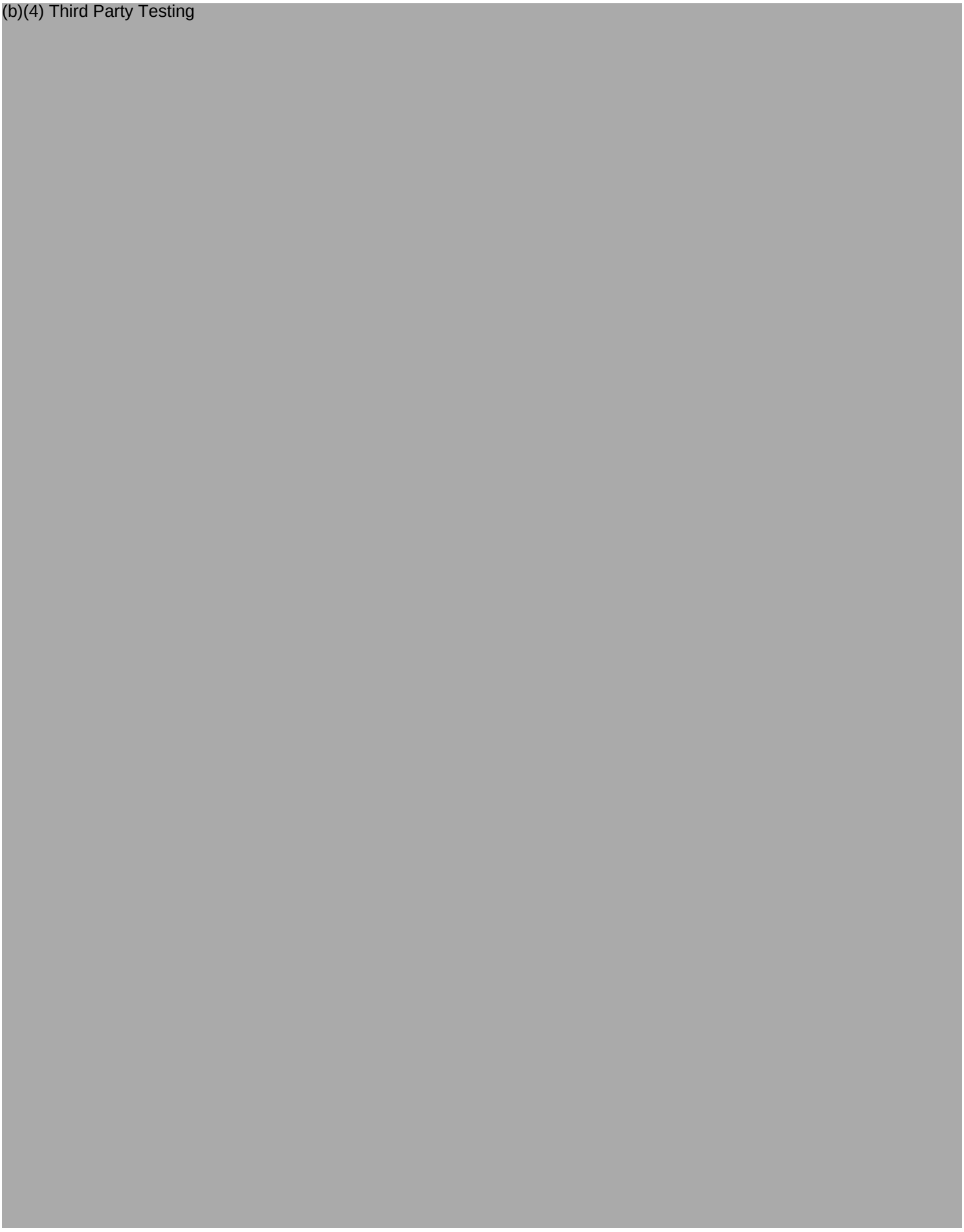

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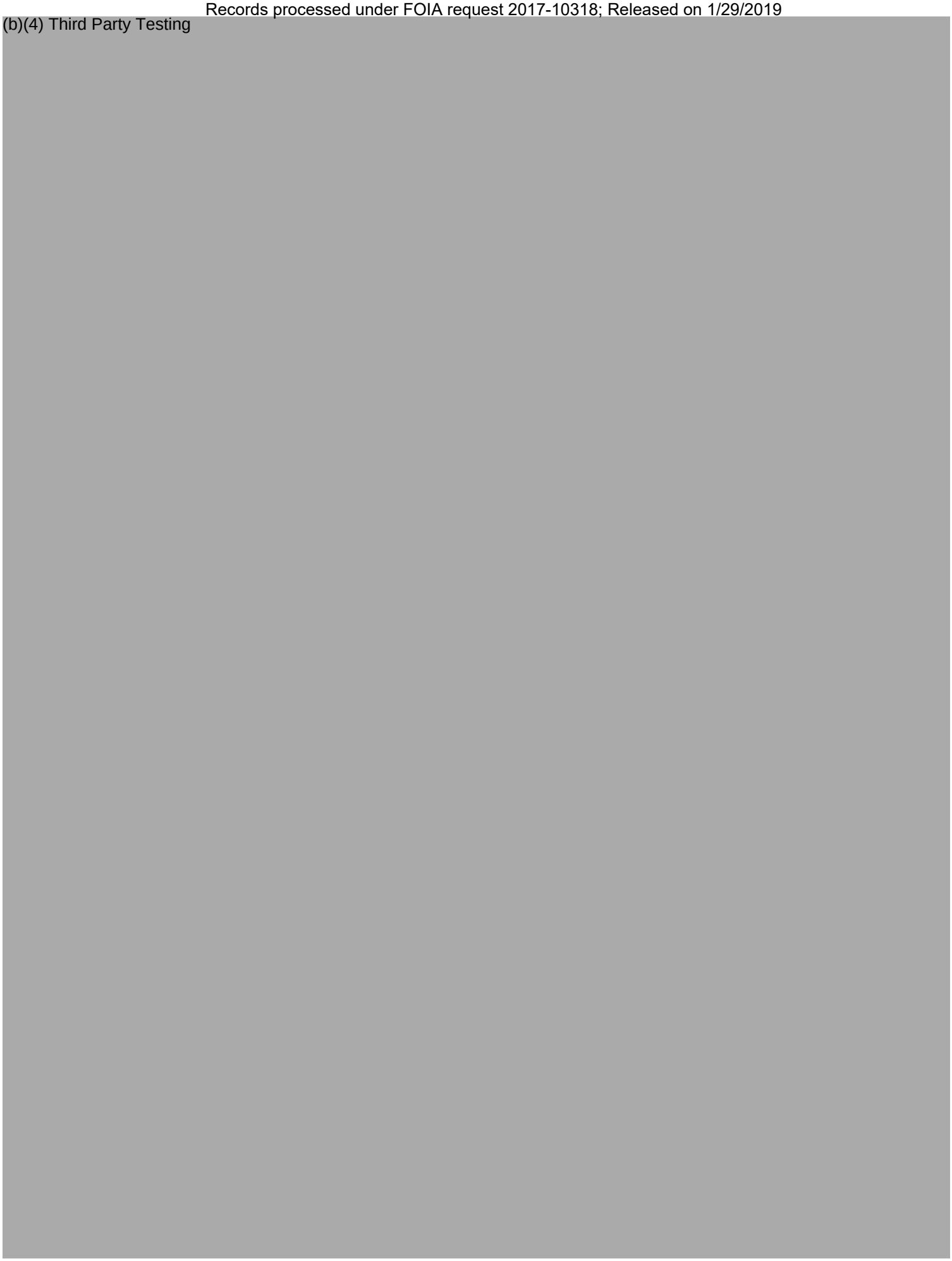

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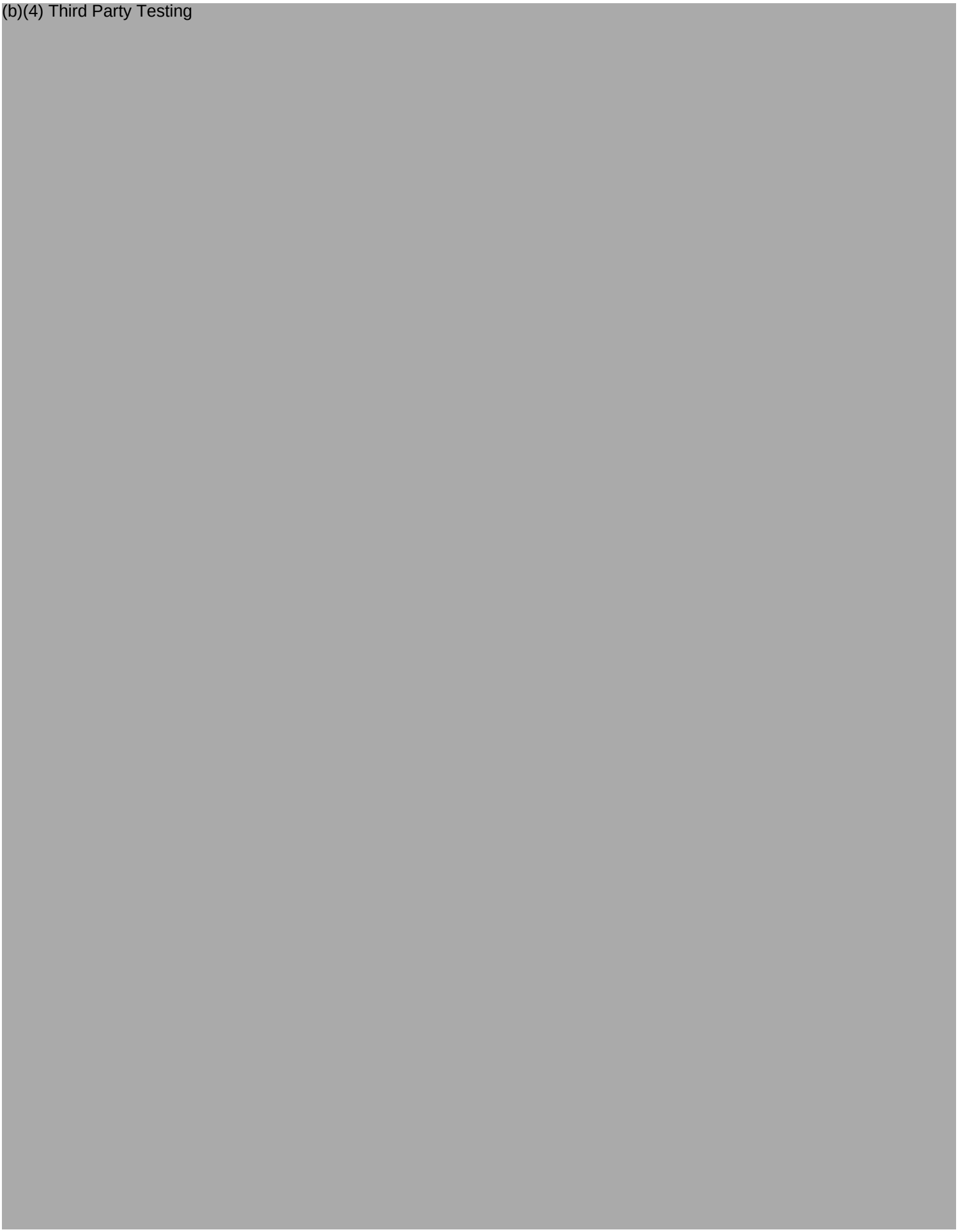

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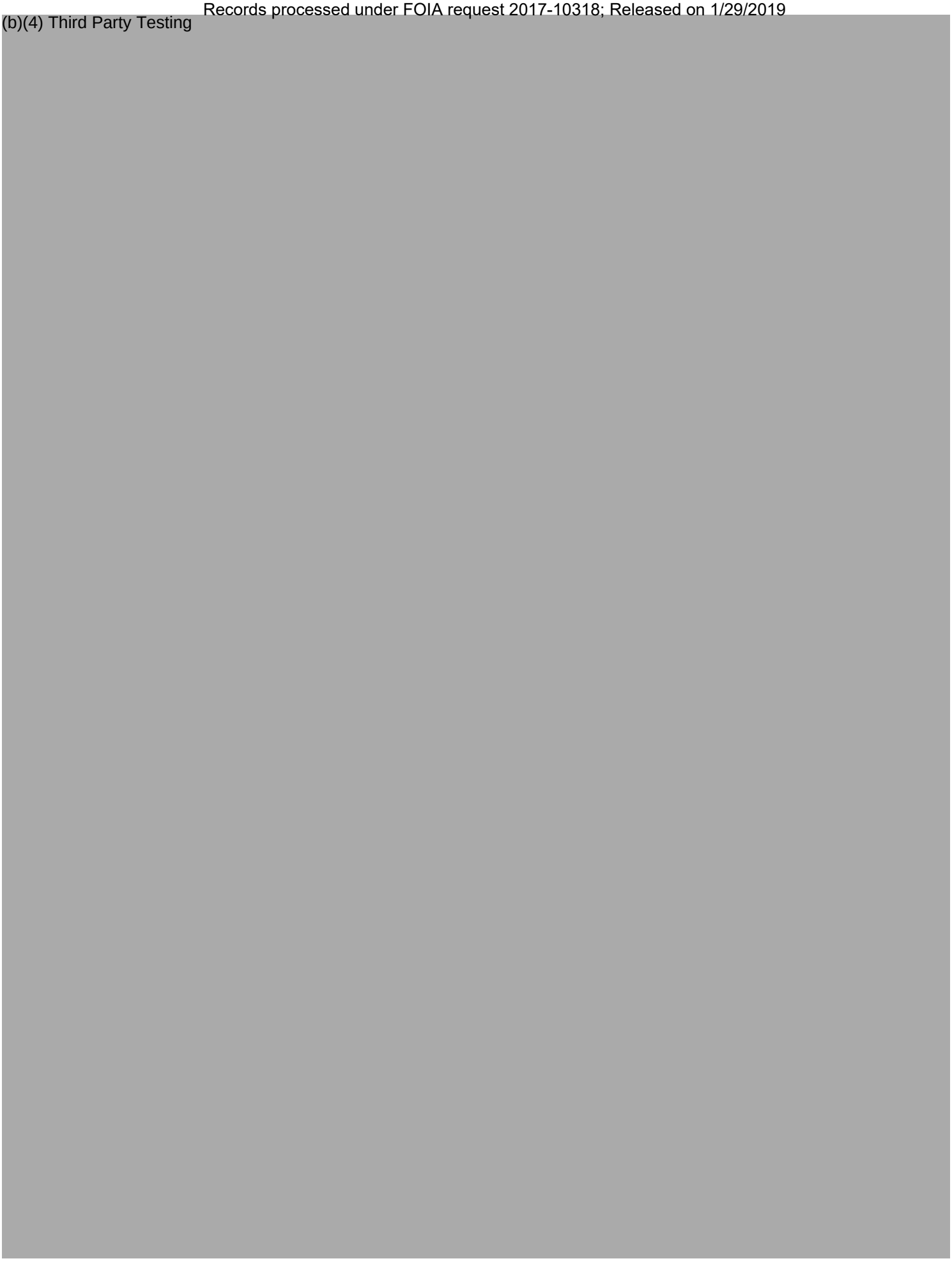

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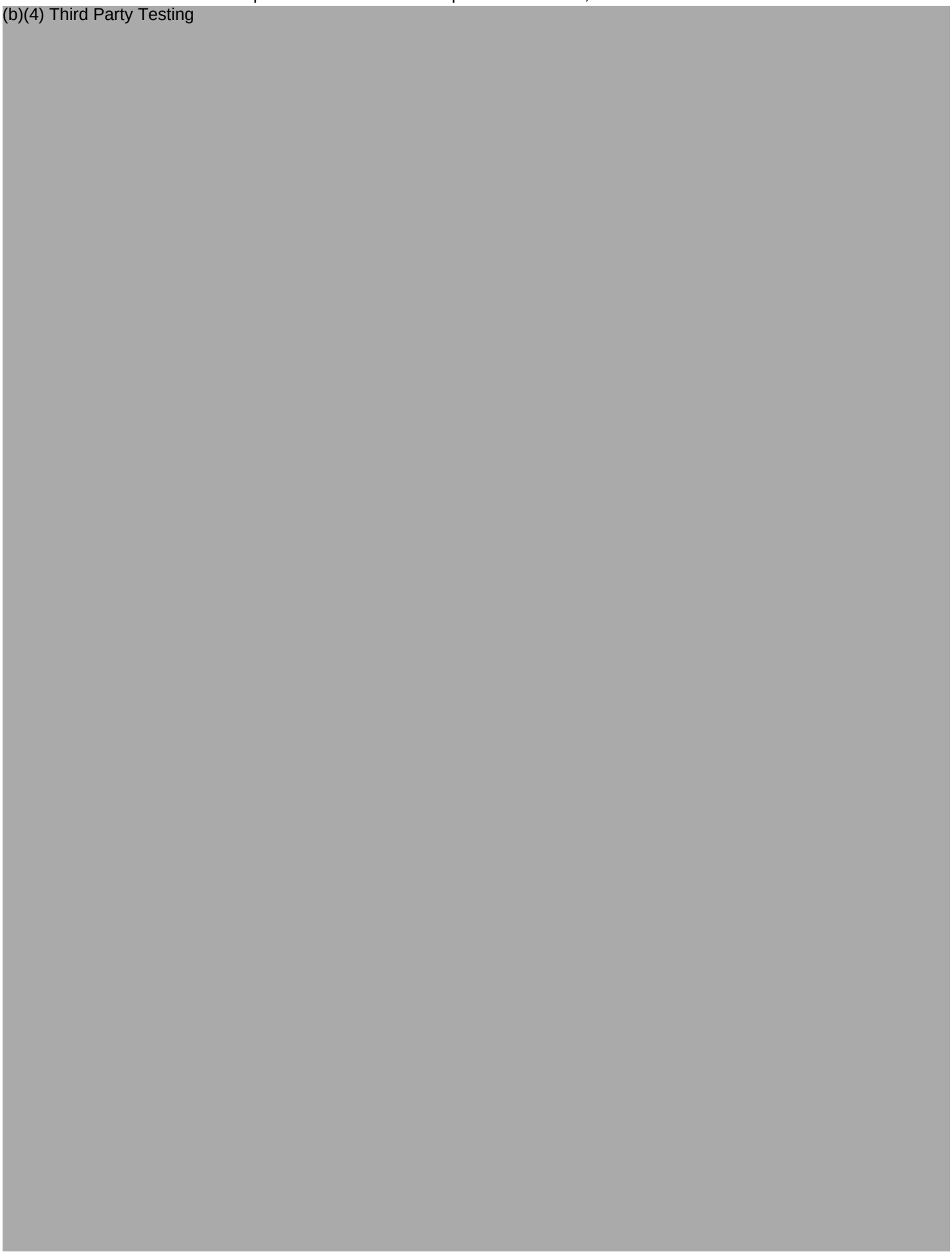

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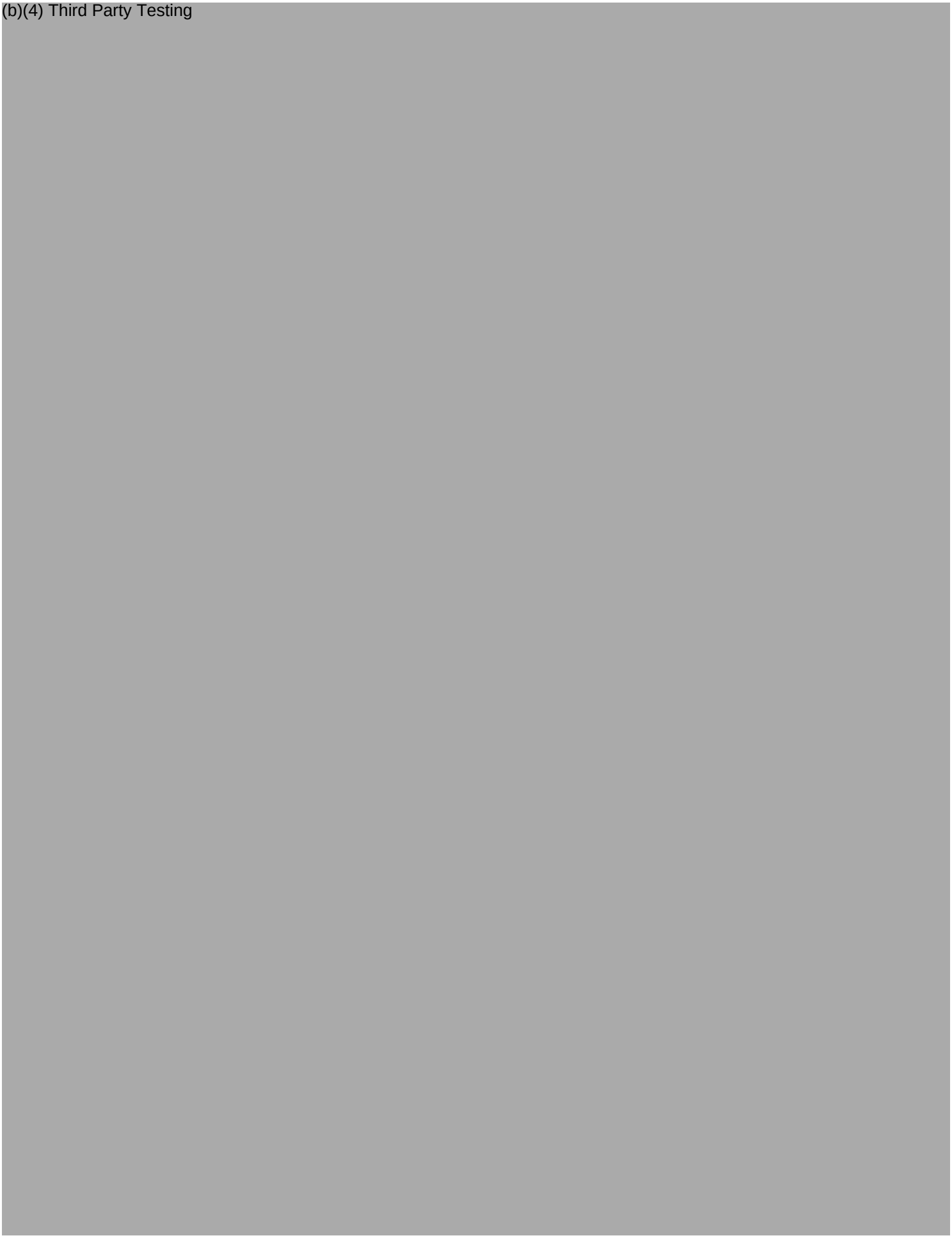

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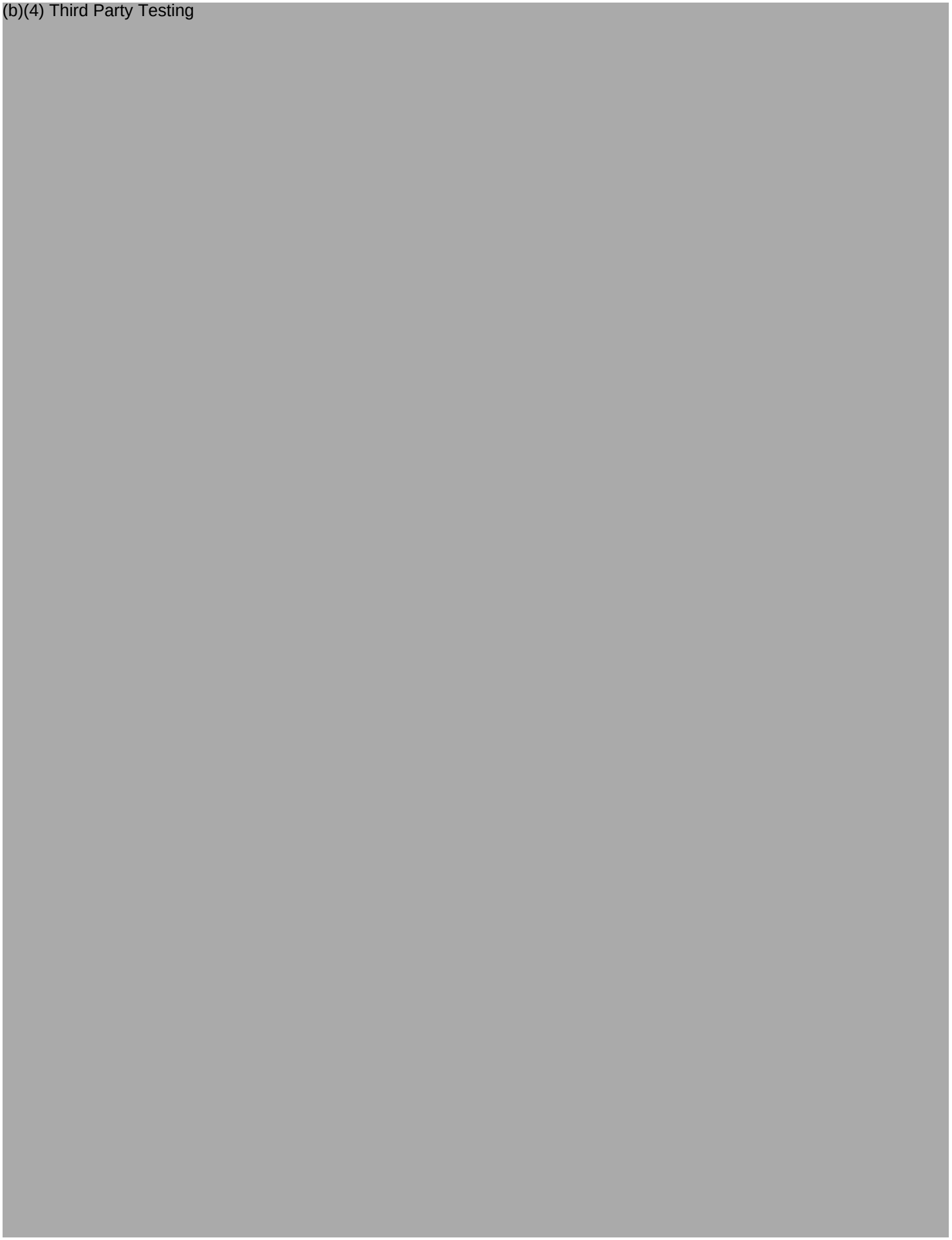

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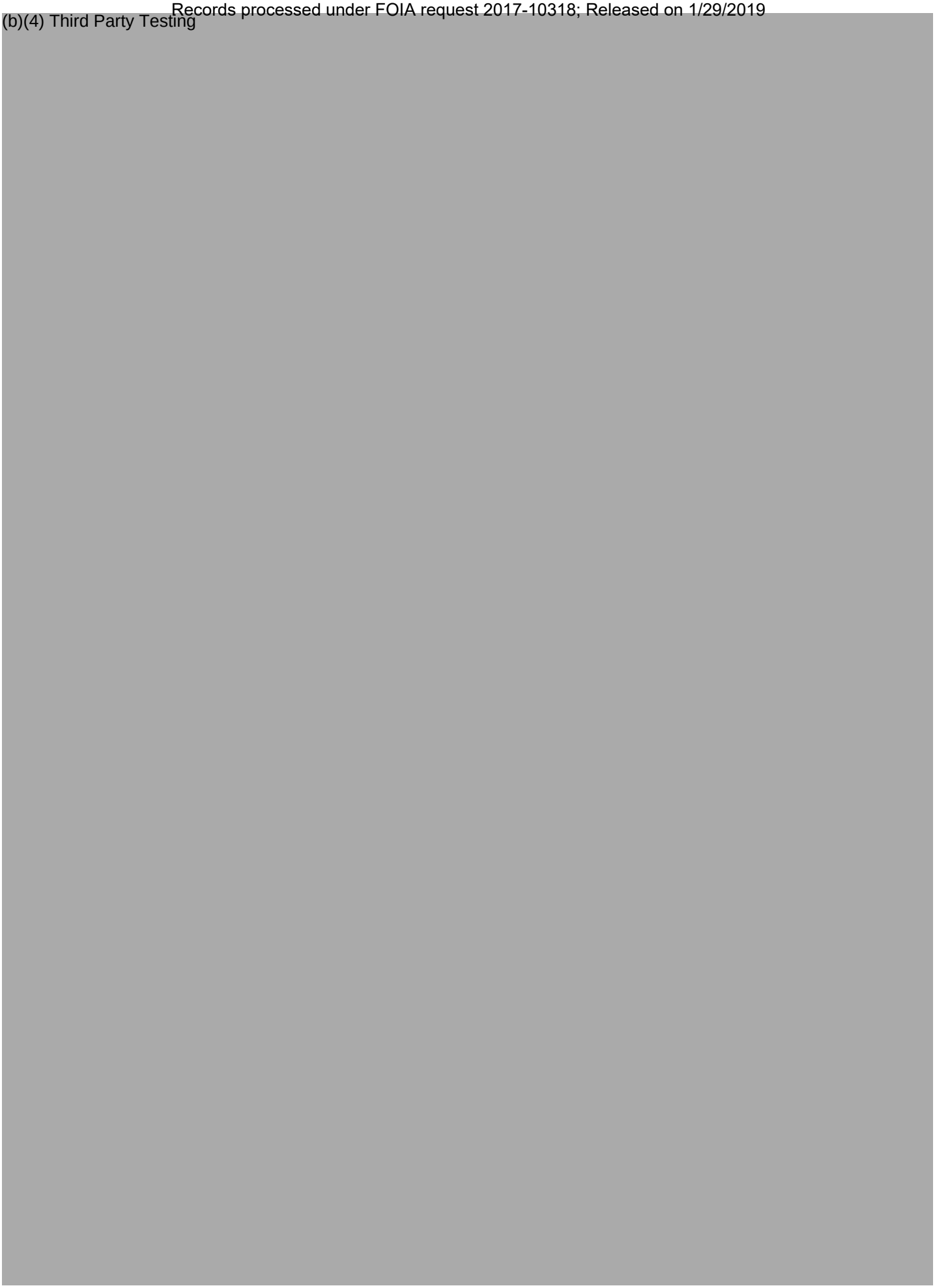

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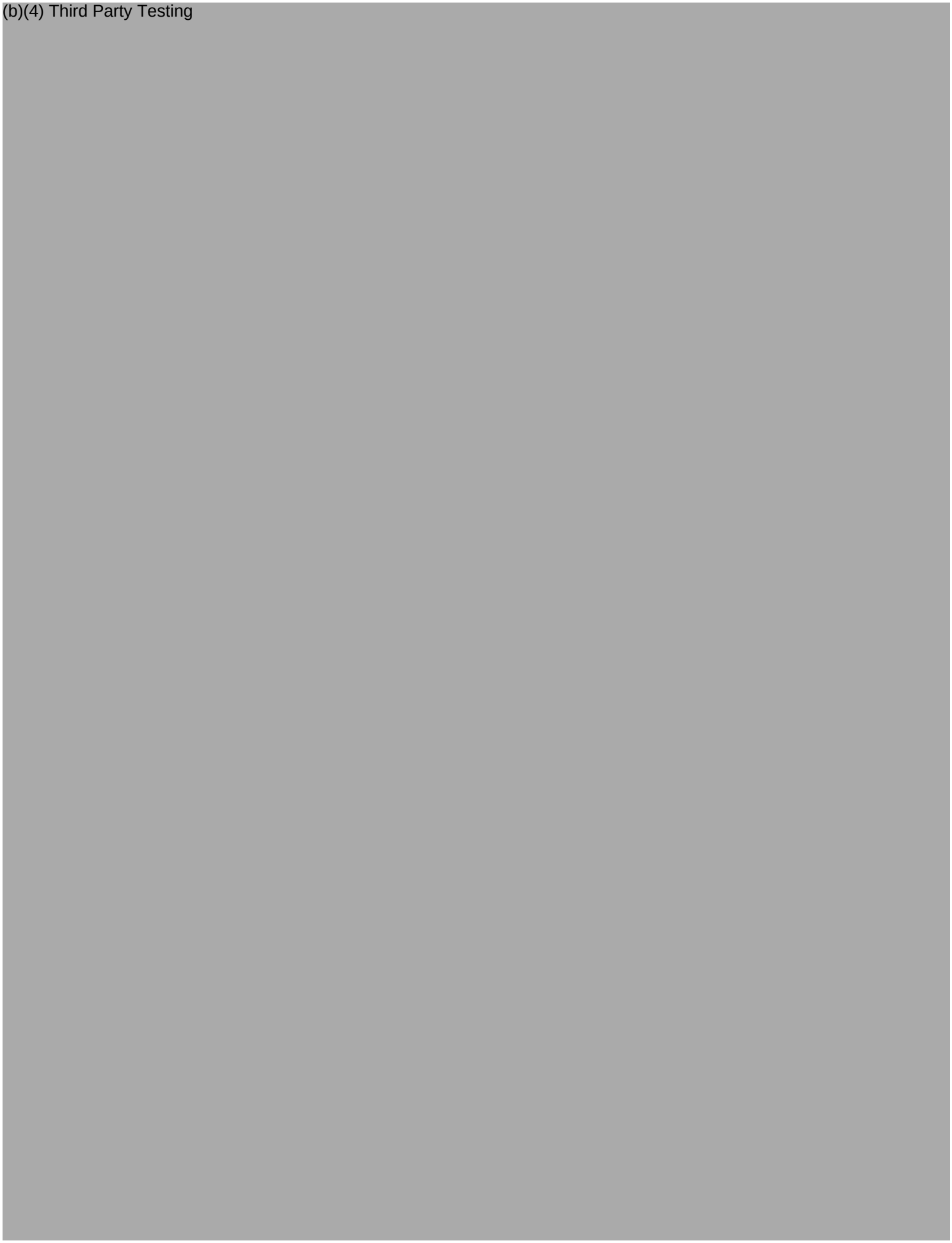

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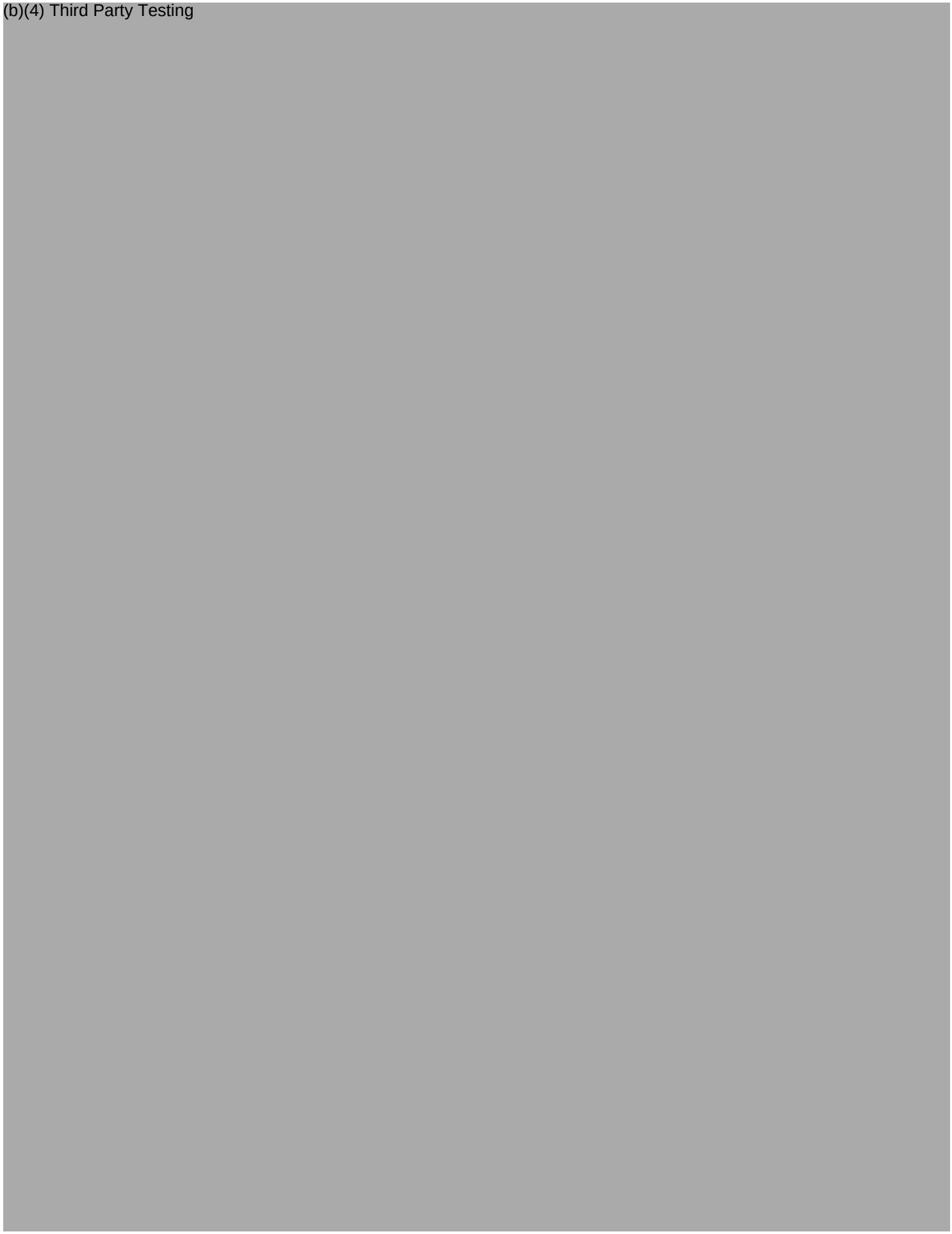

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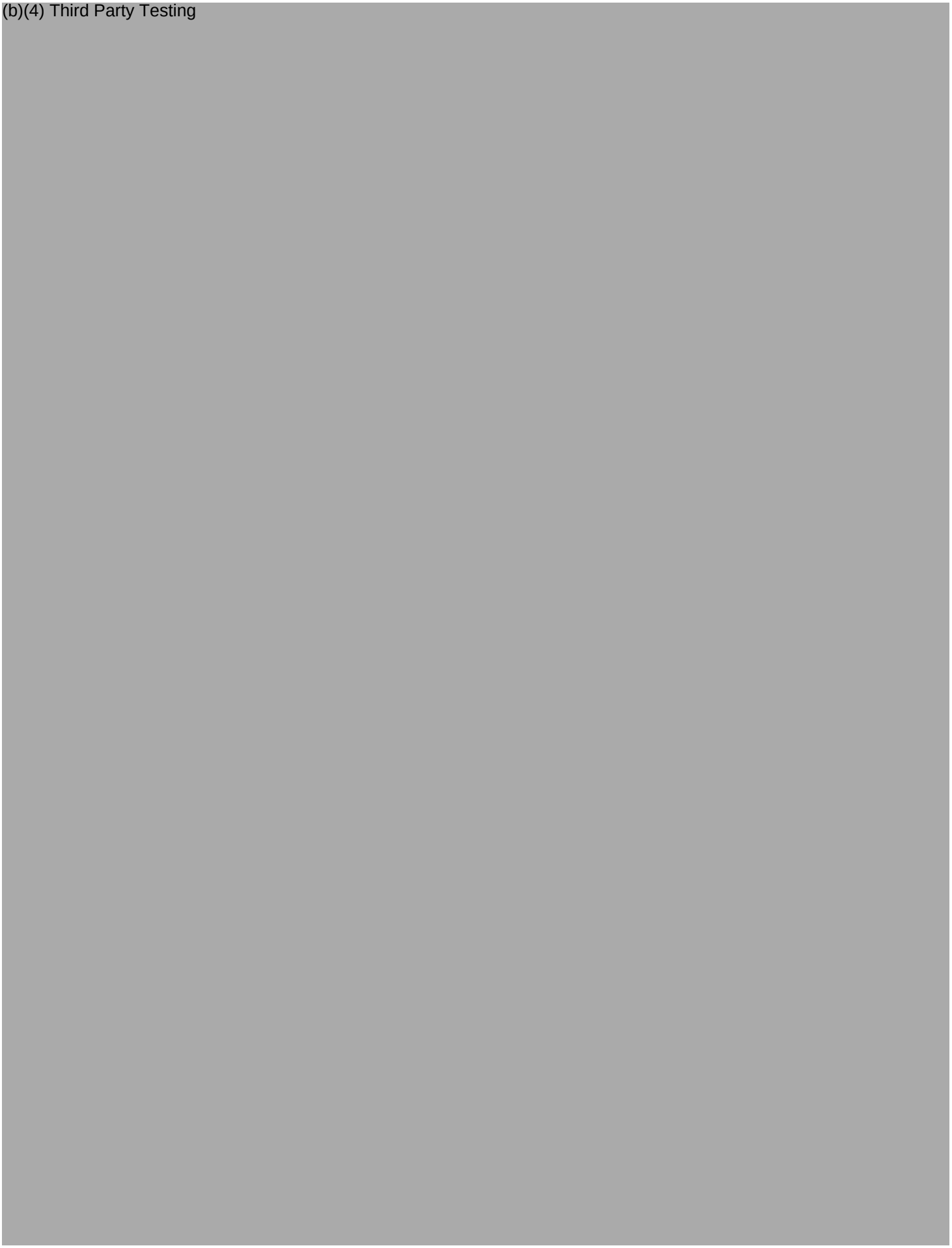

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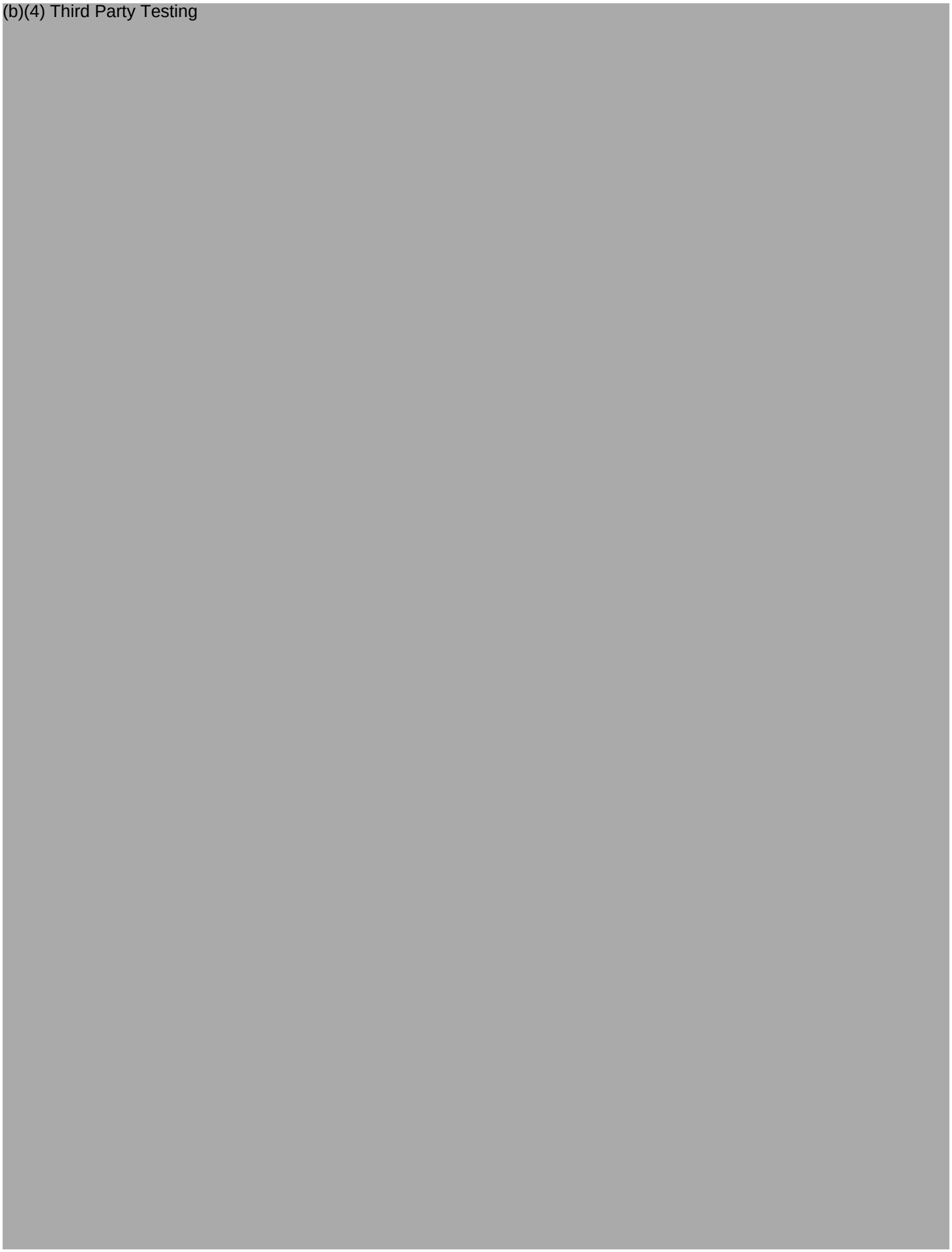

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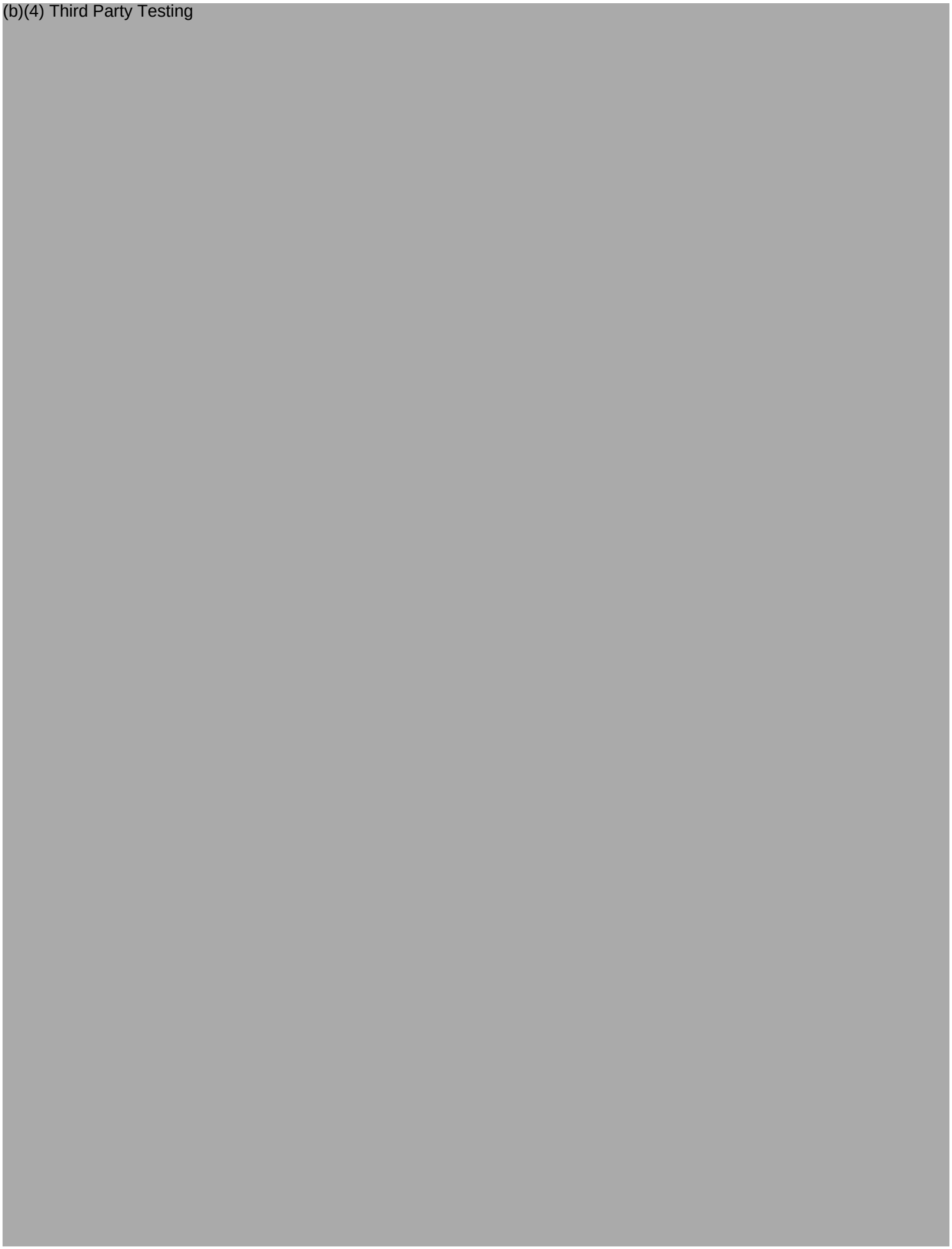

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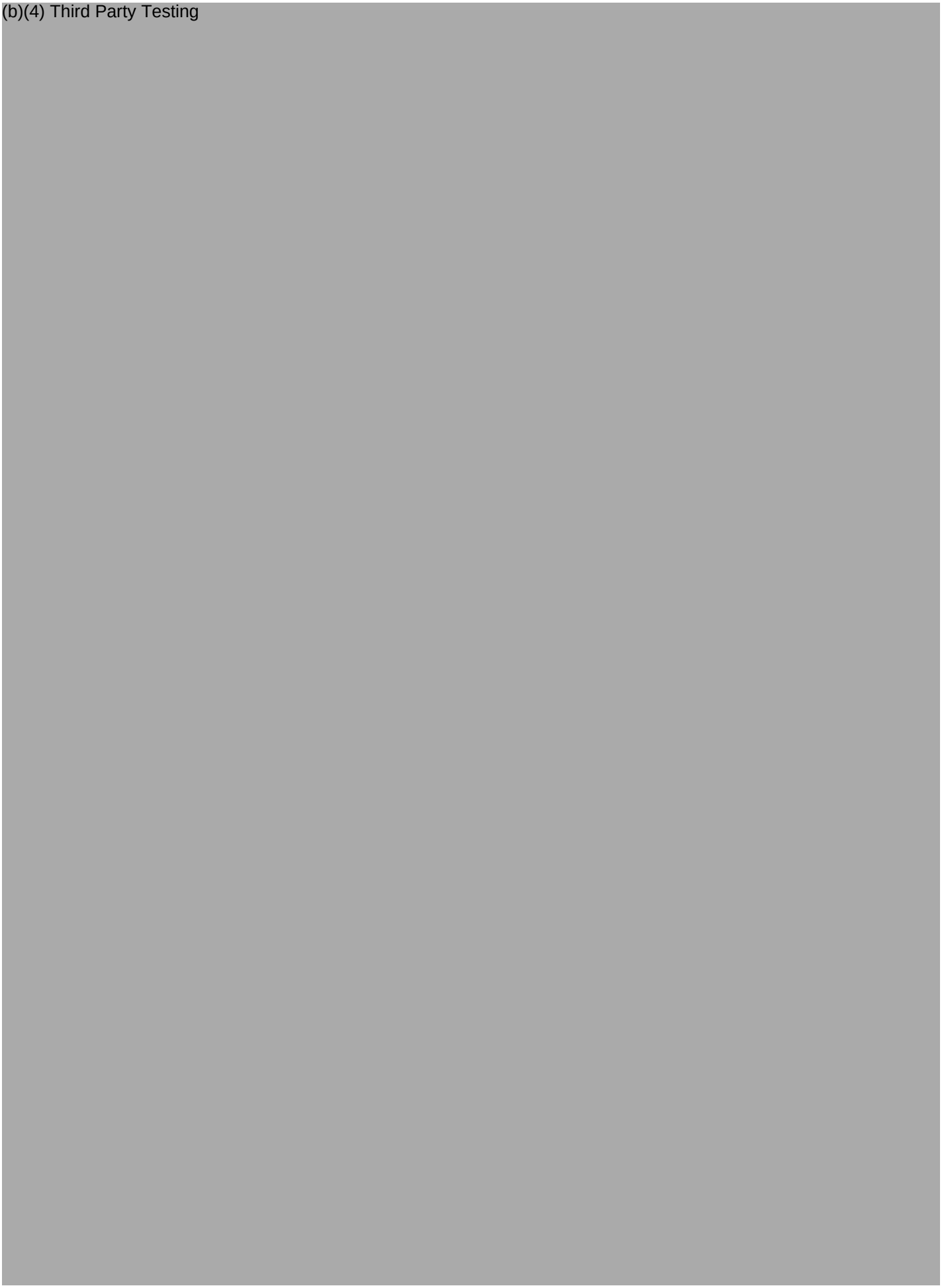

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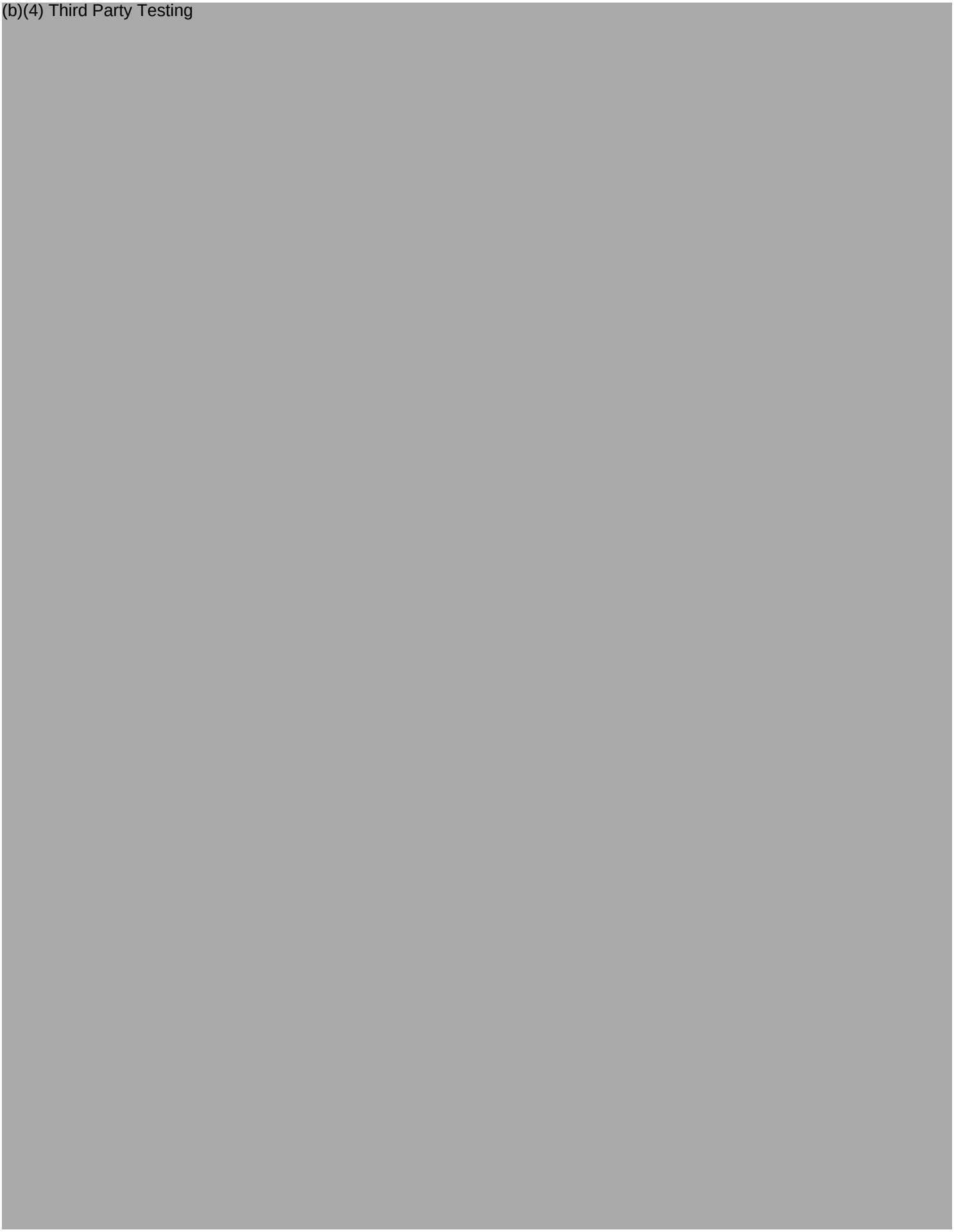

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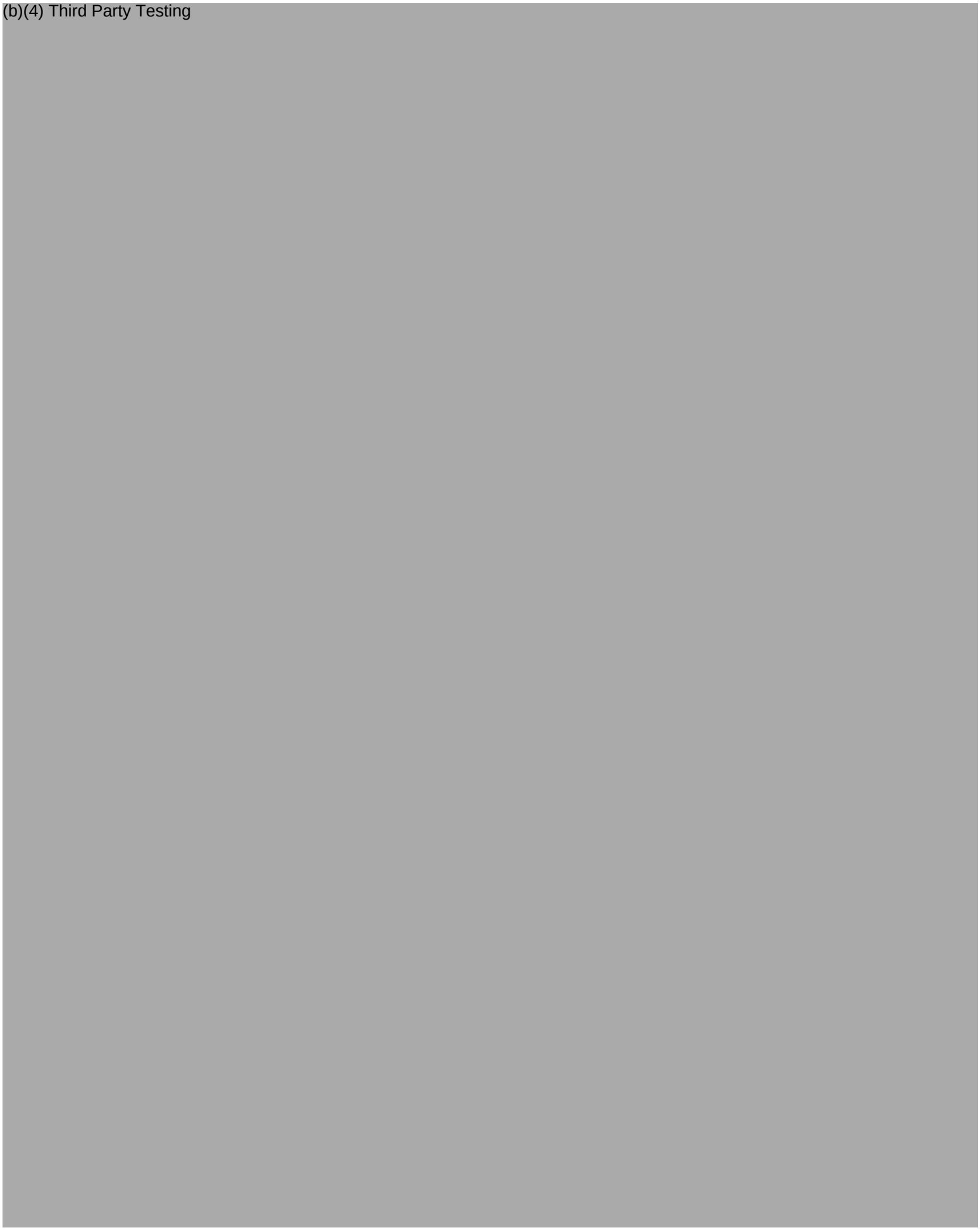

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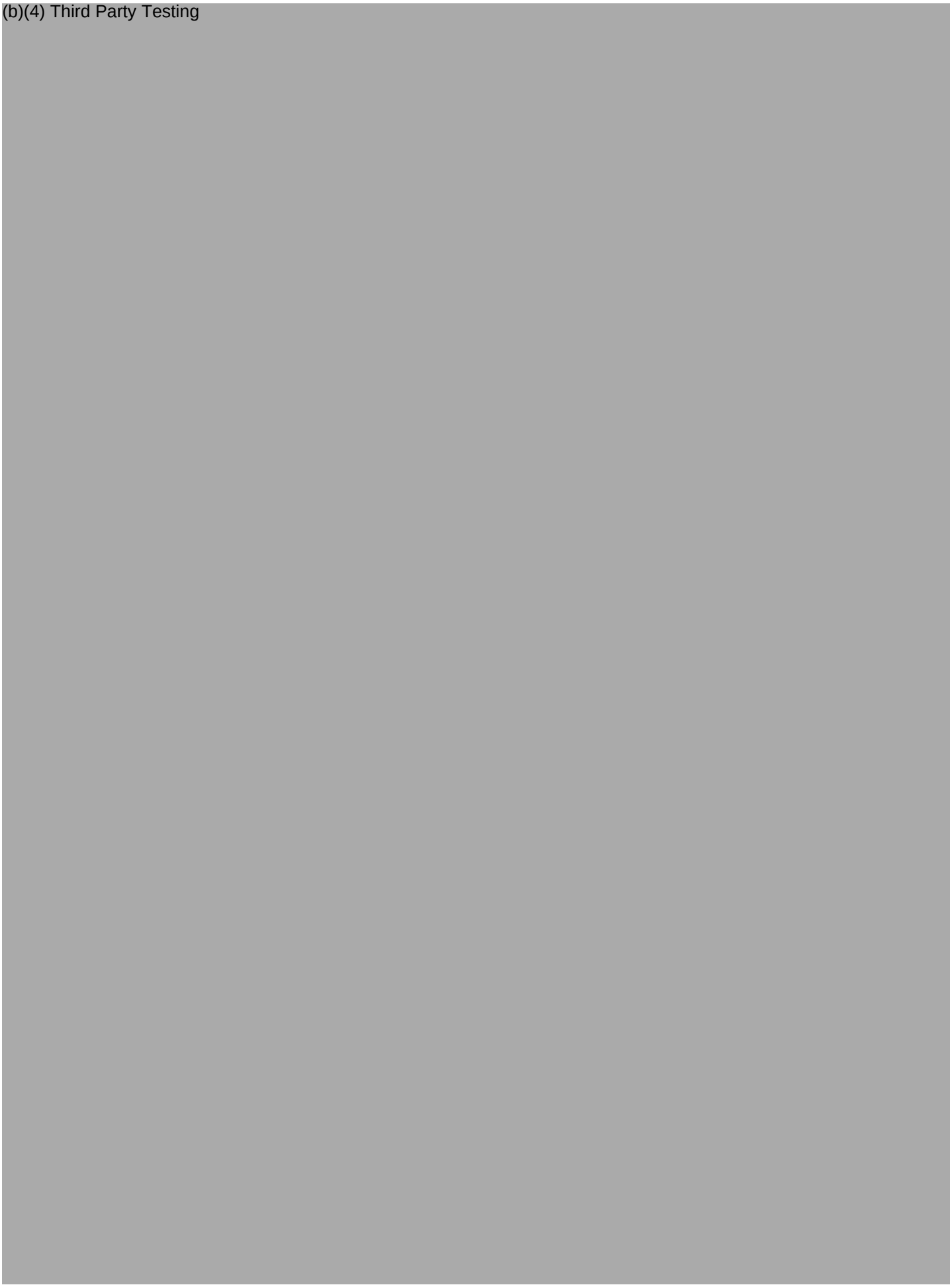

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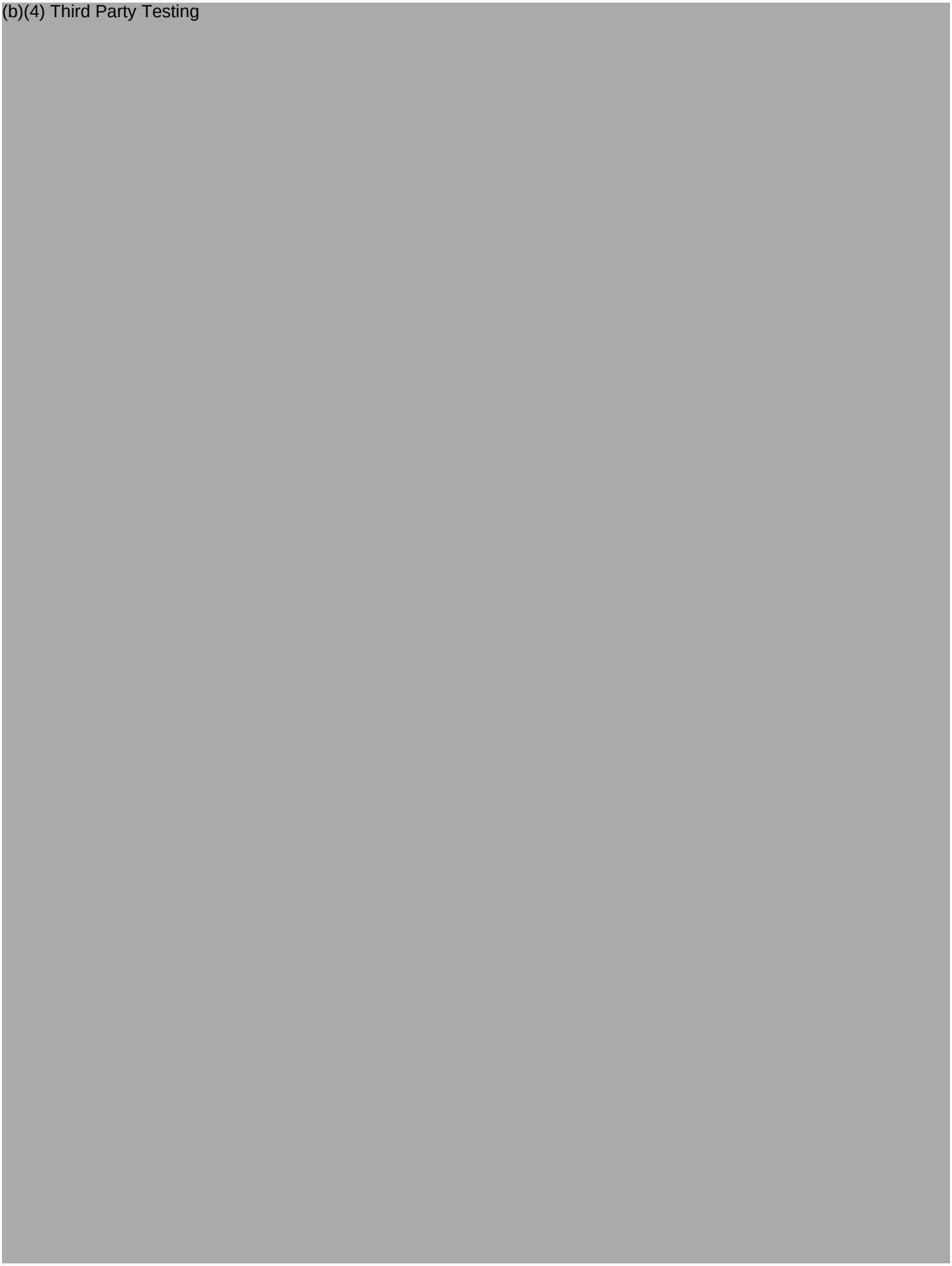

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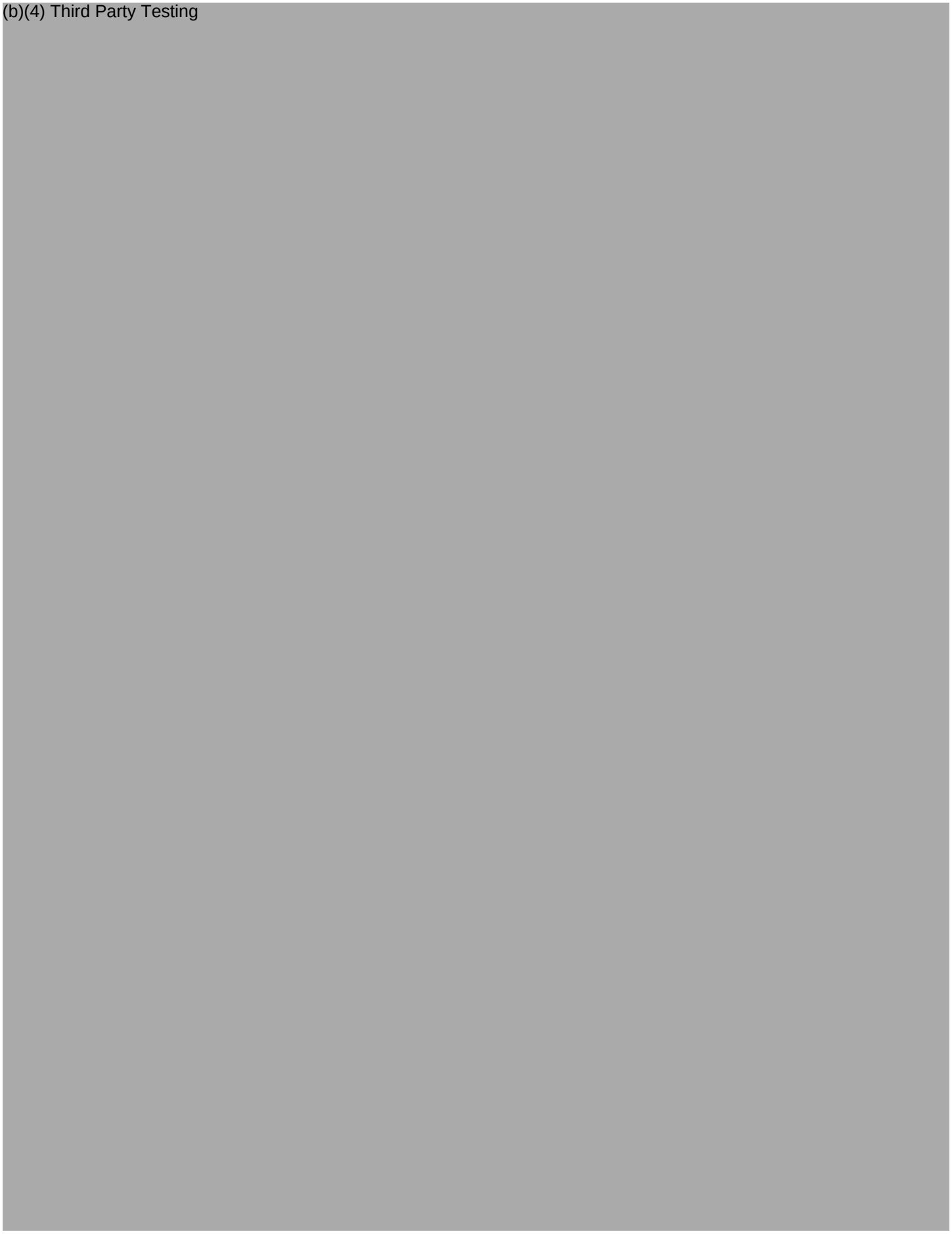

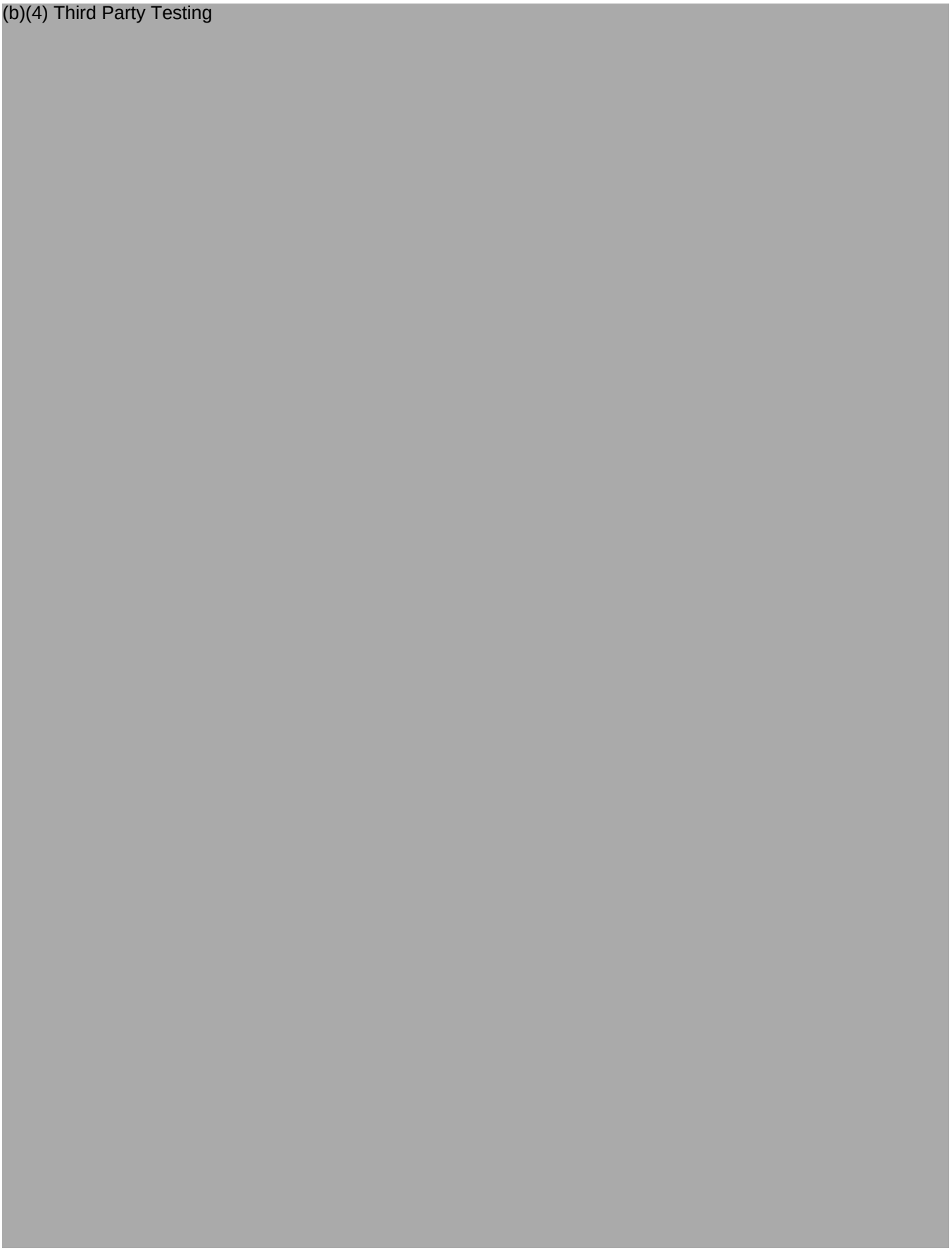

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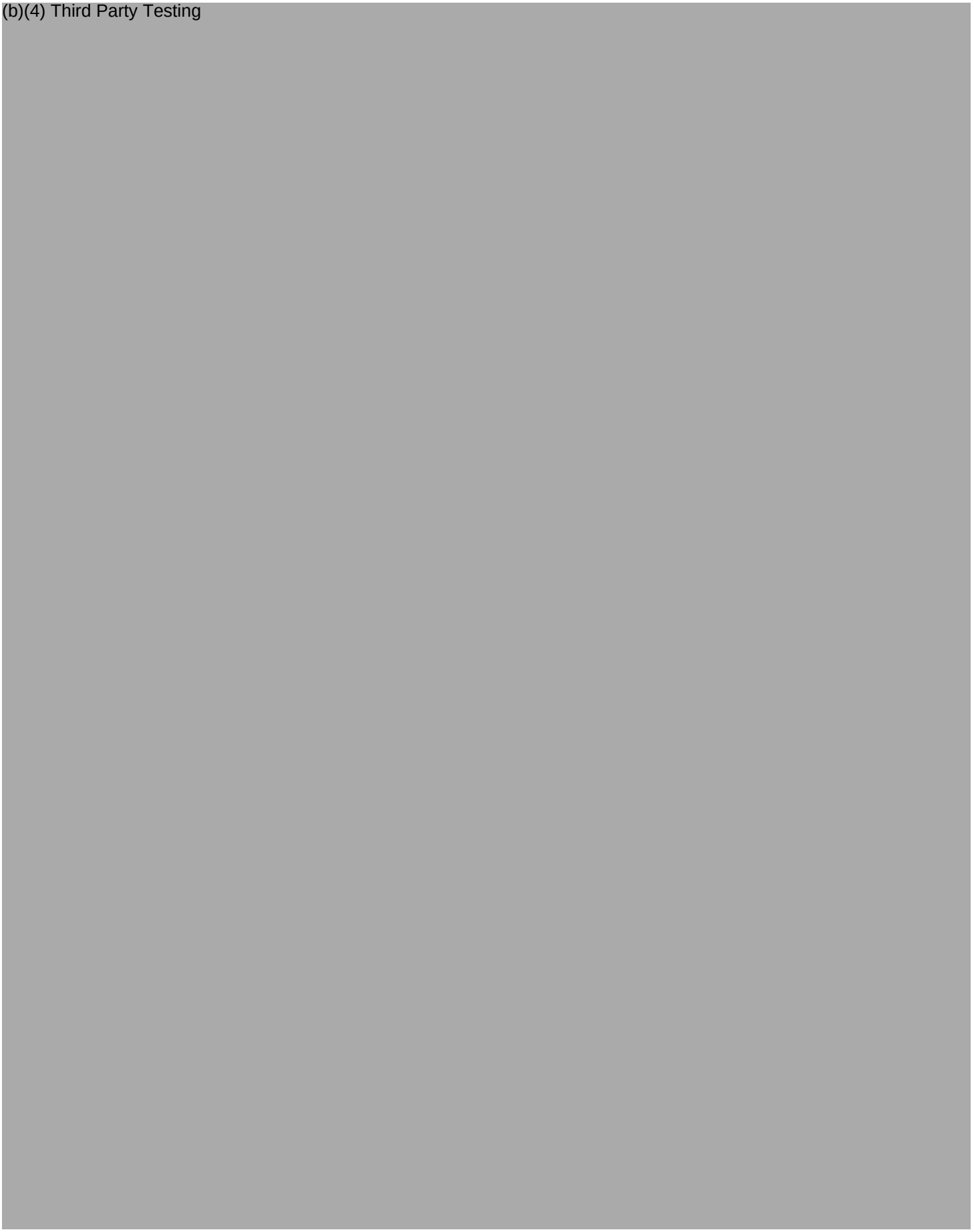

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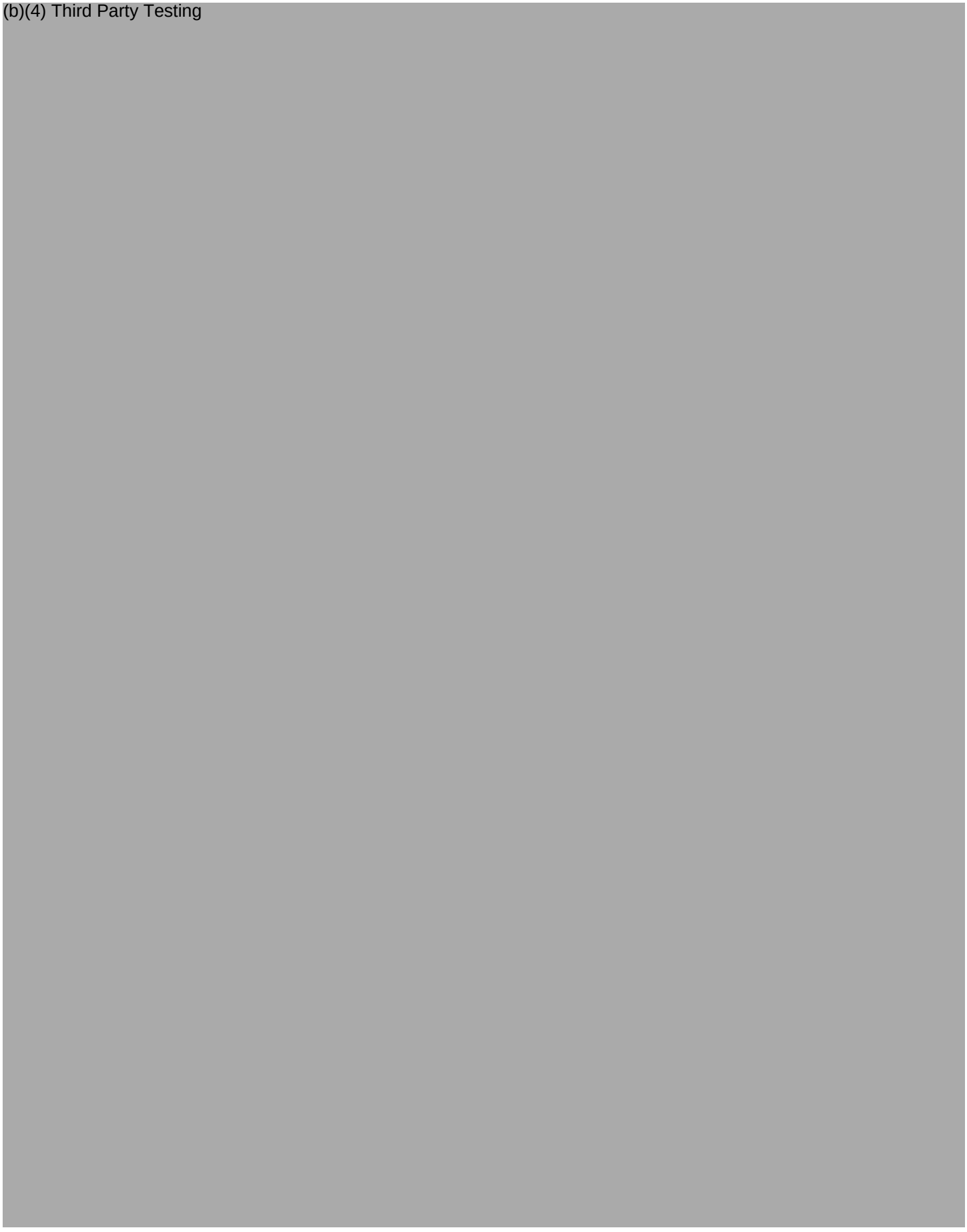

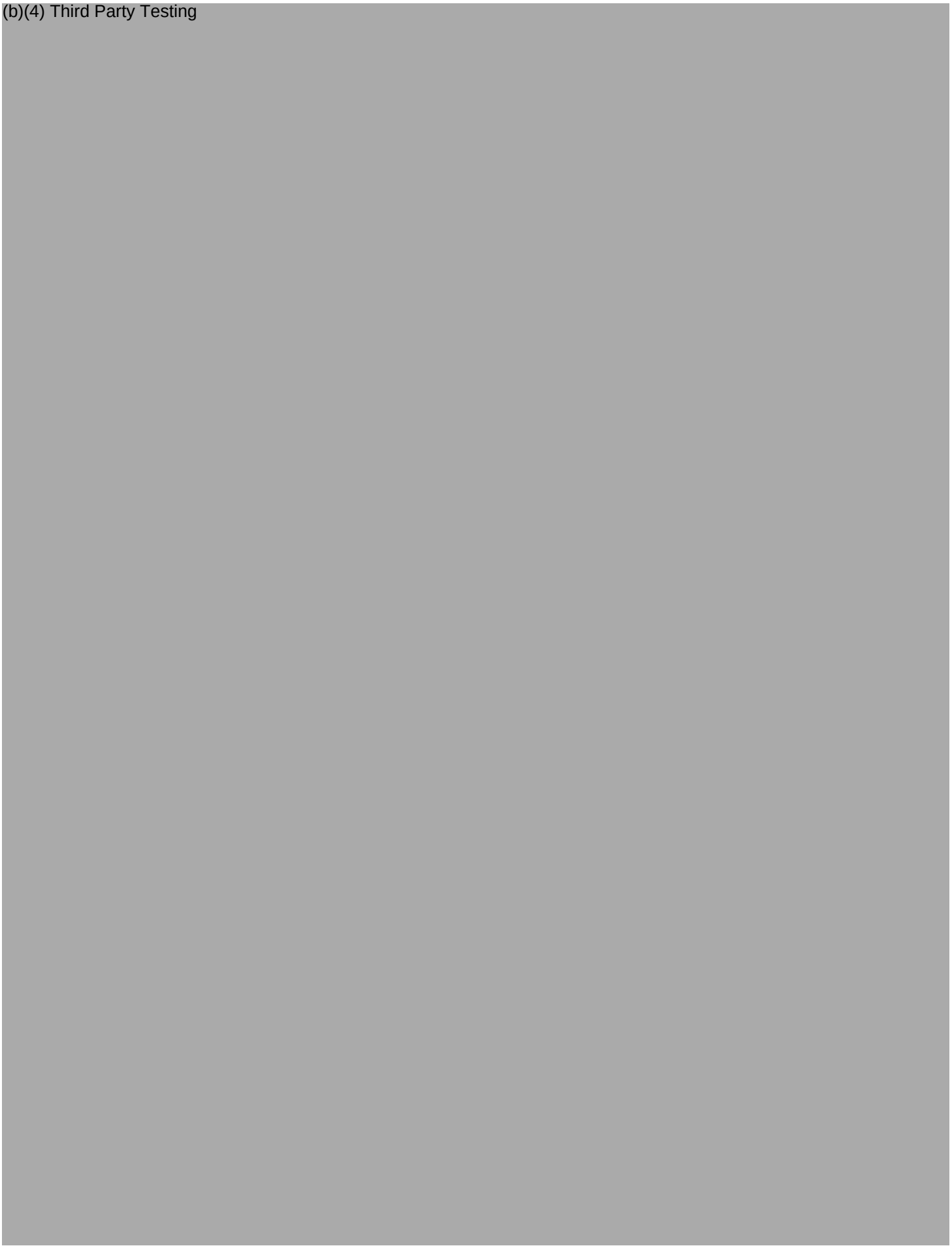

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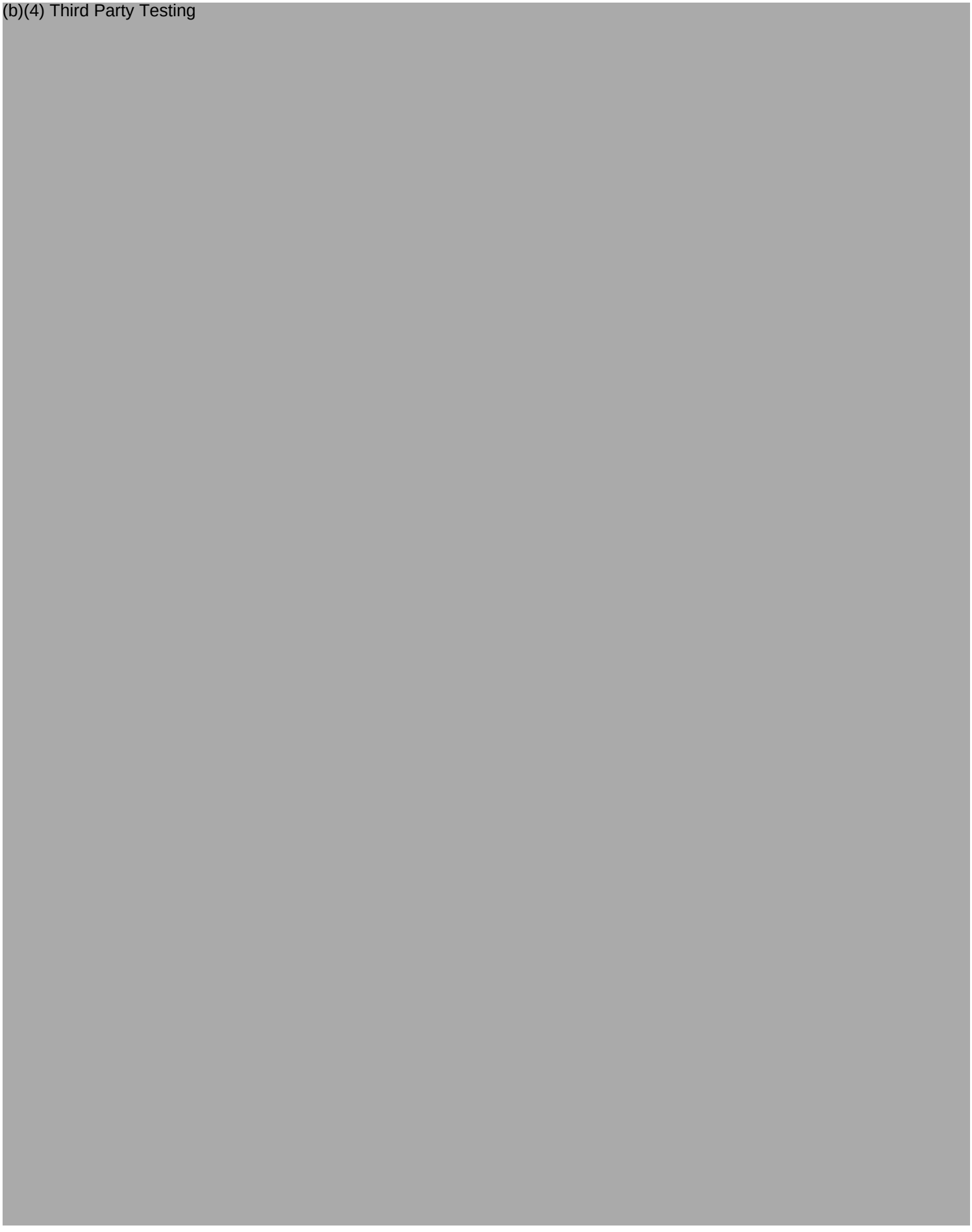

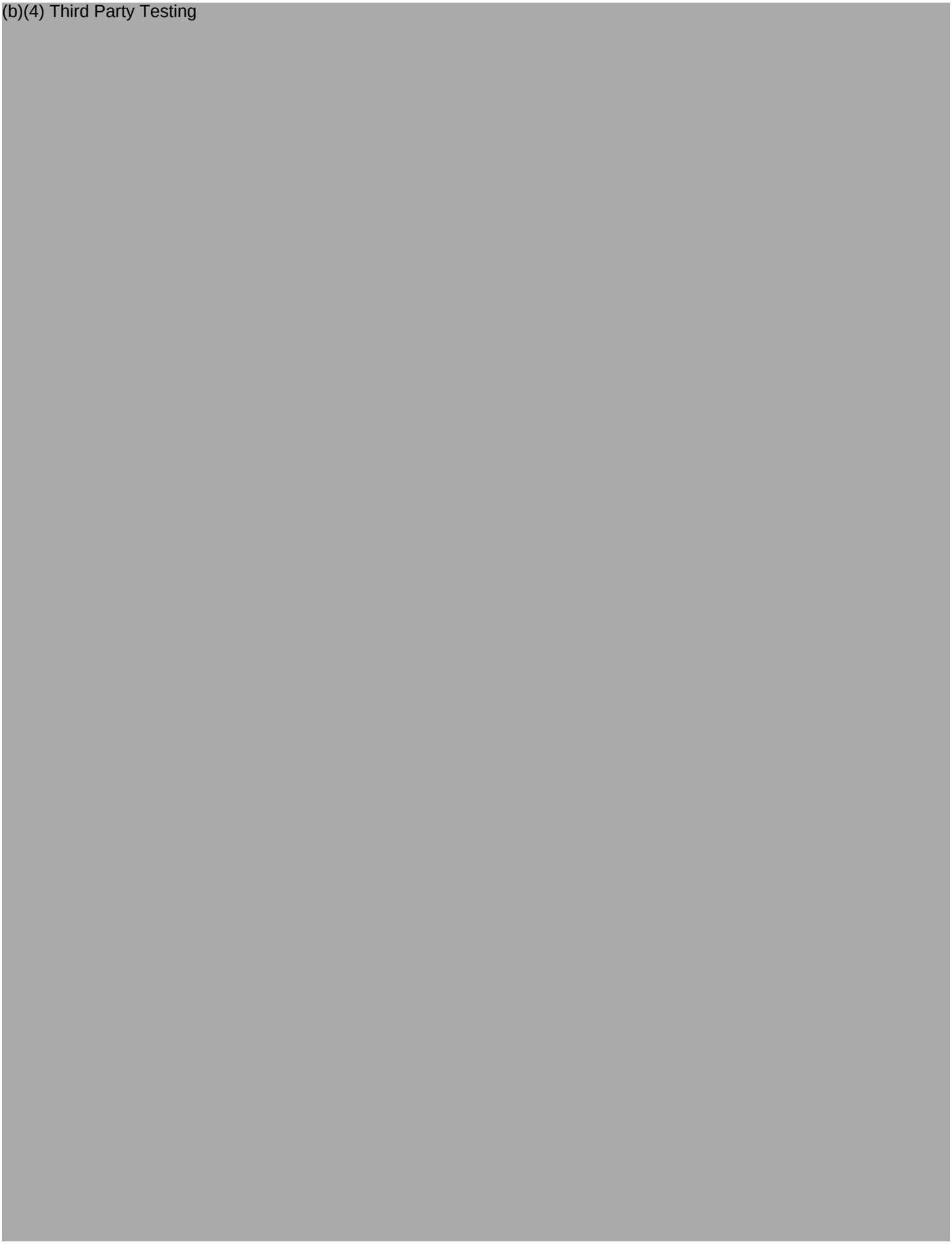

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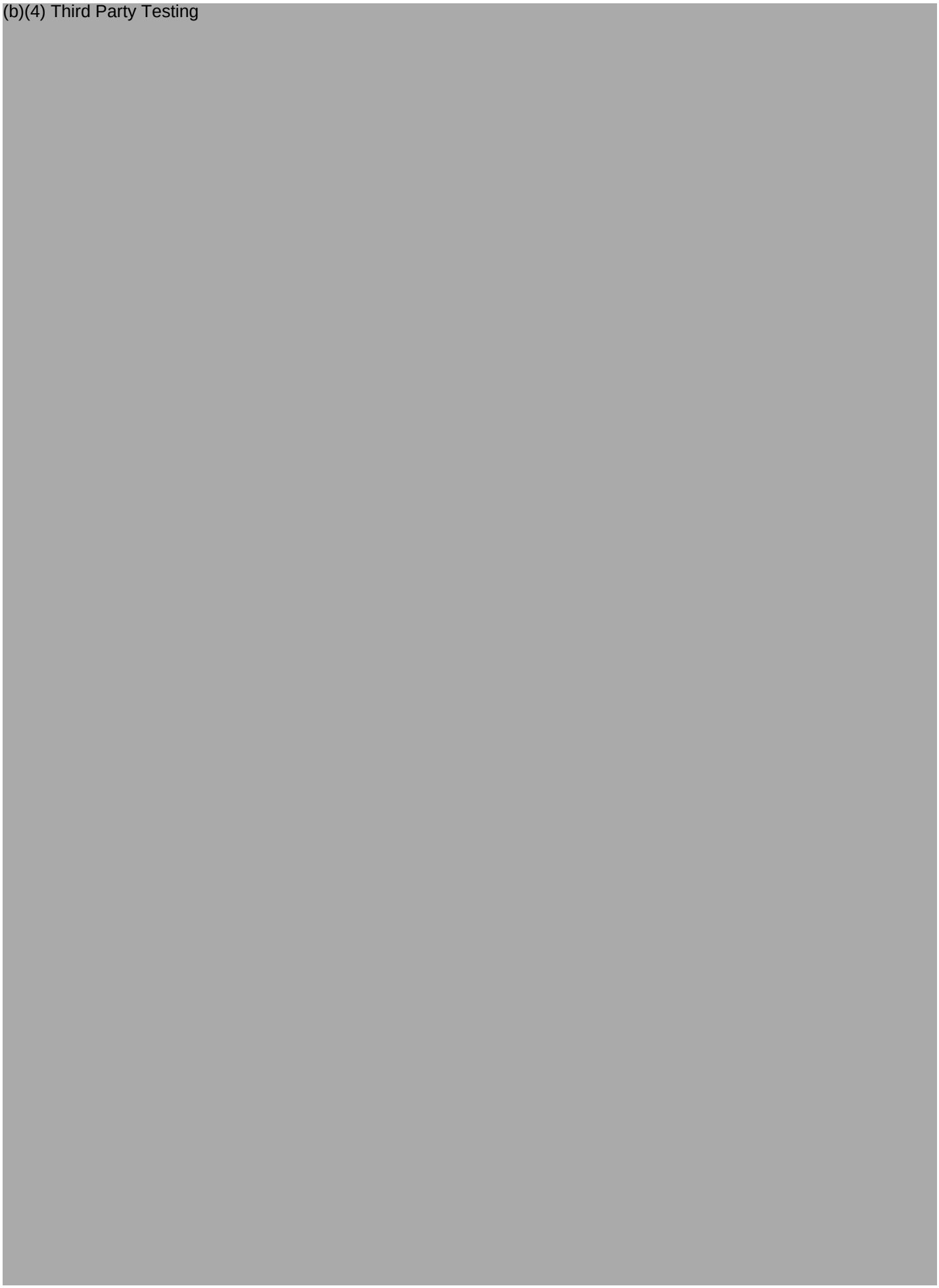

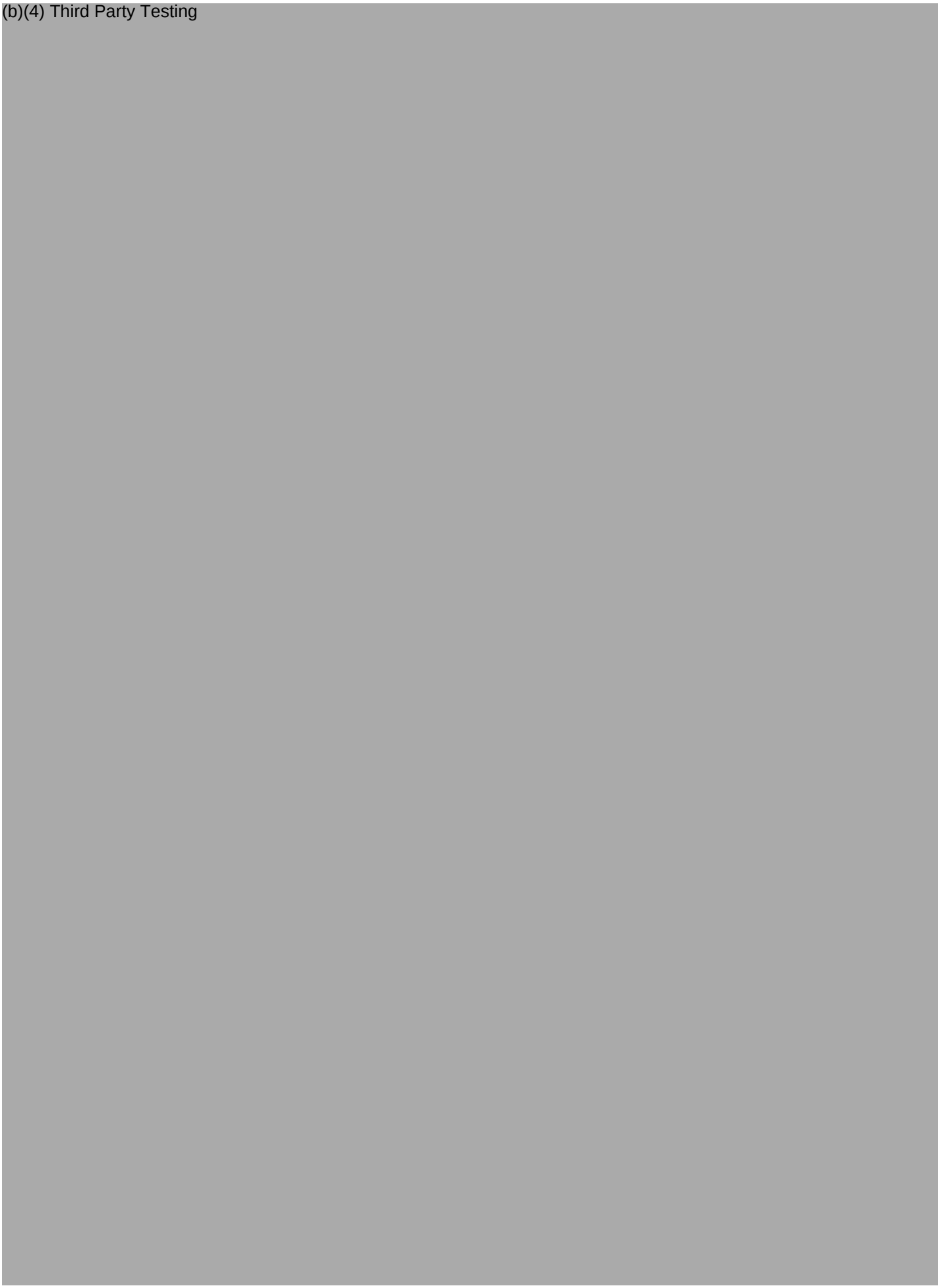

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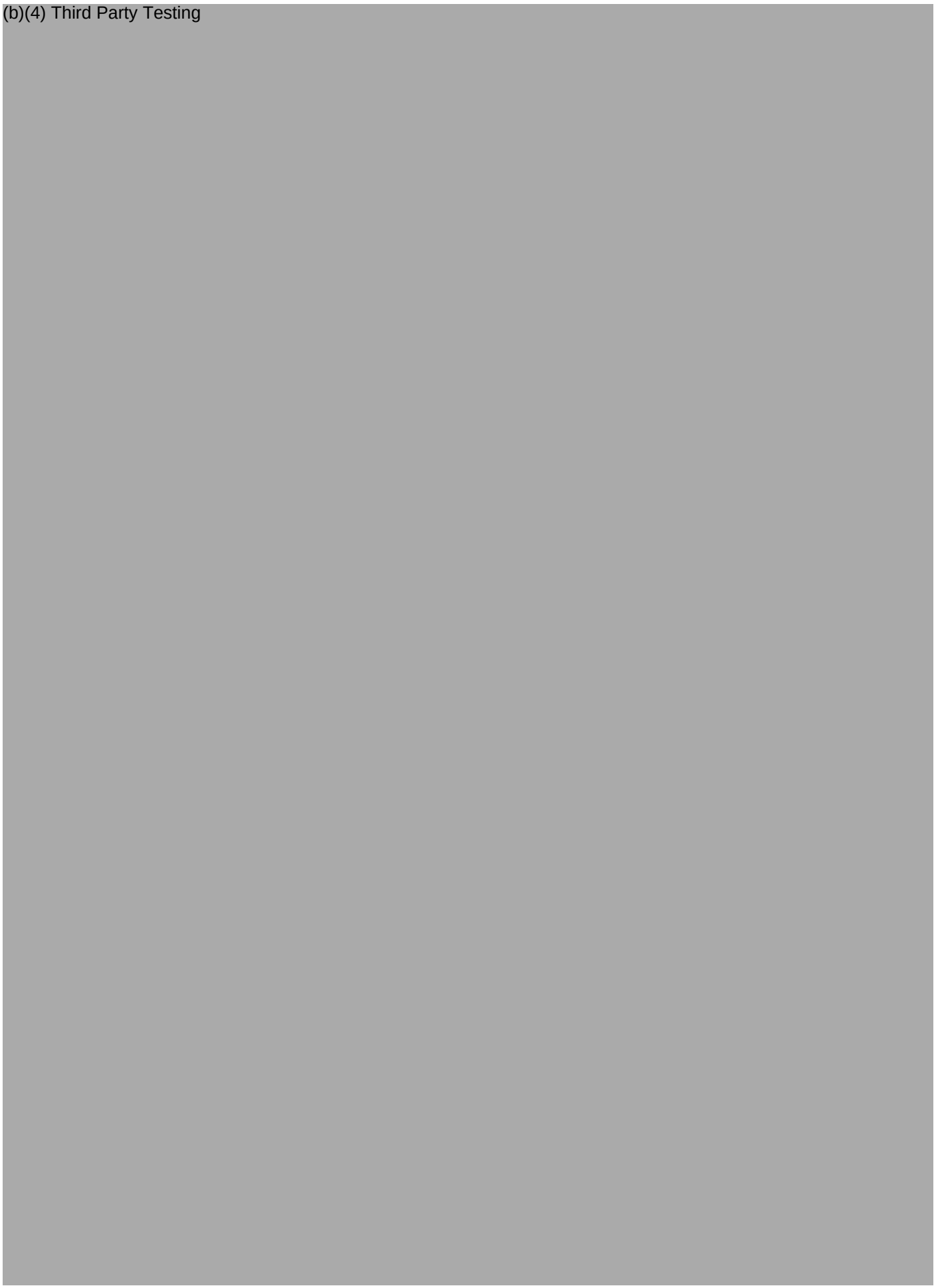

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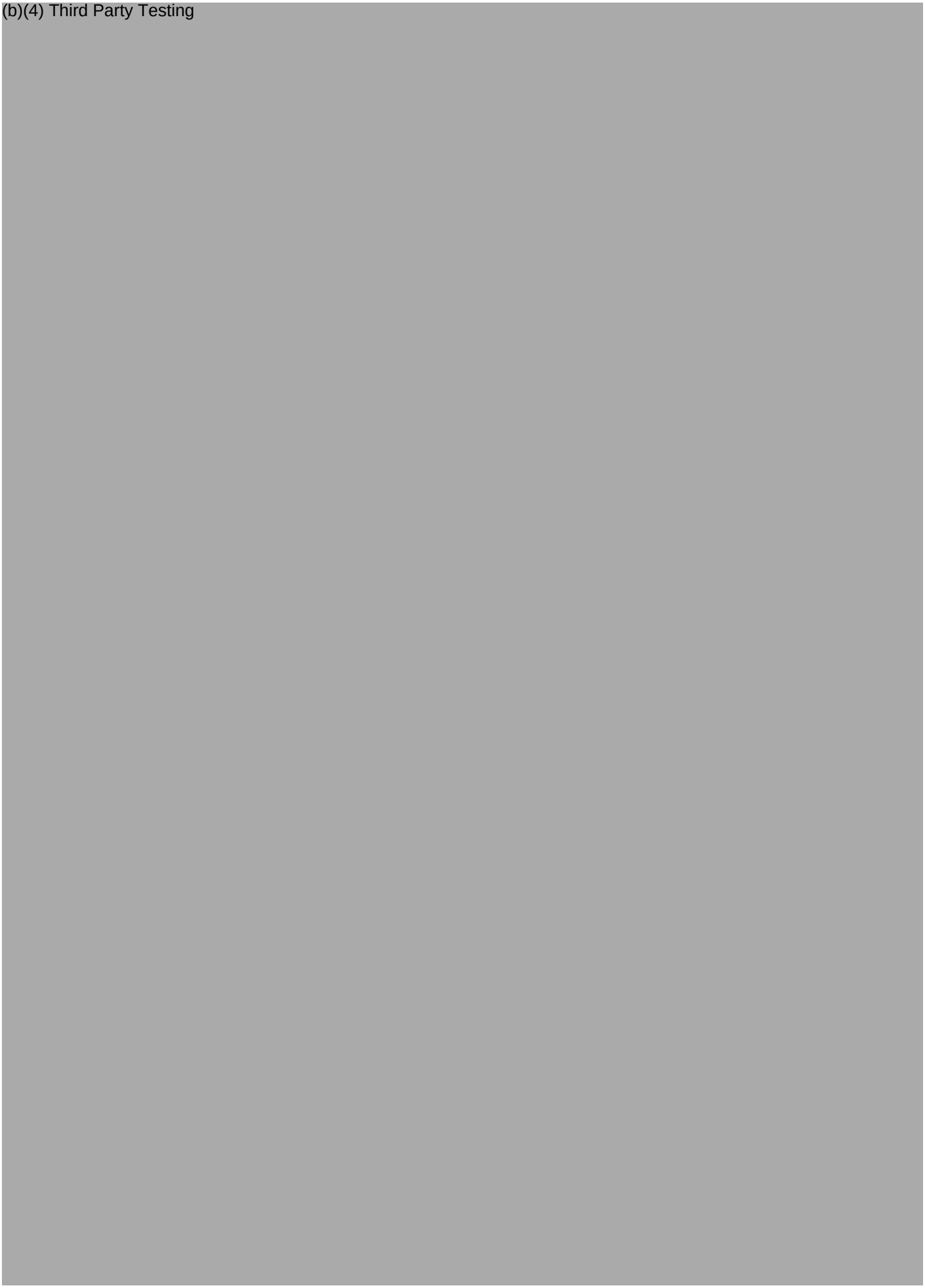

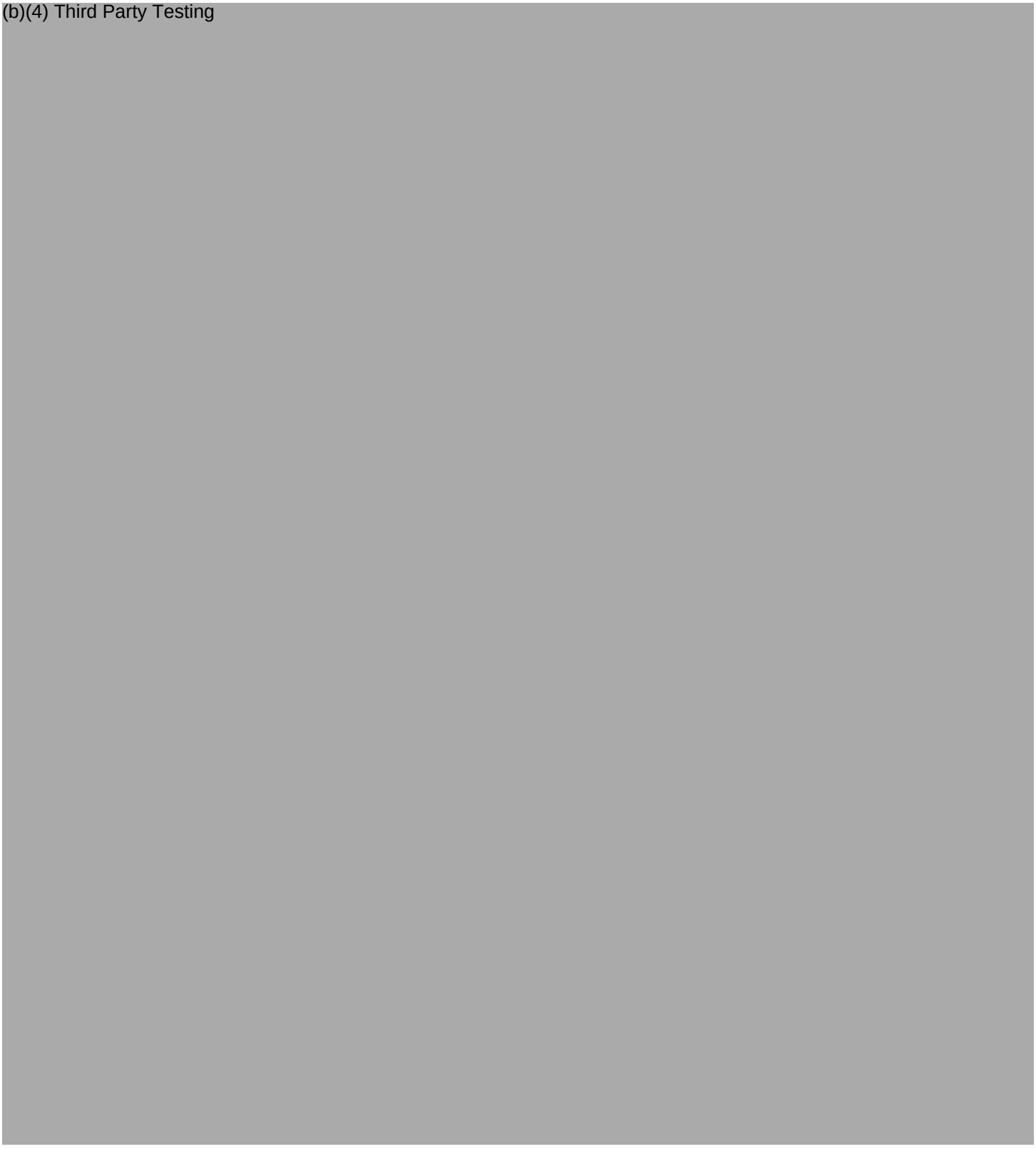

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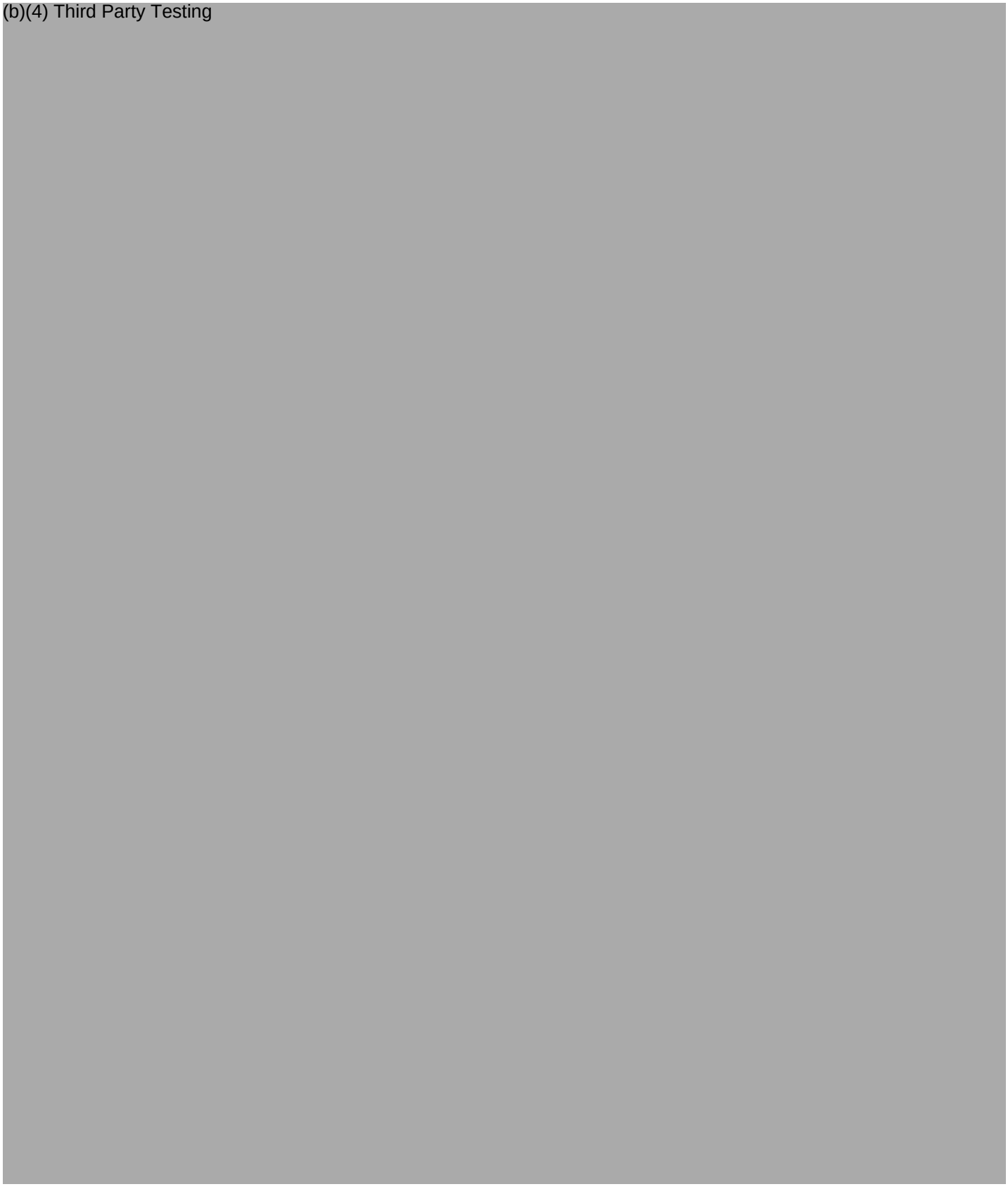

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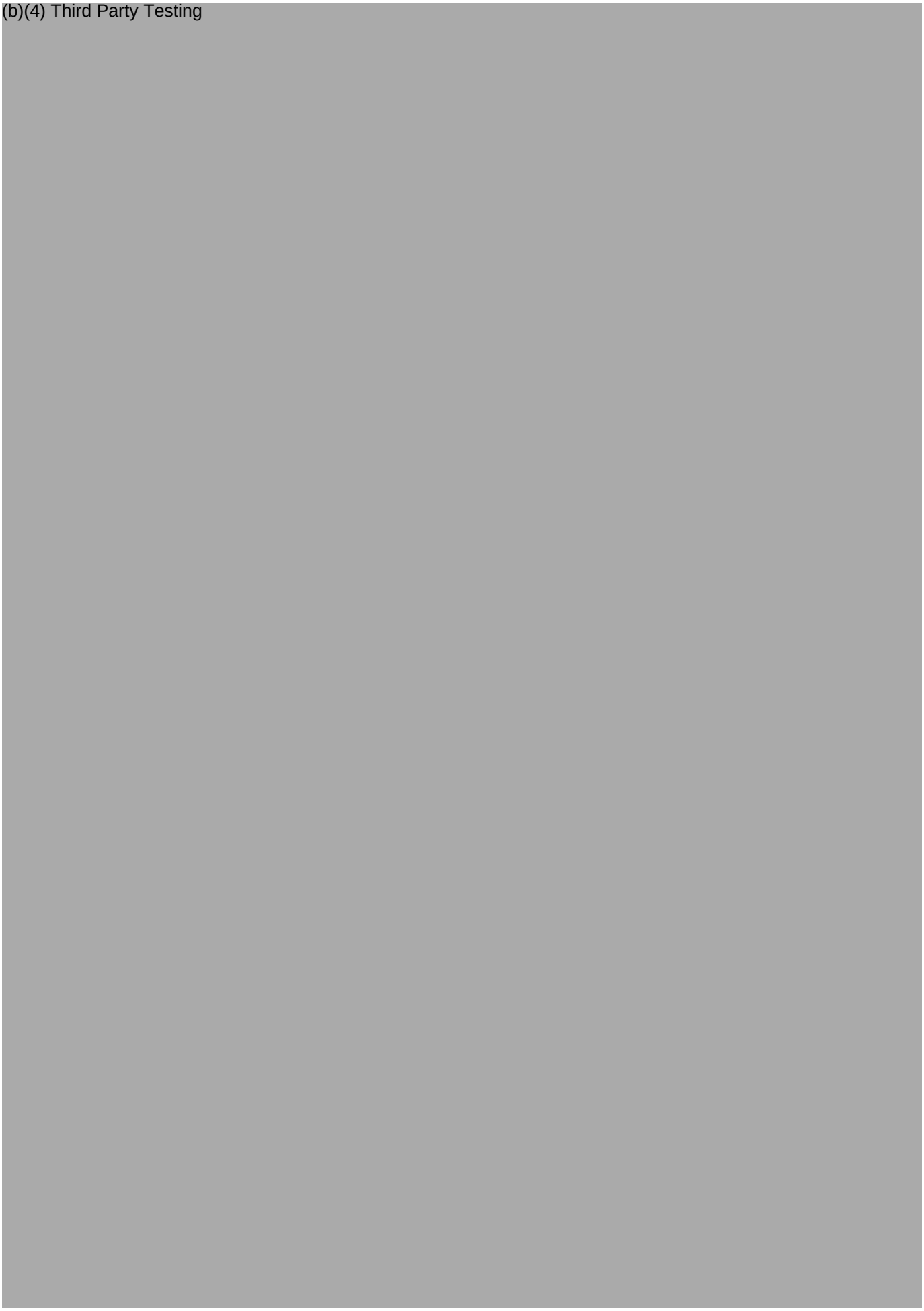

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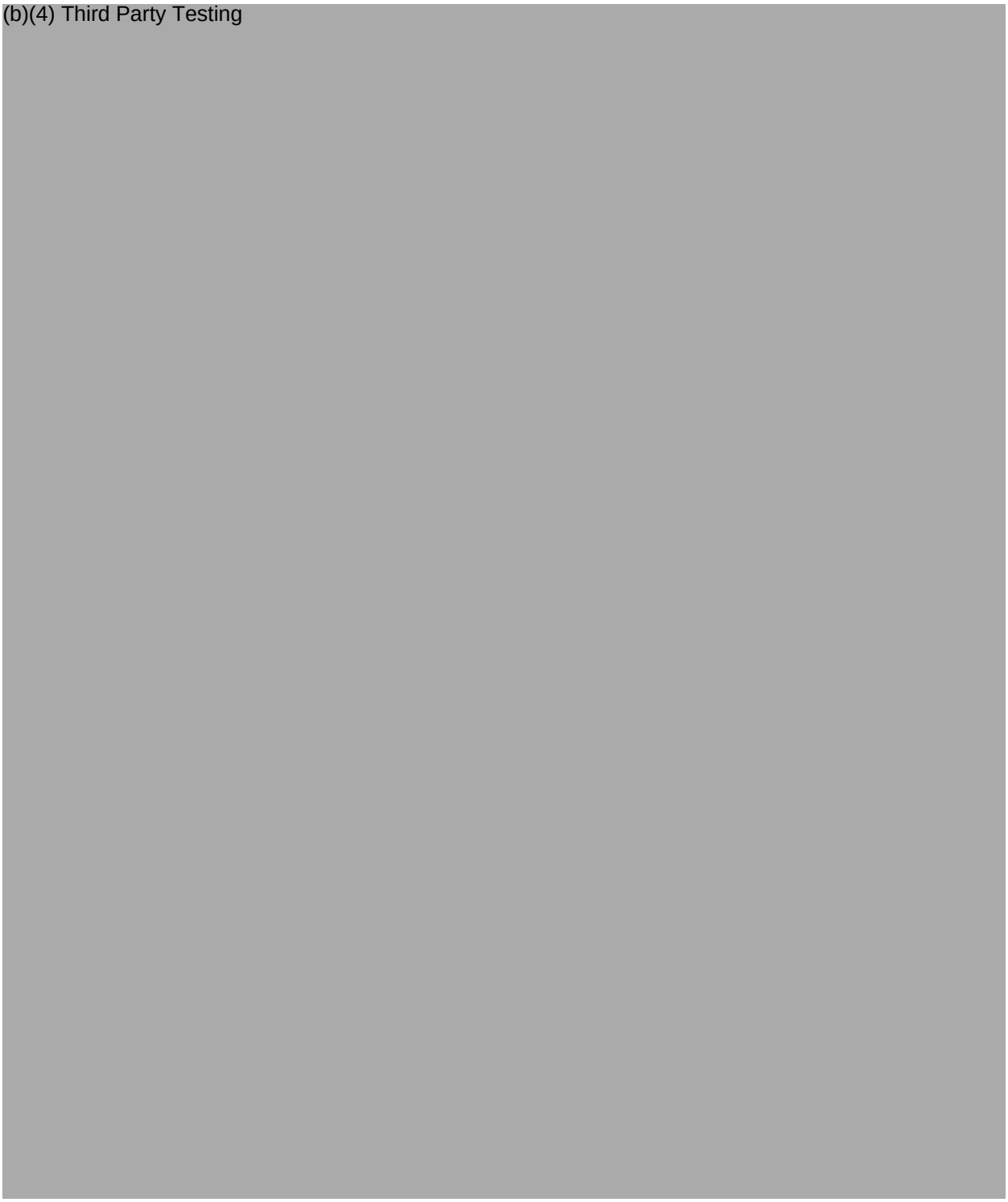

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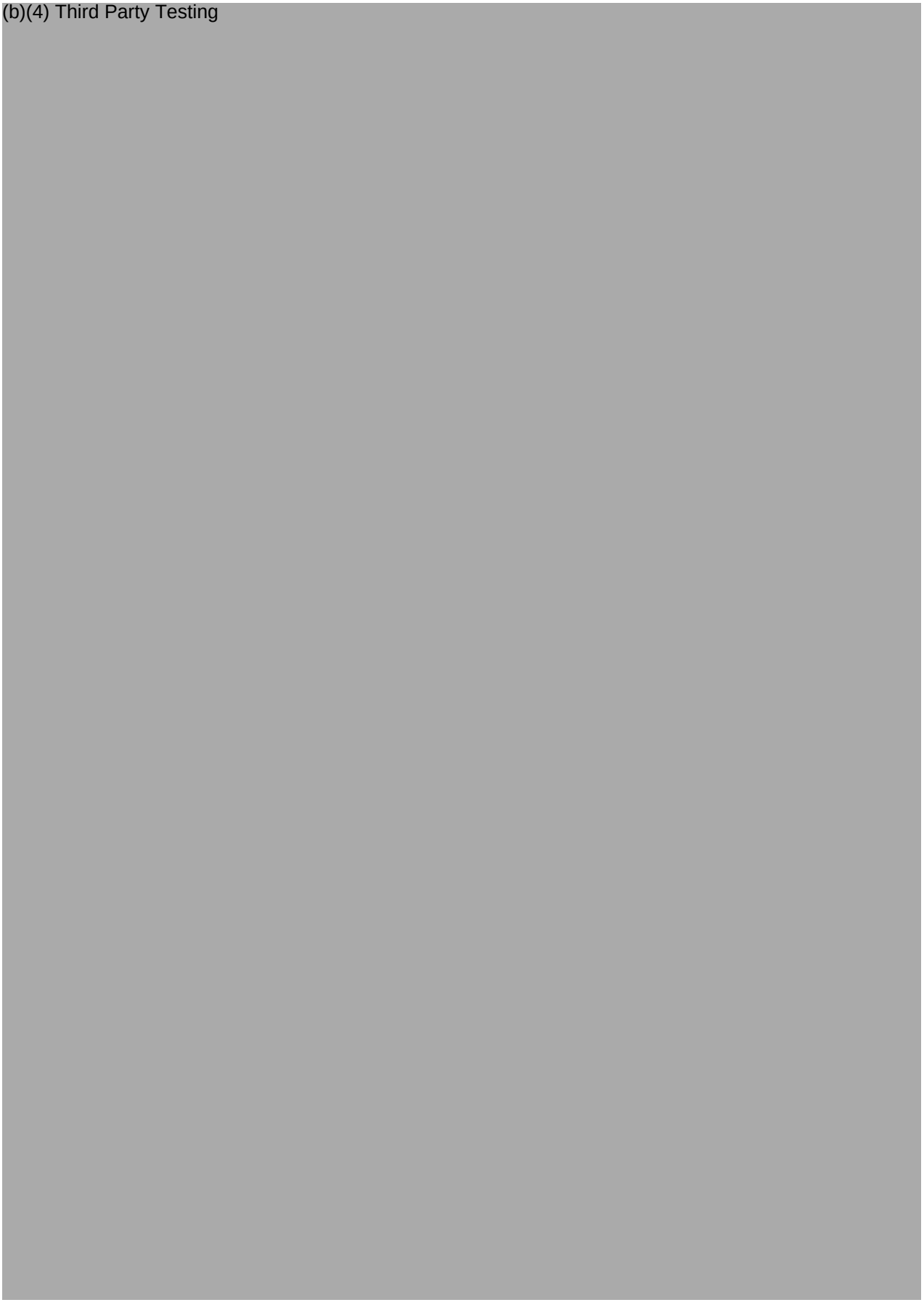

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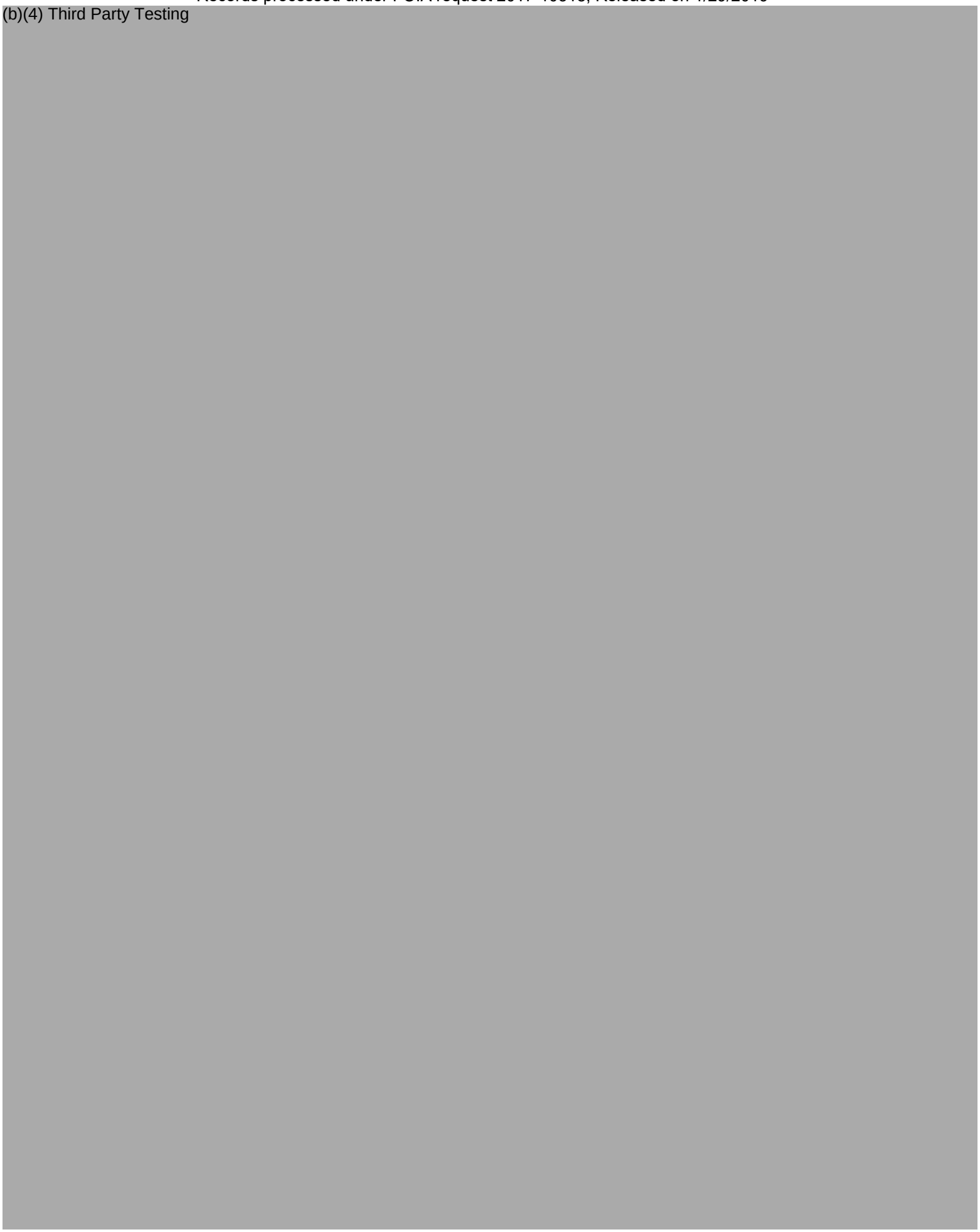

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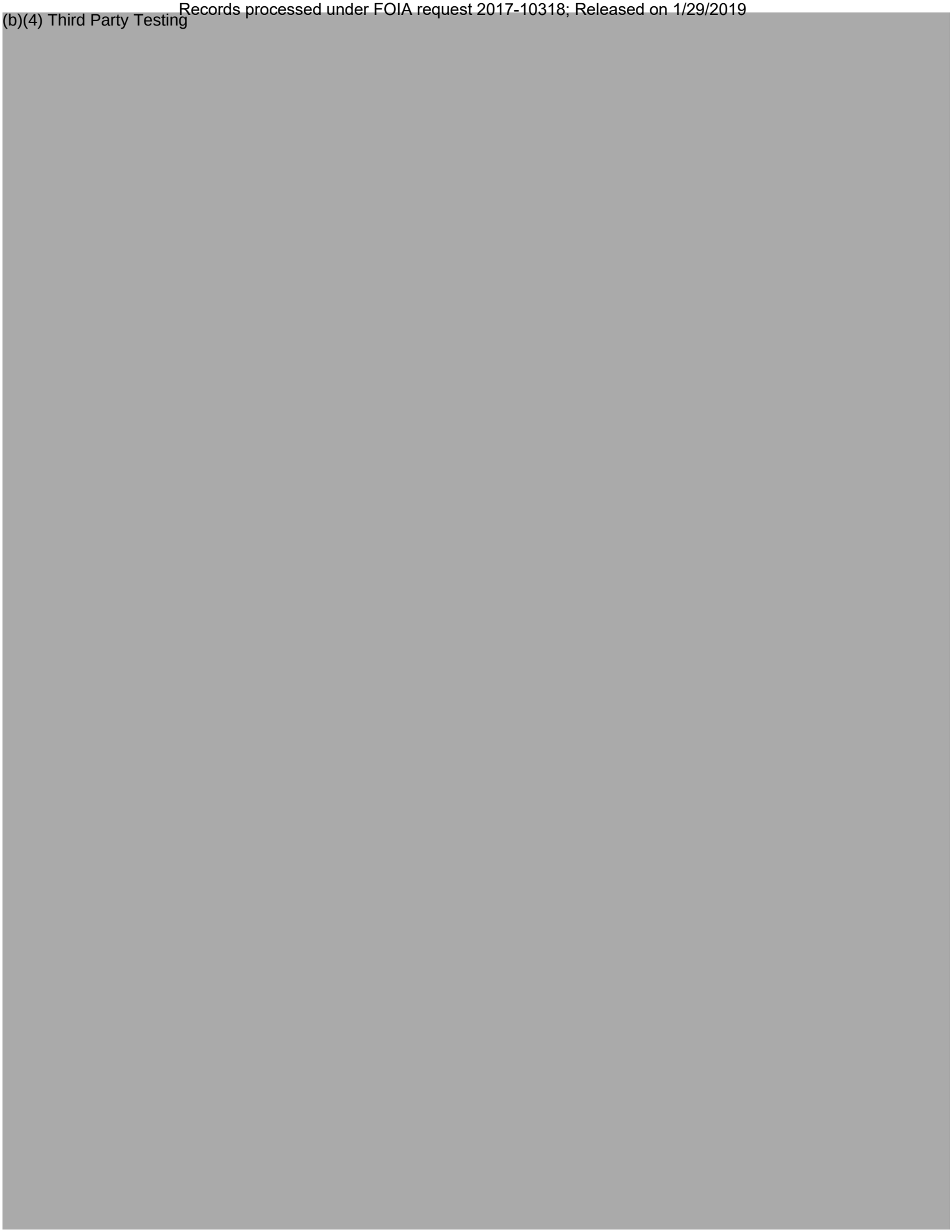

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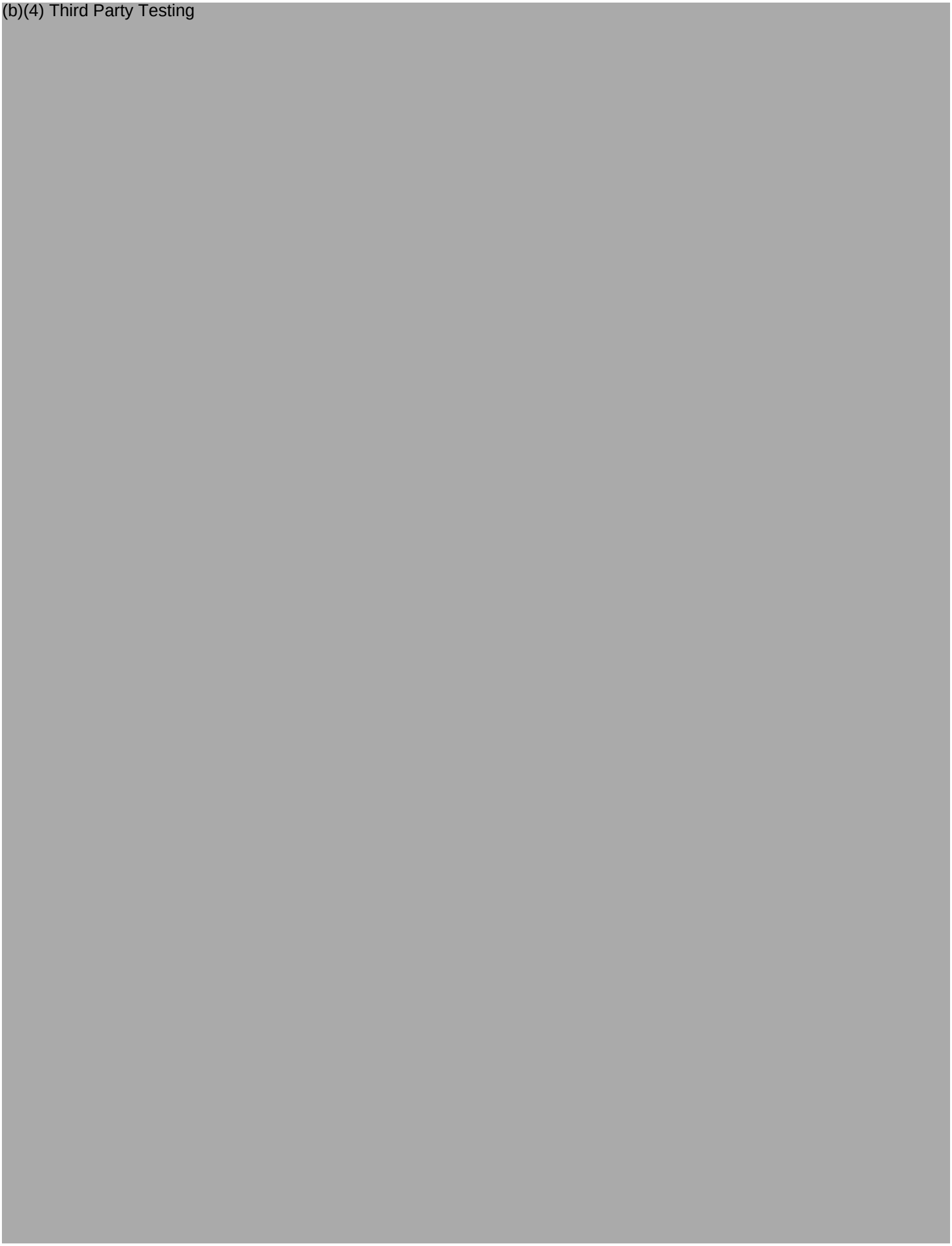

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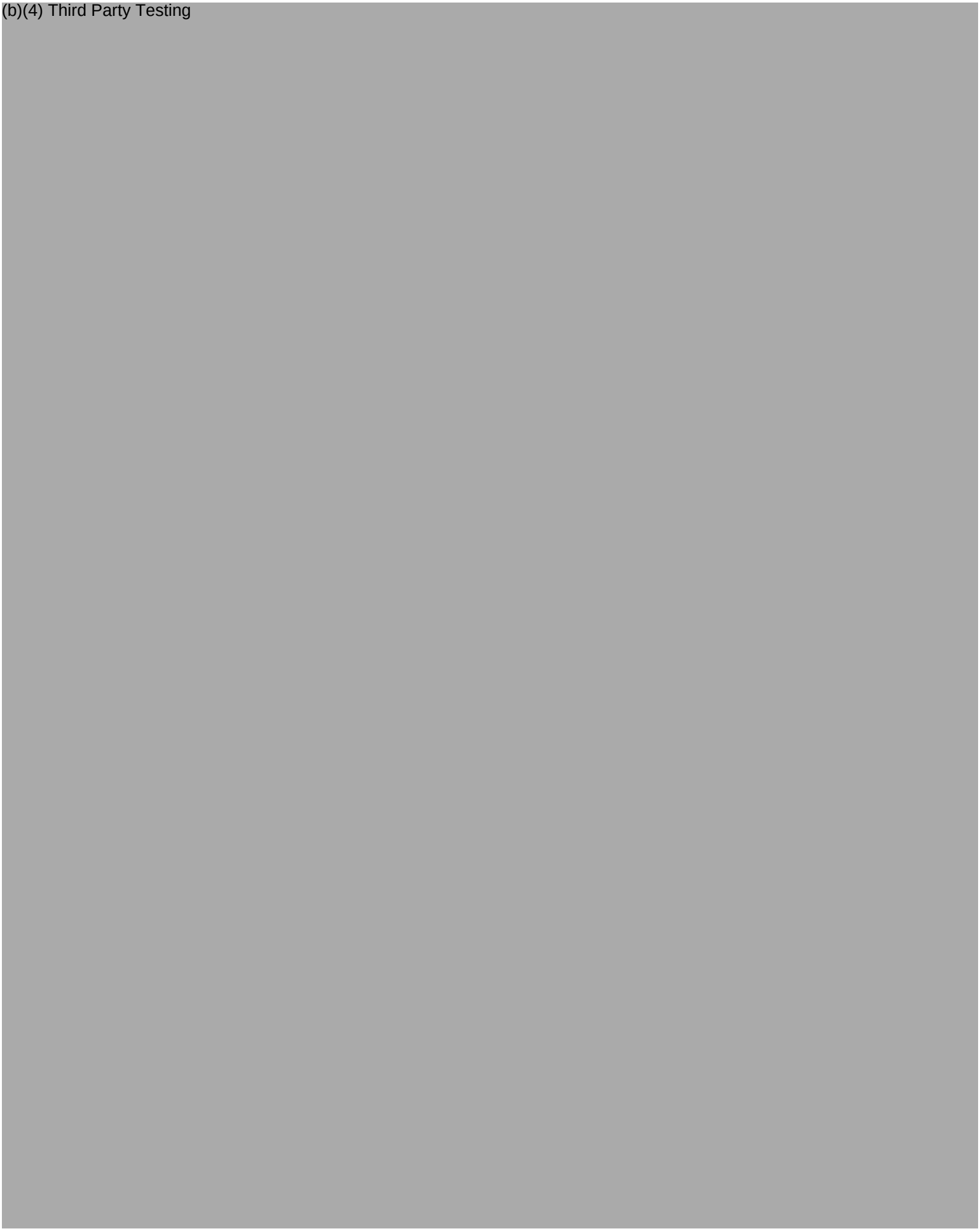

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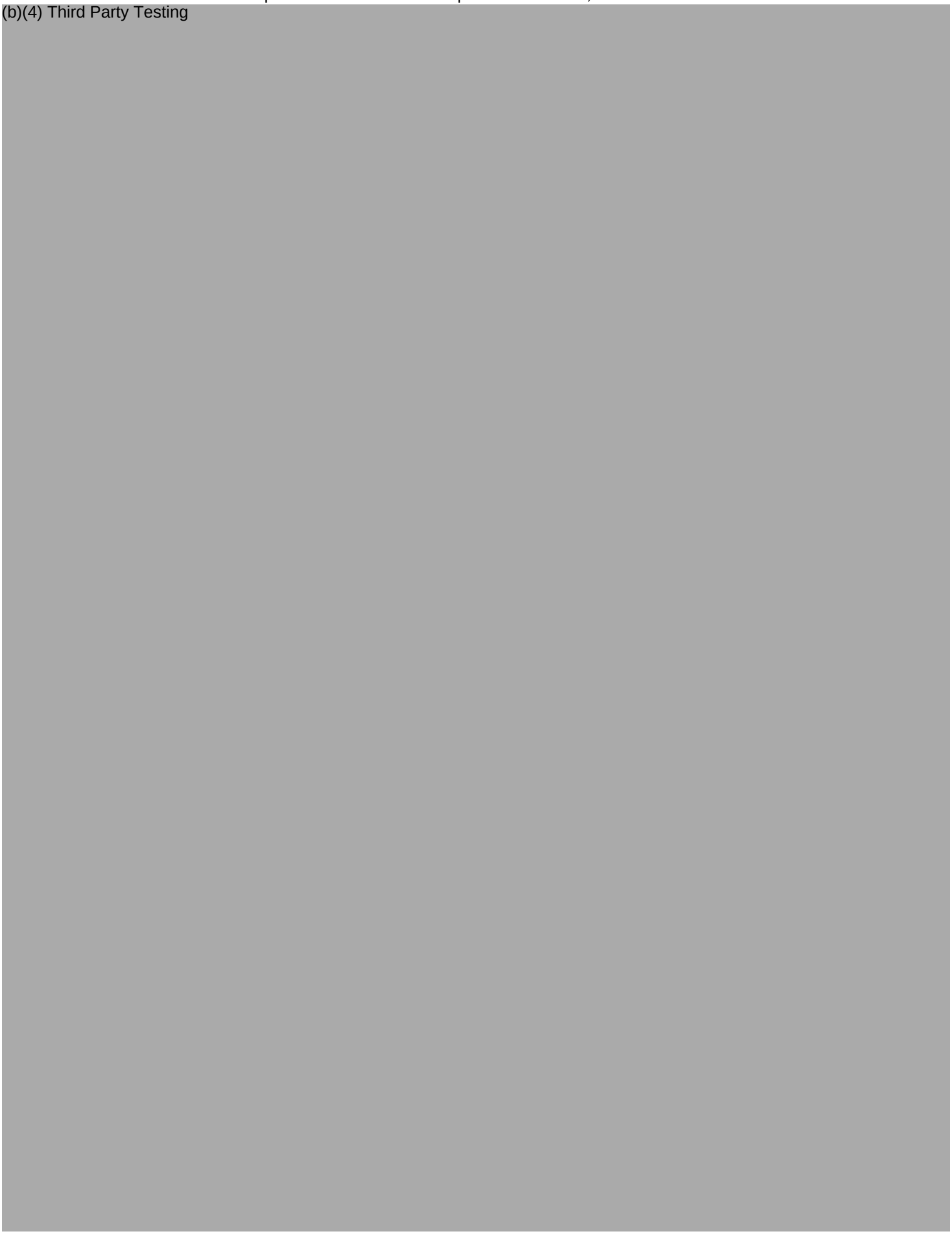

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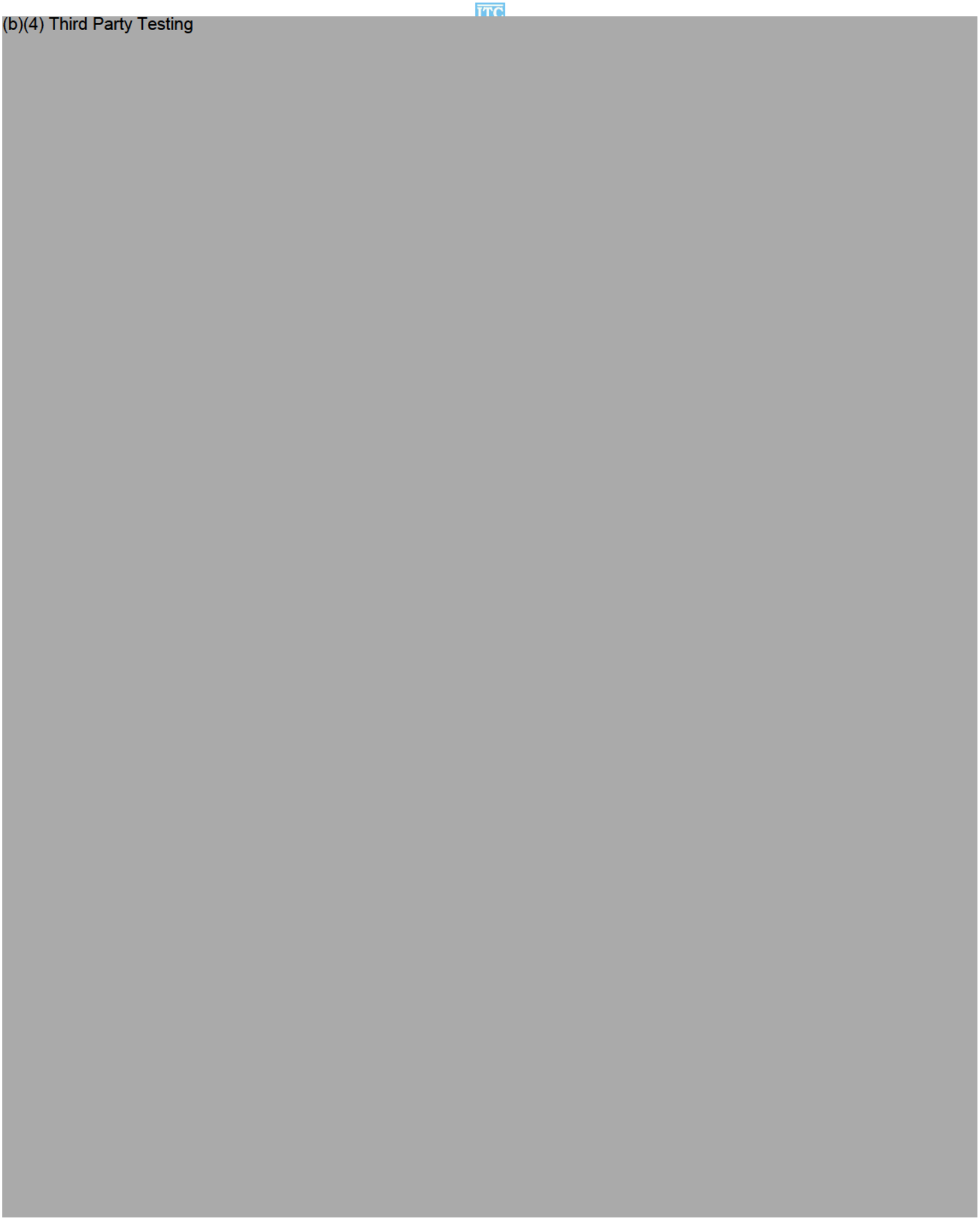

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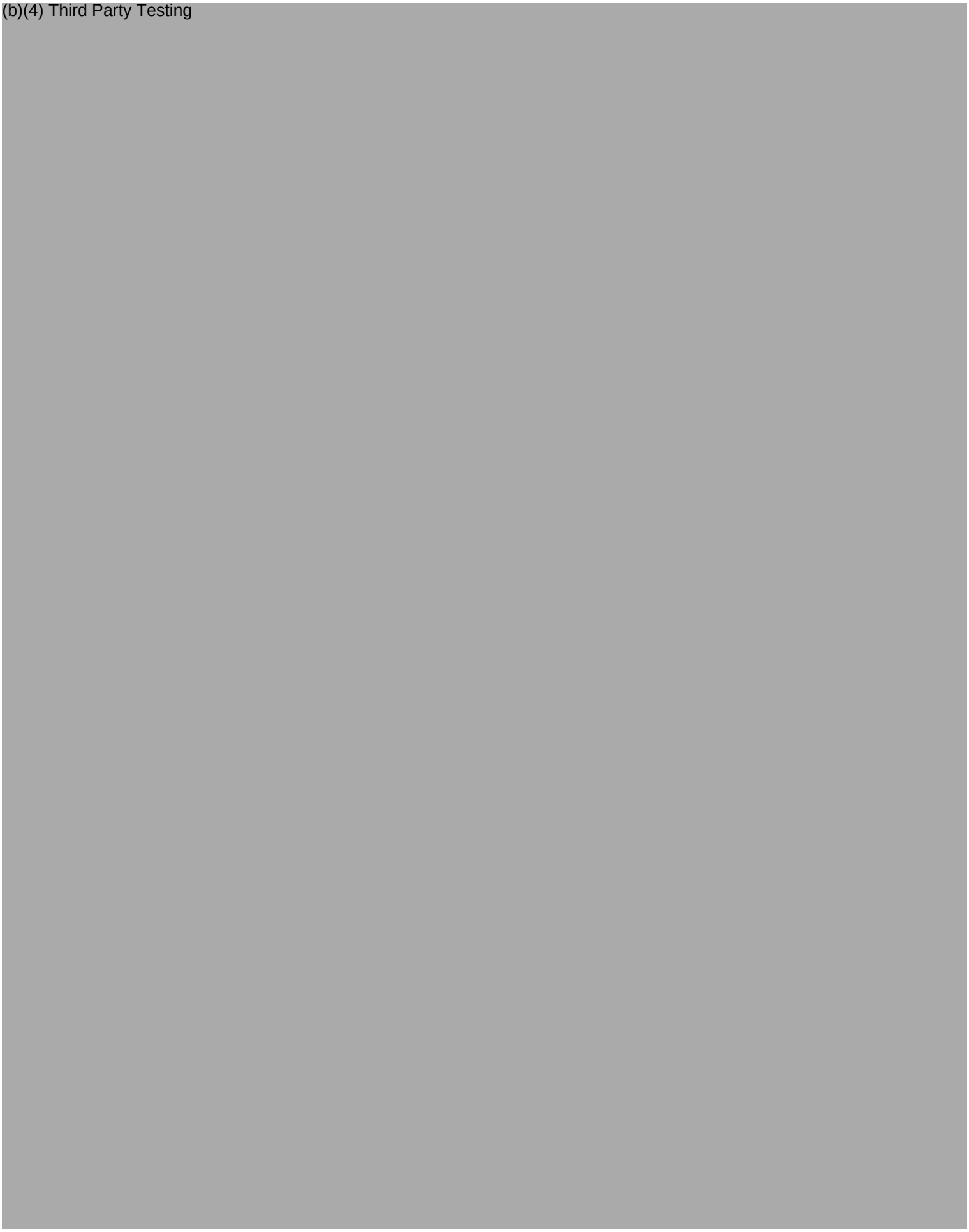

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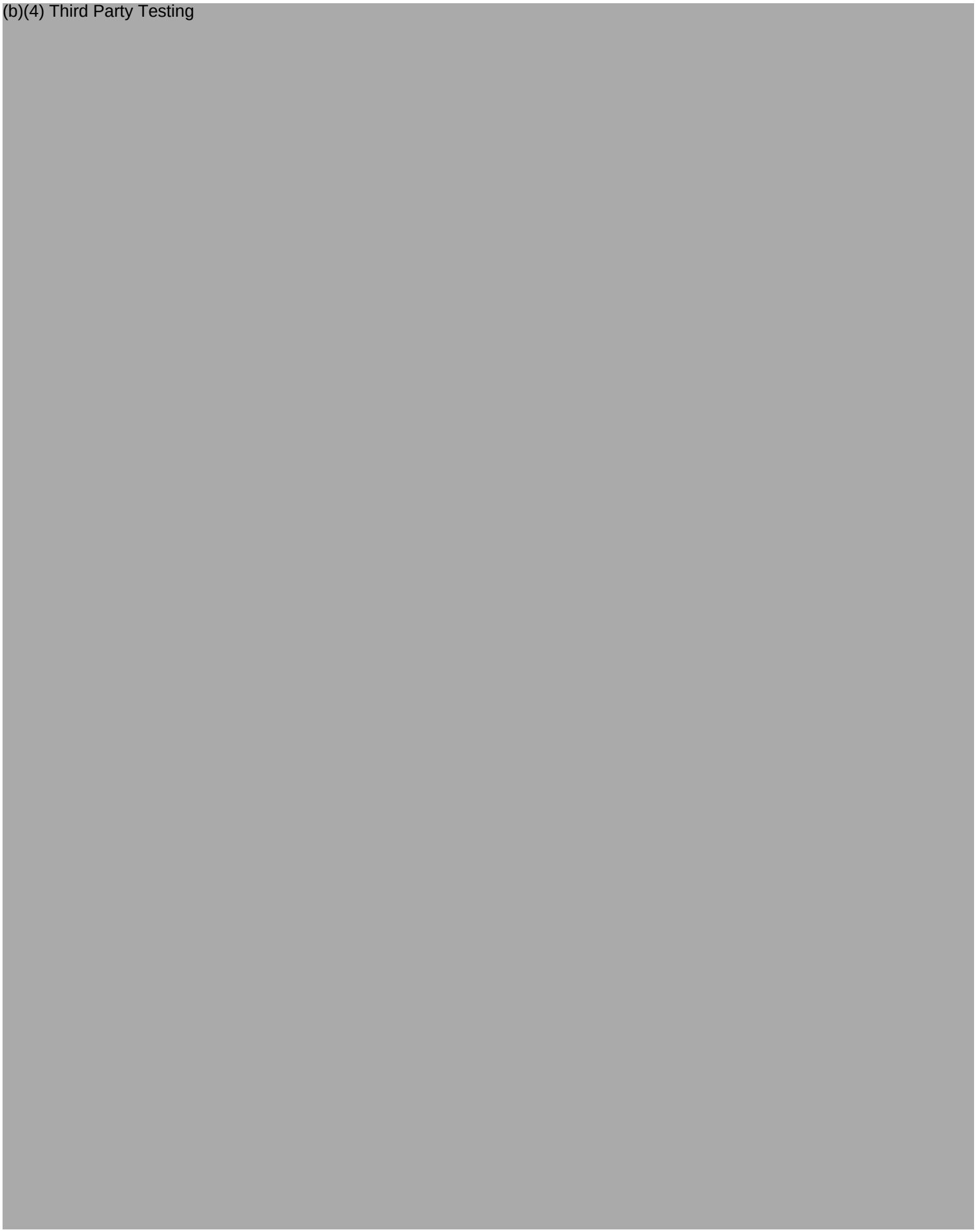

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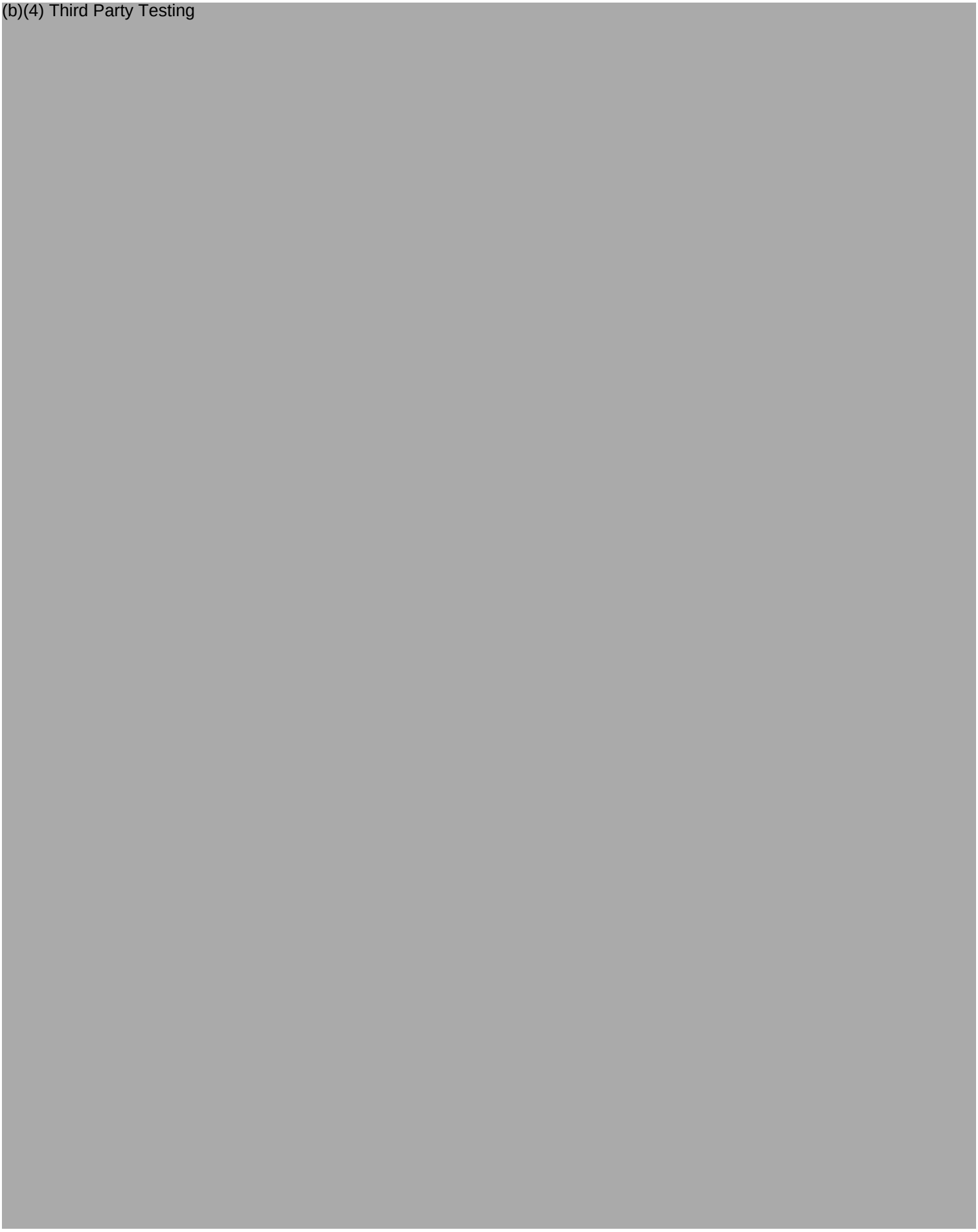

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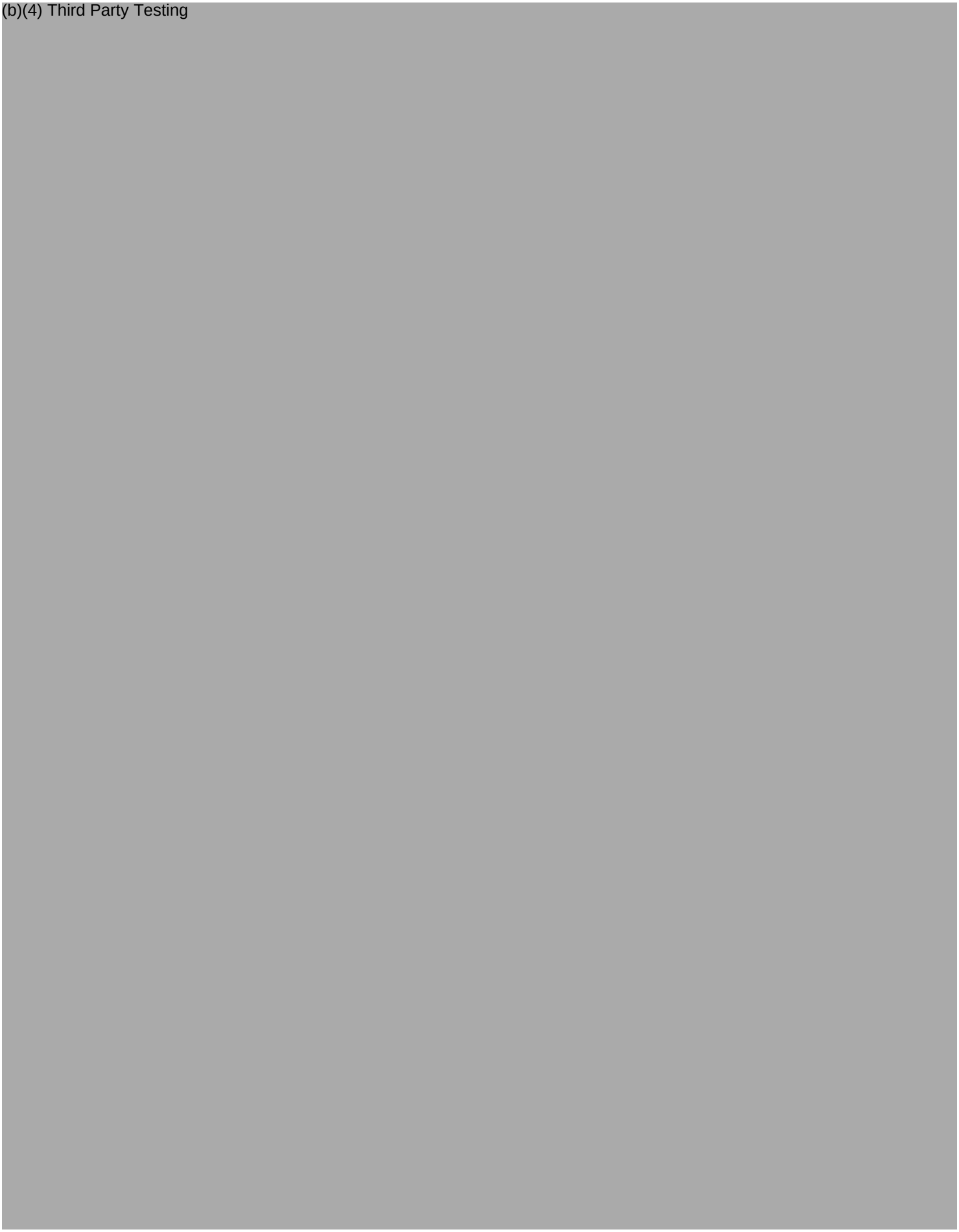

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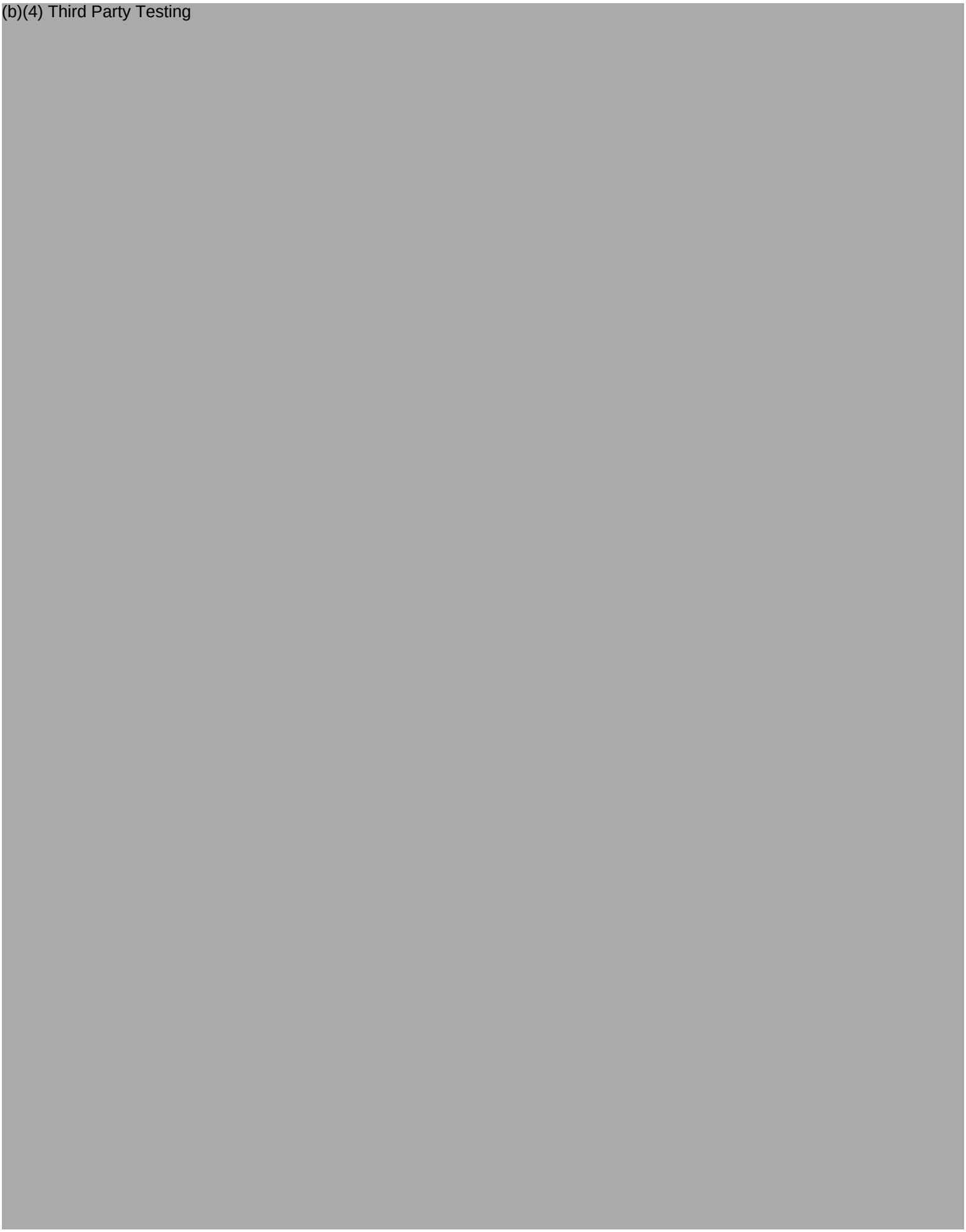

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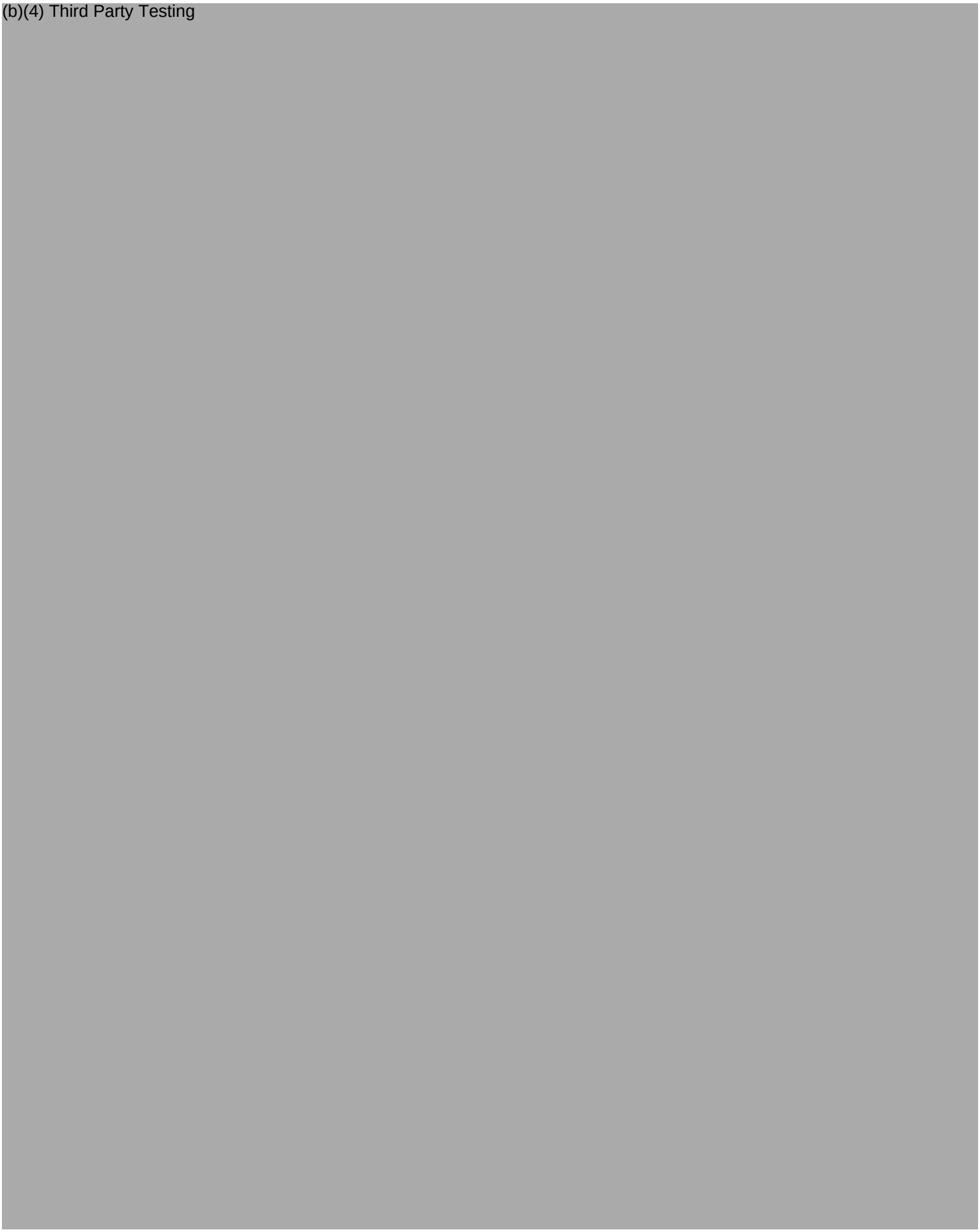

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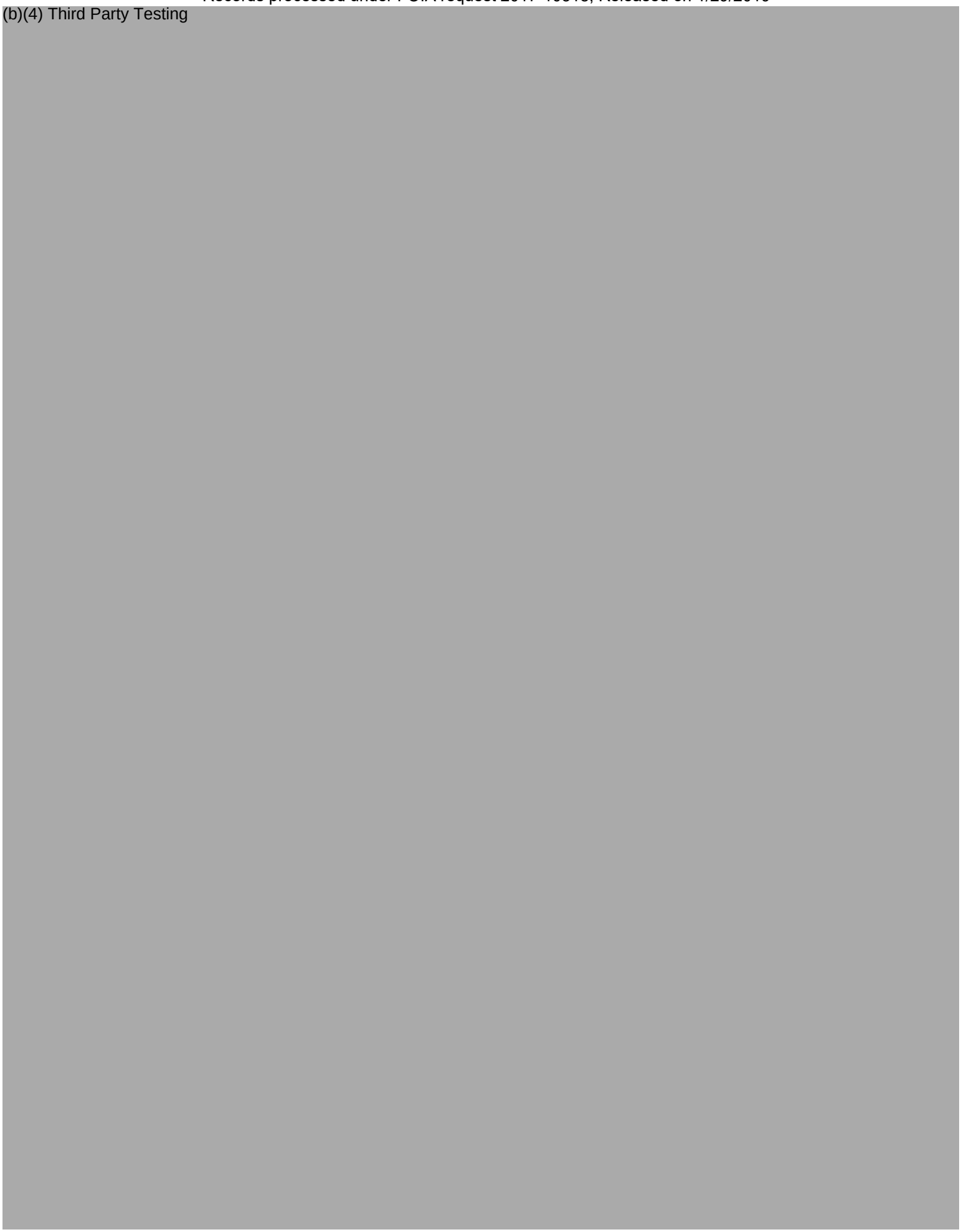

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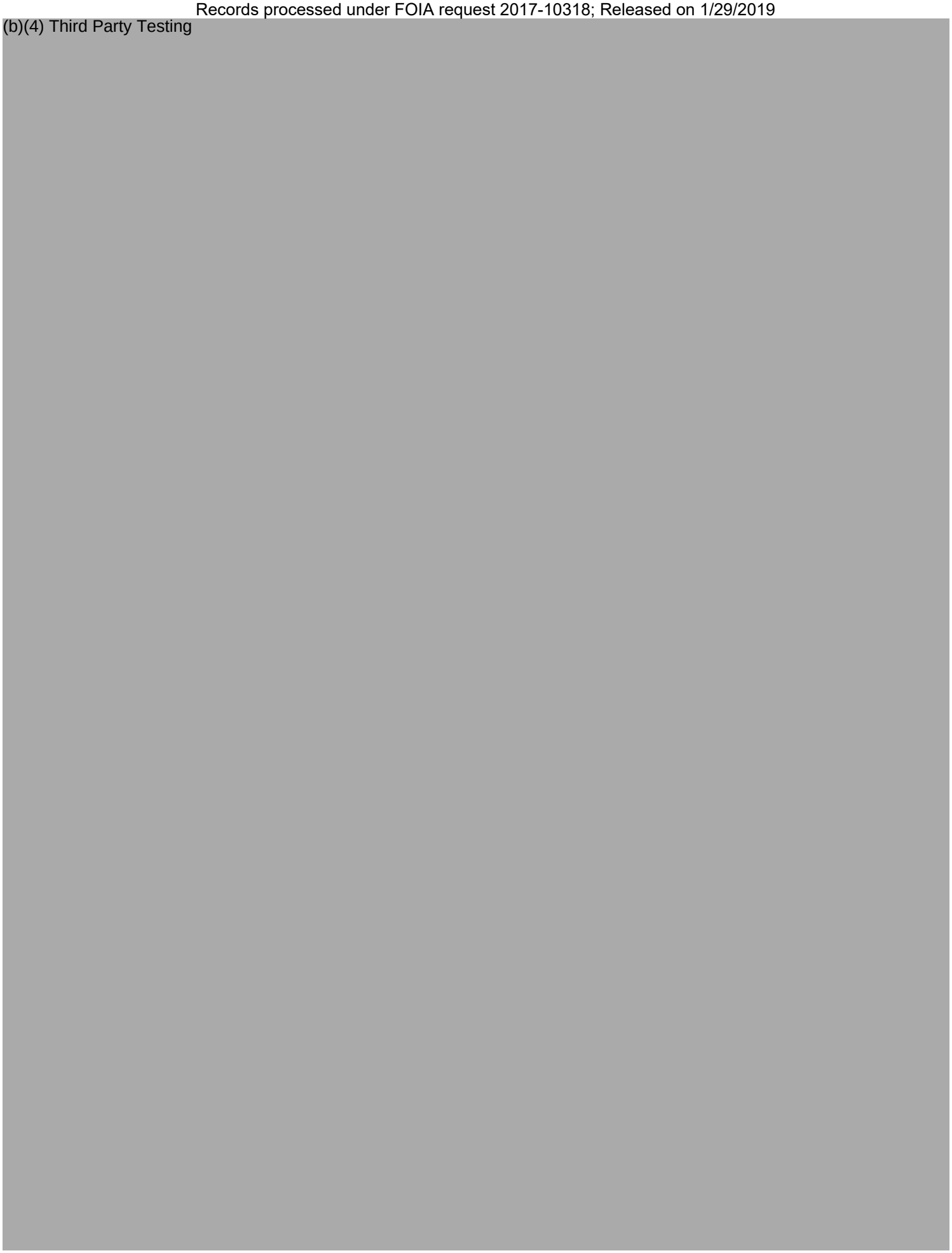

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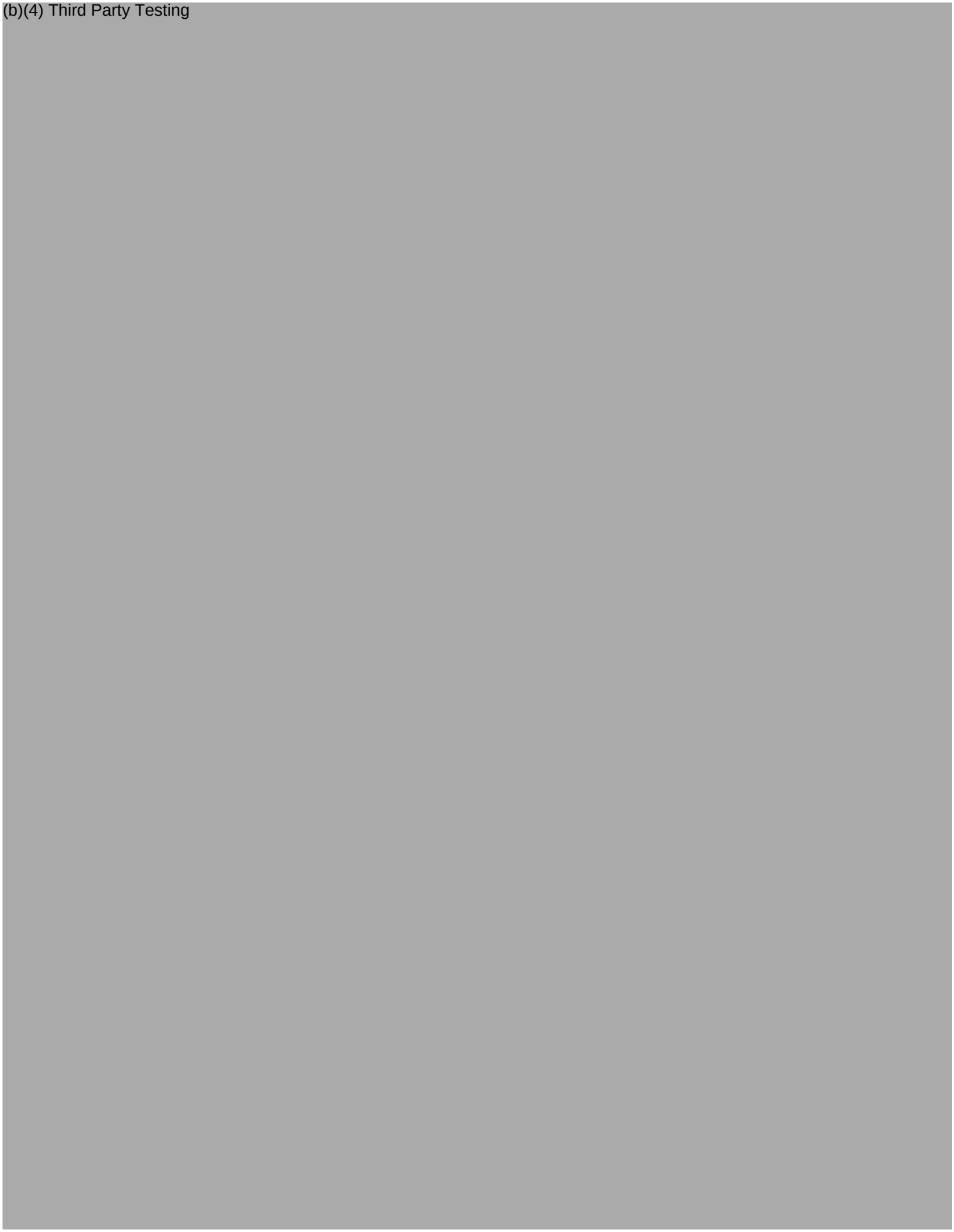

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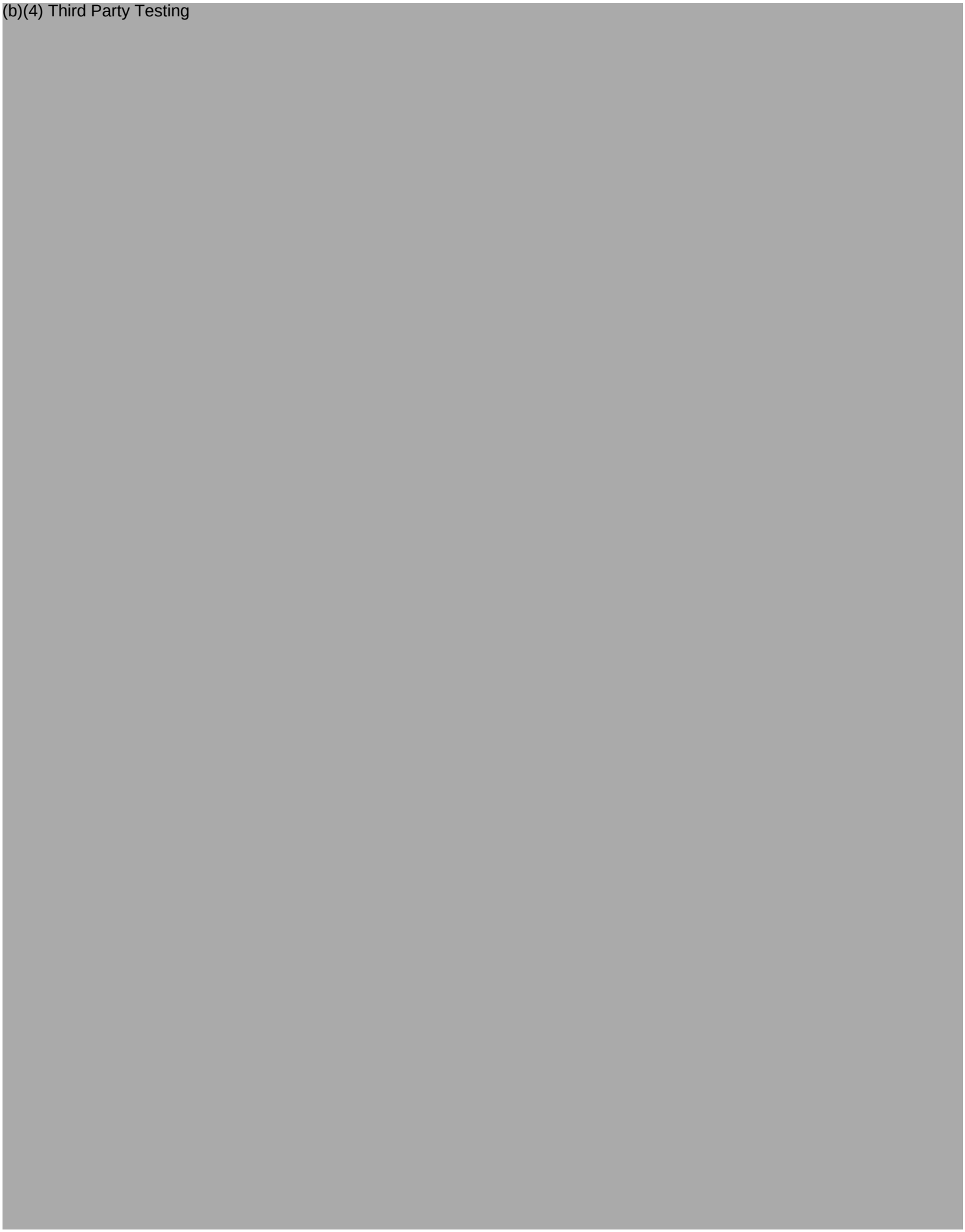

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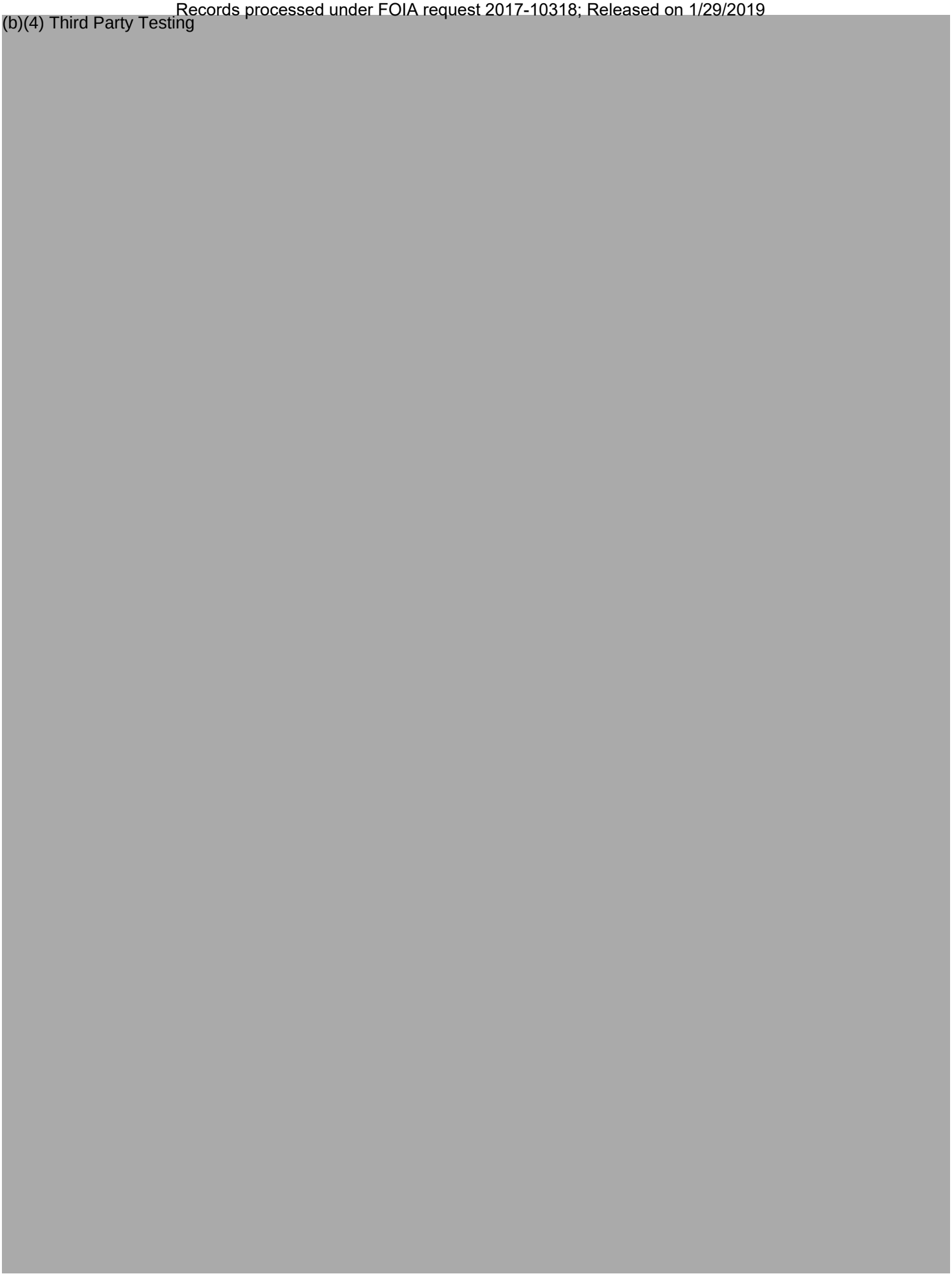

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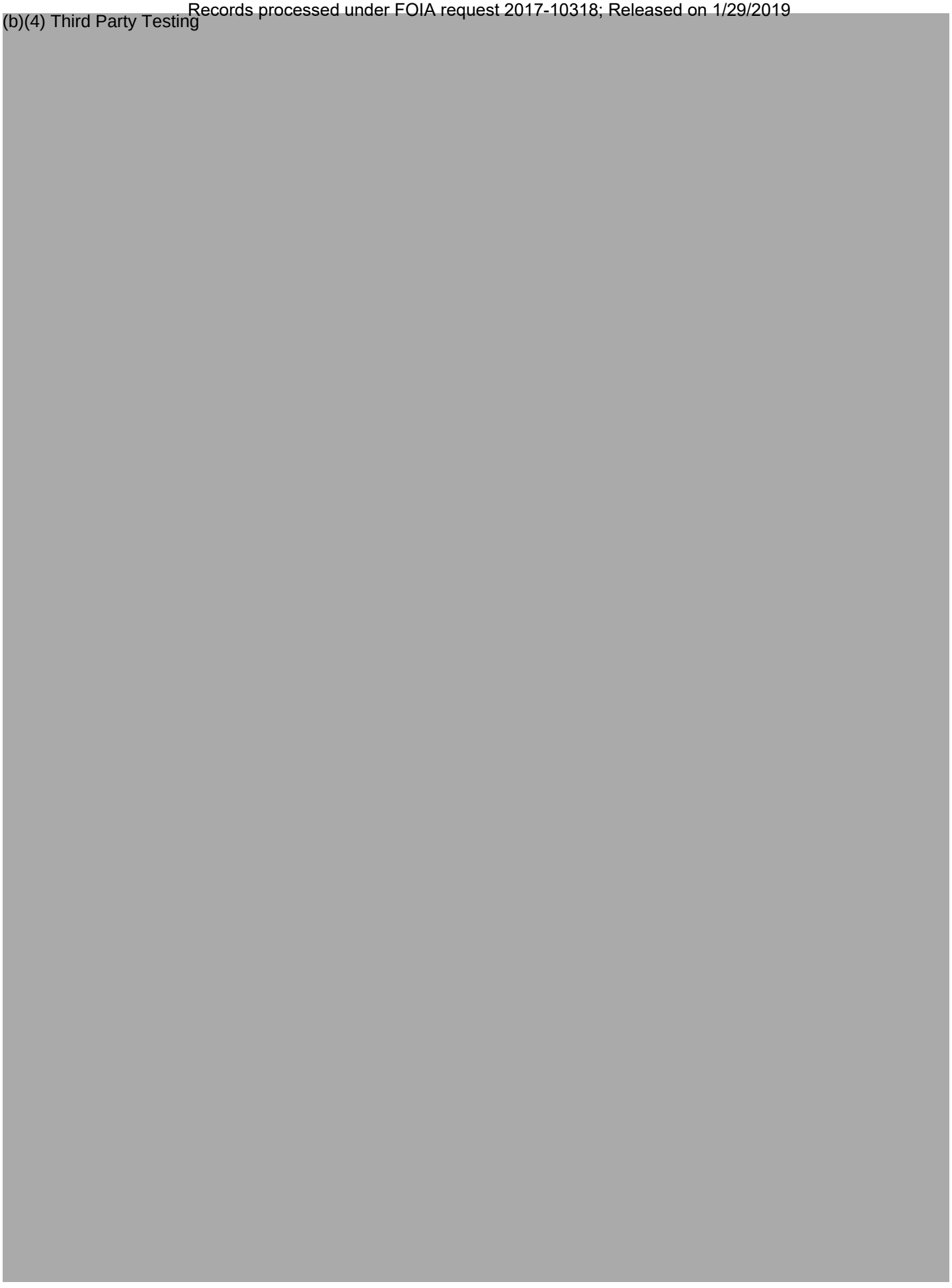

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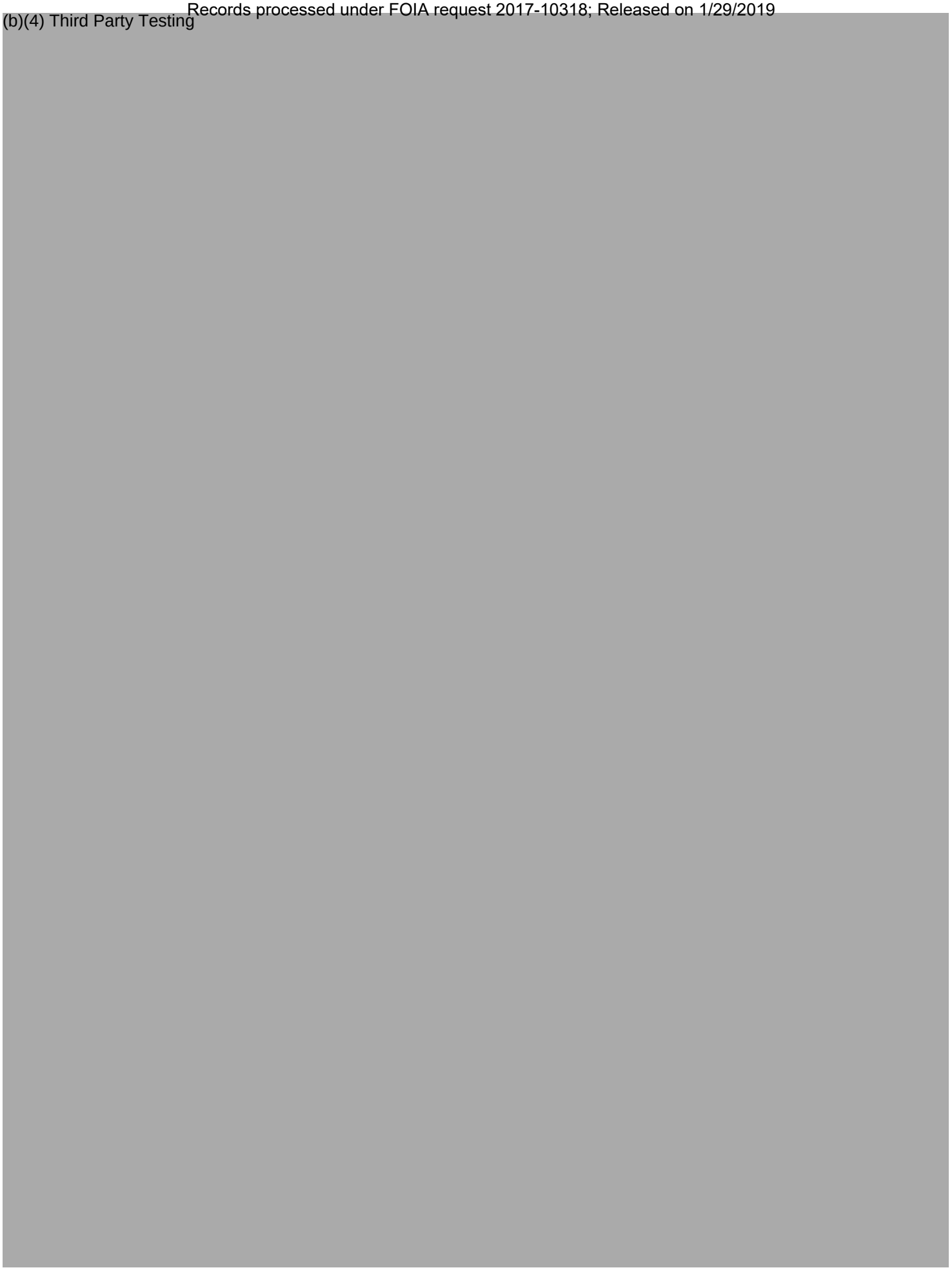

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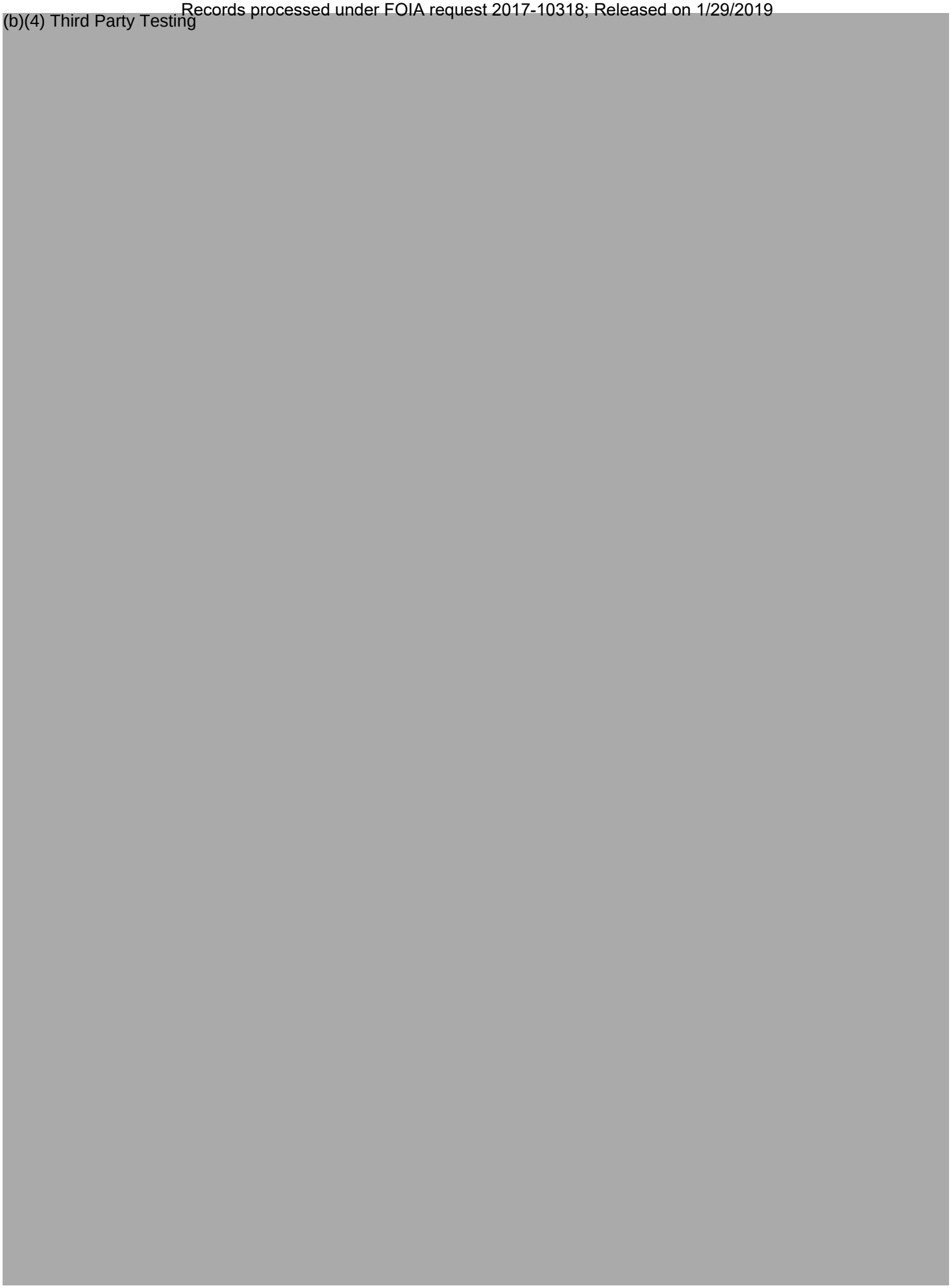

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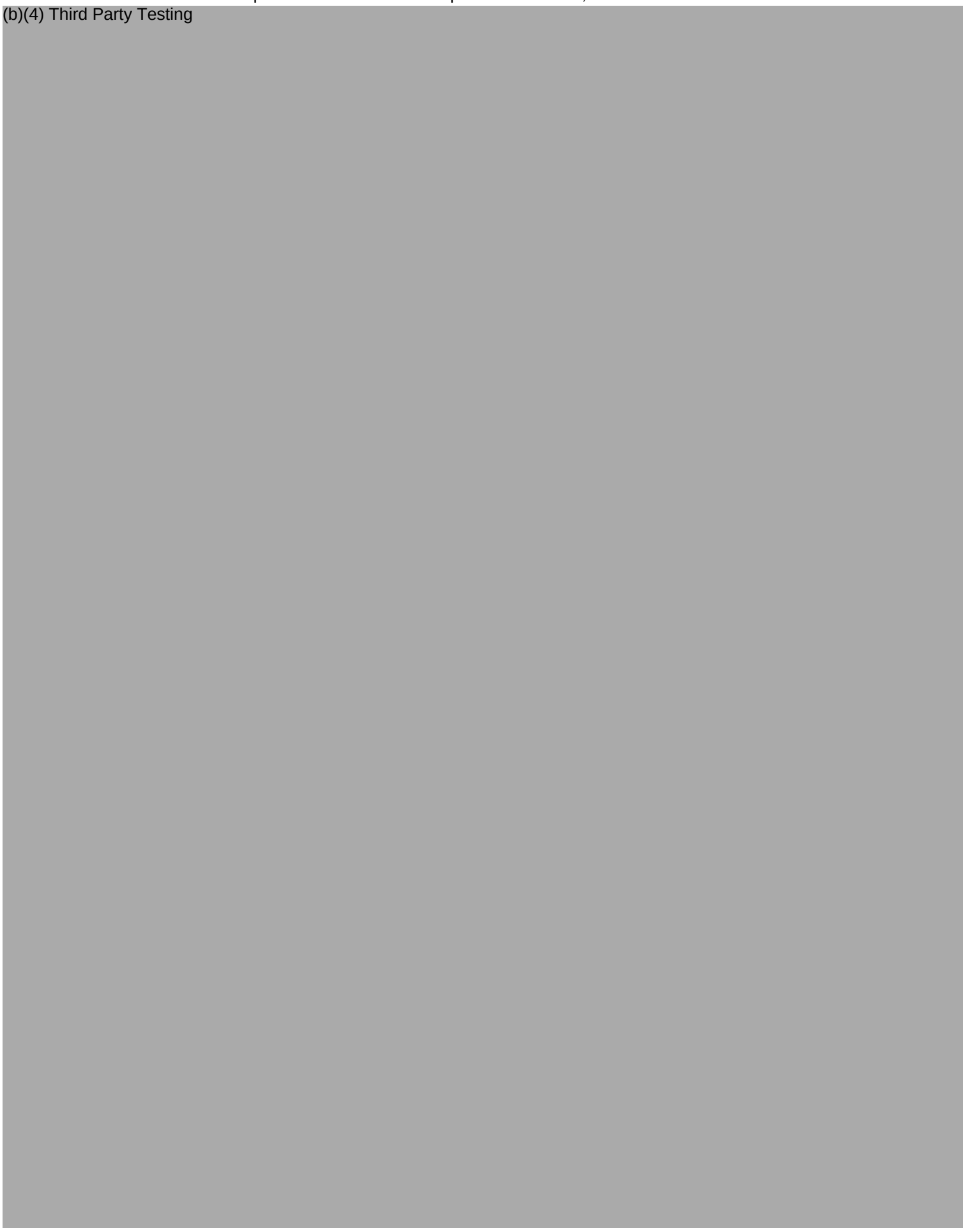

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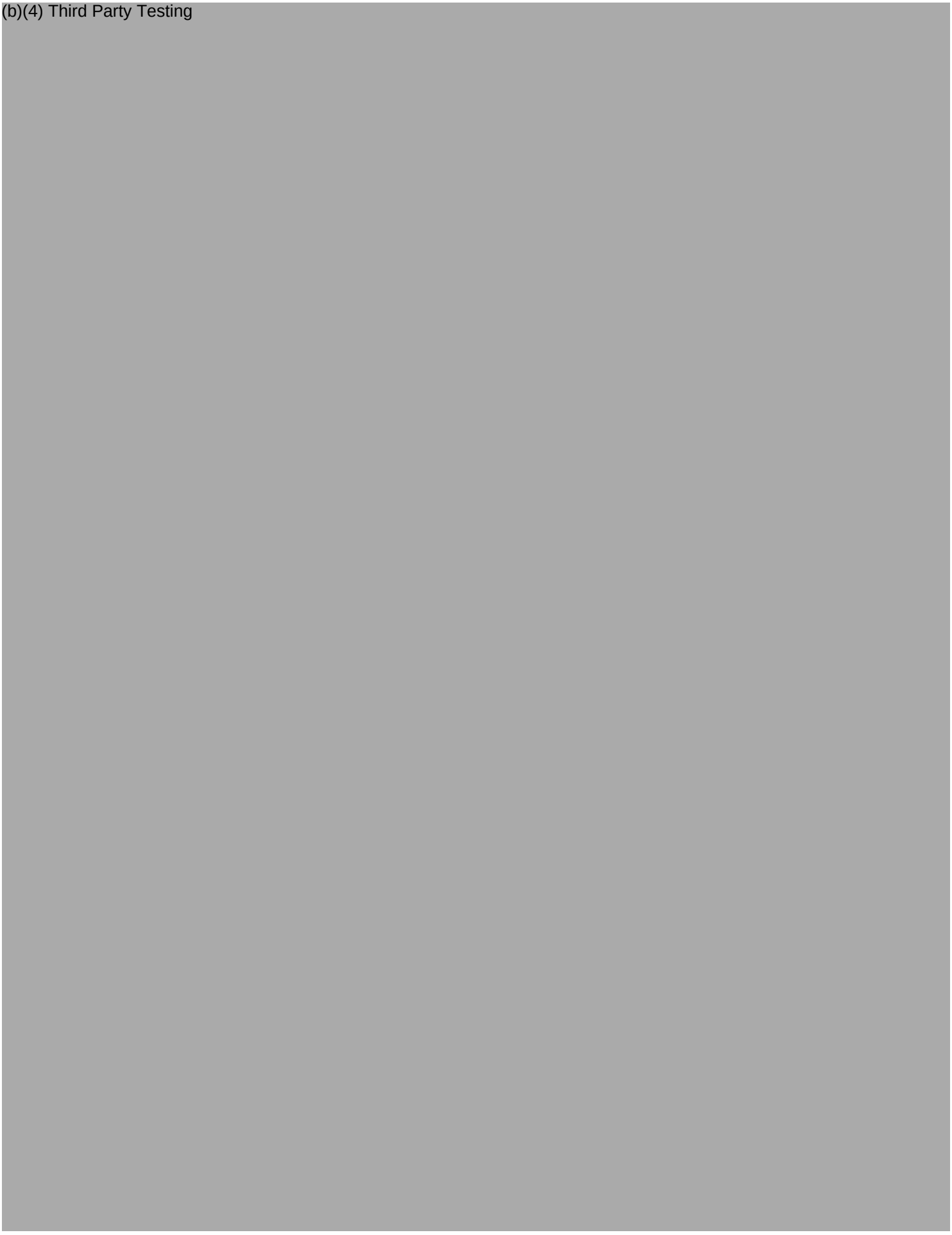

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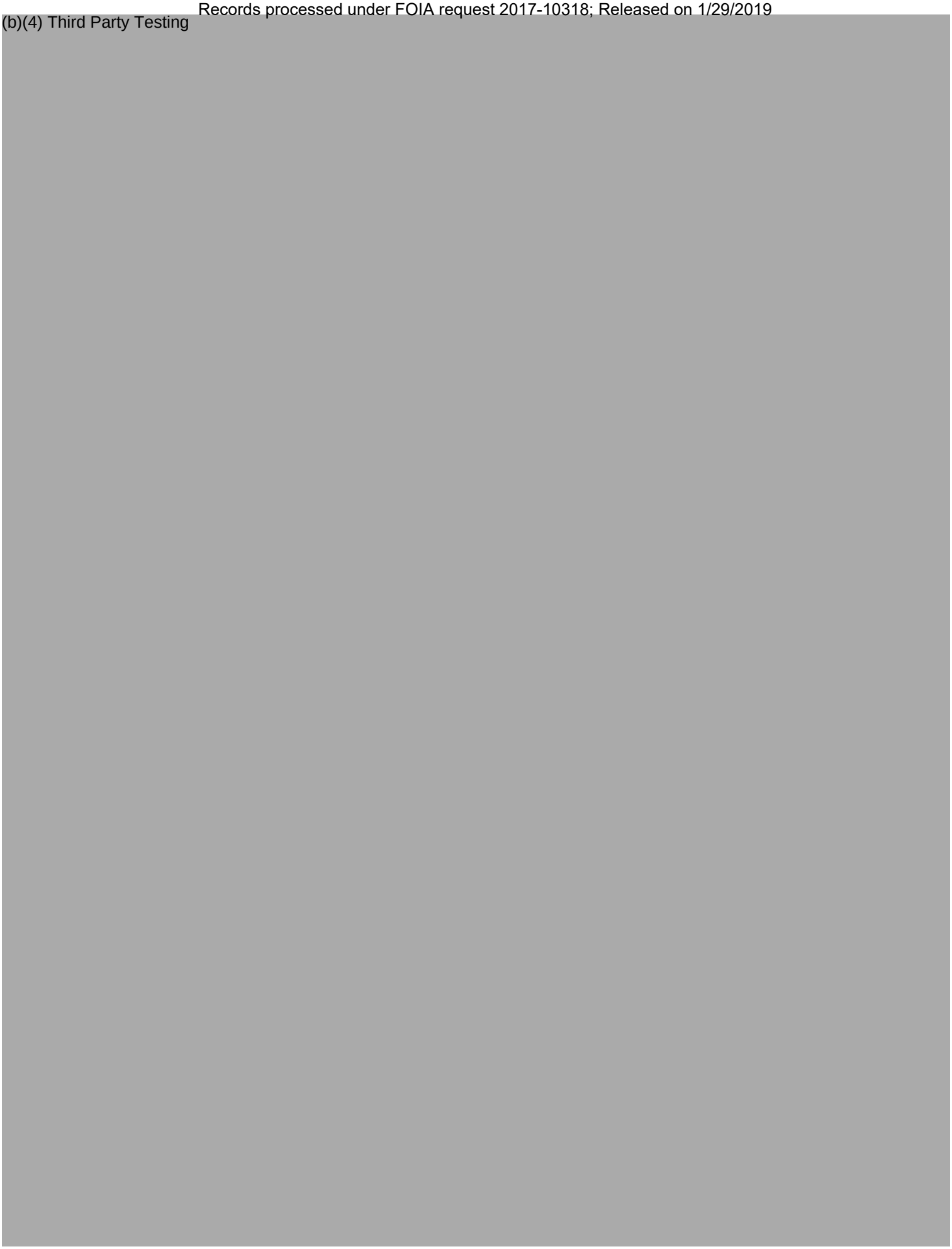

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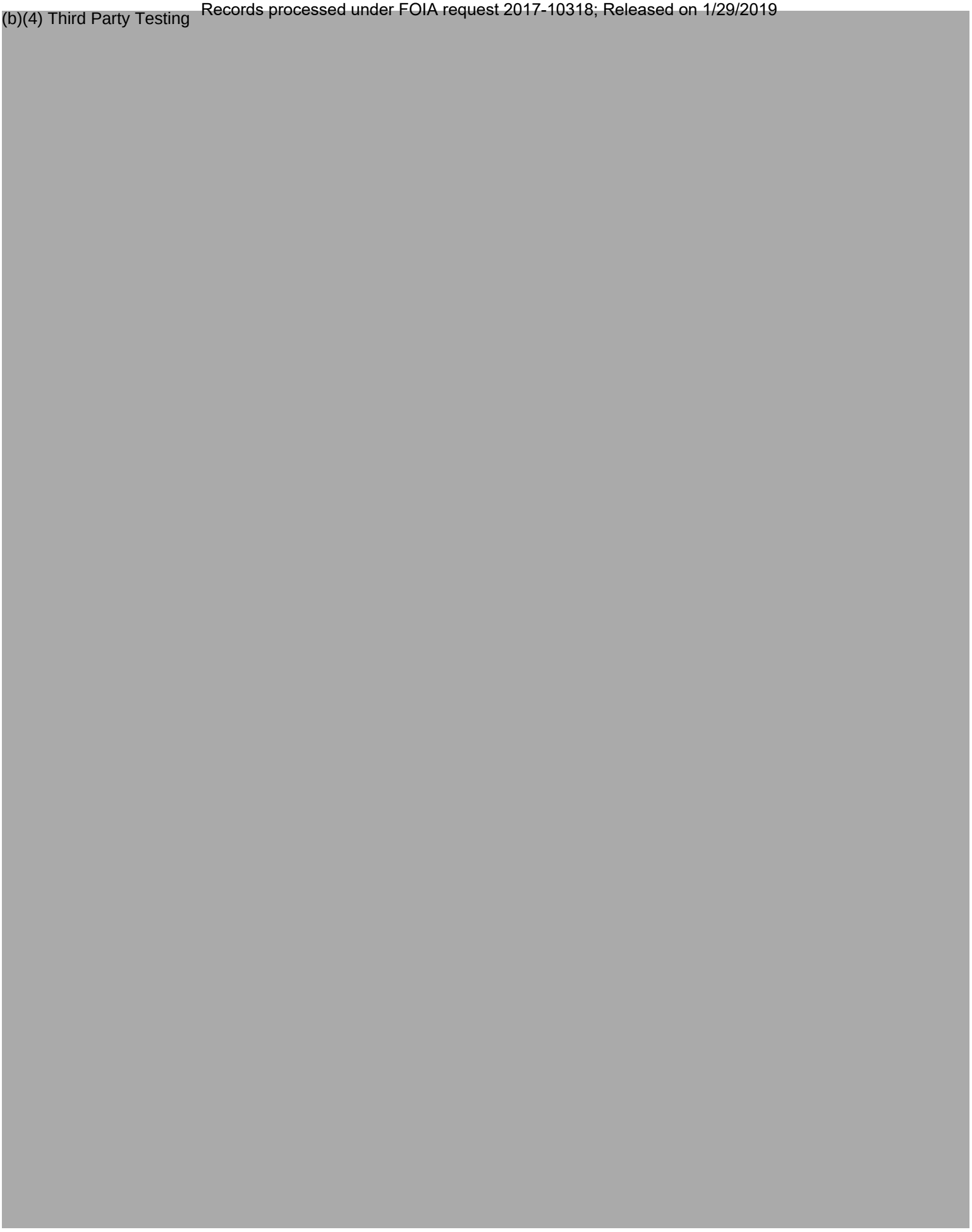

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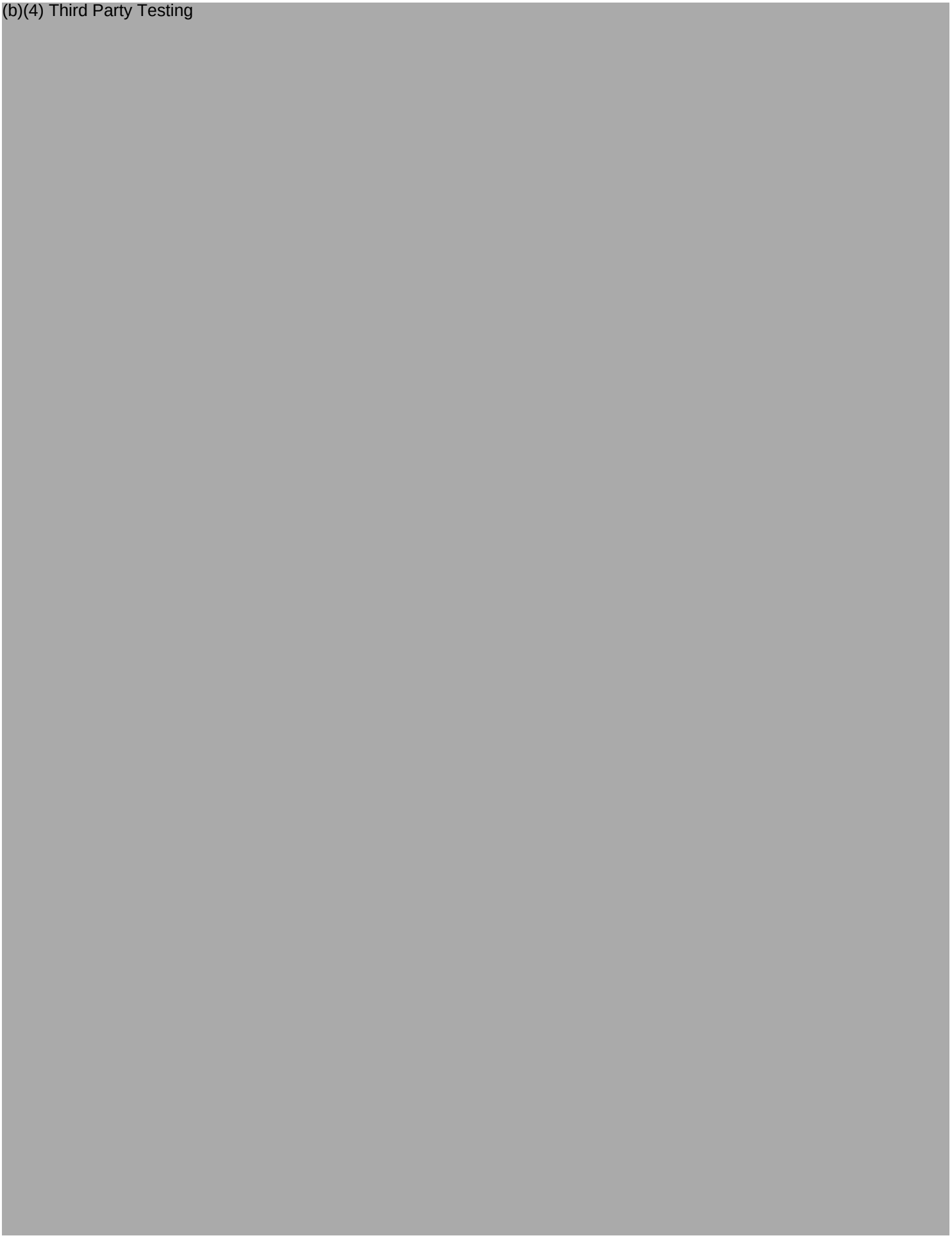

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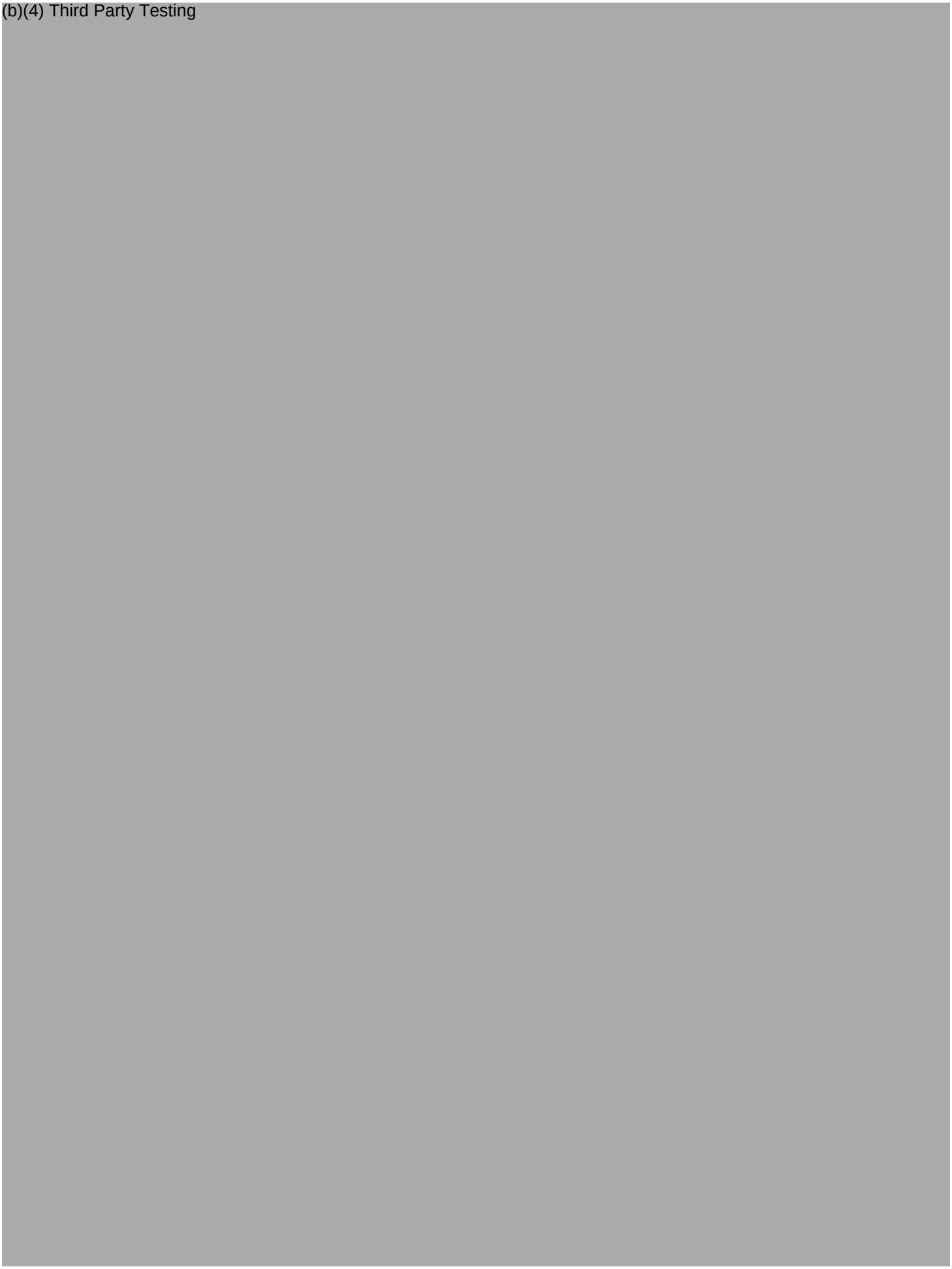

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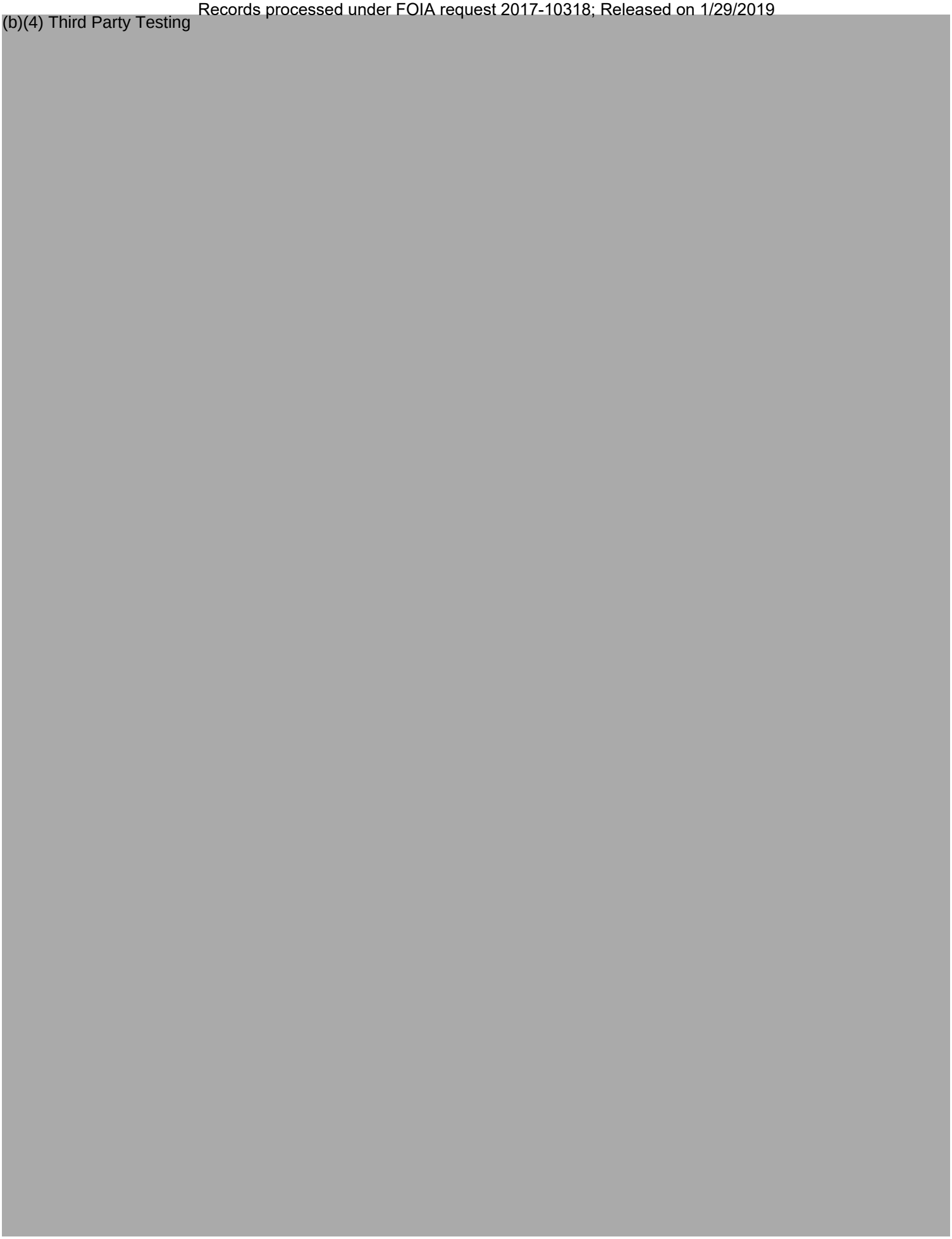

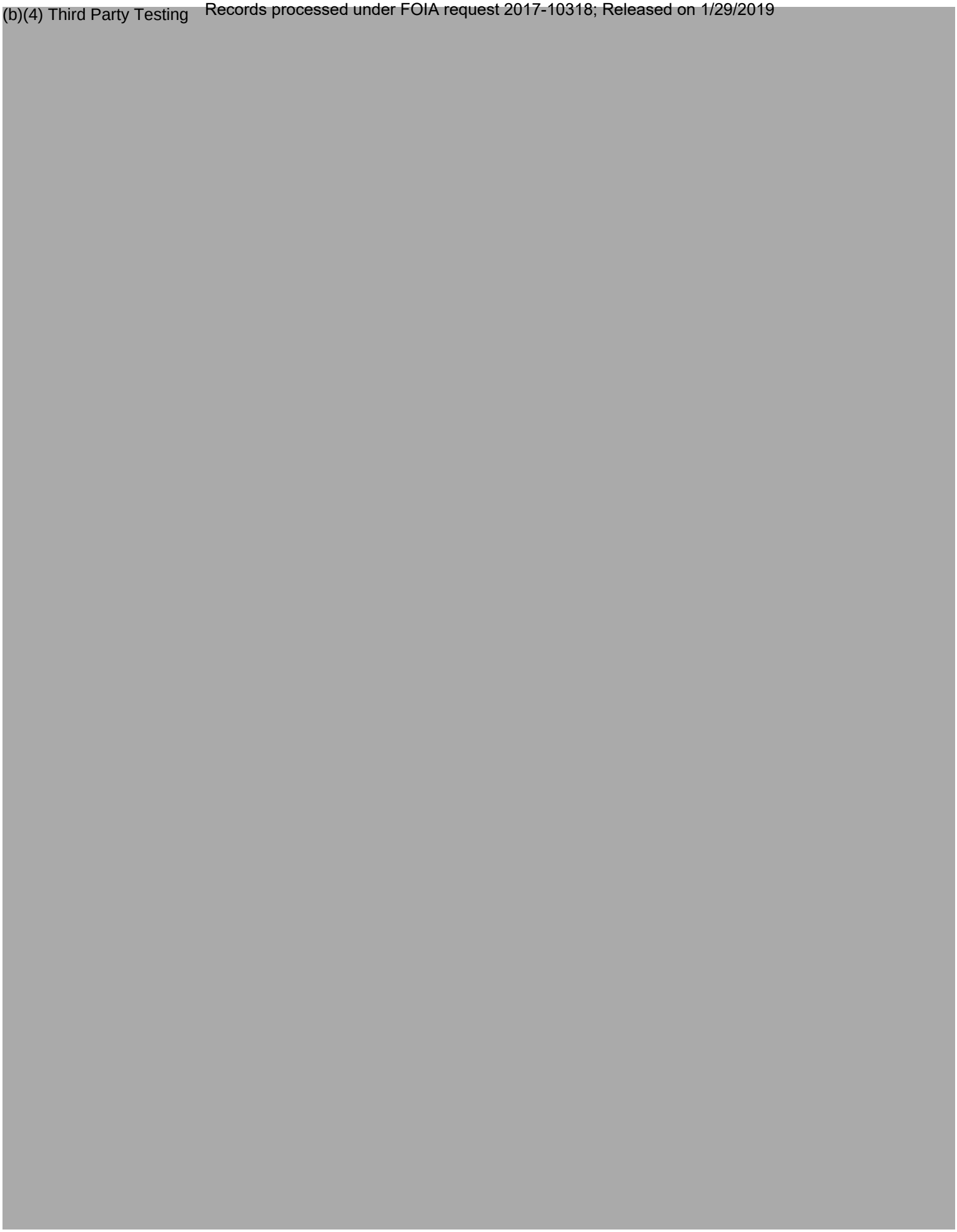

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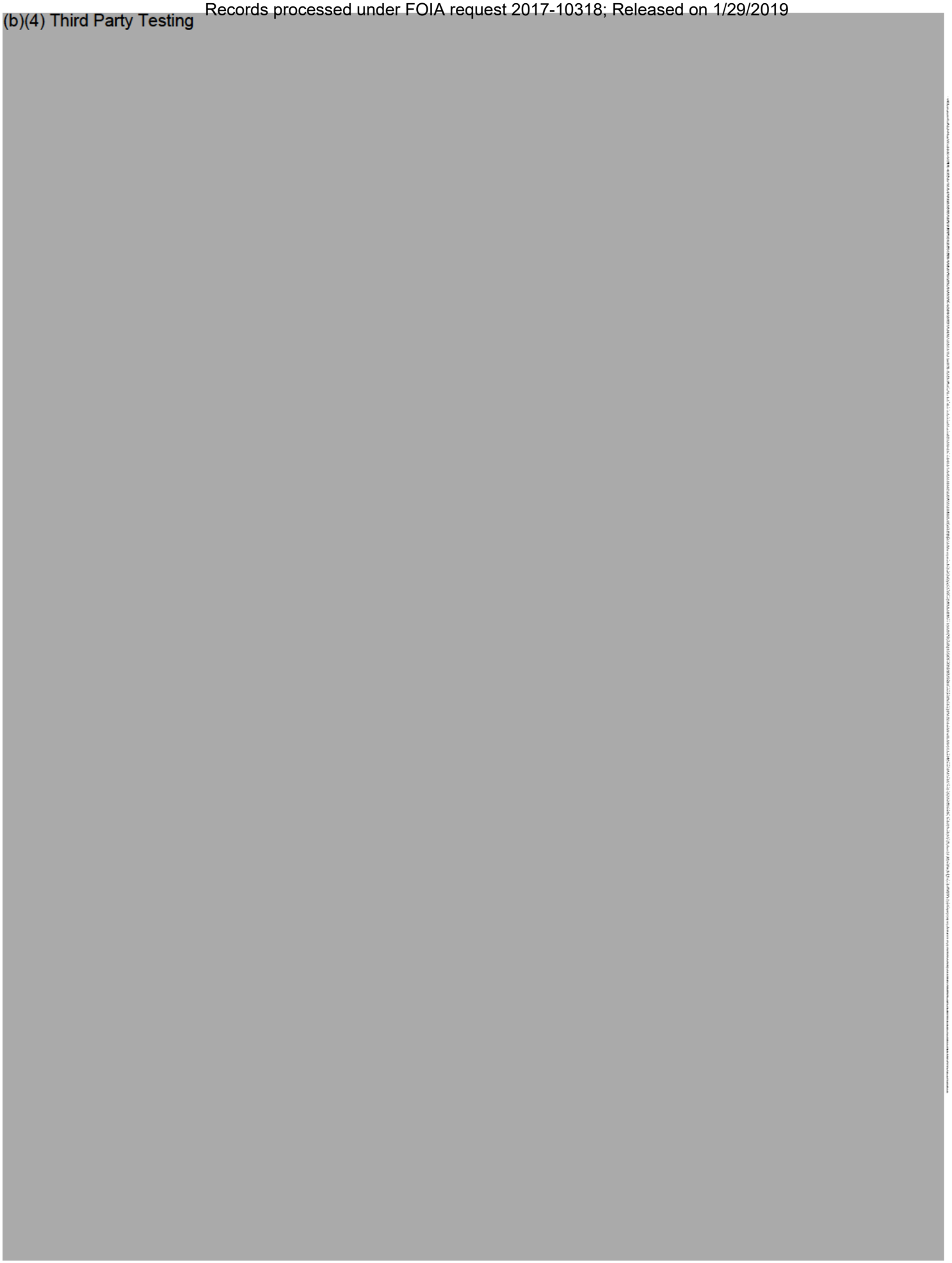

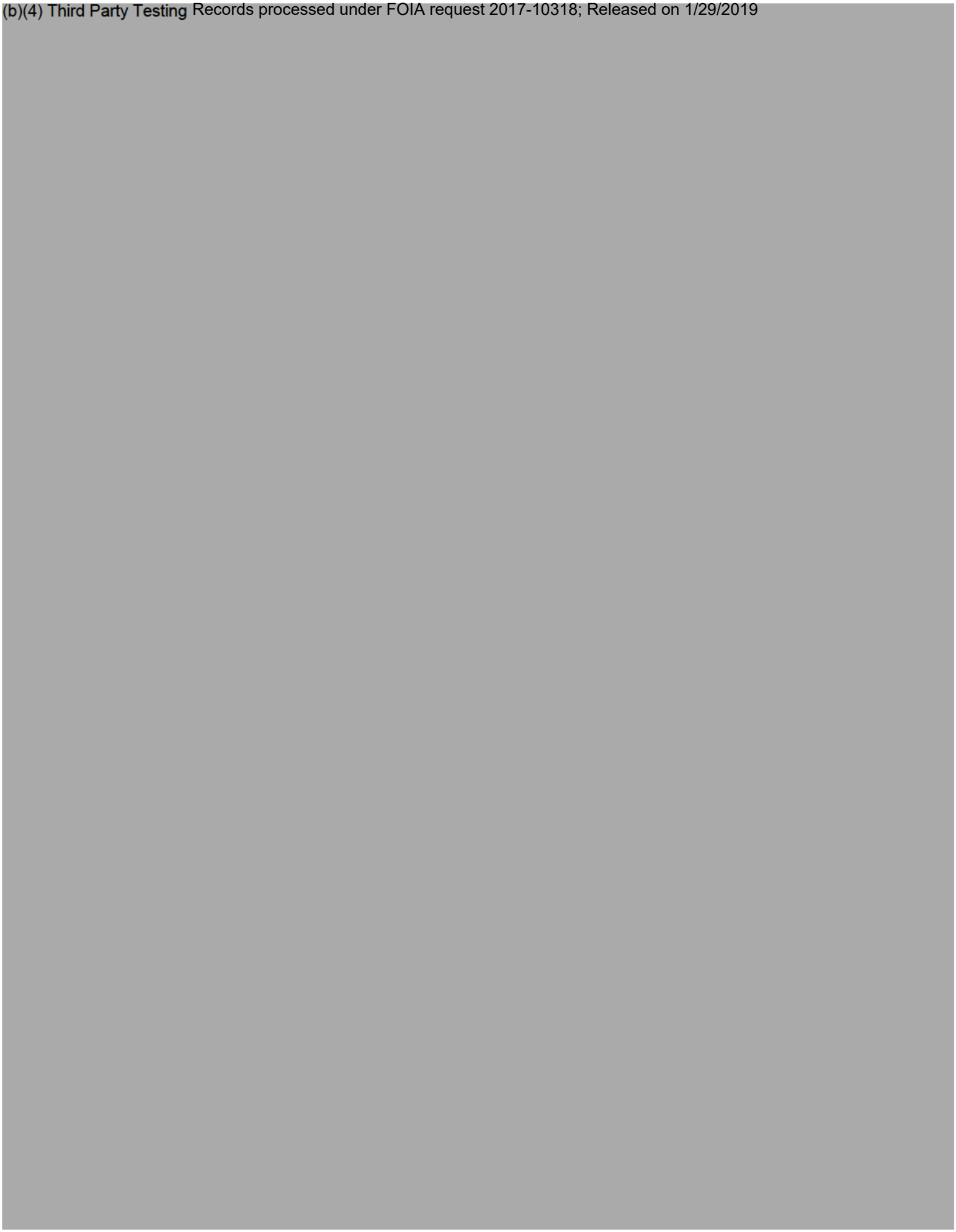

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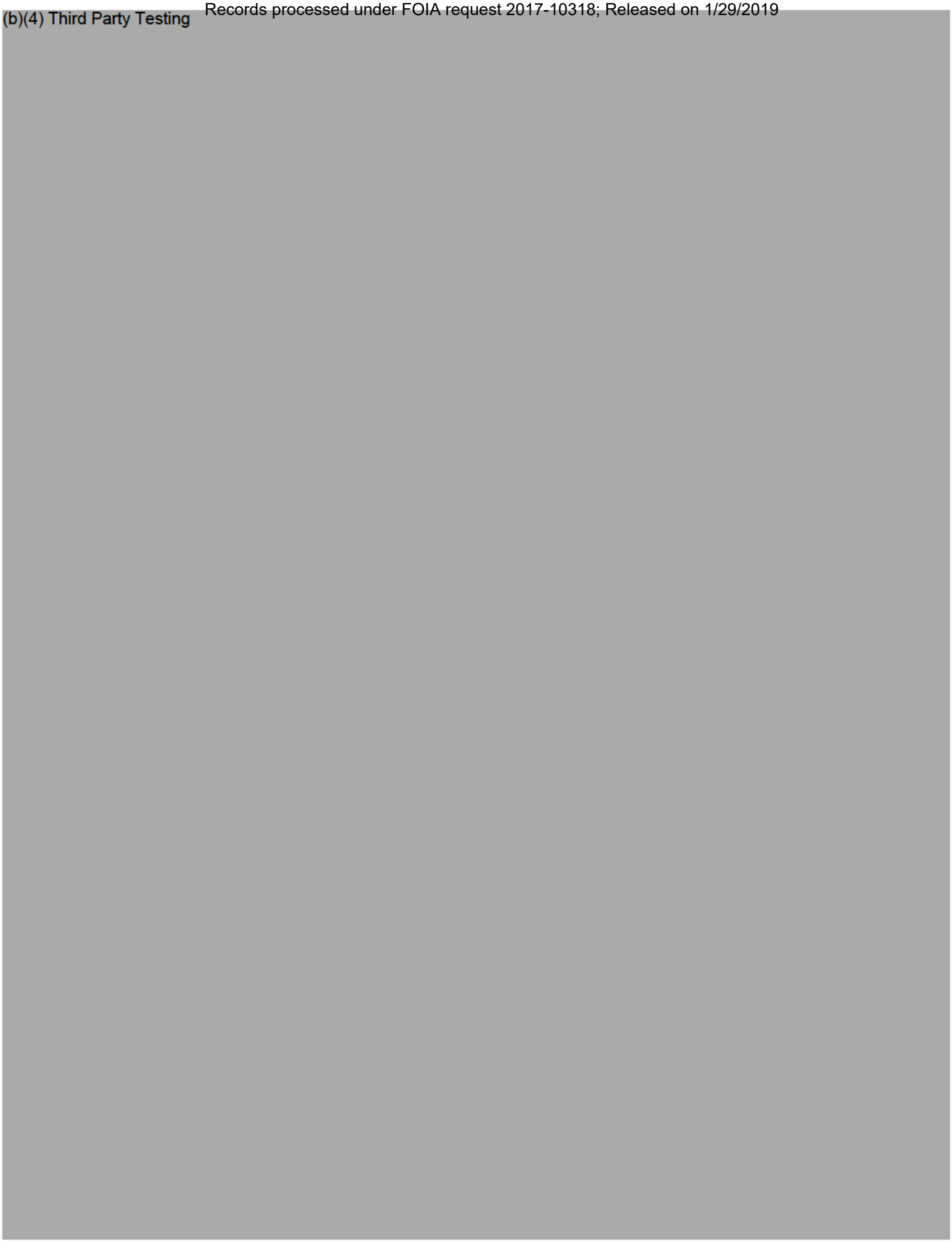

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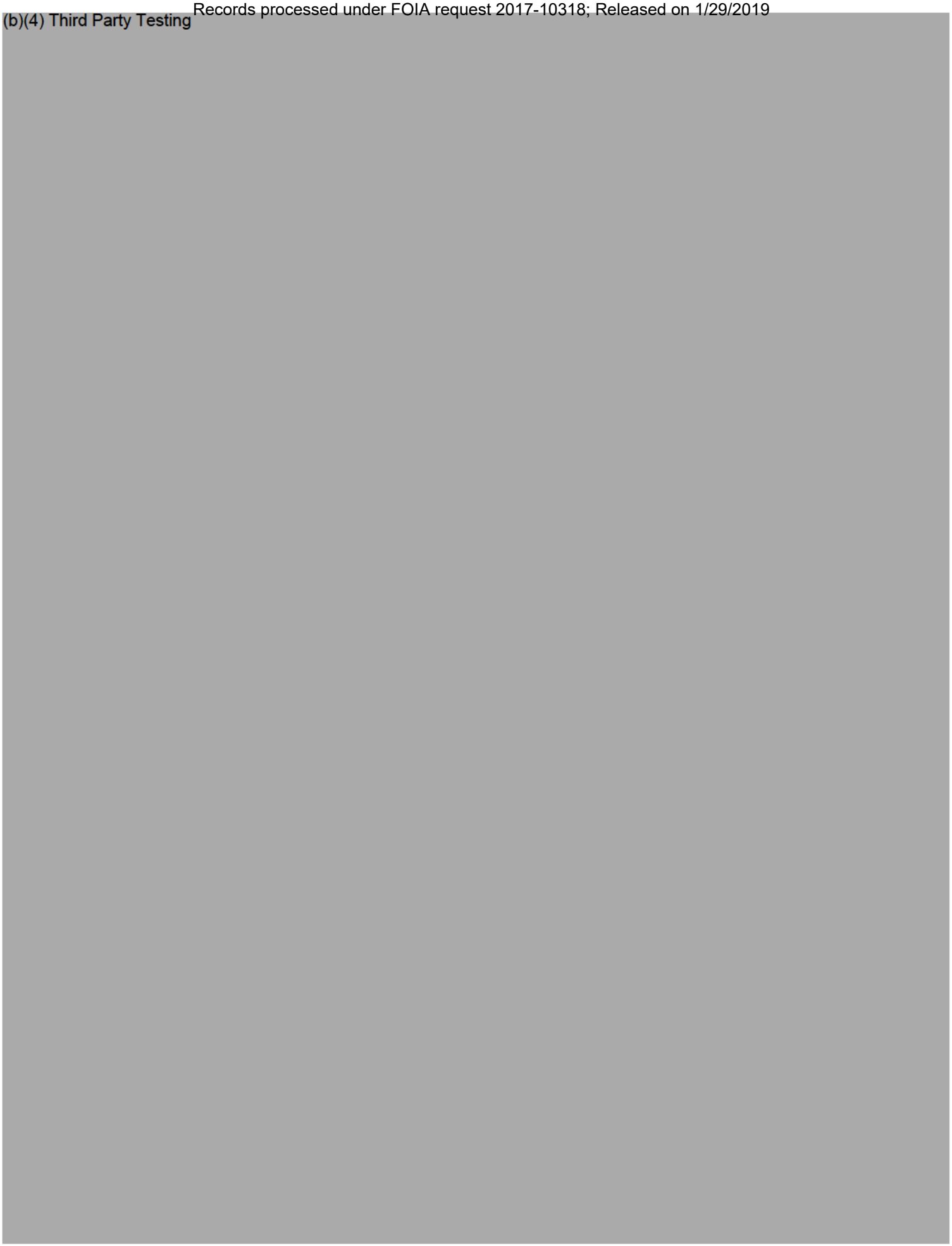

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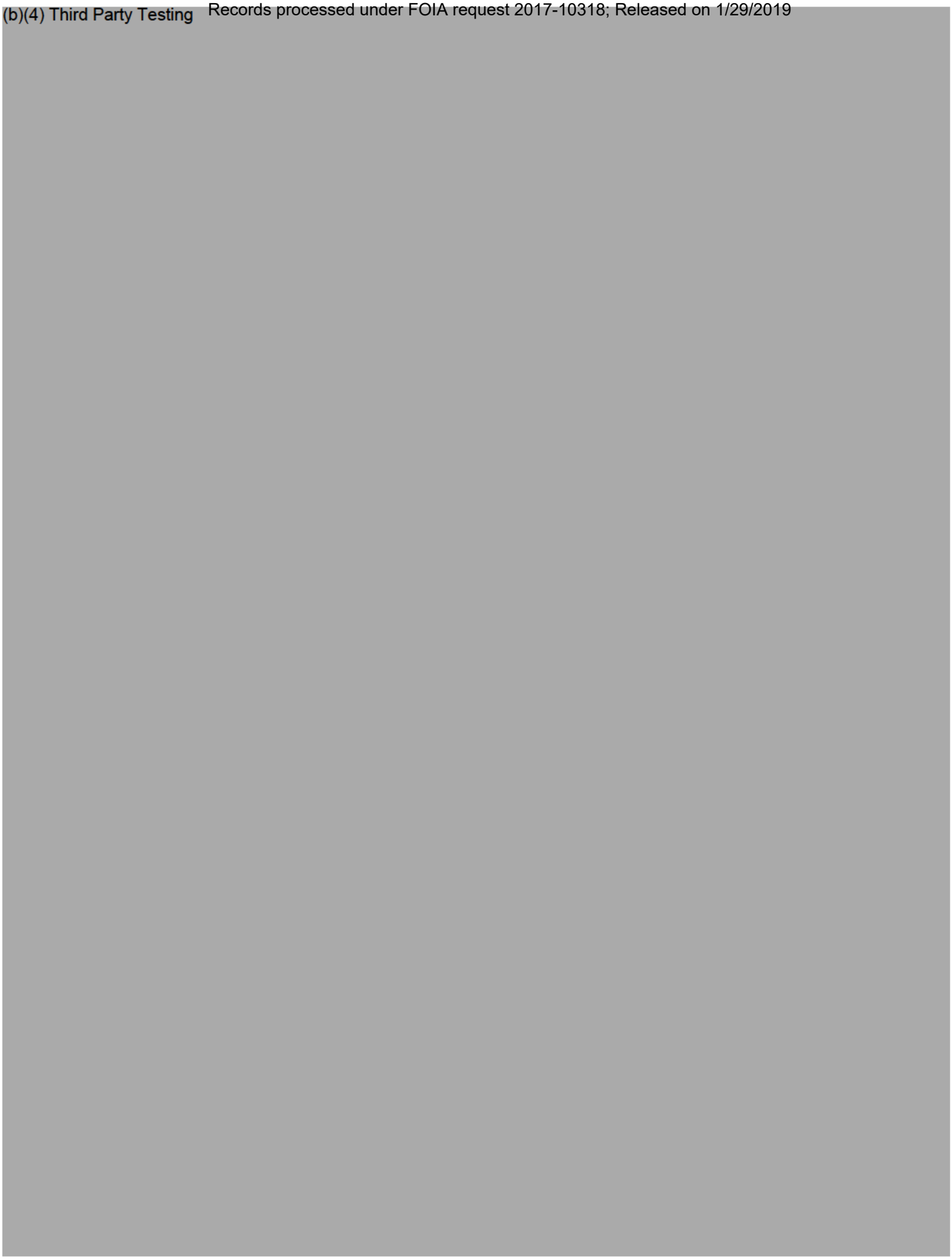

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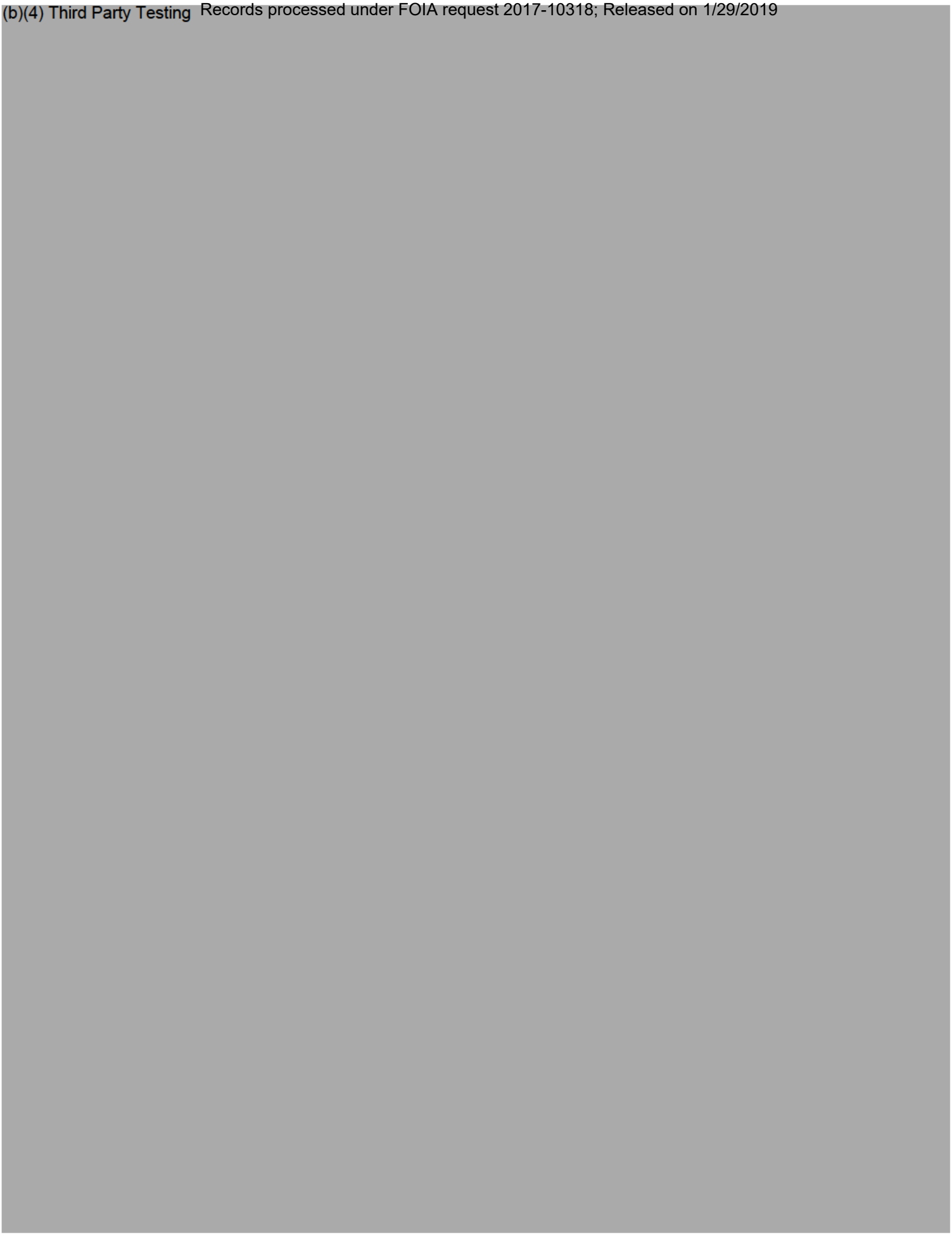

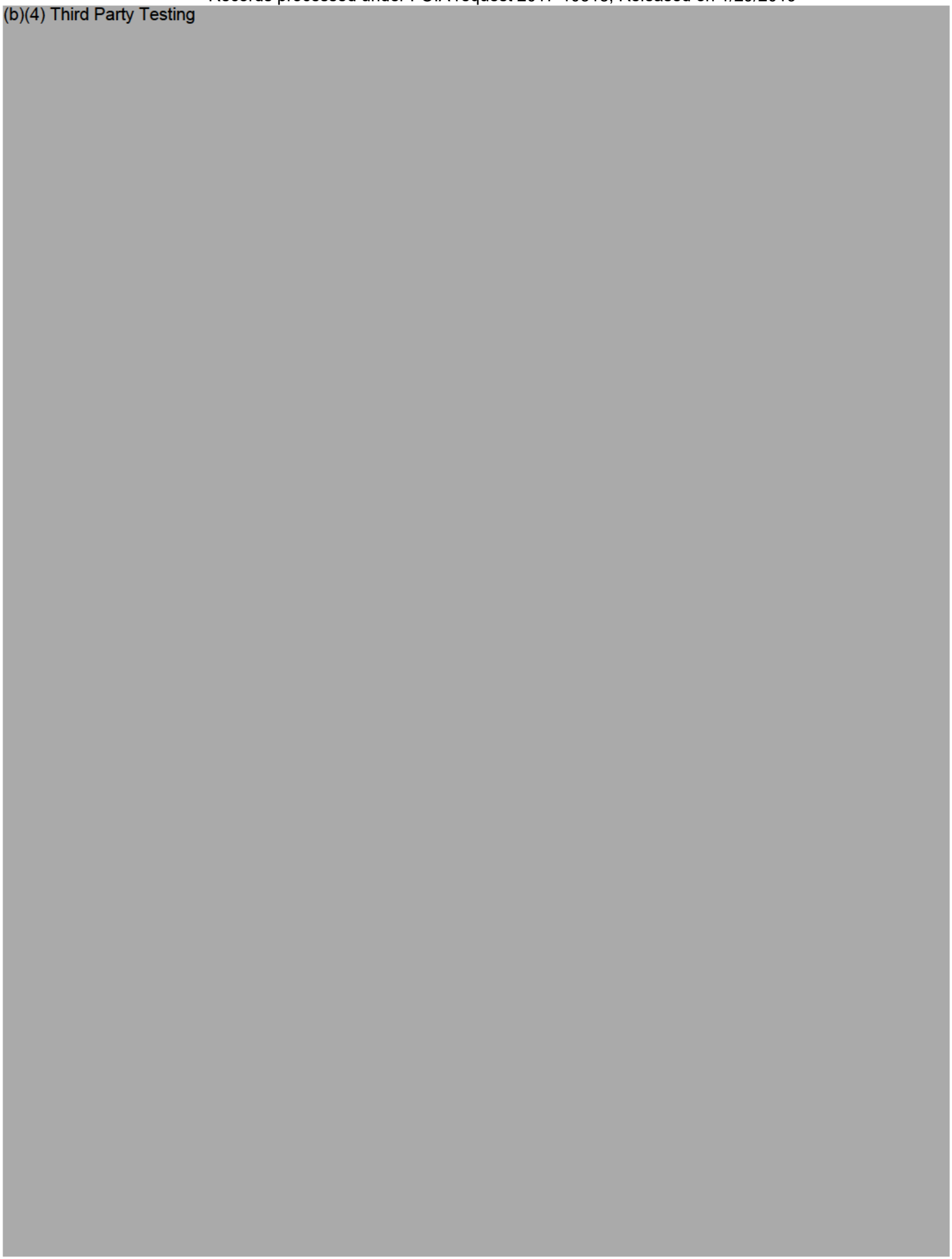

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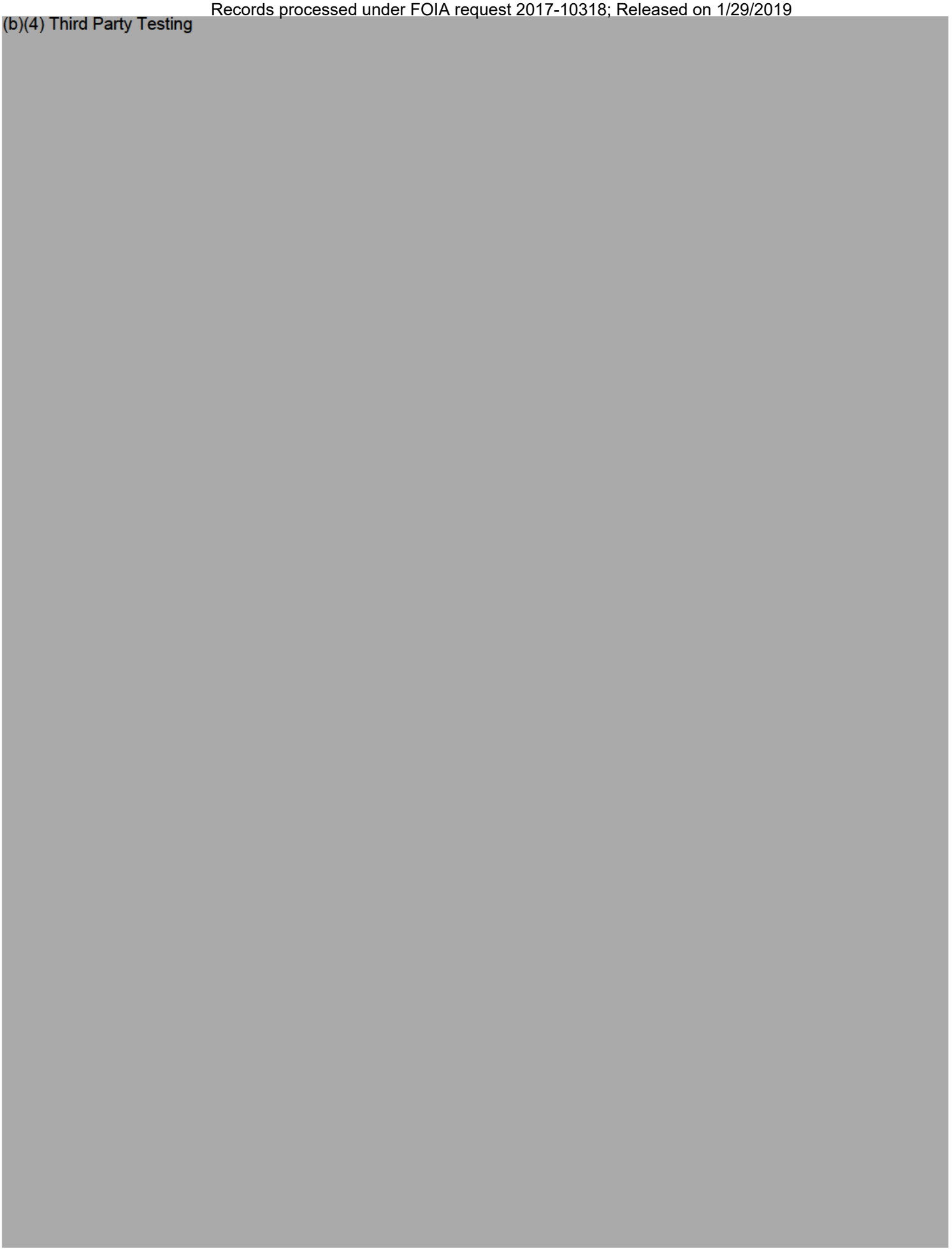

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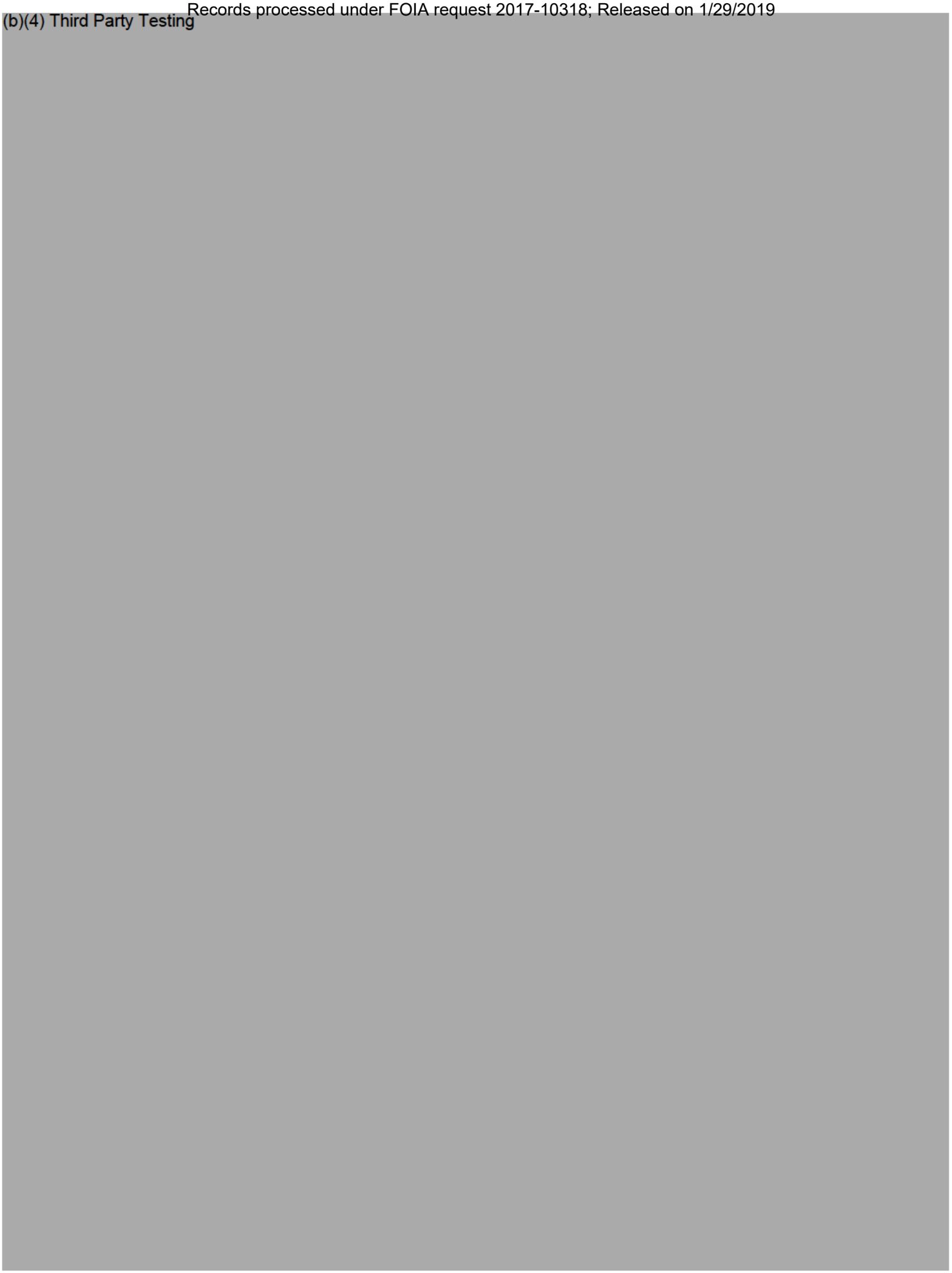

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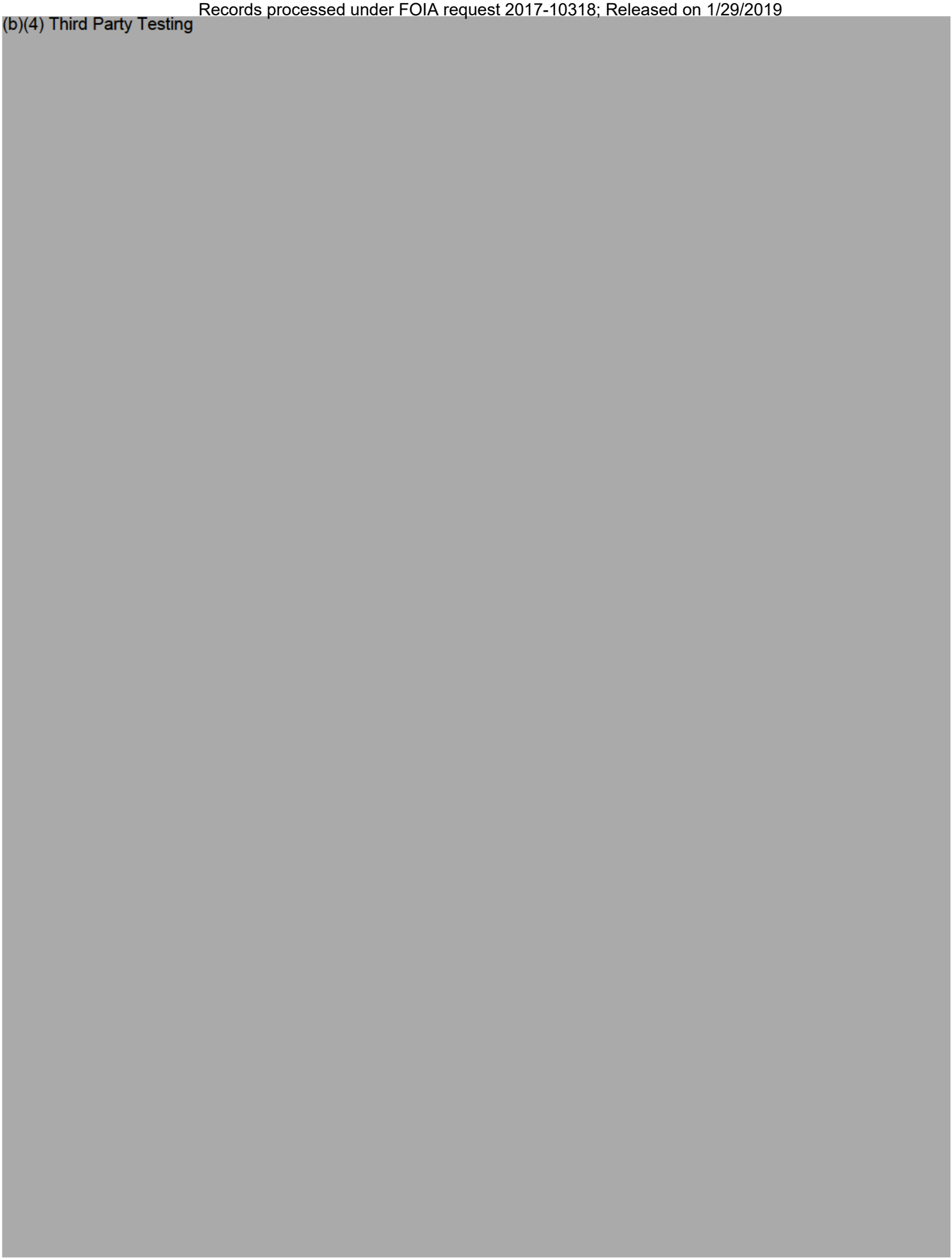

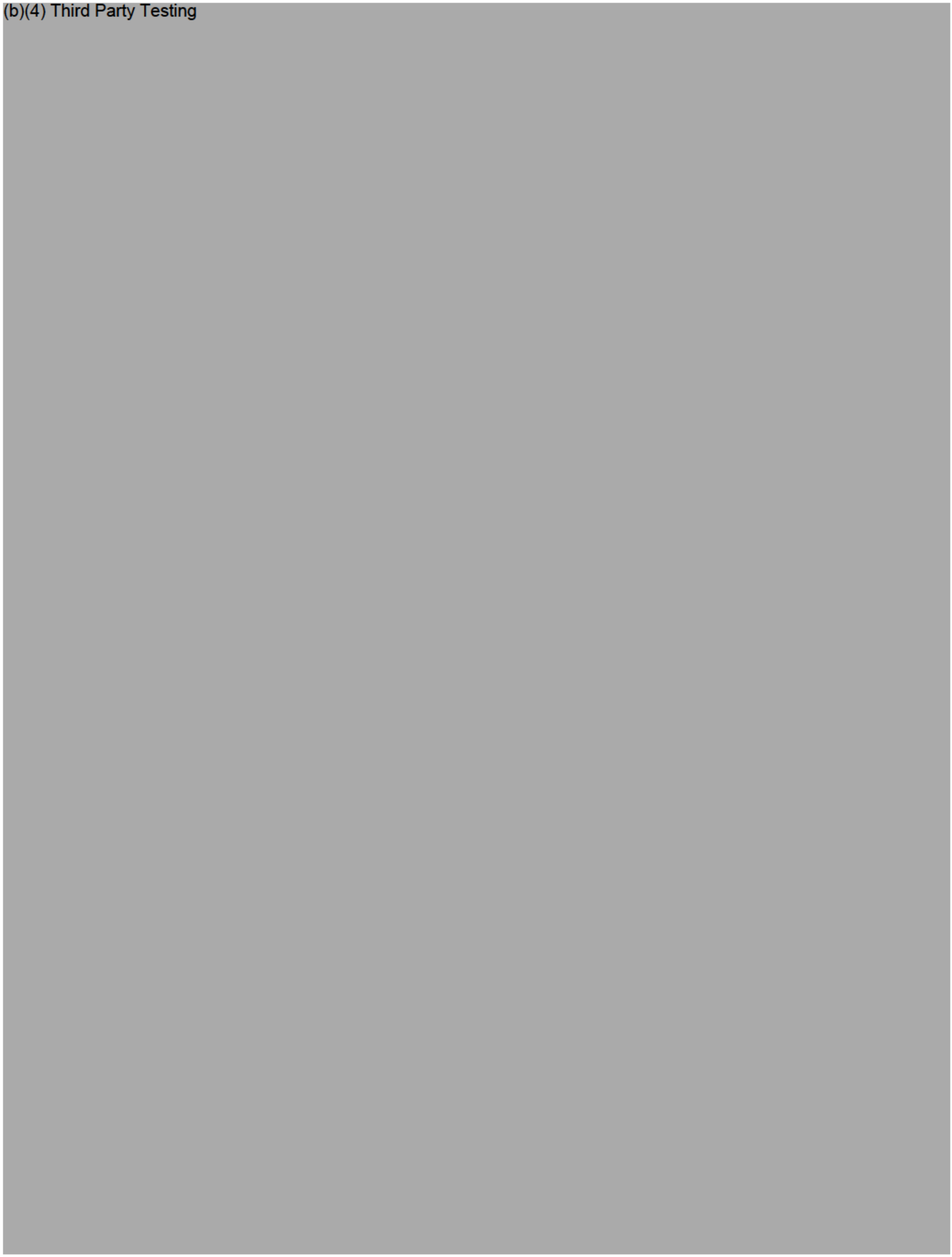

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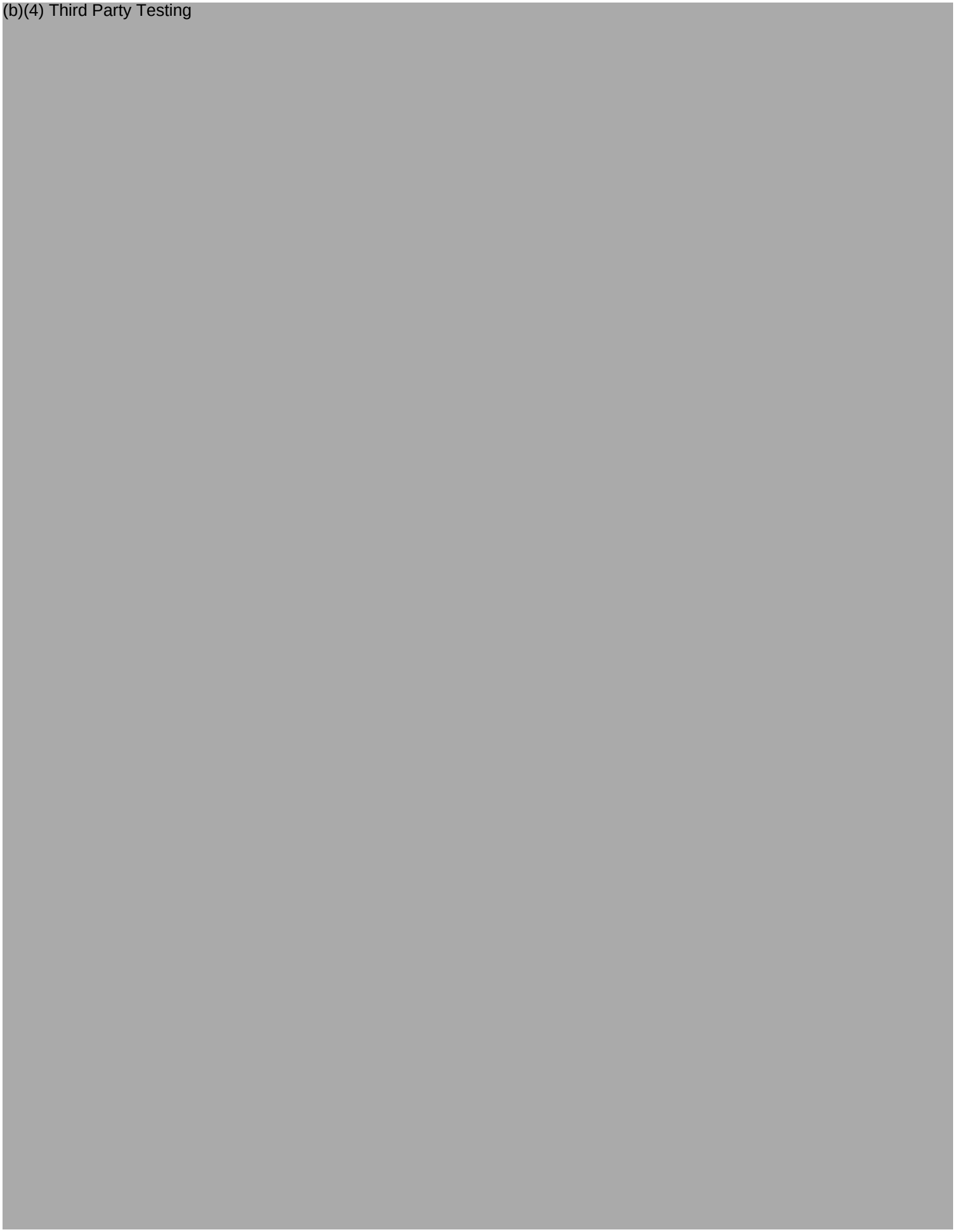

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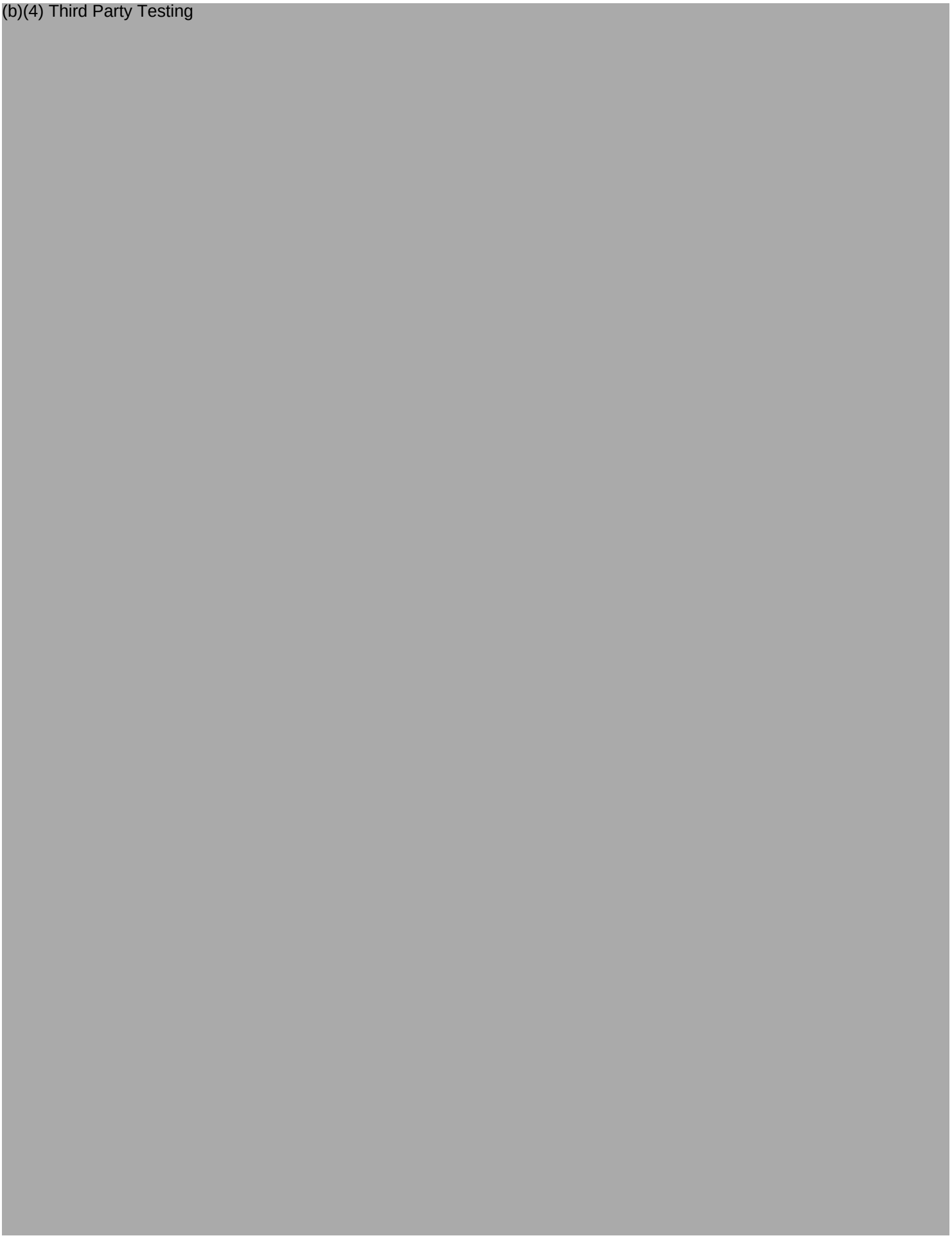

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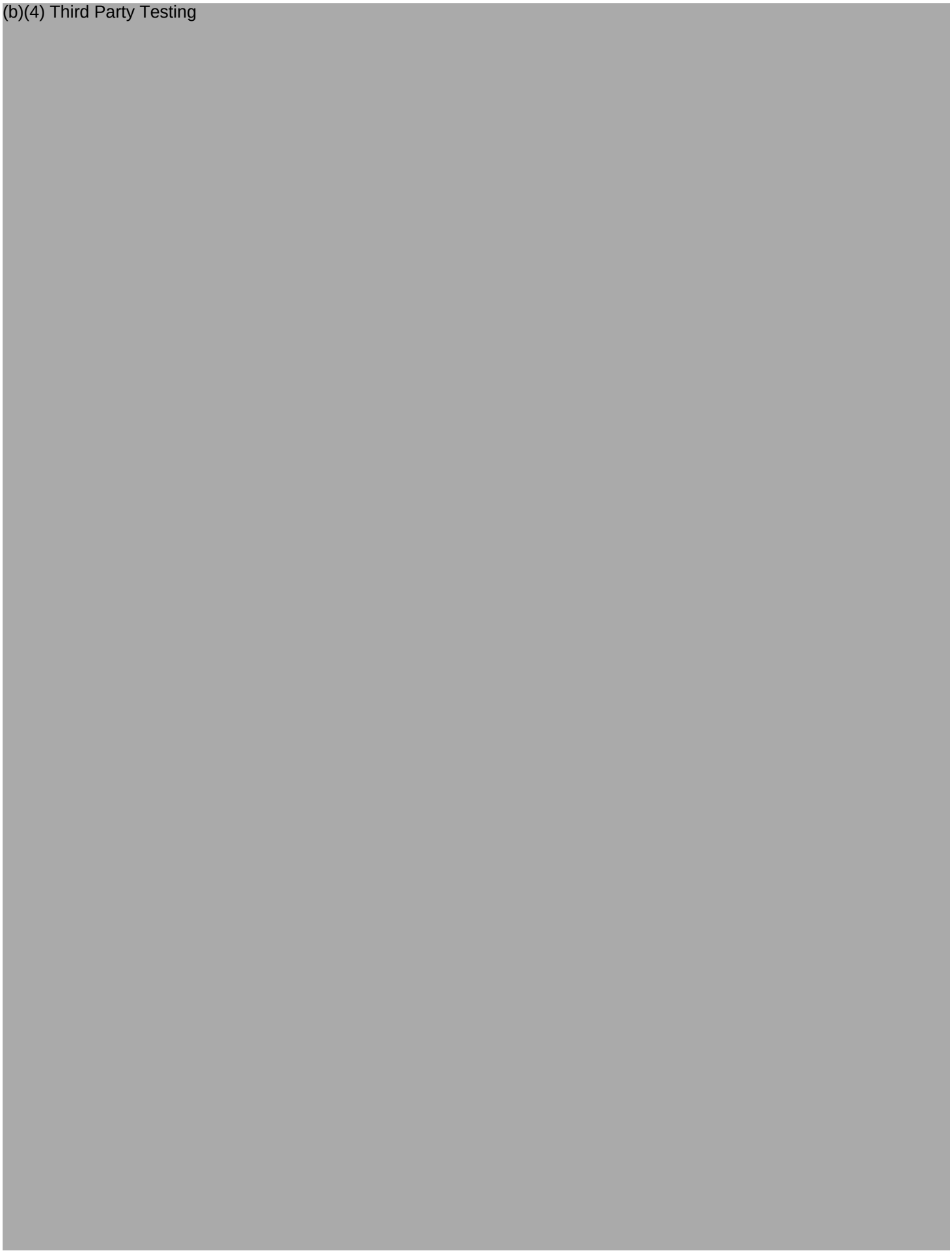


APPENDIX 8
PERFORMANCE TESTING - BENCH

Provided in this appendix are the following test reports discussed within this 510(k) submission:

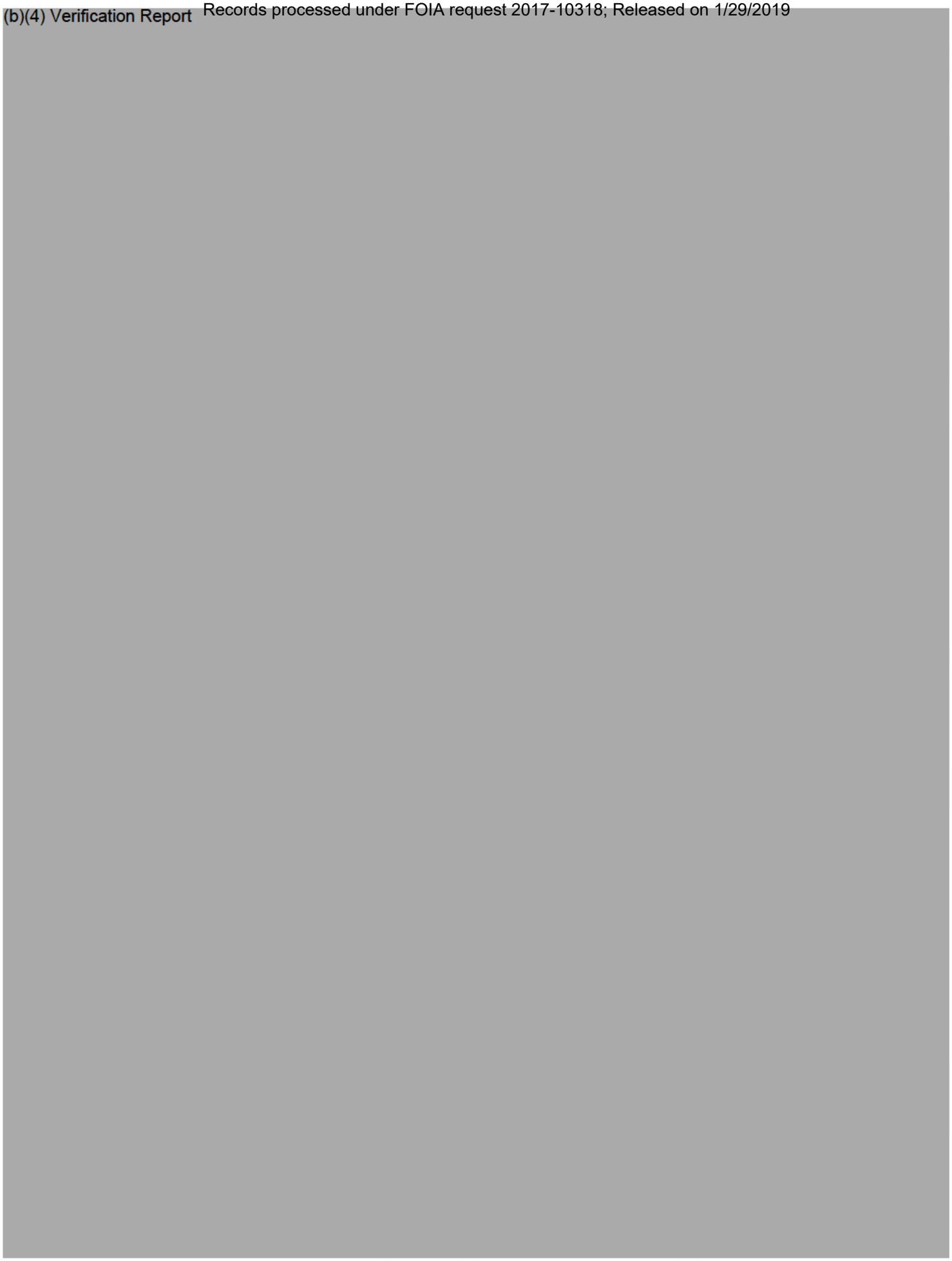
(b) (4)

(b)(4) Verification Report

AliveCor®

444 Castro Street, Suite 600
Mountain View, CA. 94041

(b)(4) Verification Report



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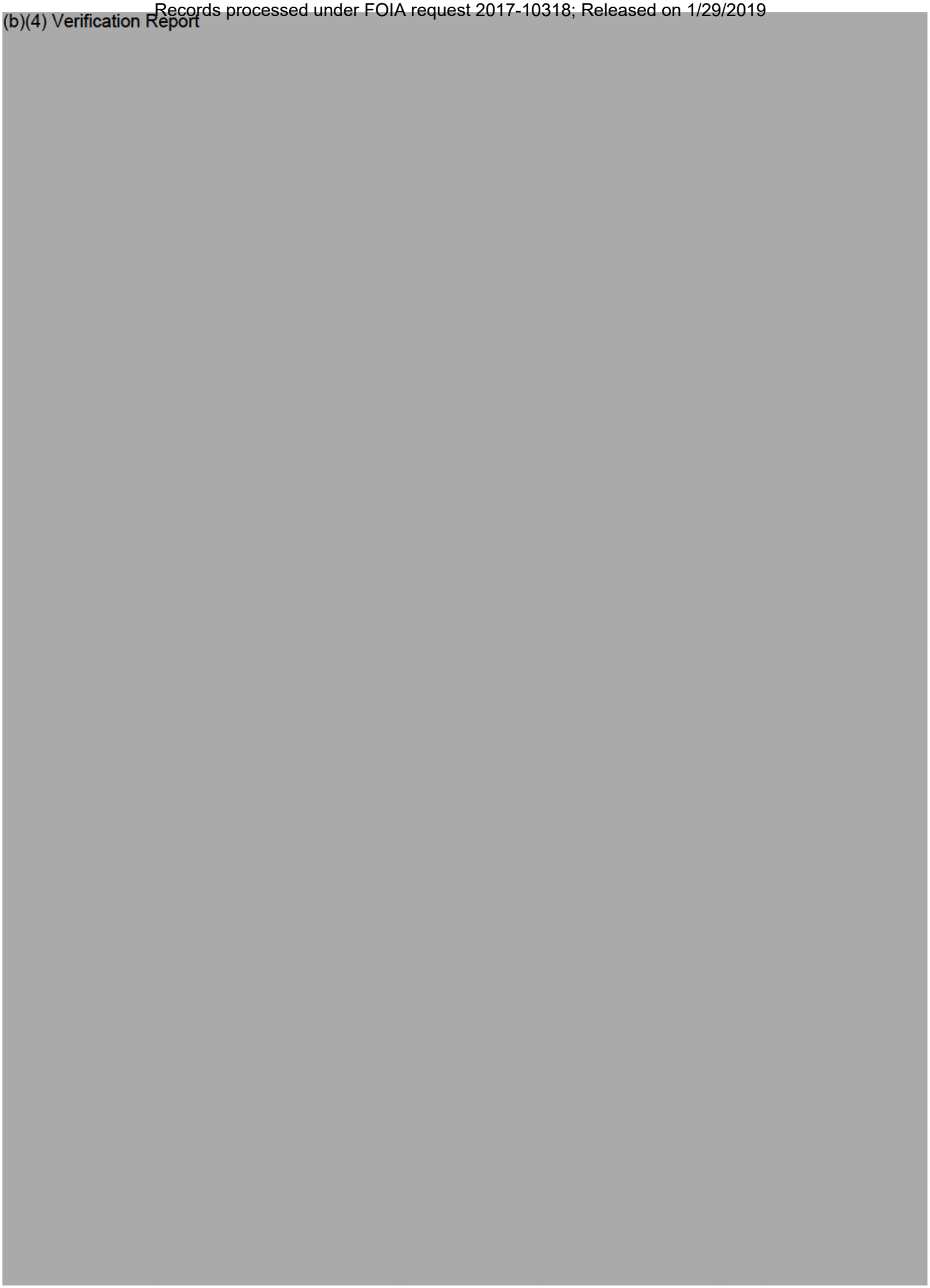
(b)(4) Verification Report



(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

AliveCor Watchband ECG

Fabrication and Assembly Information

jbeck@alivecor.com

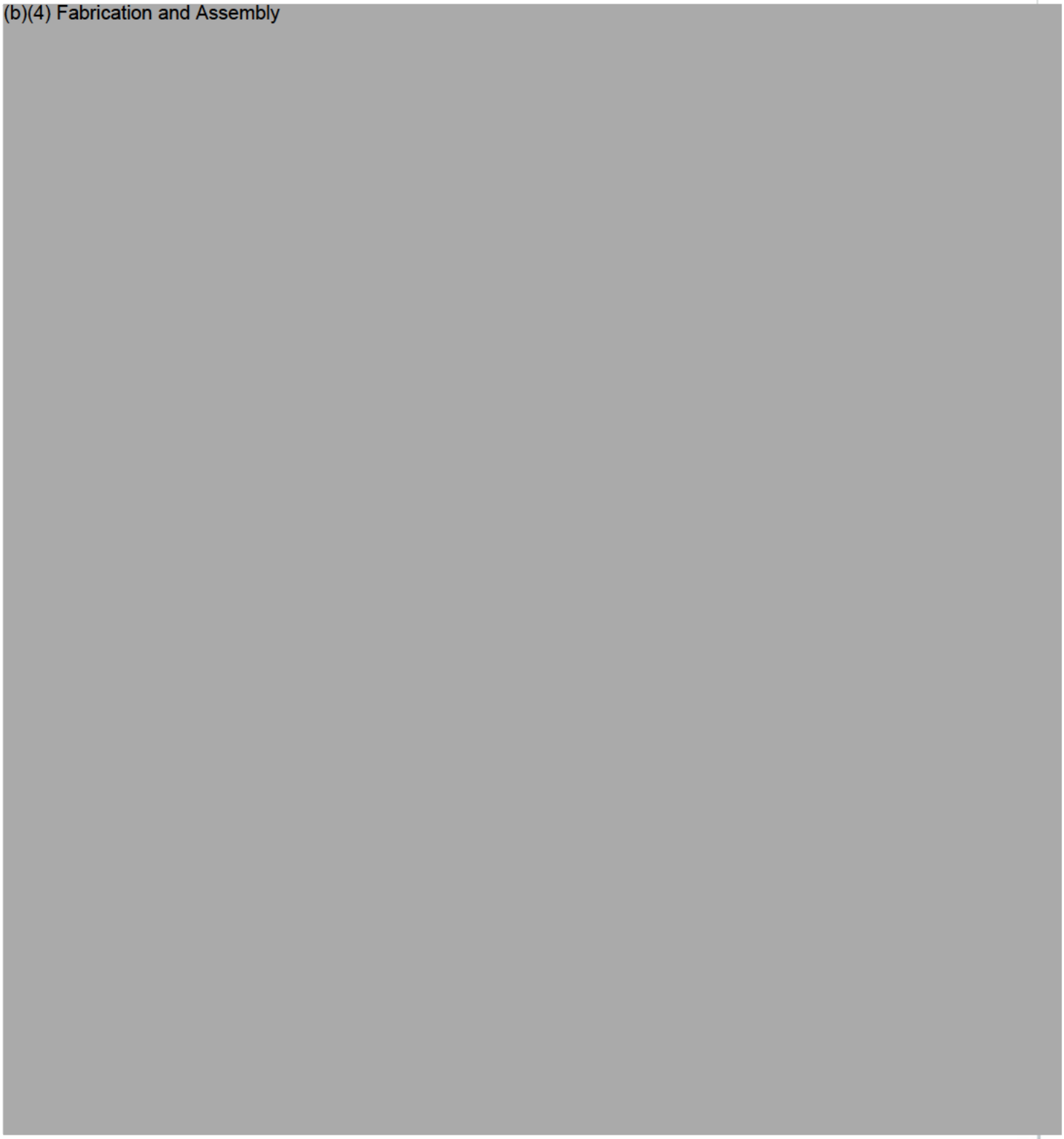
(b)(4) Fabrication and Assembly

Components

(b)(4) Fabrication and Assembly

(b)(4) Fabrication and Assembly

(b)(4) Fabrication and Assembly



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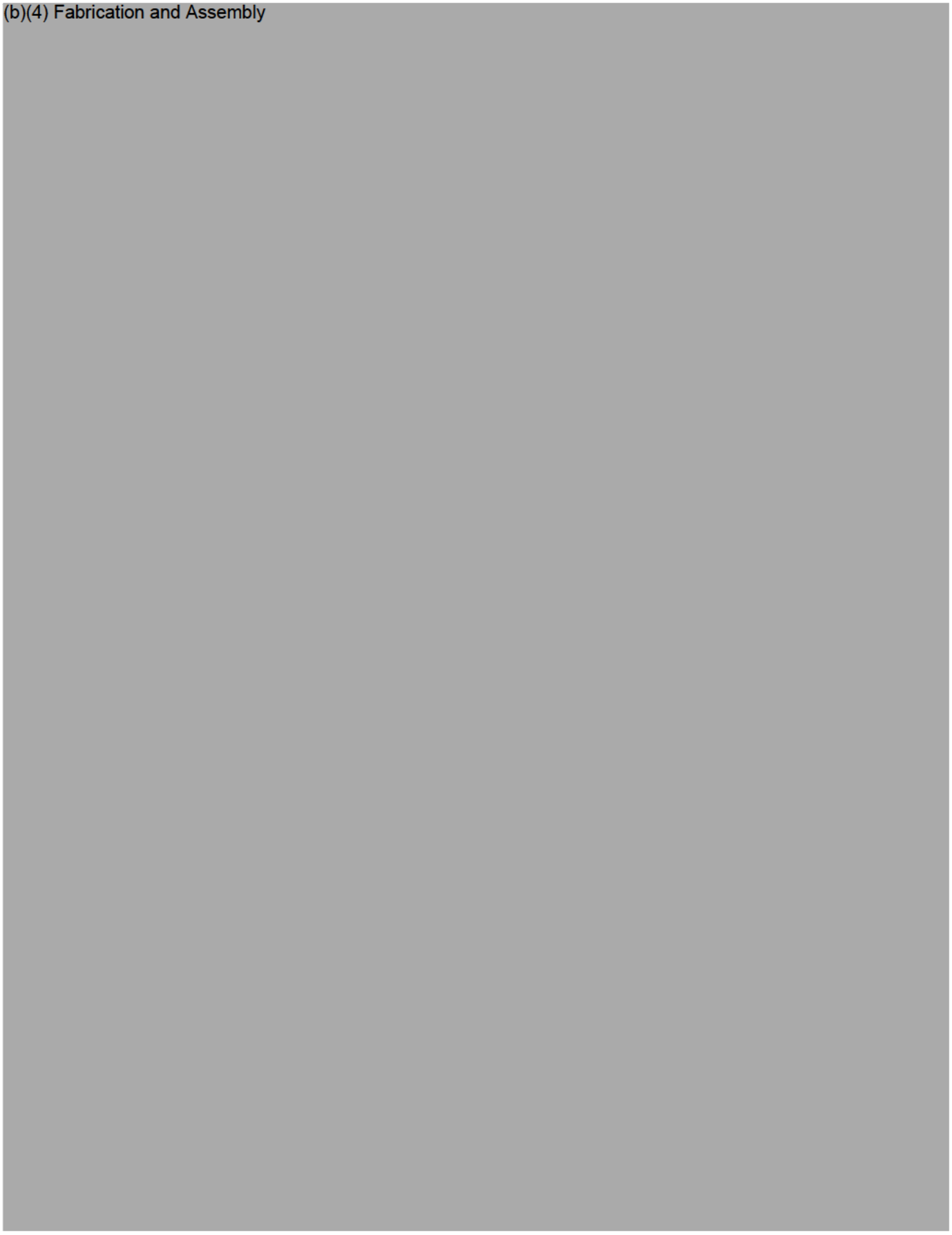

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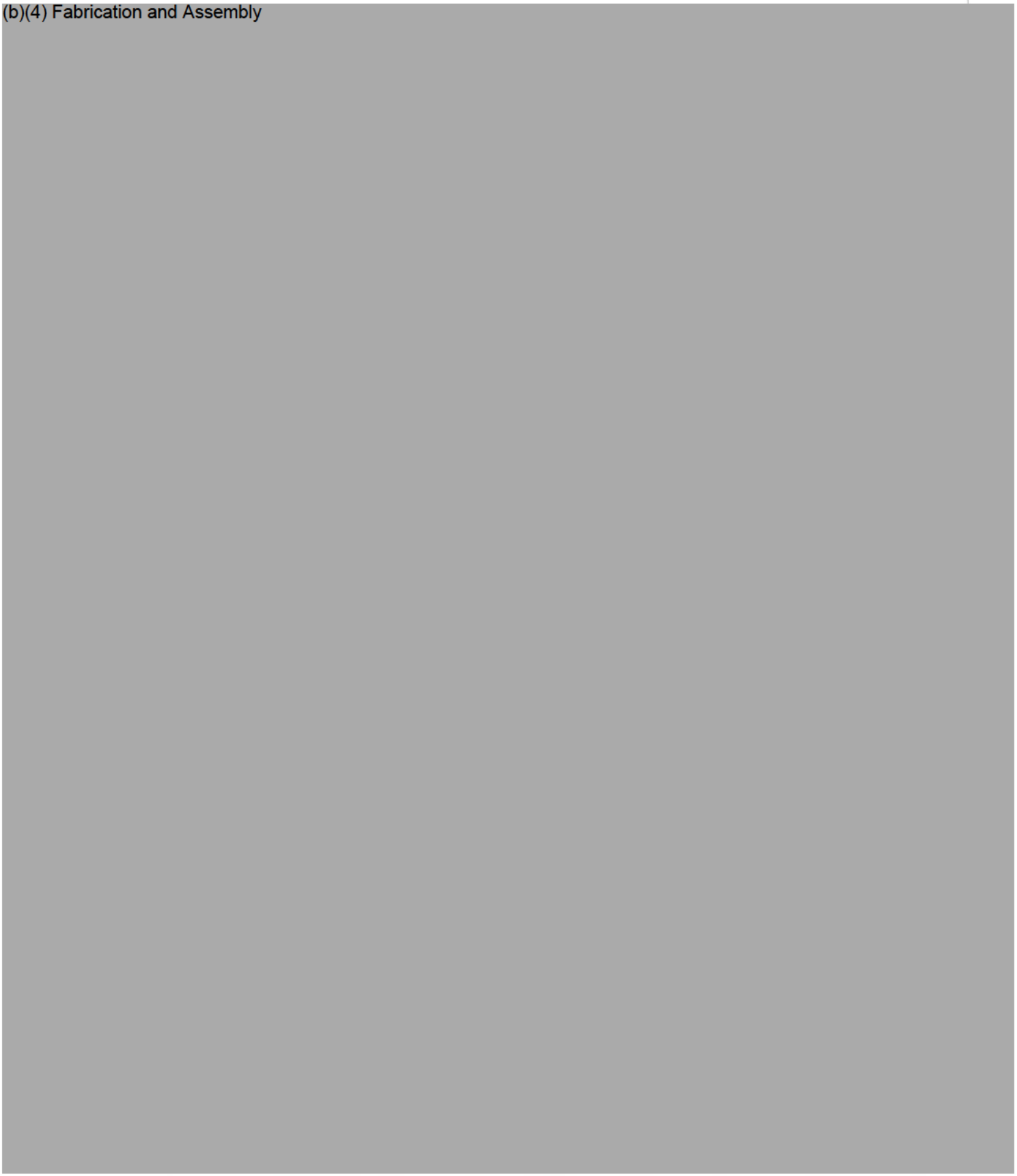

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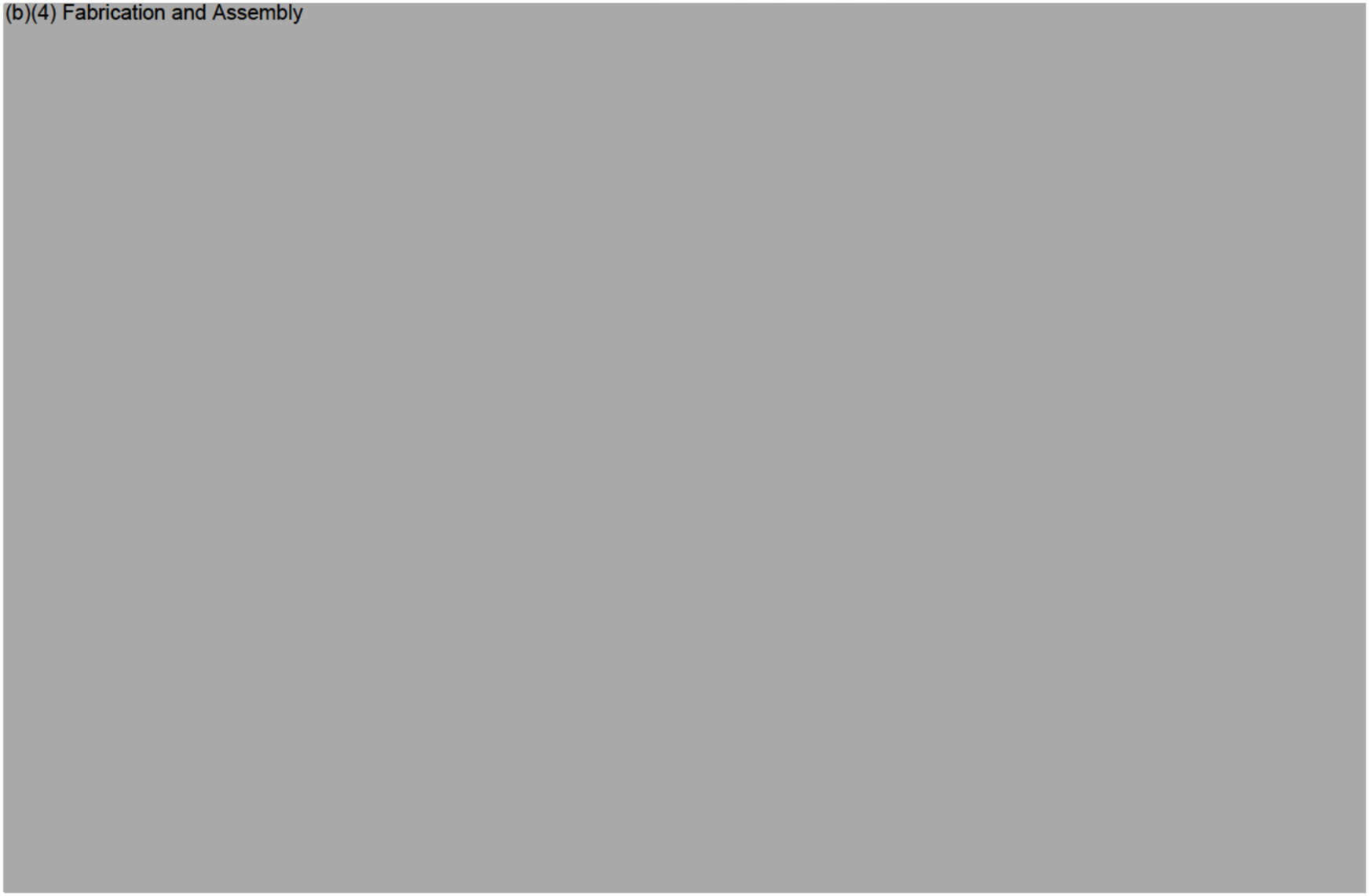

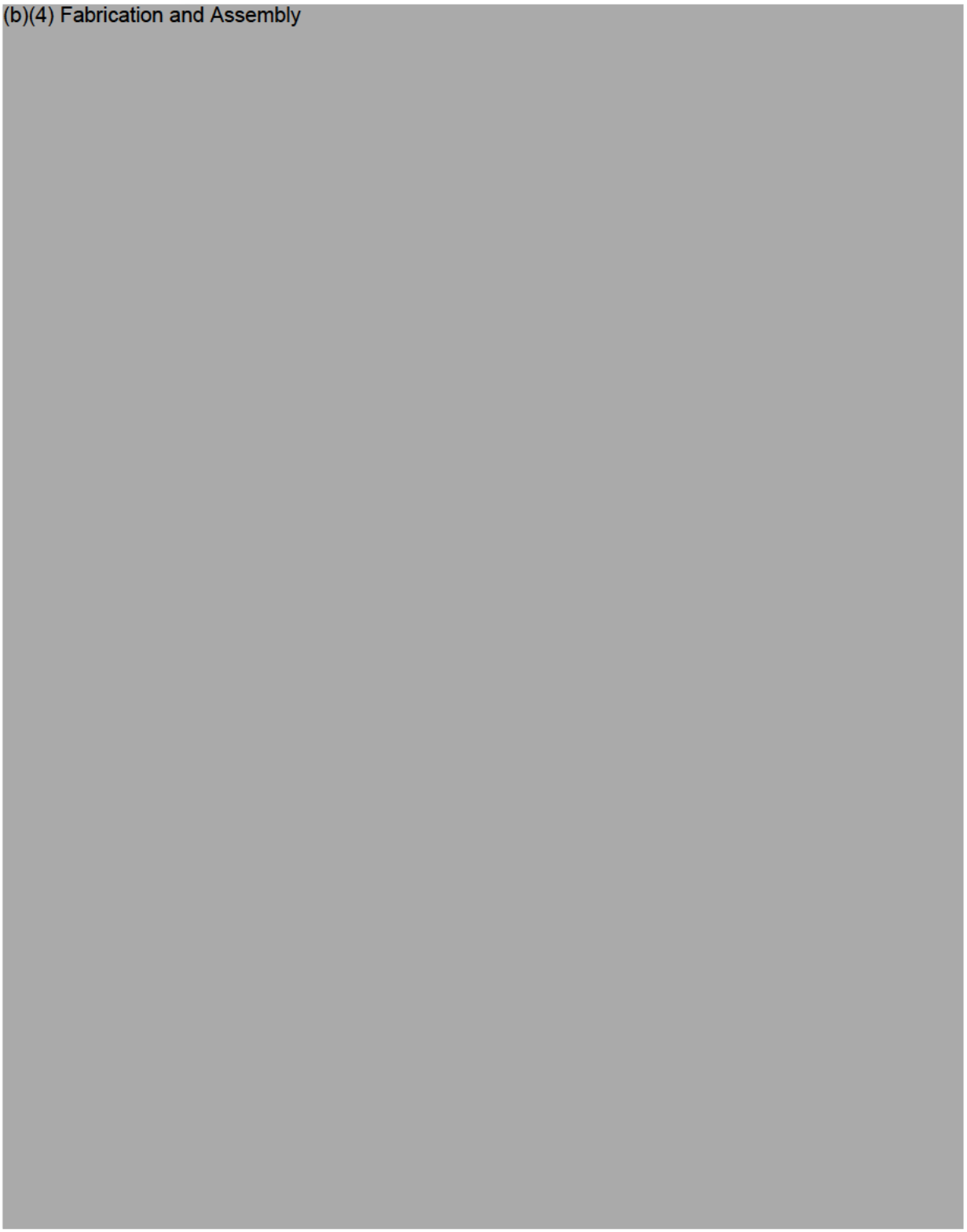

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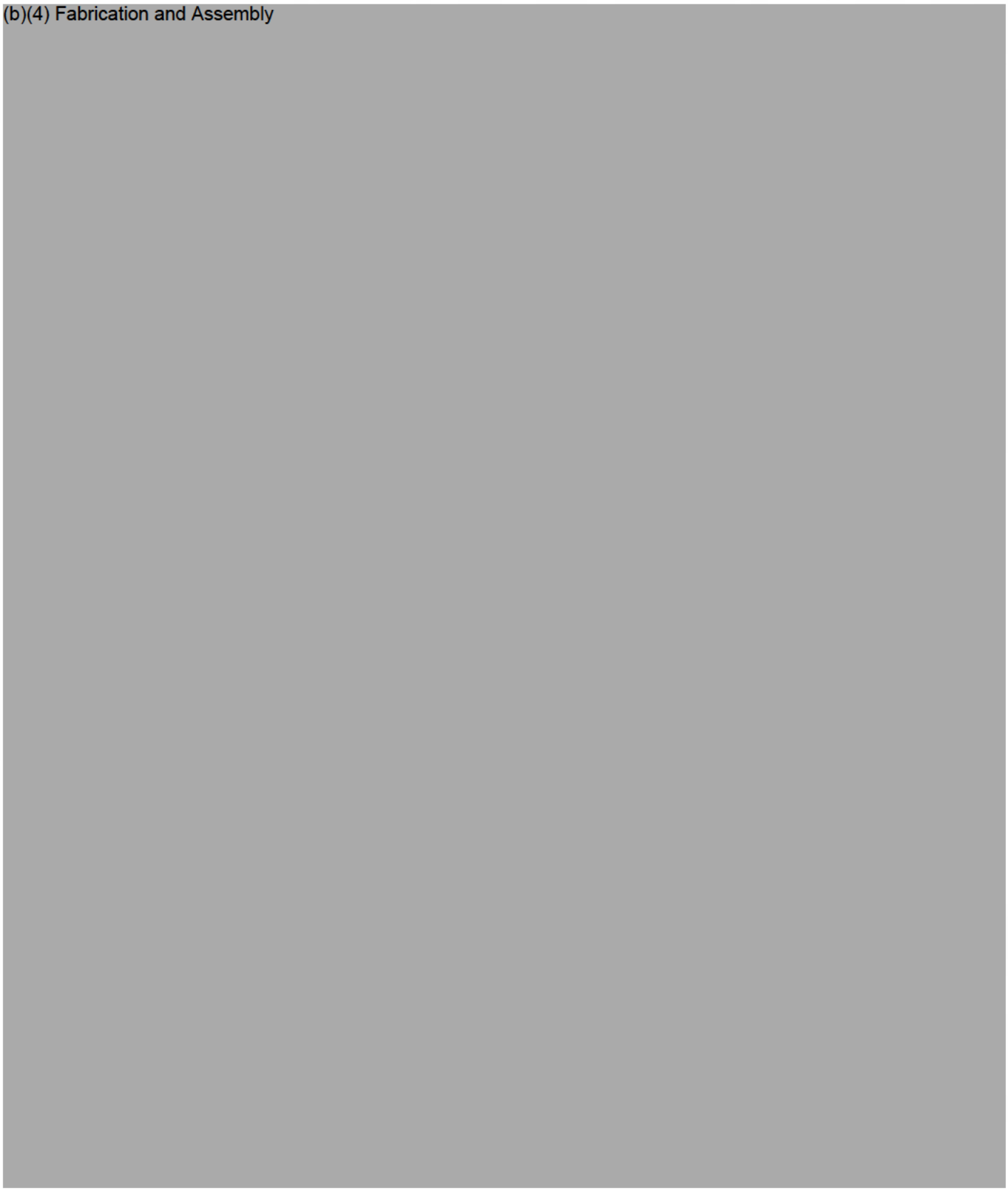

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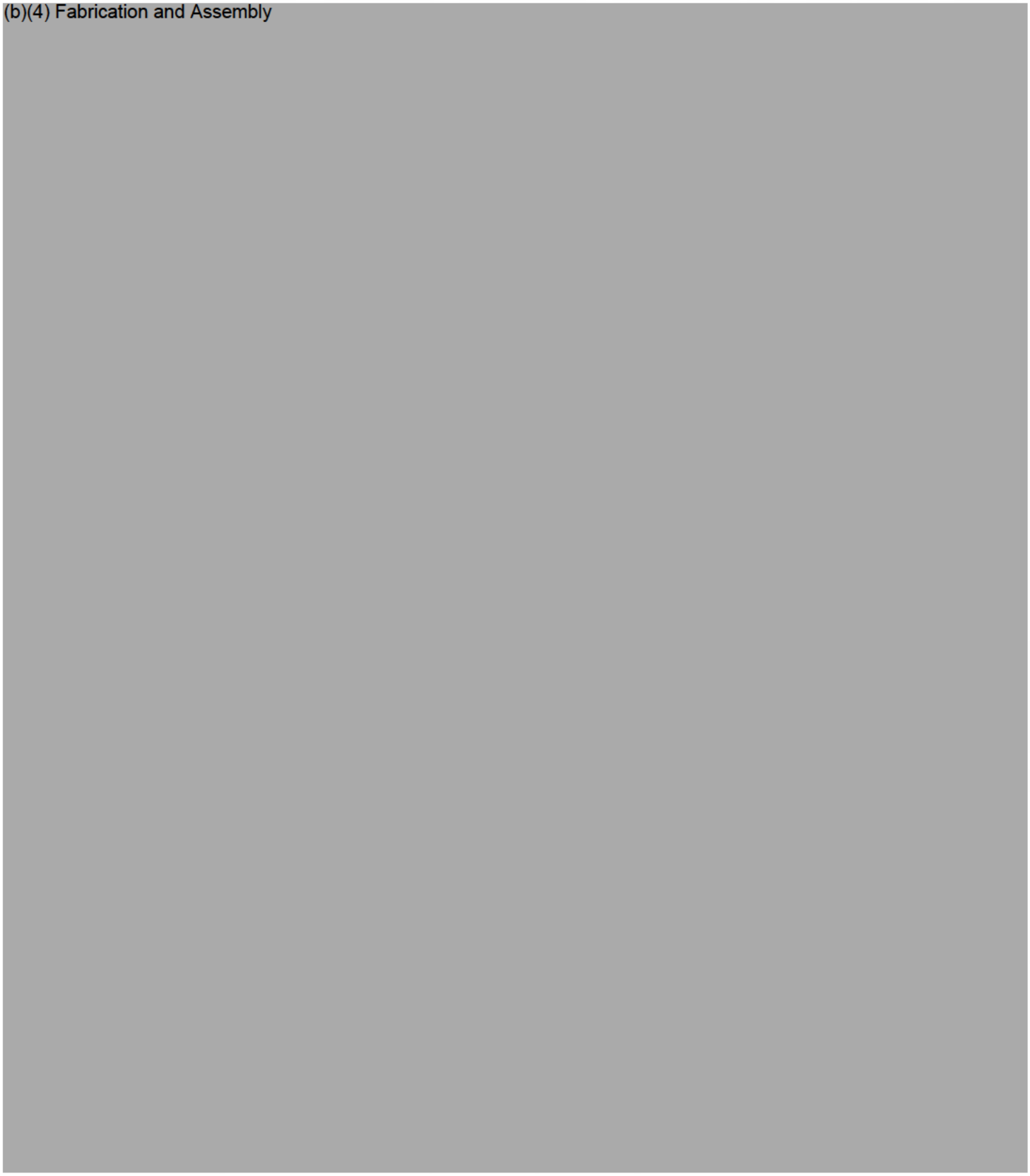
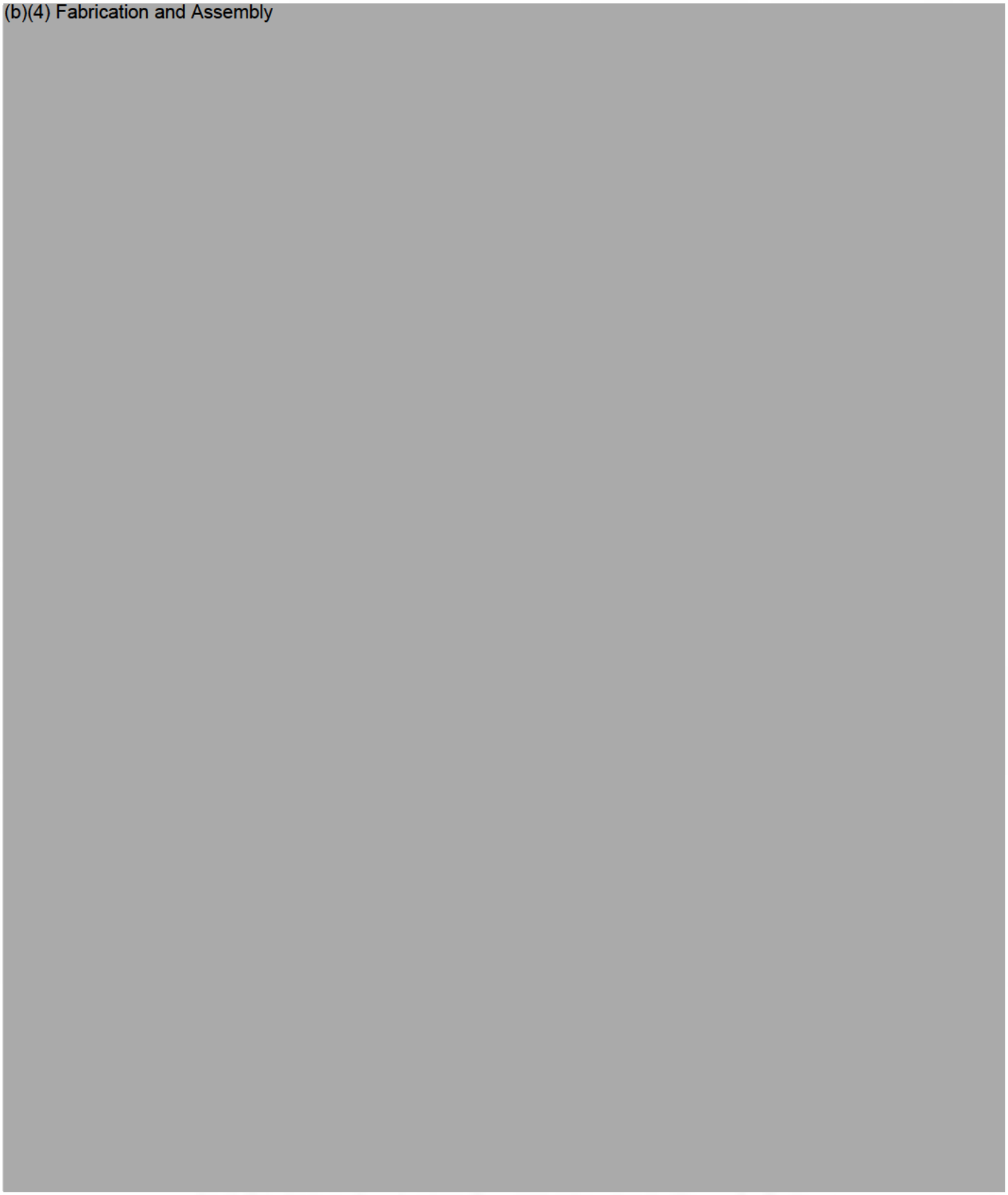


(b)(4) Fabrication and Assembly



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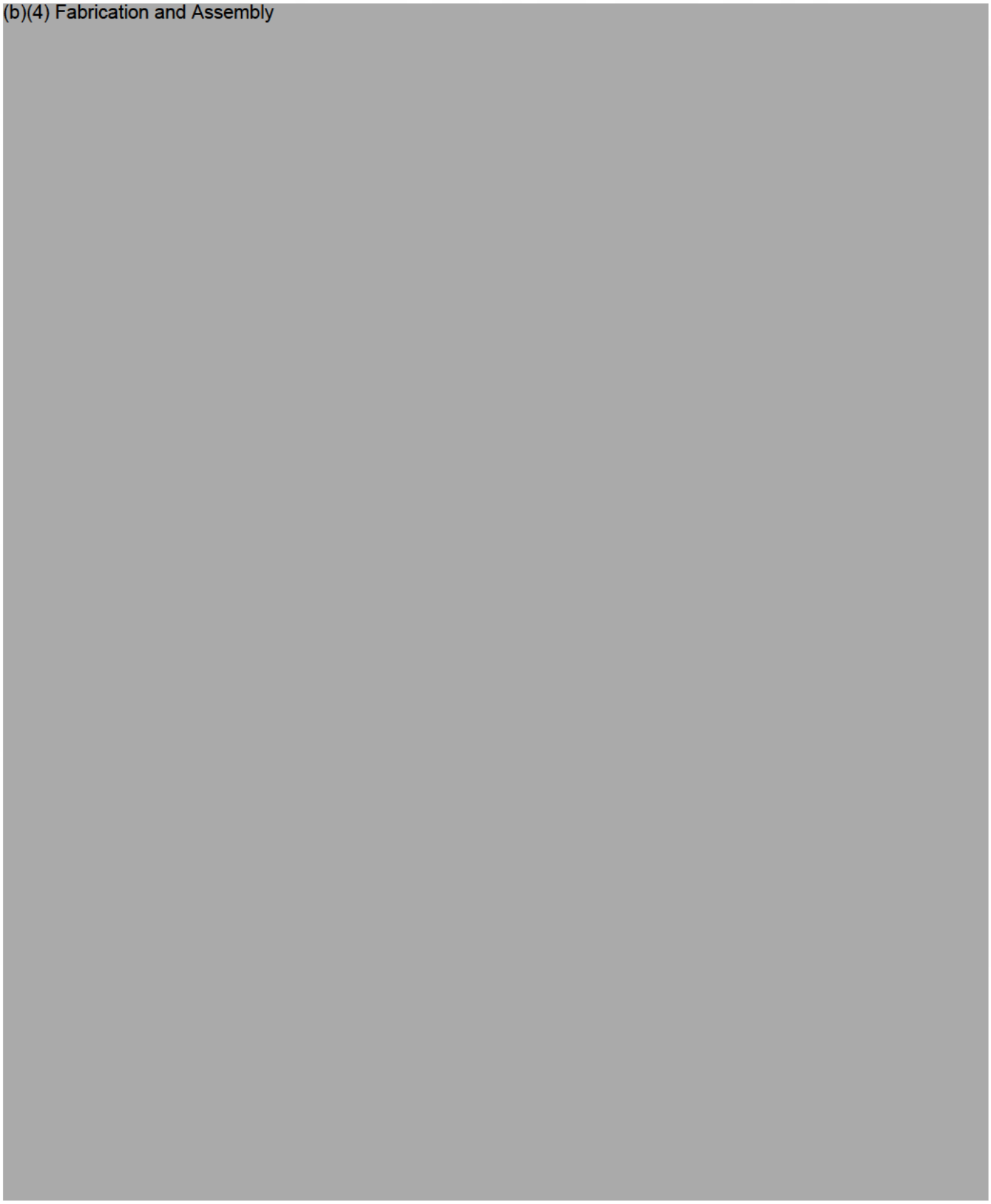

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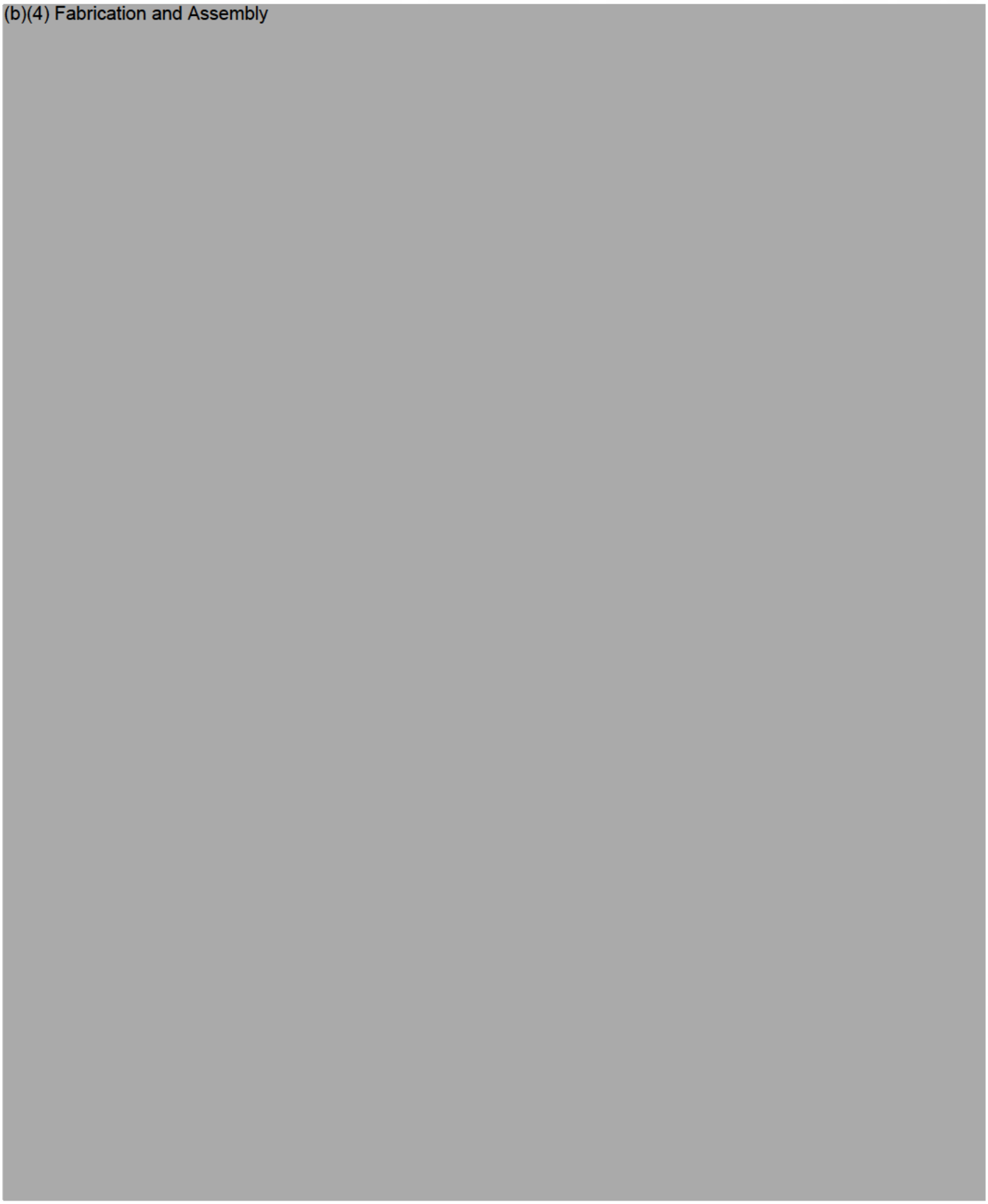

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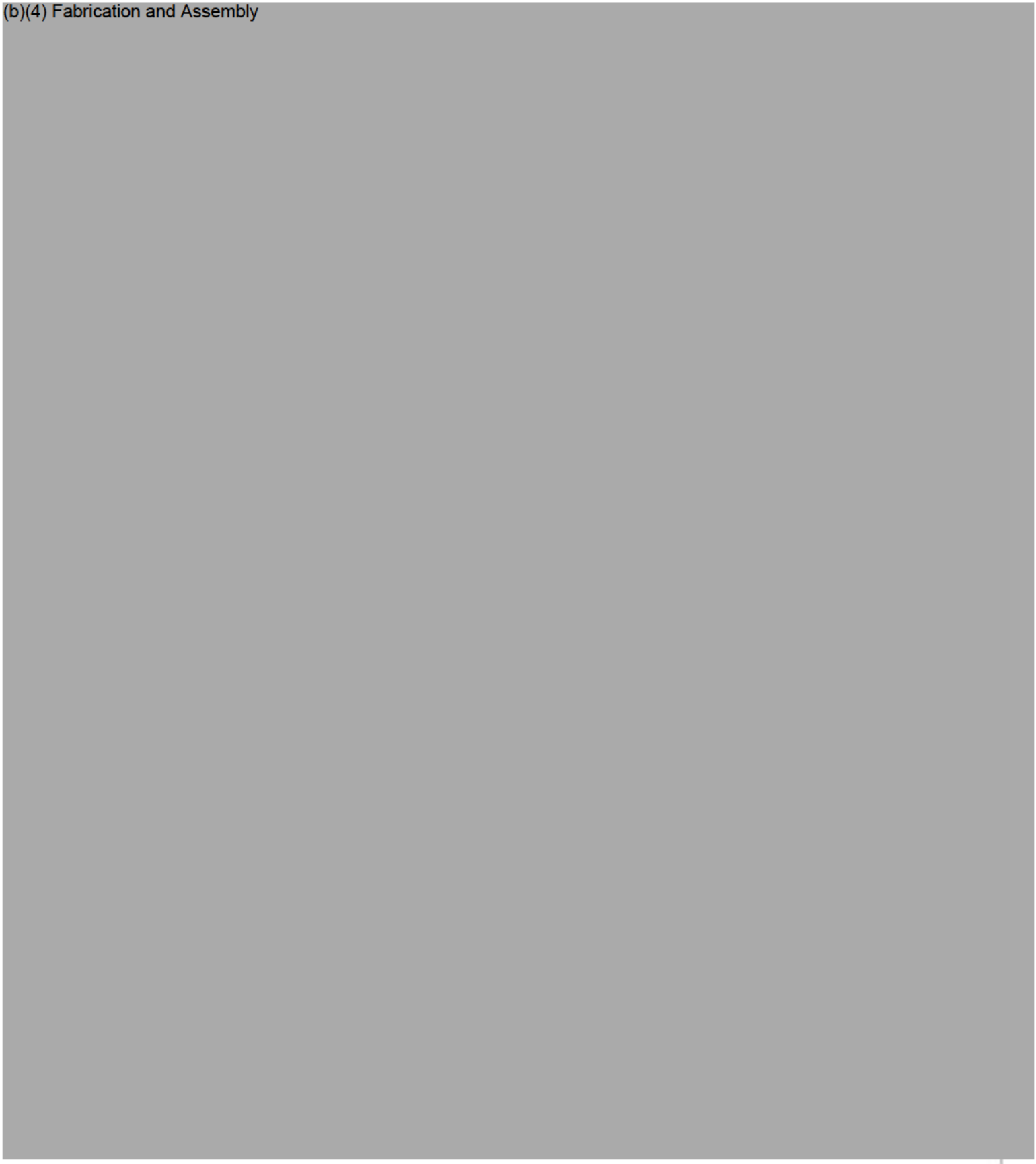

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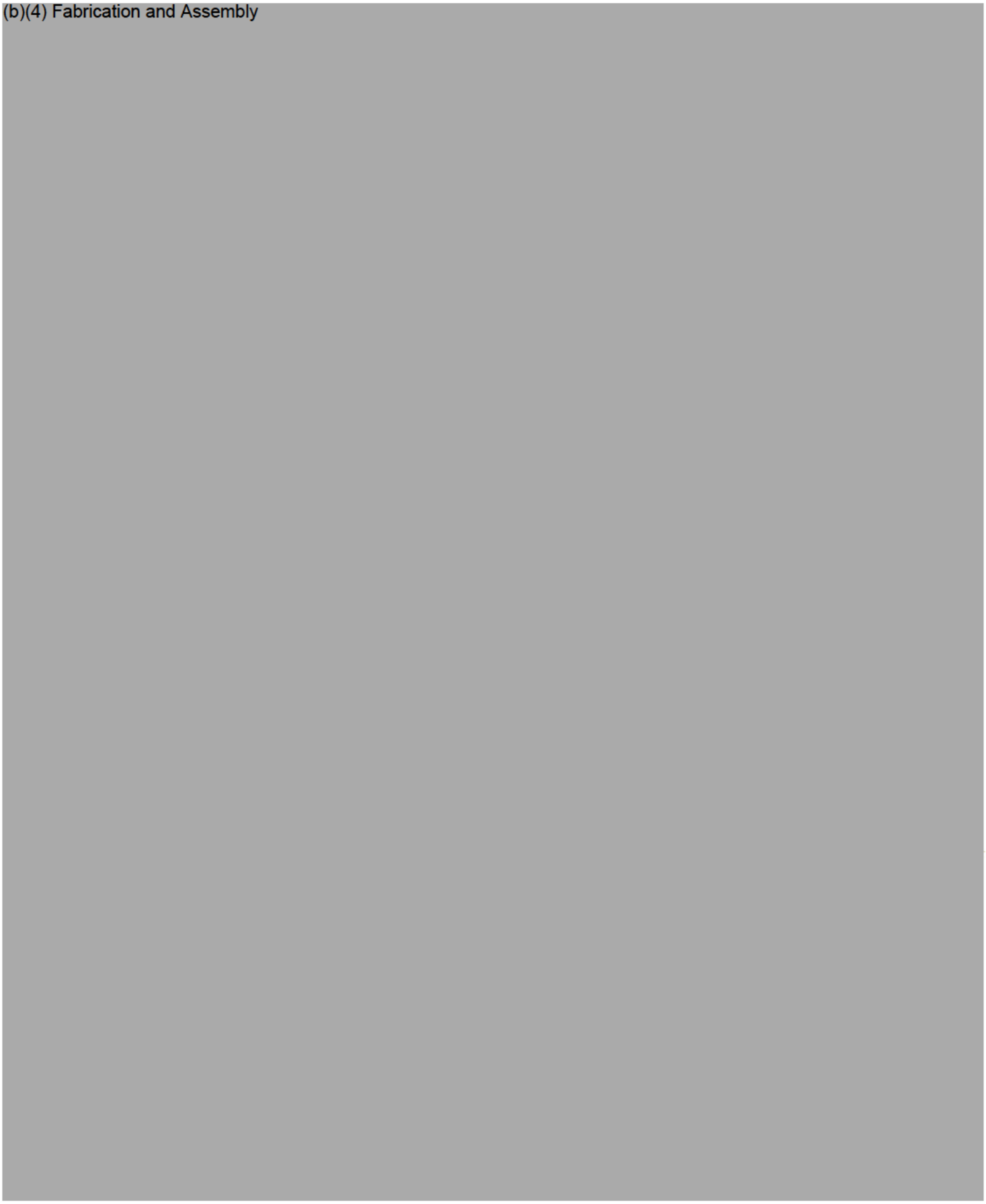

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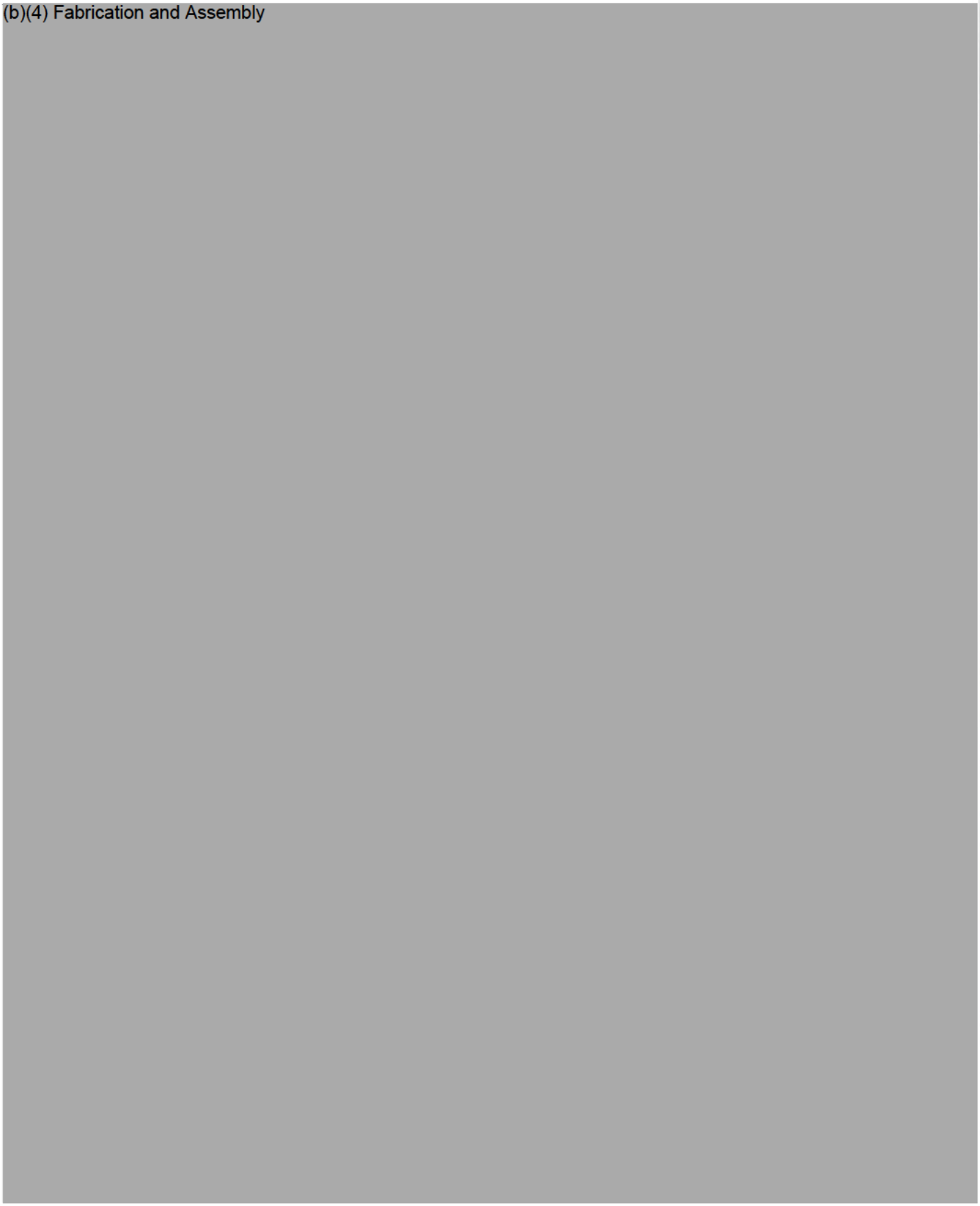

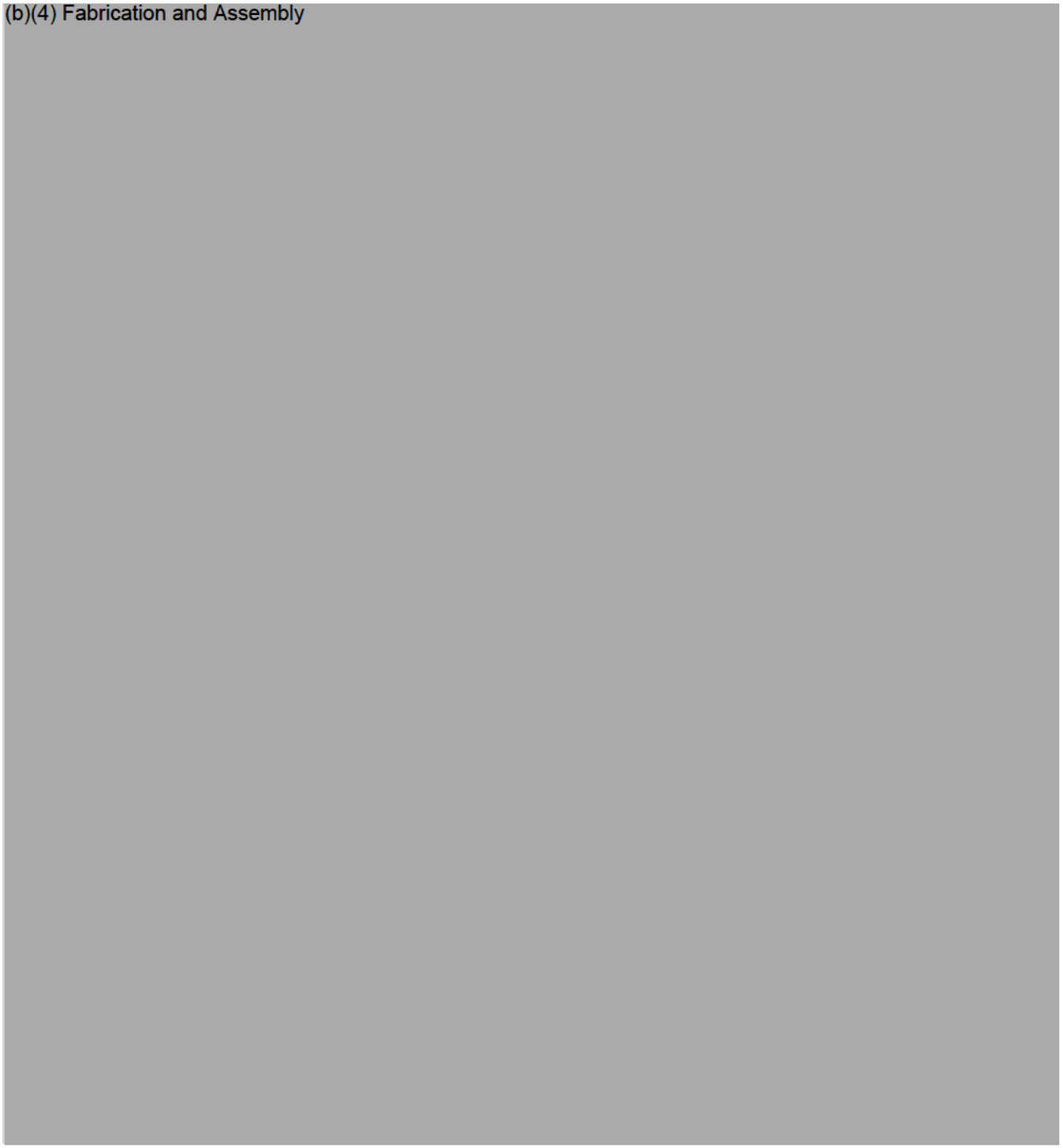

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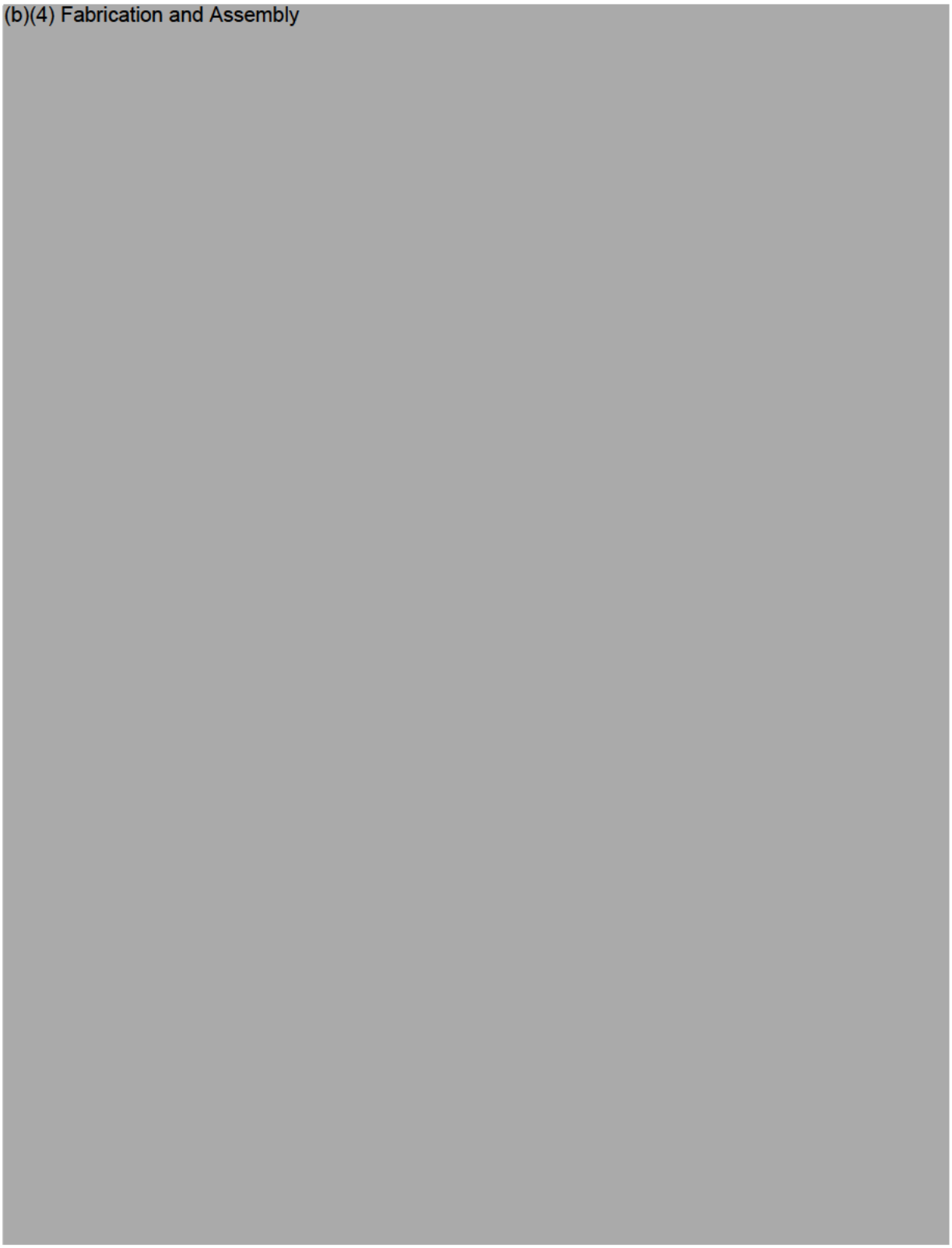

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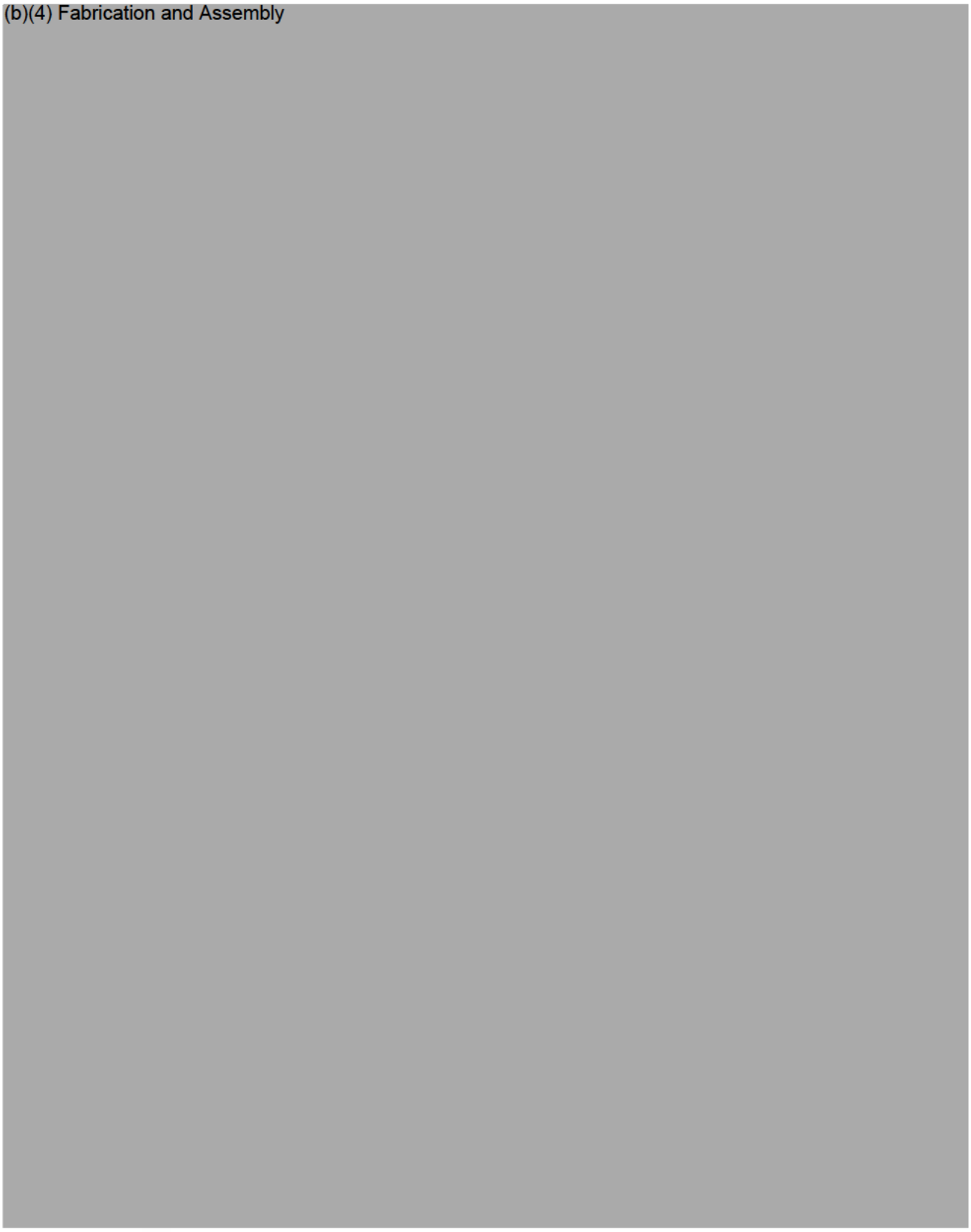

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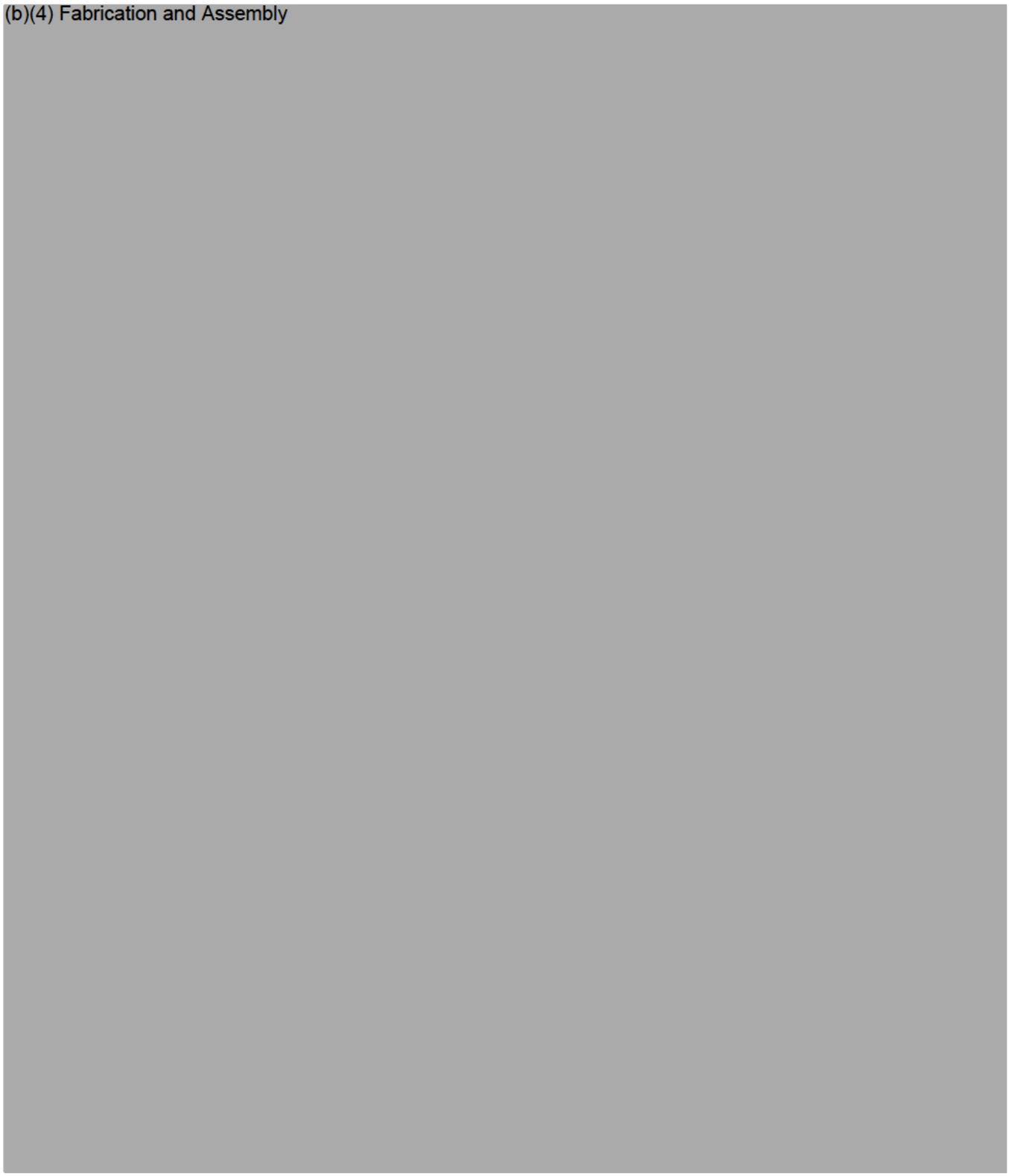

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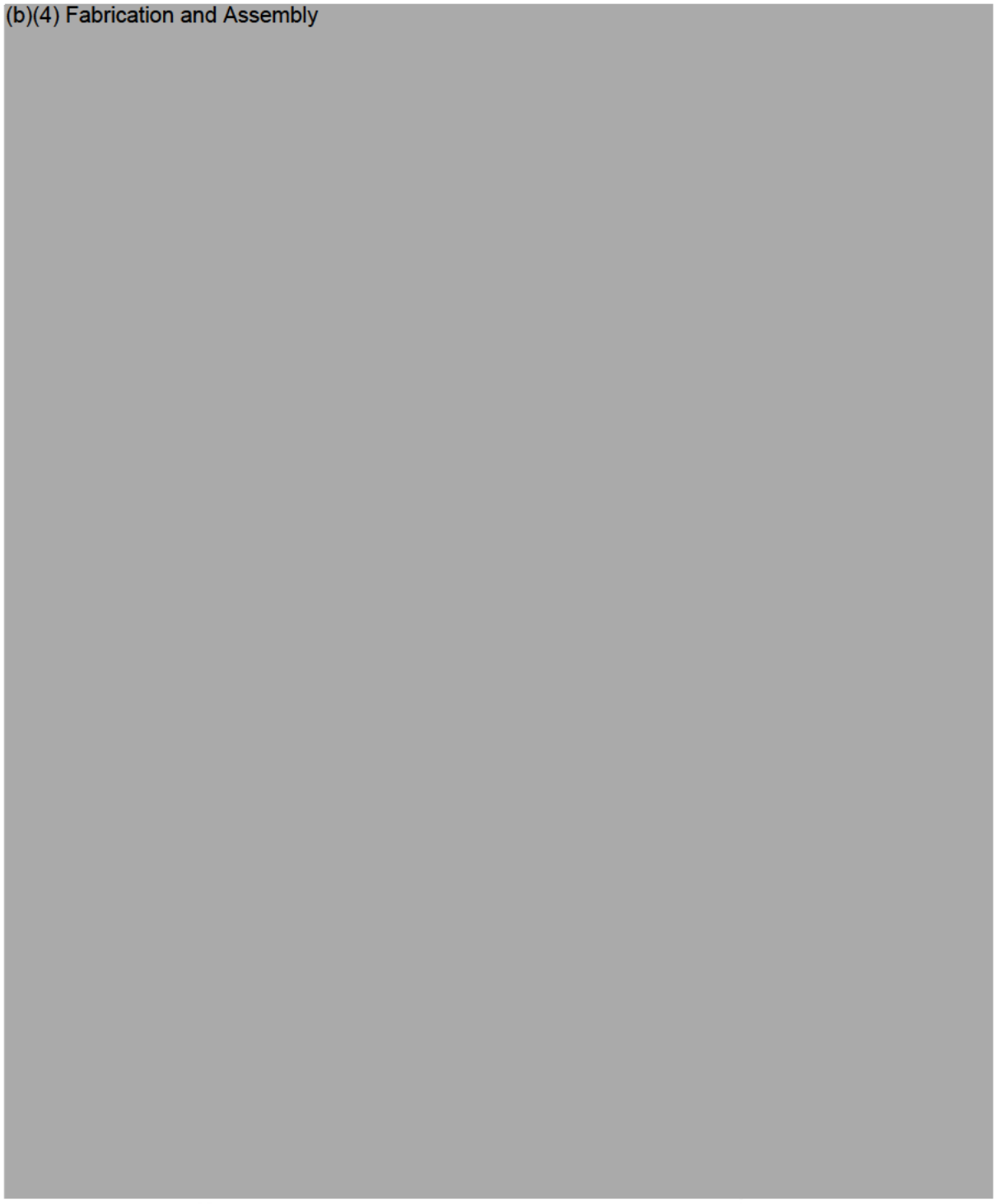
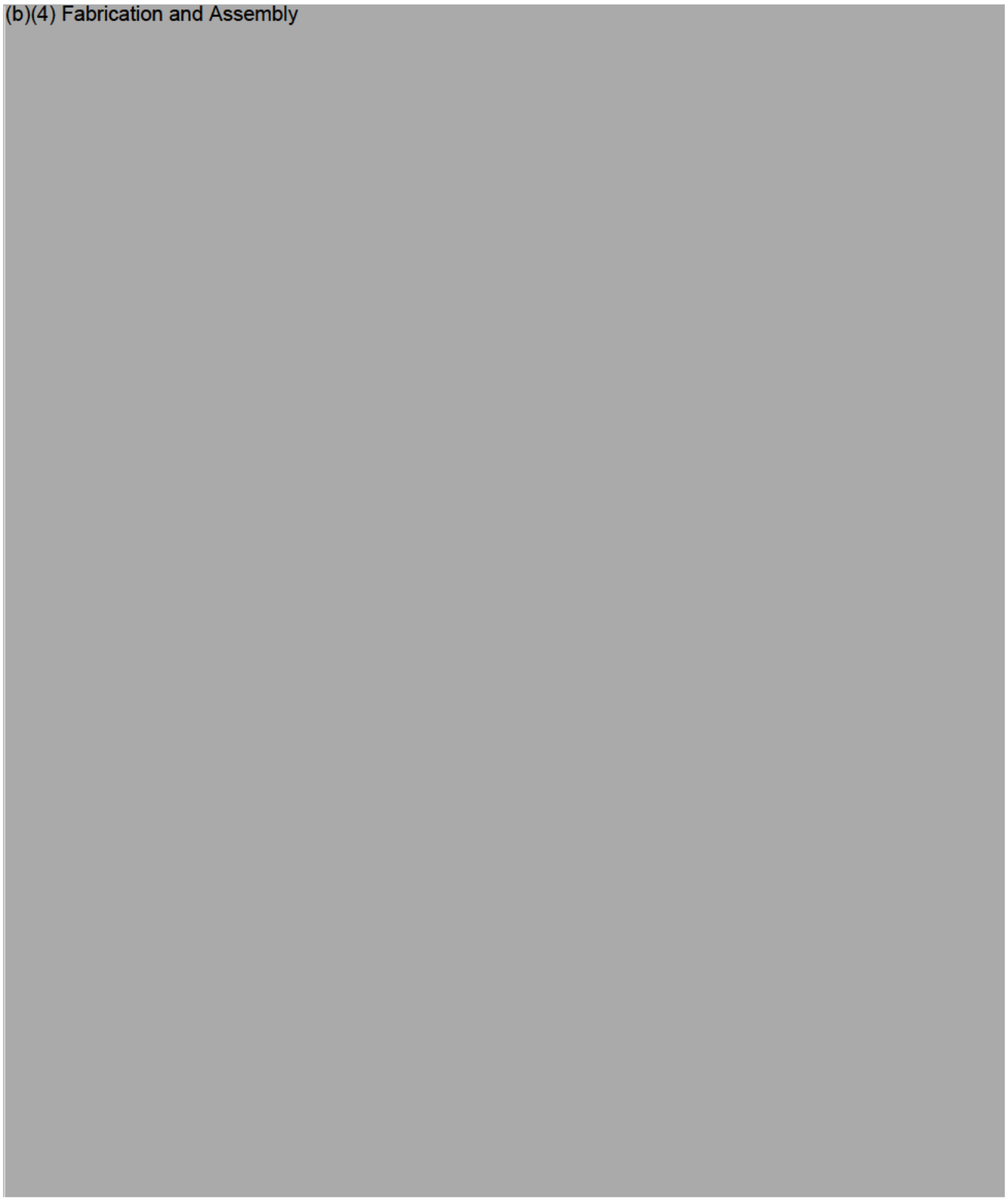


Band Assembly



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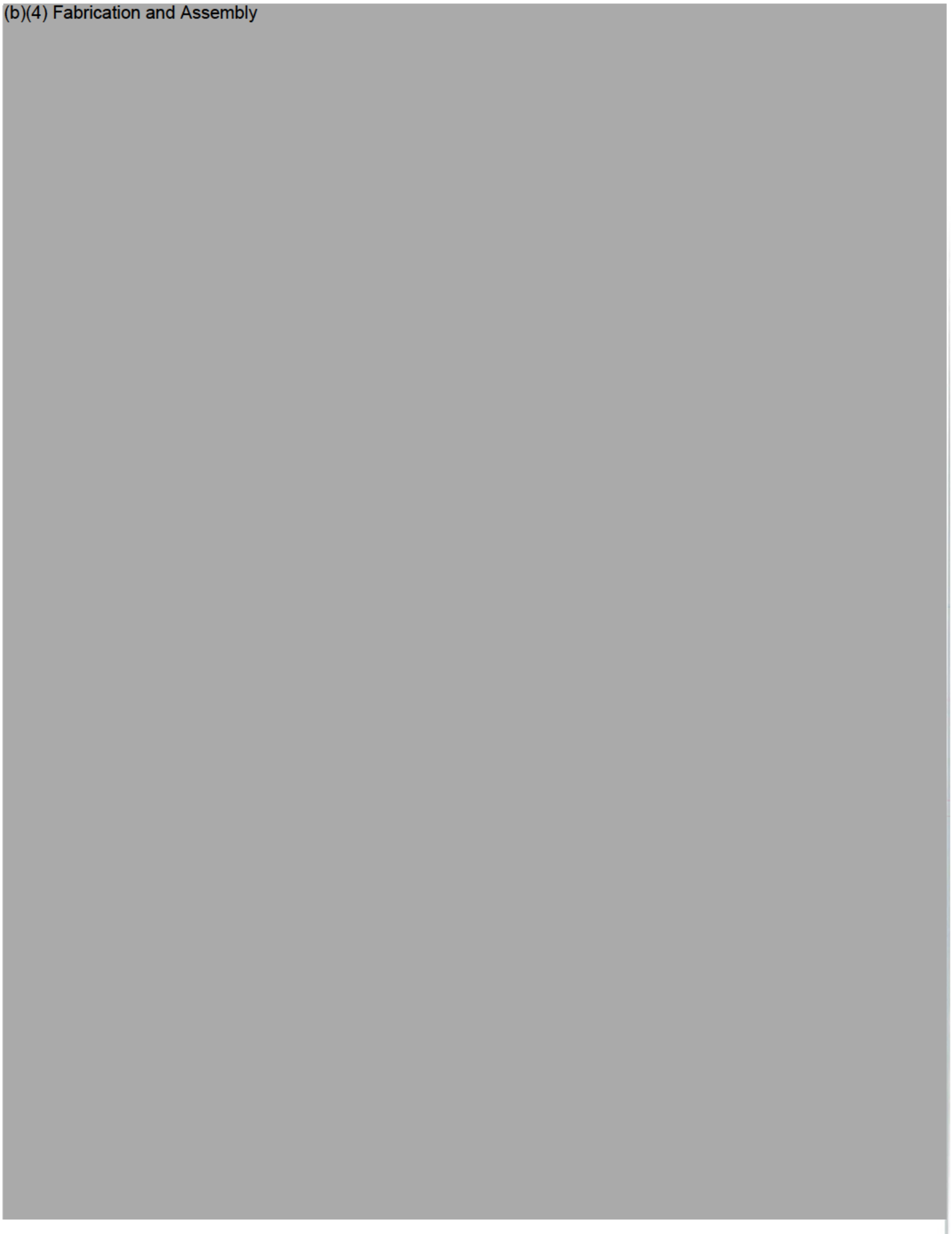

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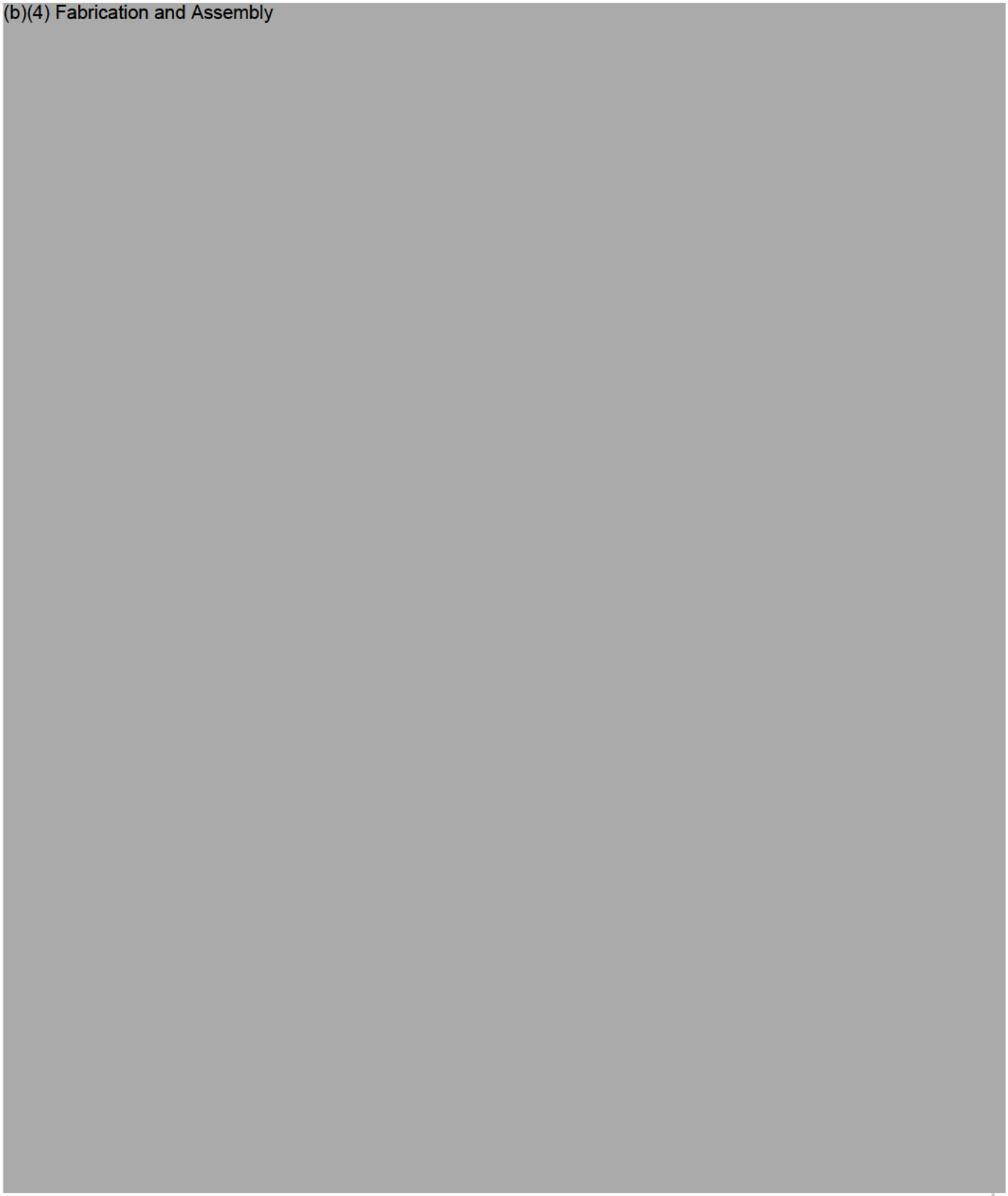

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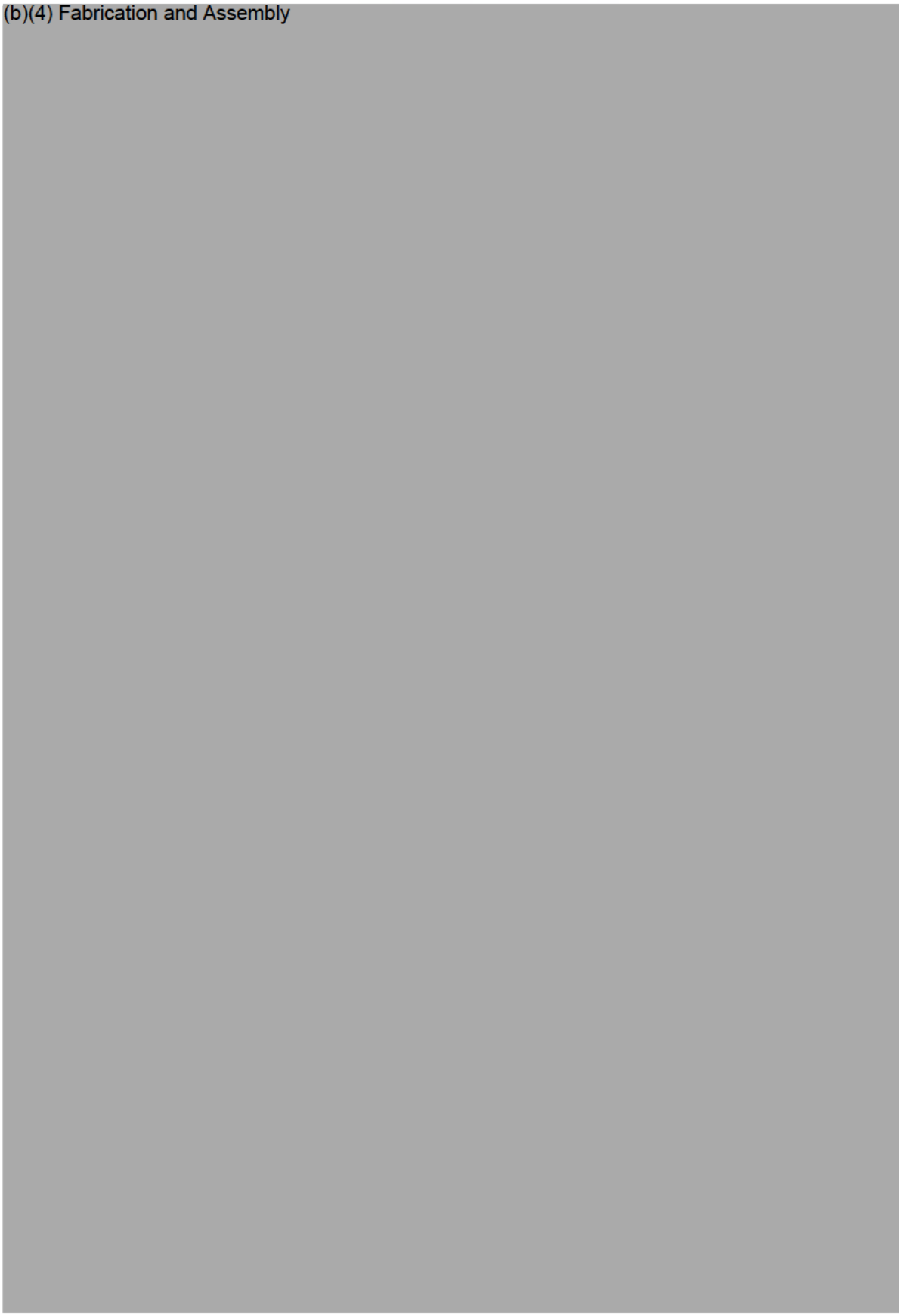

(b)(4) Third Party Test Report

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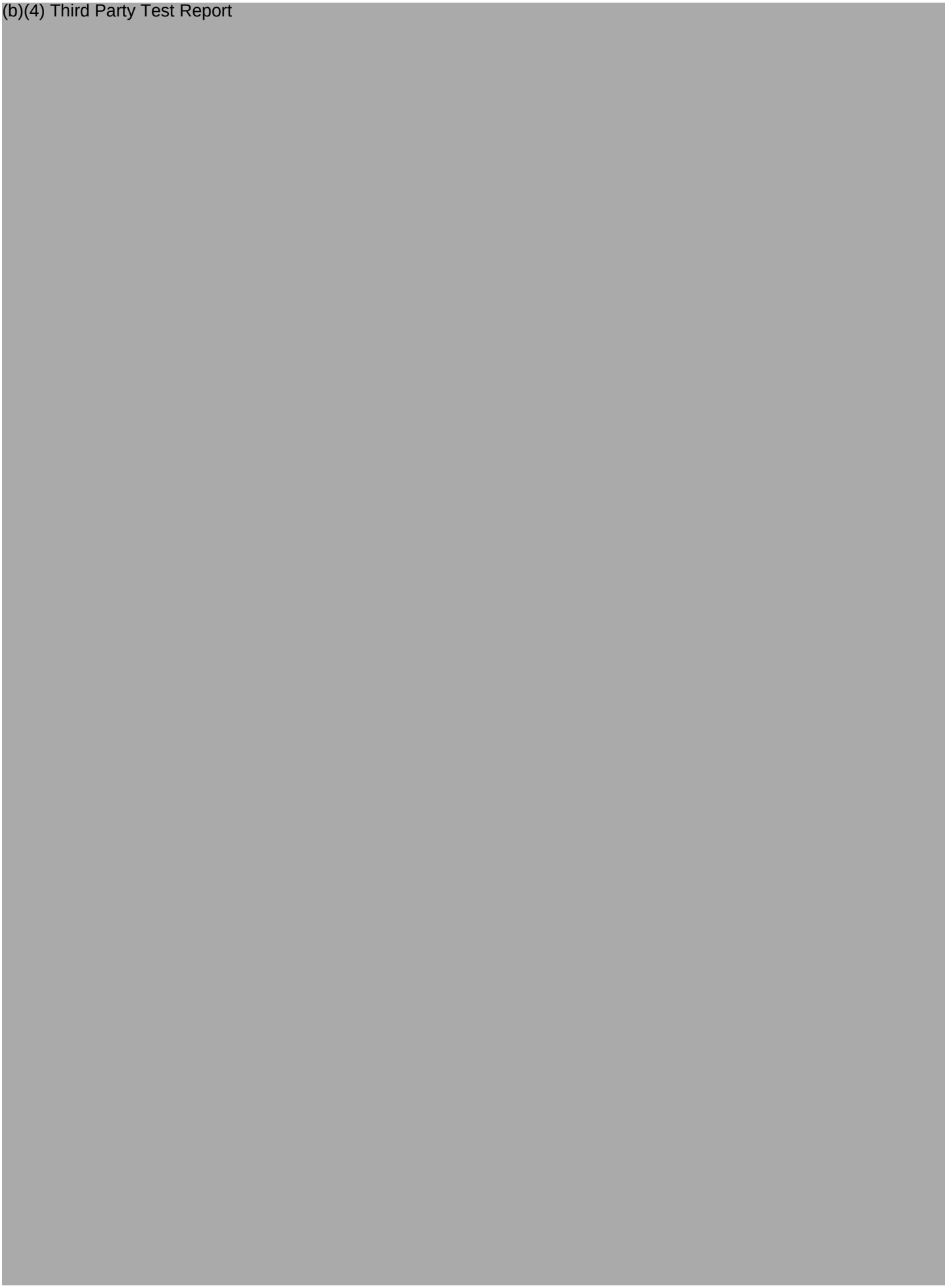

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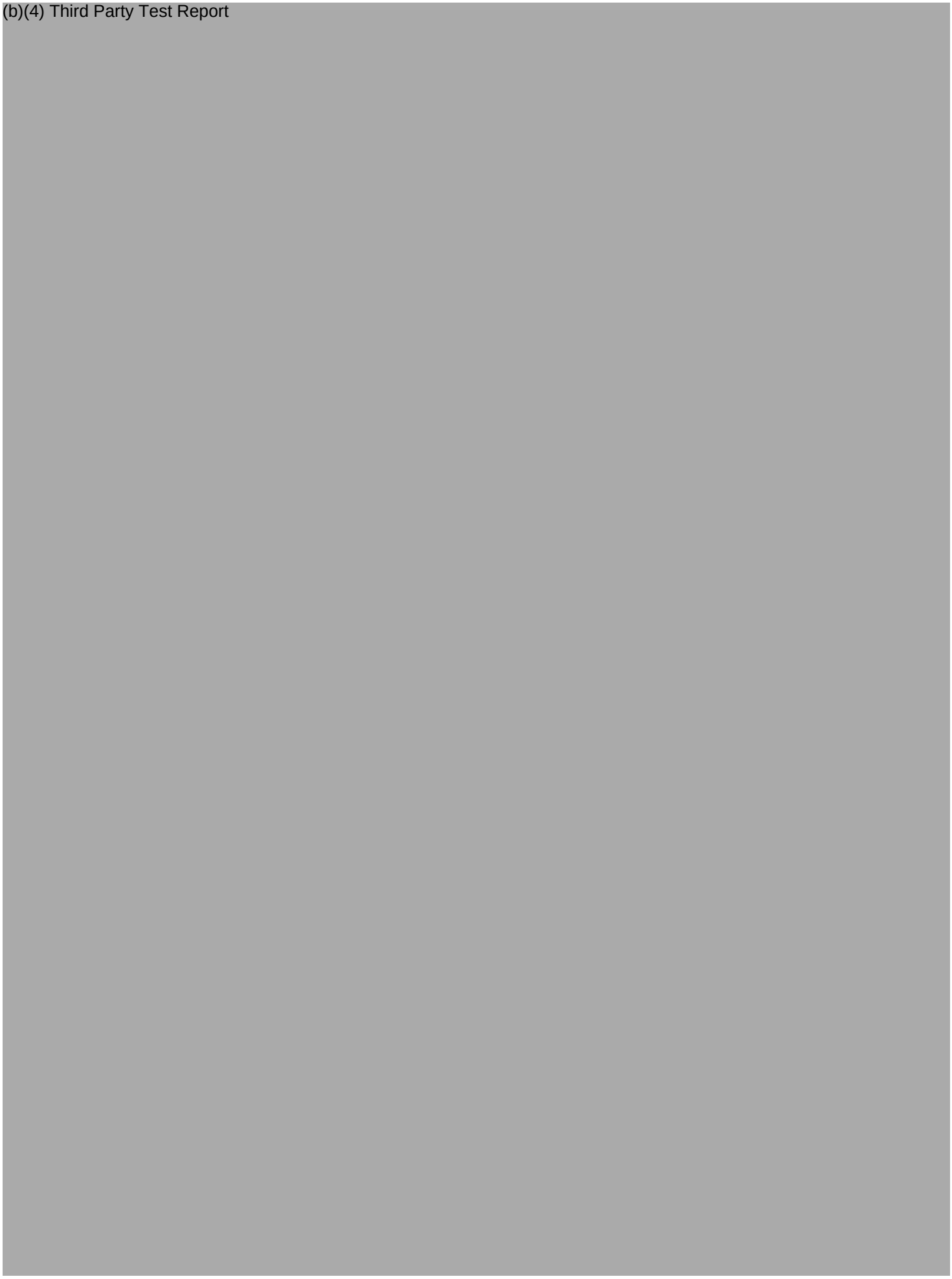

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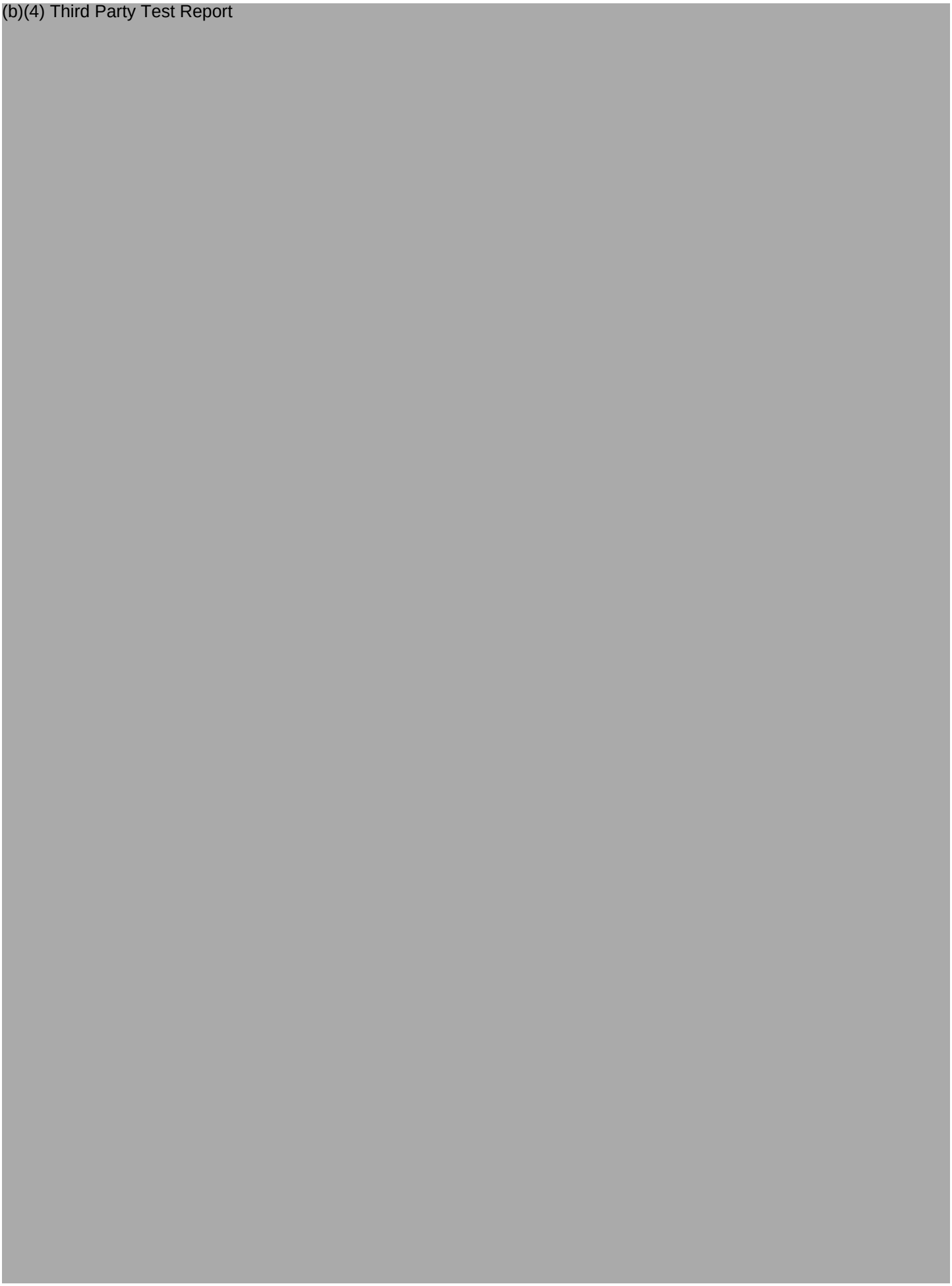

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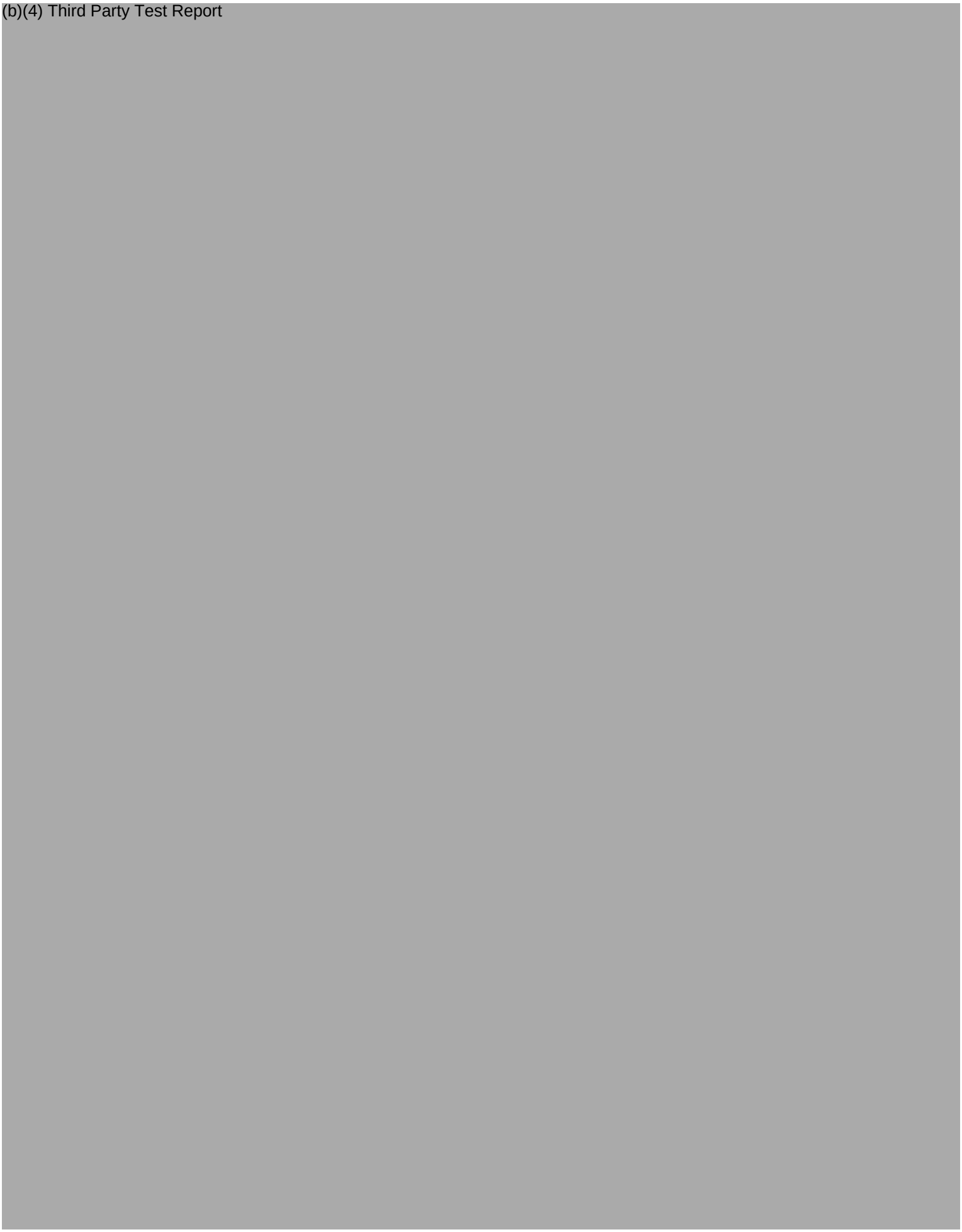

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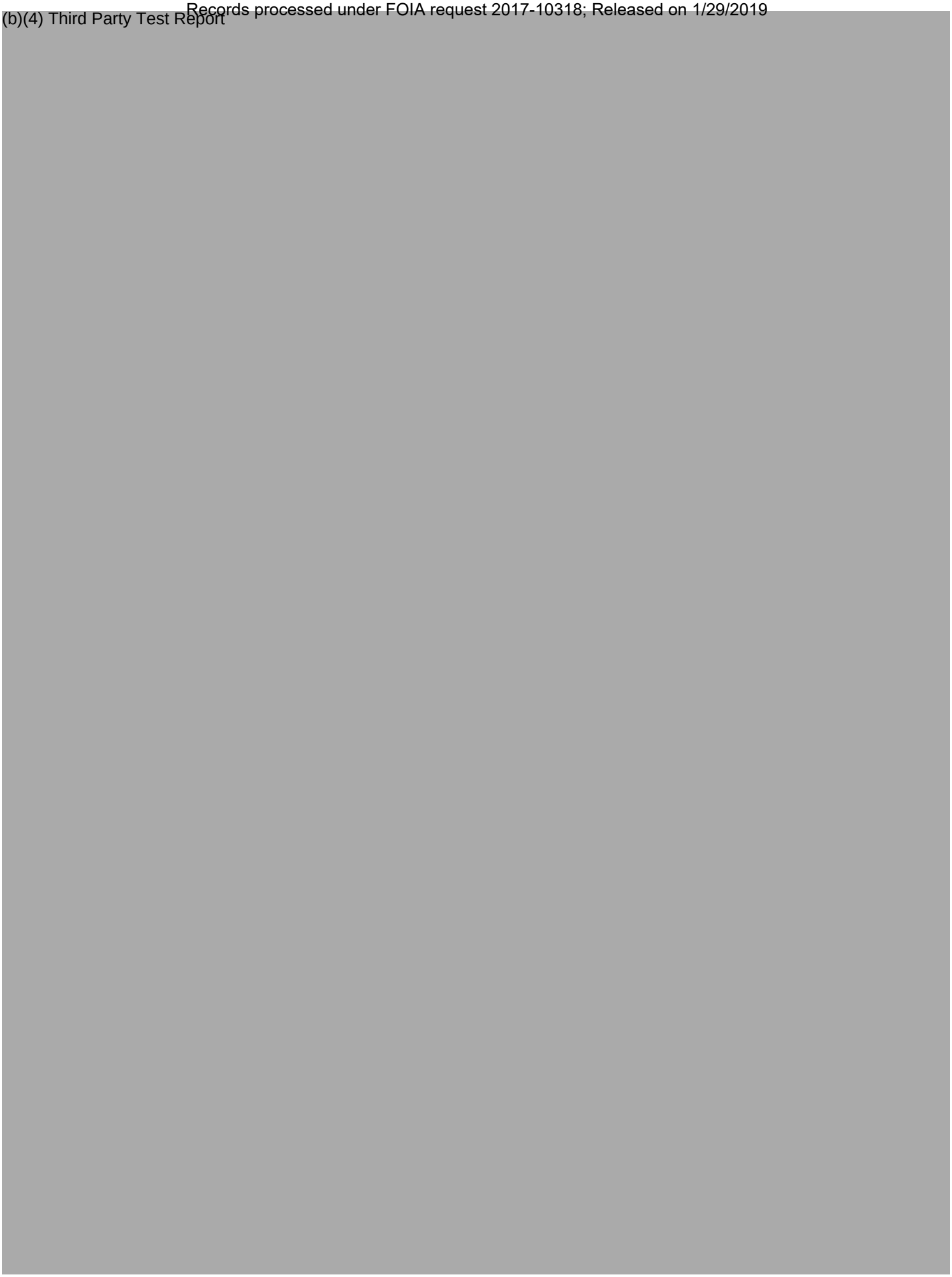

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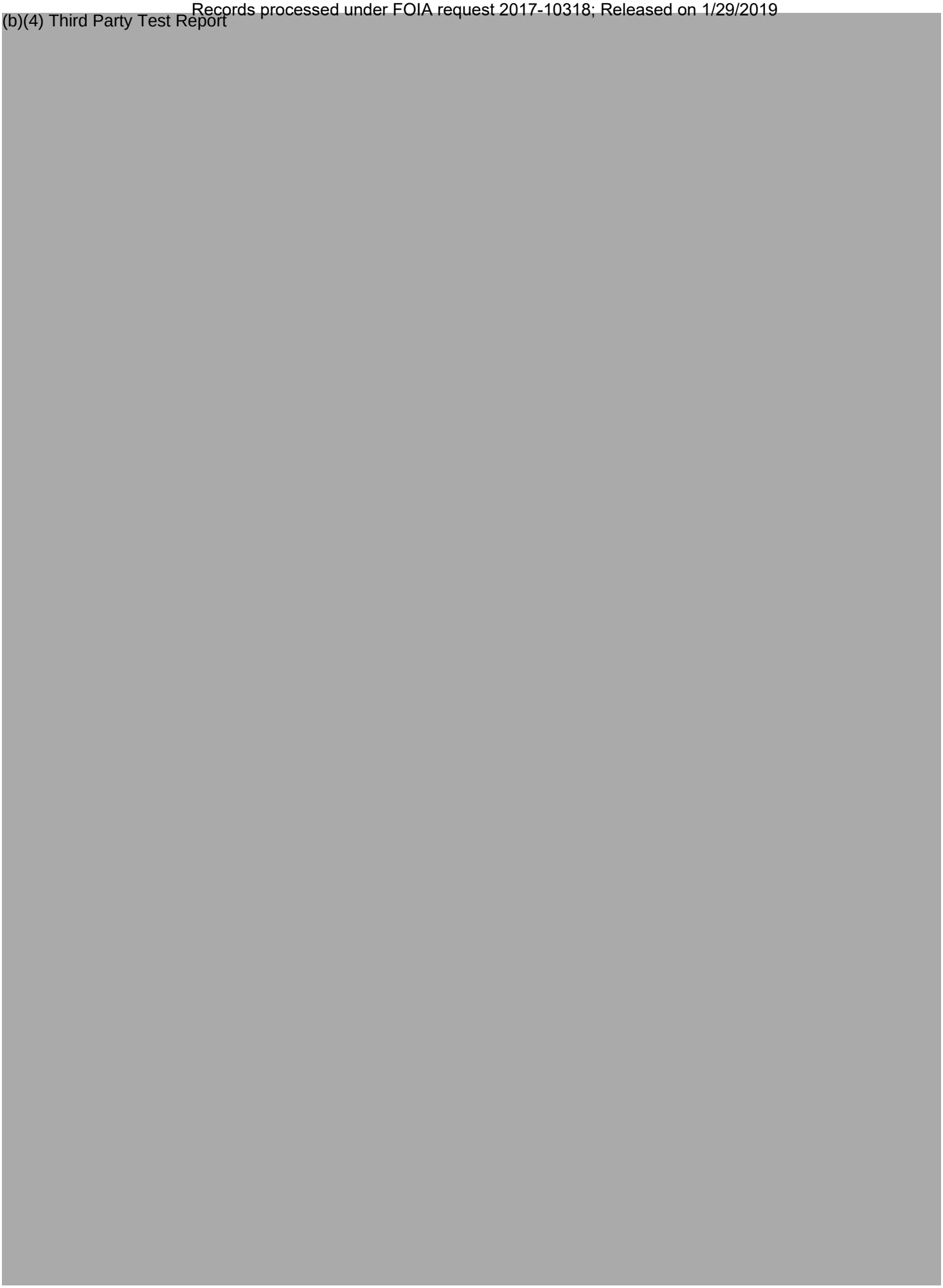

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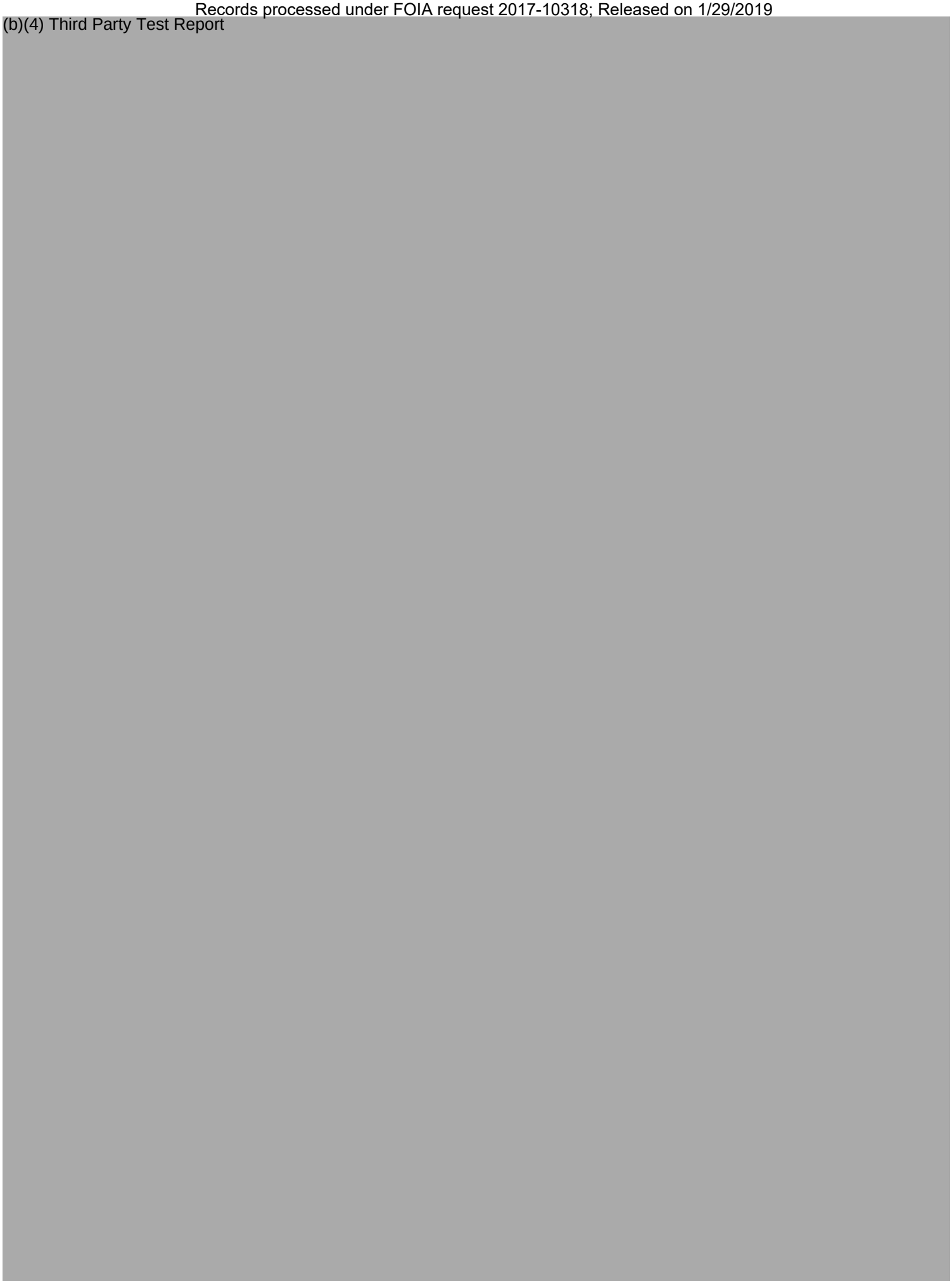

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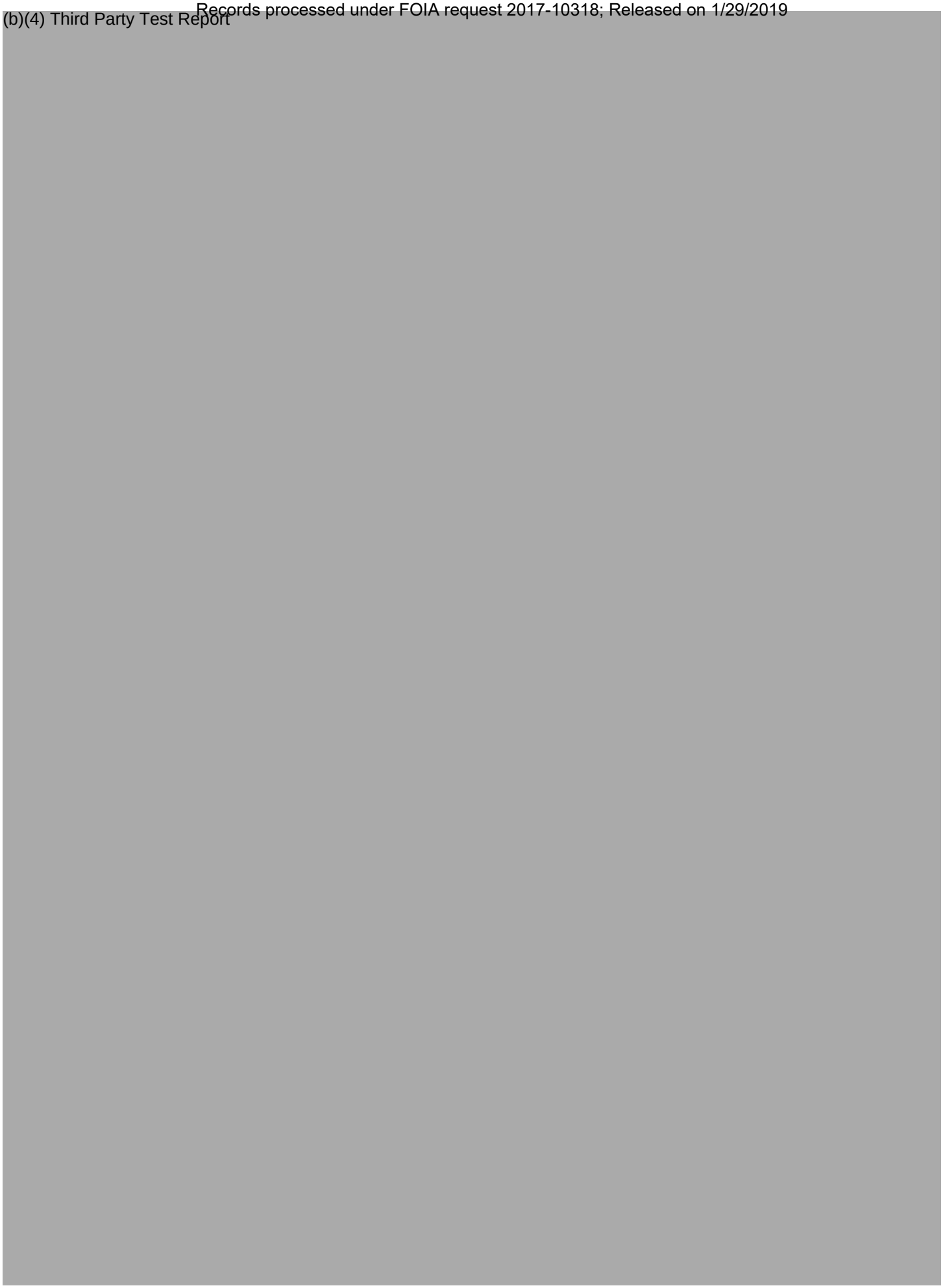

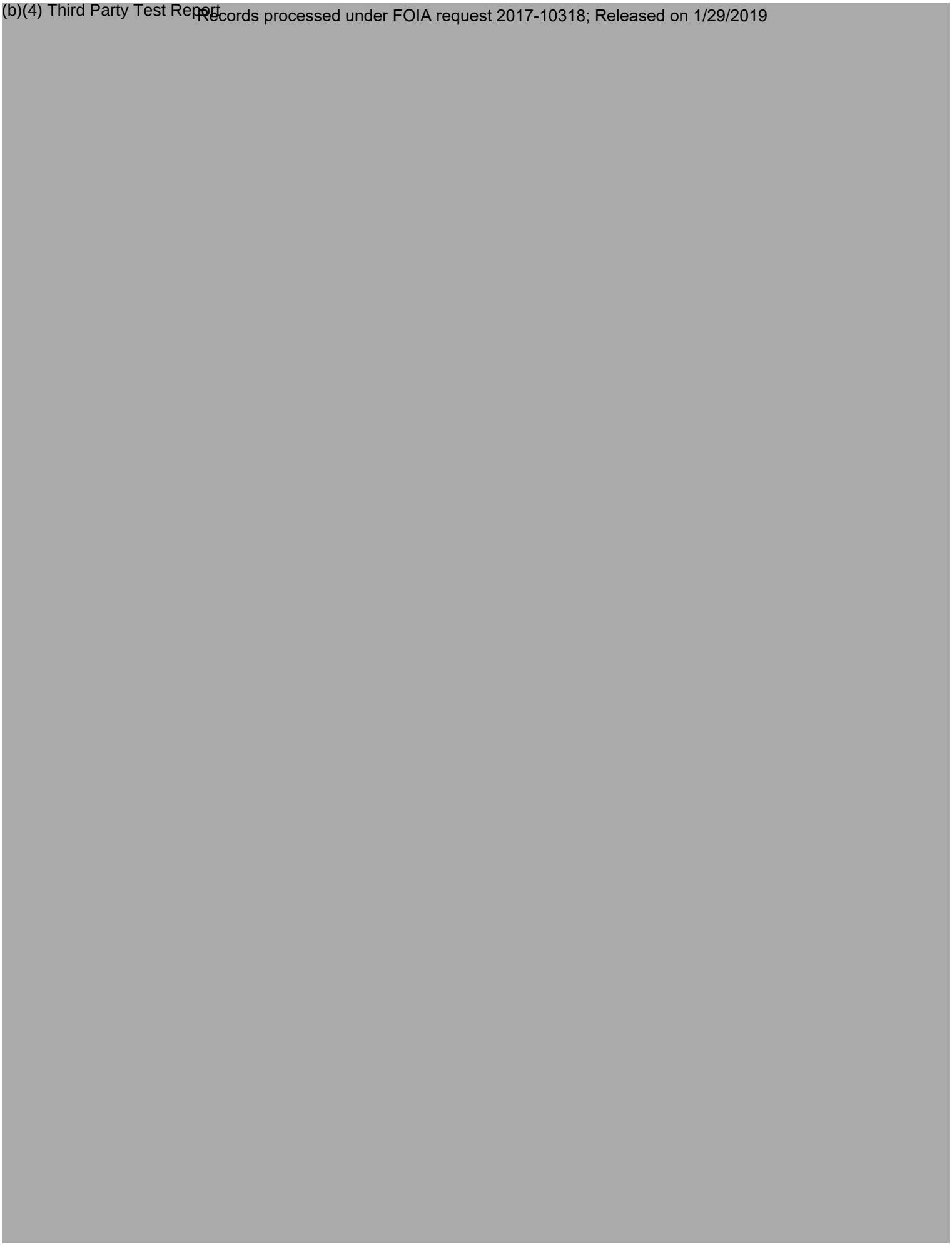

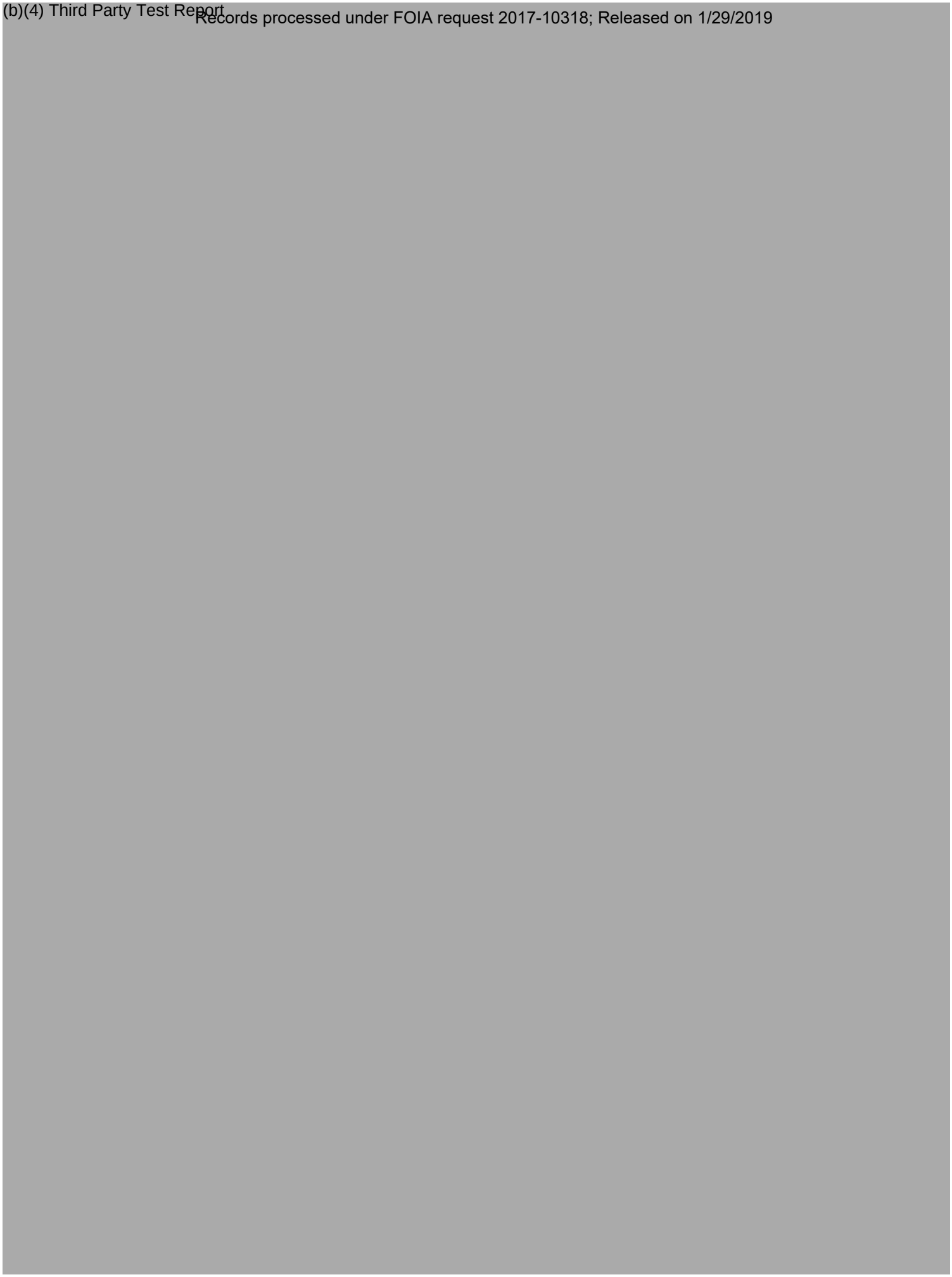

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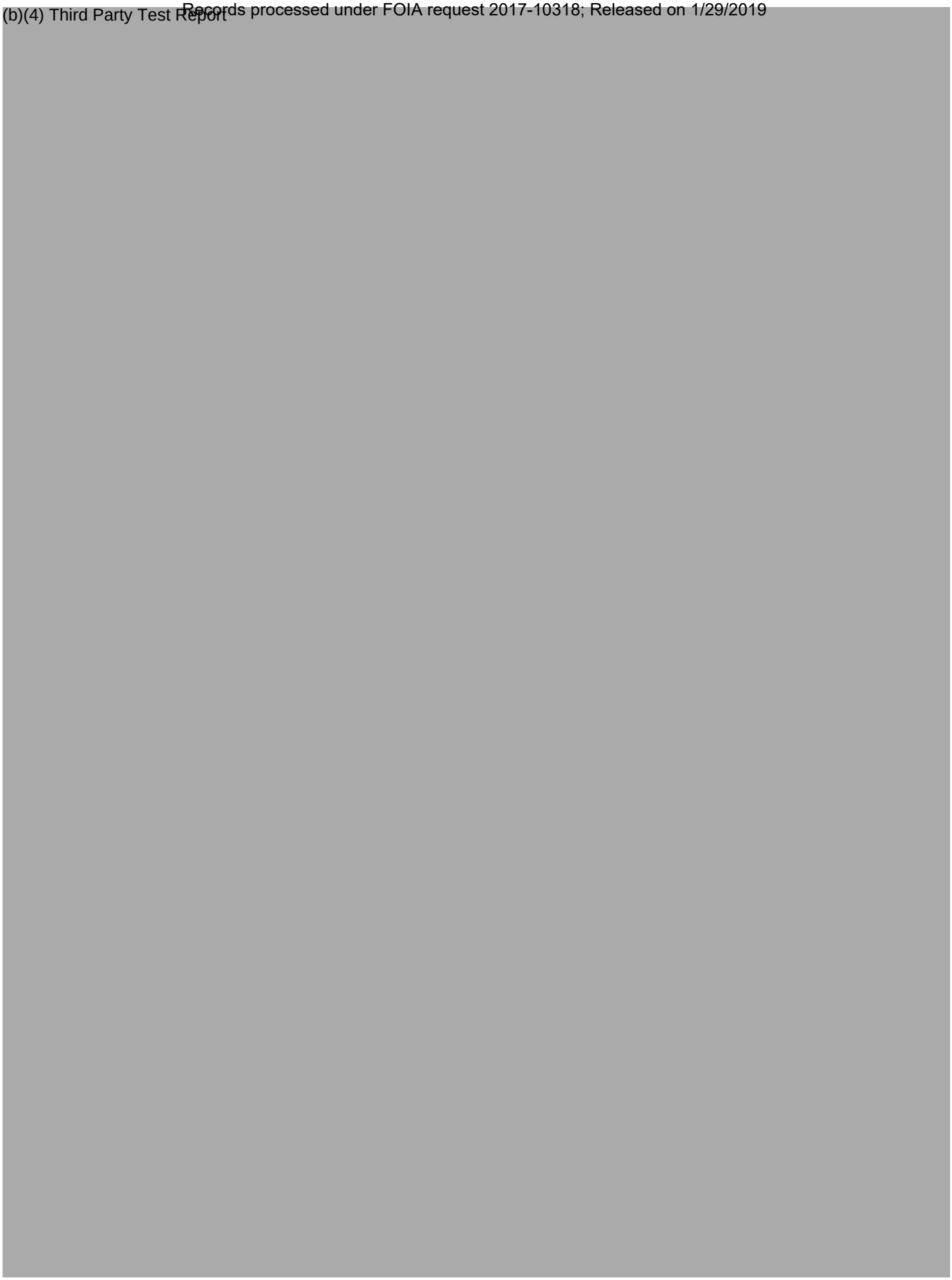

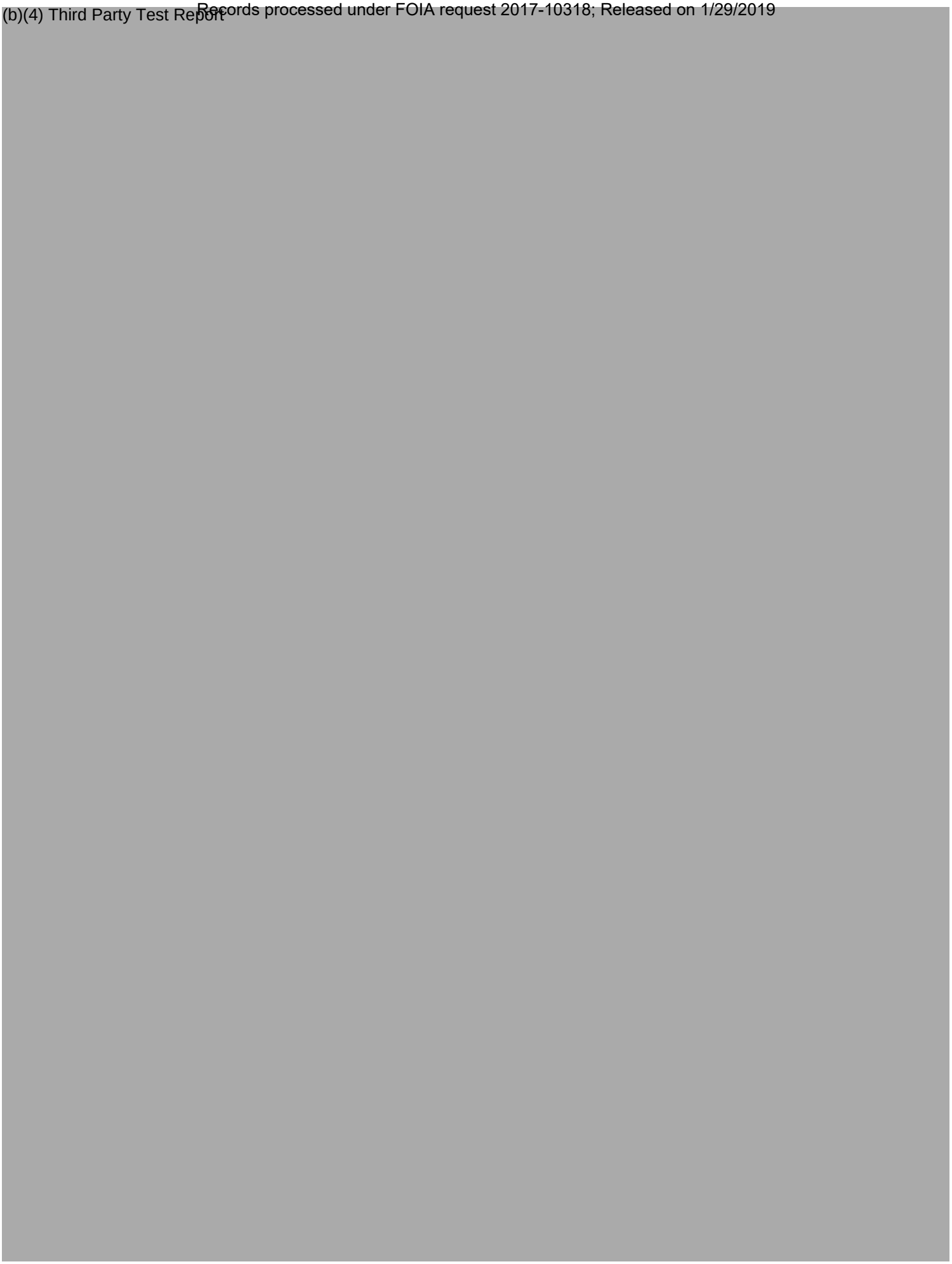

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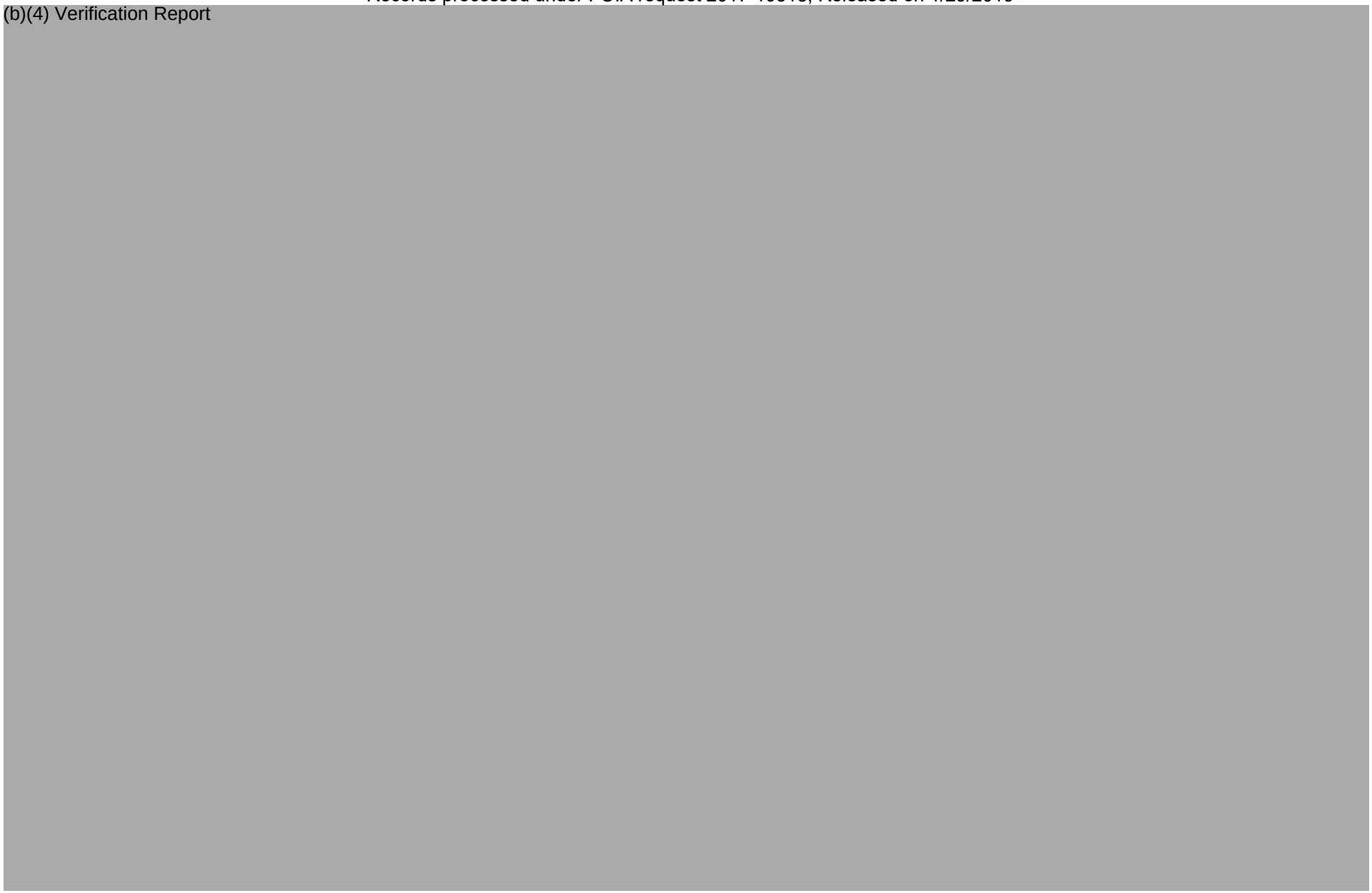

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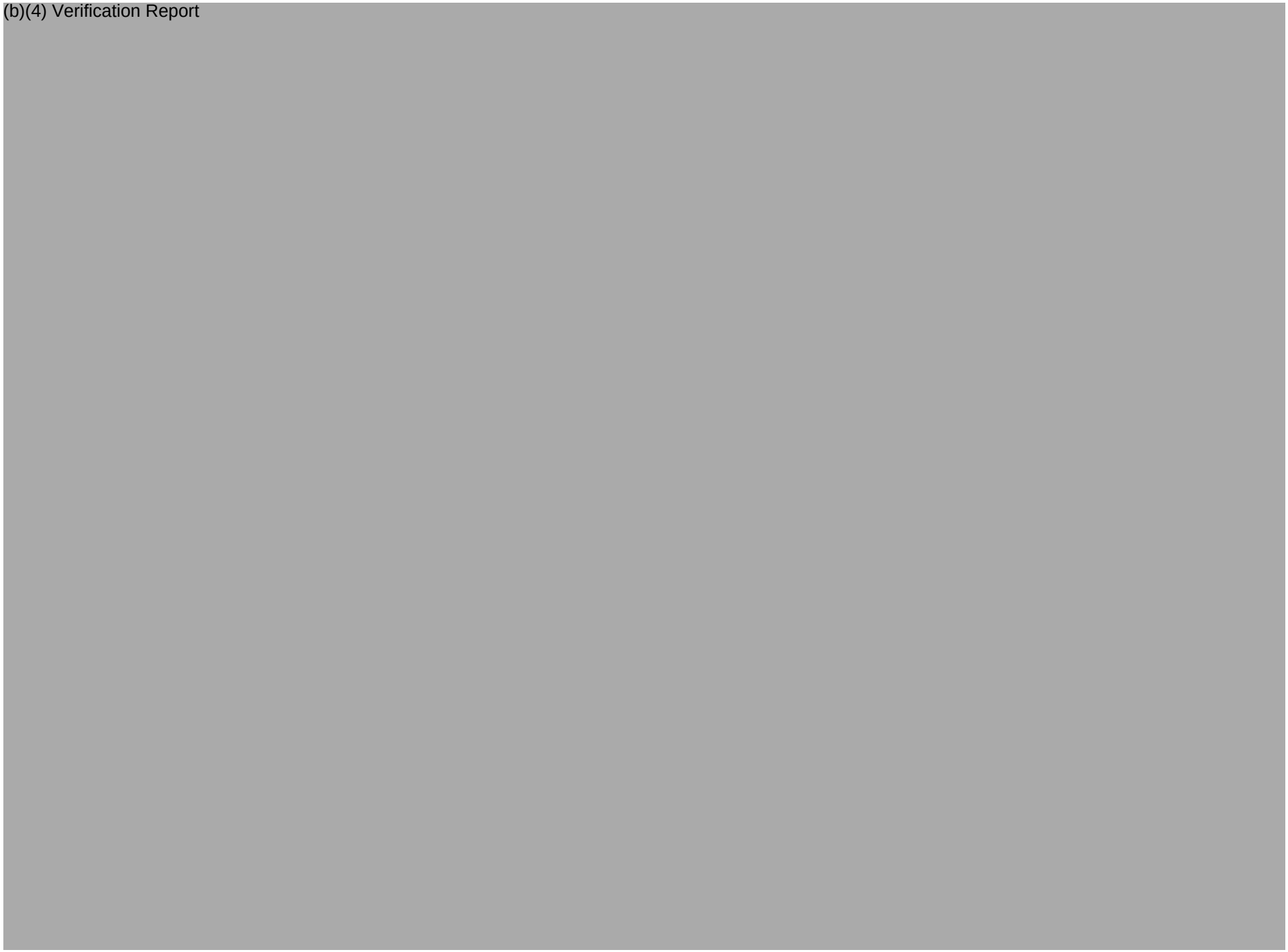

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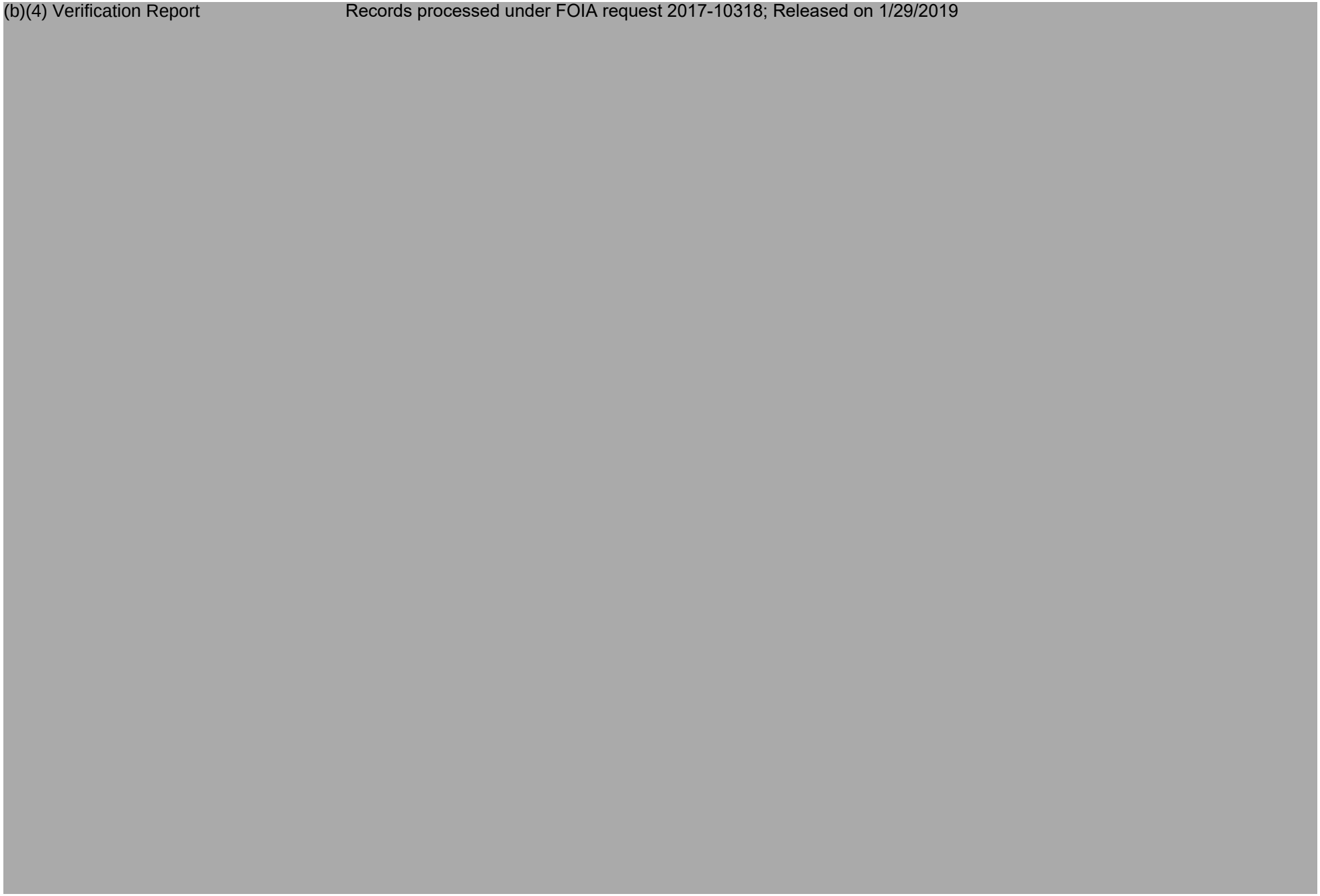

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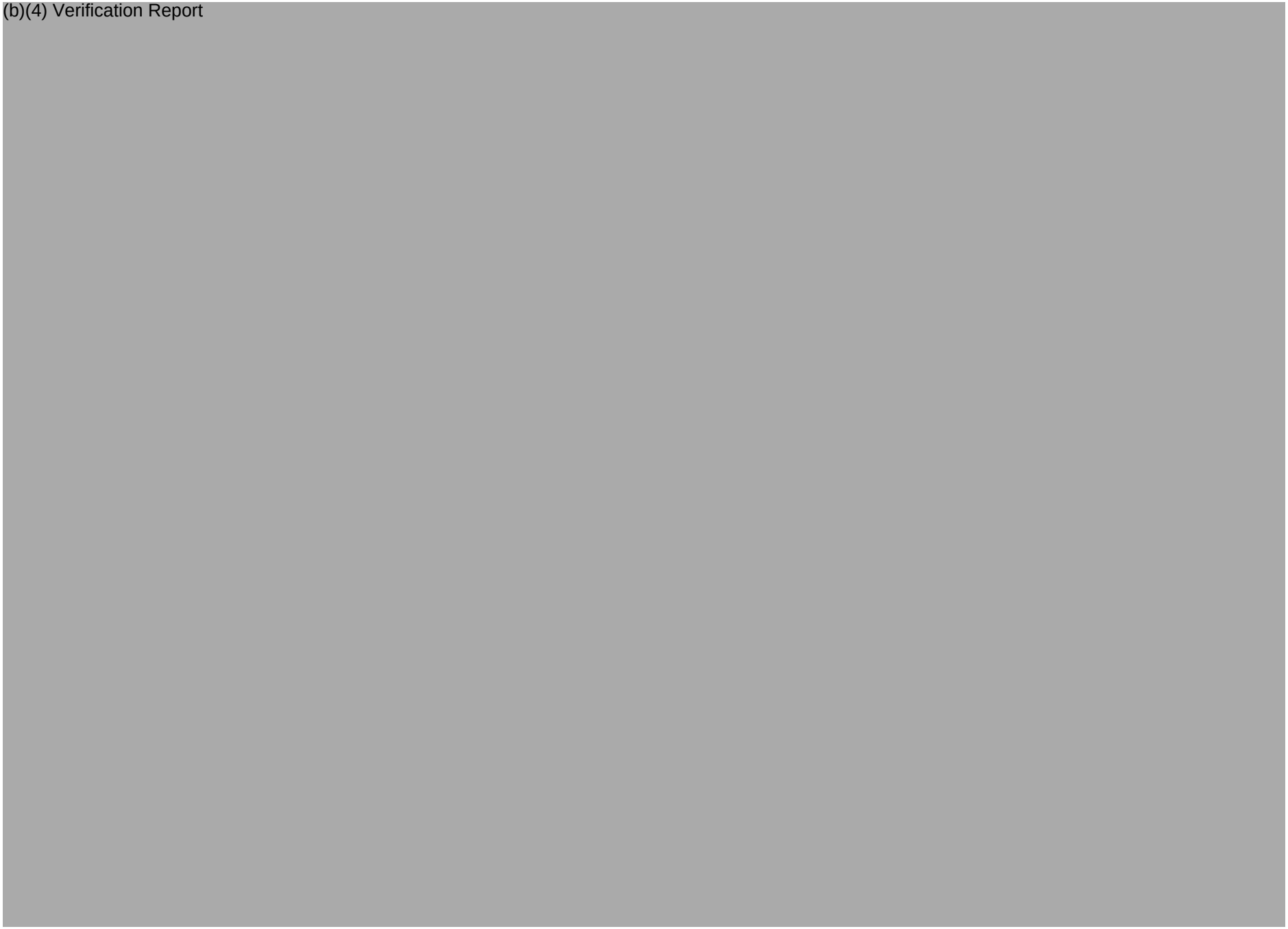

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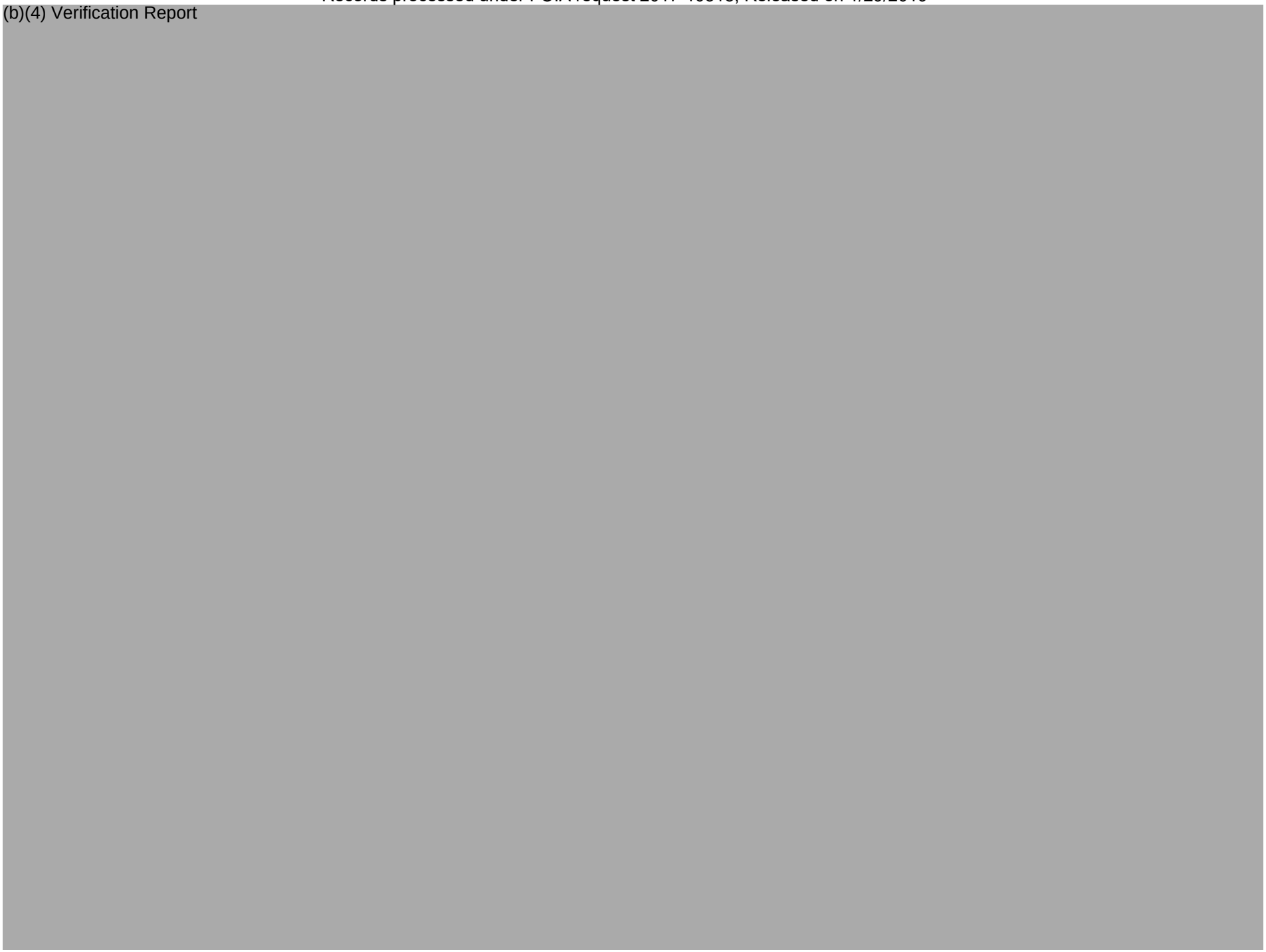

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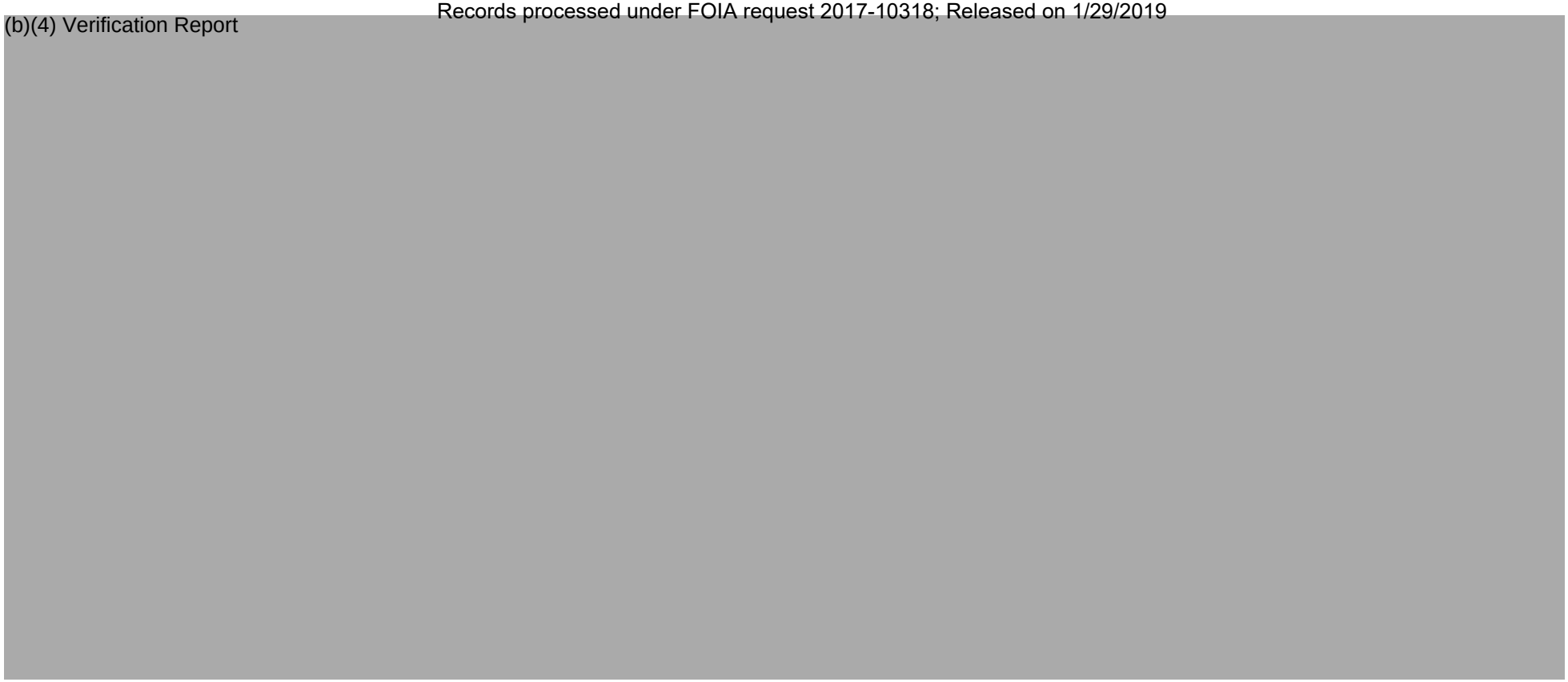

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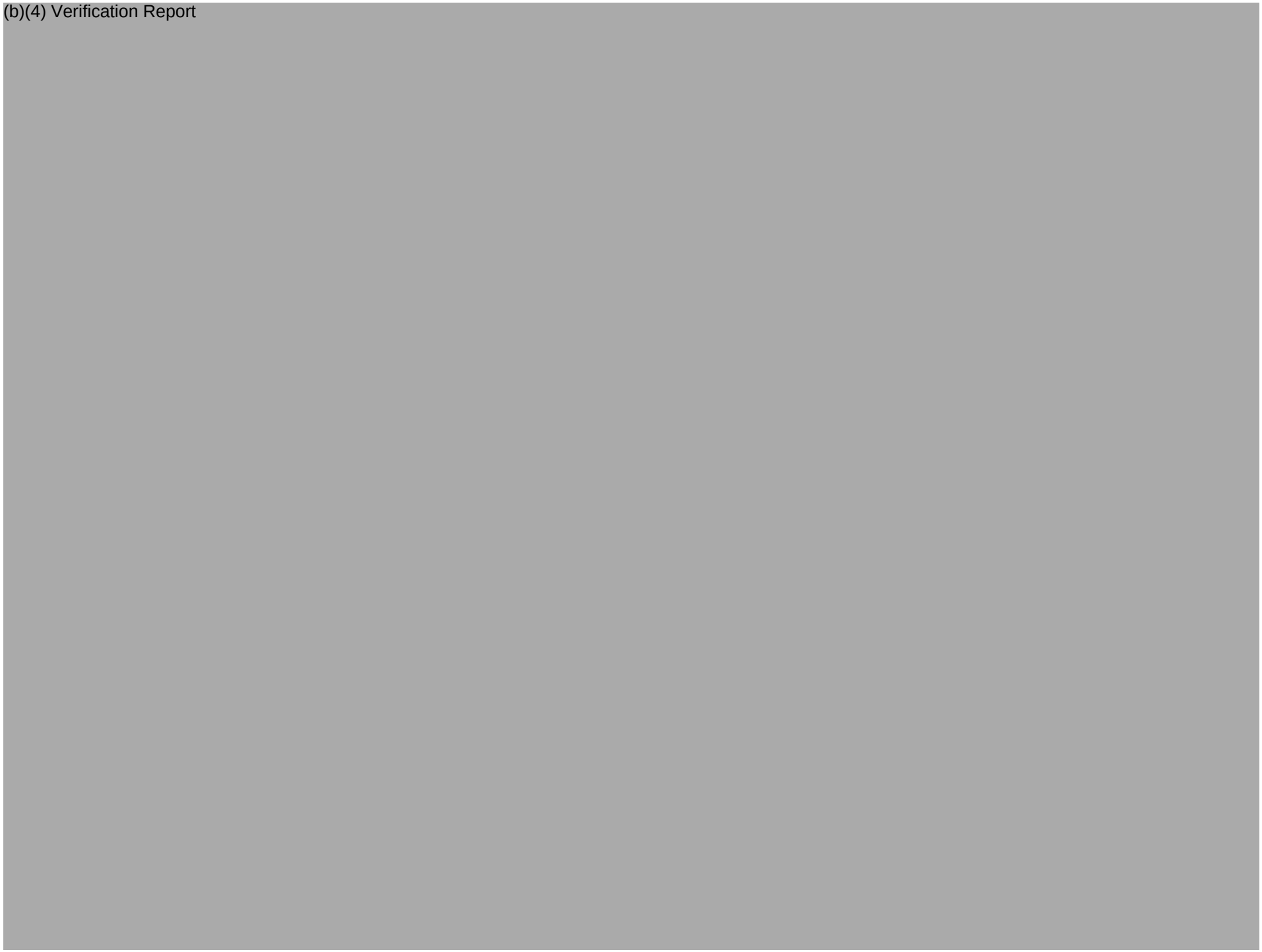

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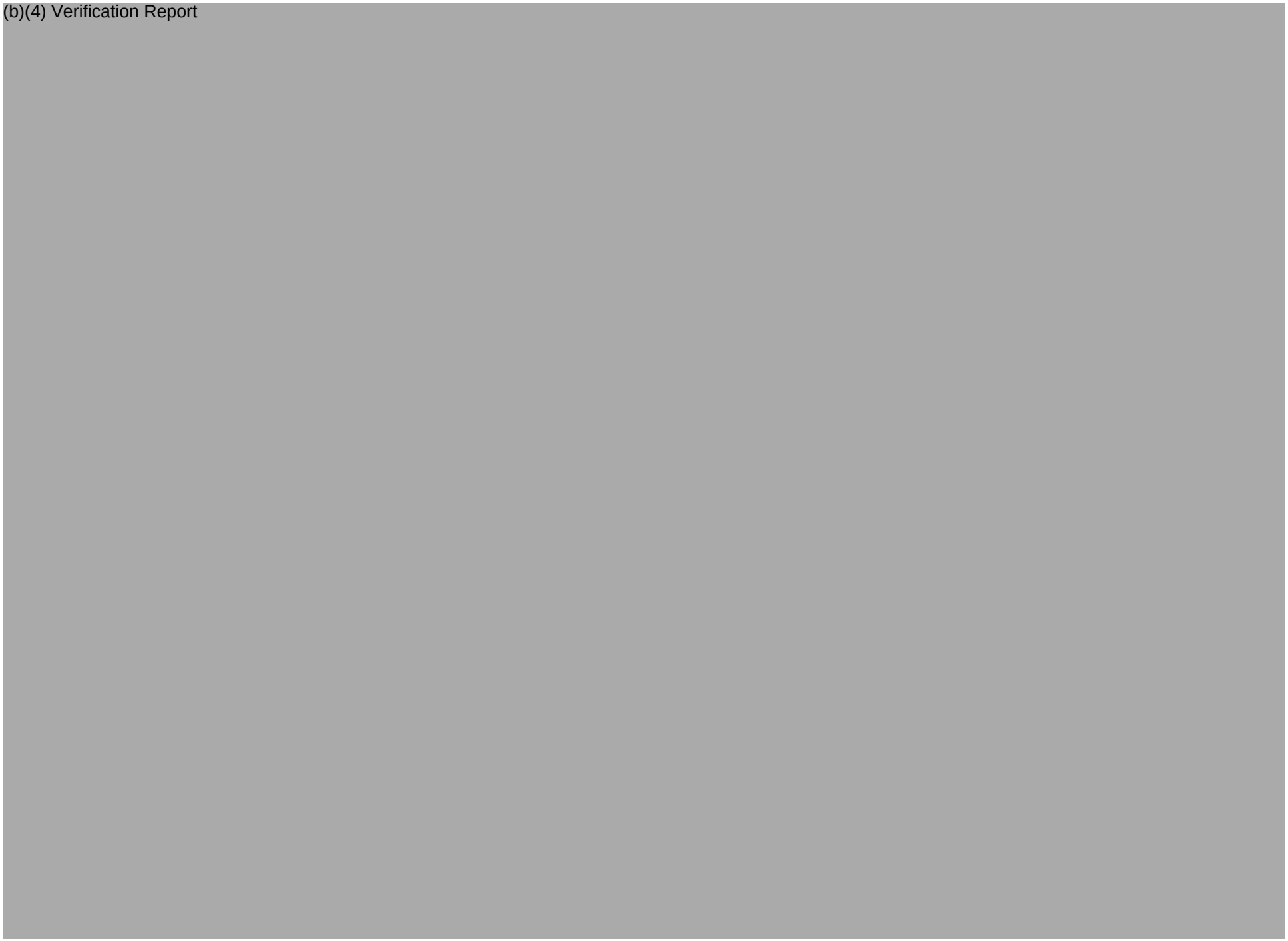

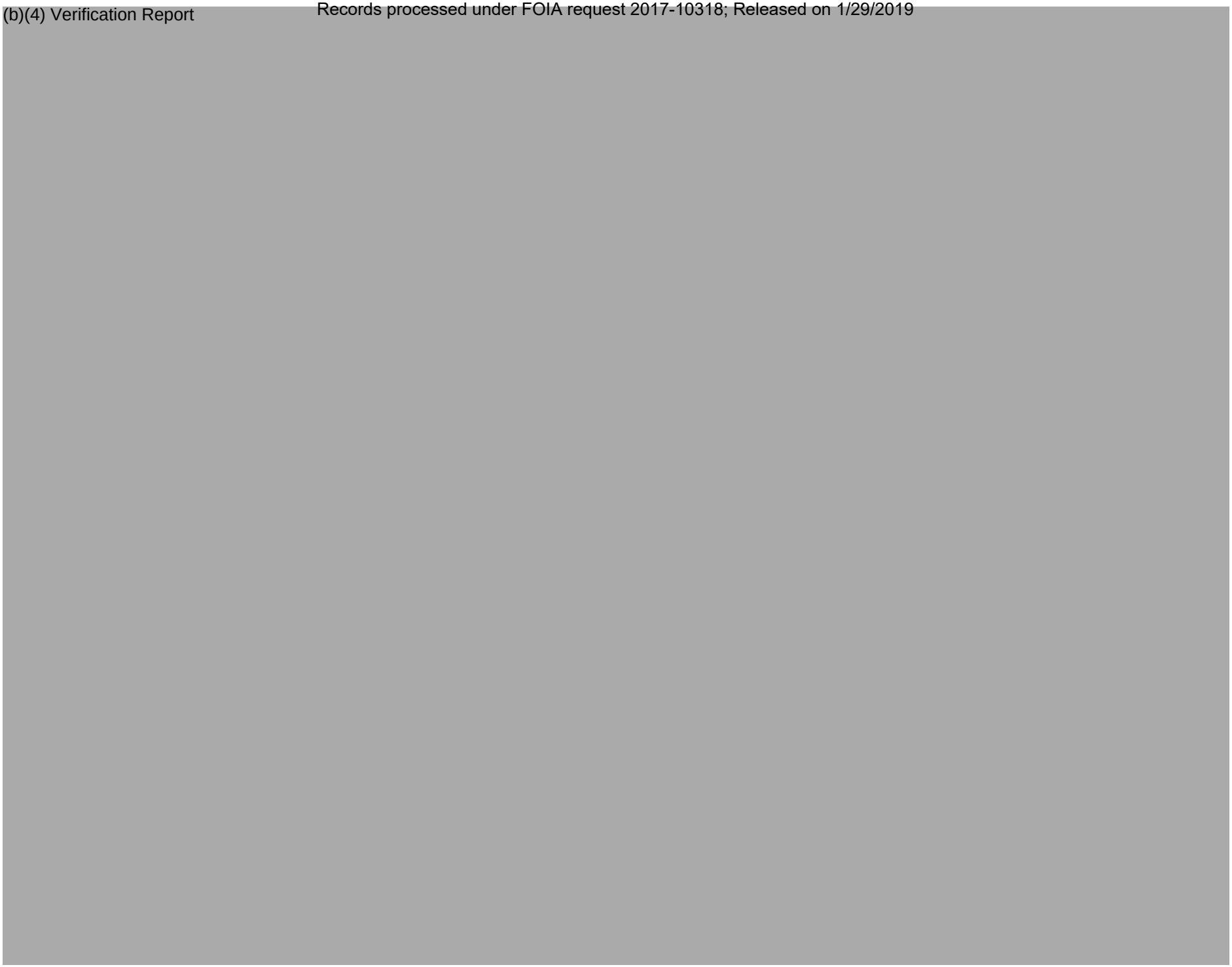

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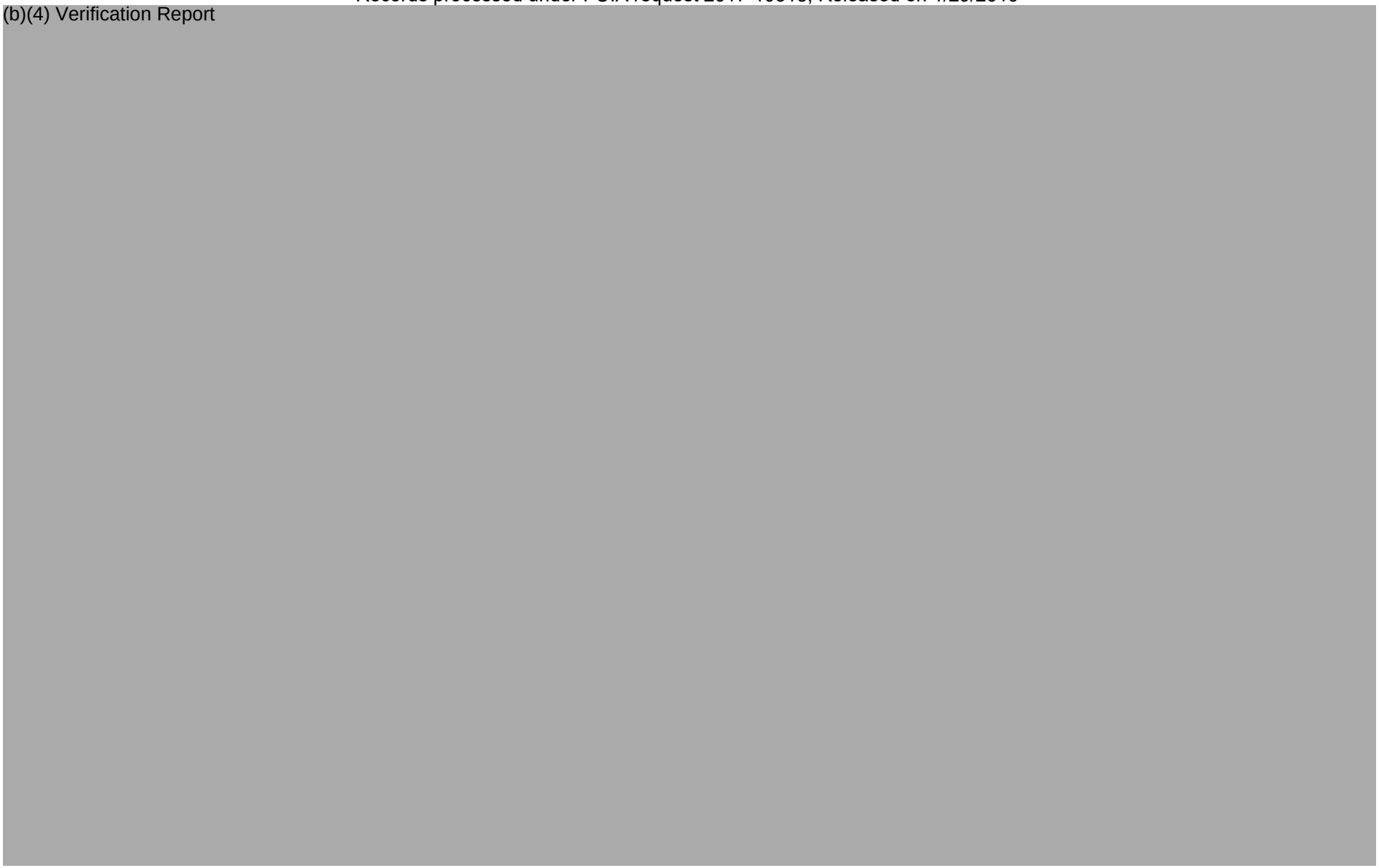

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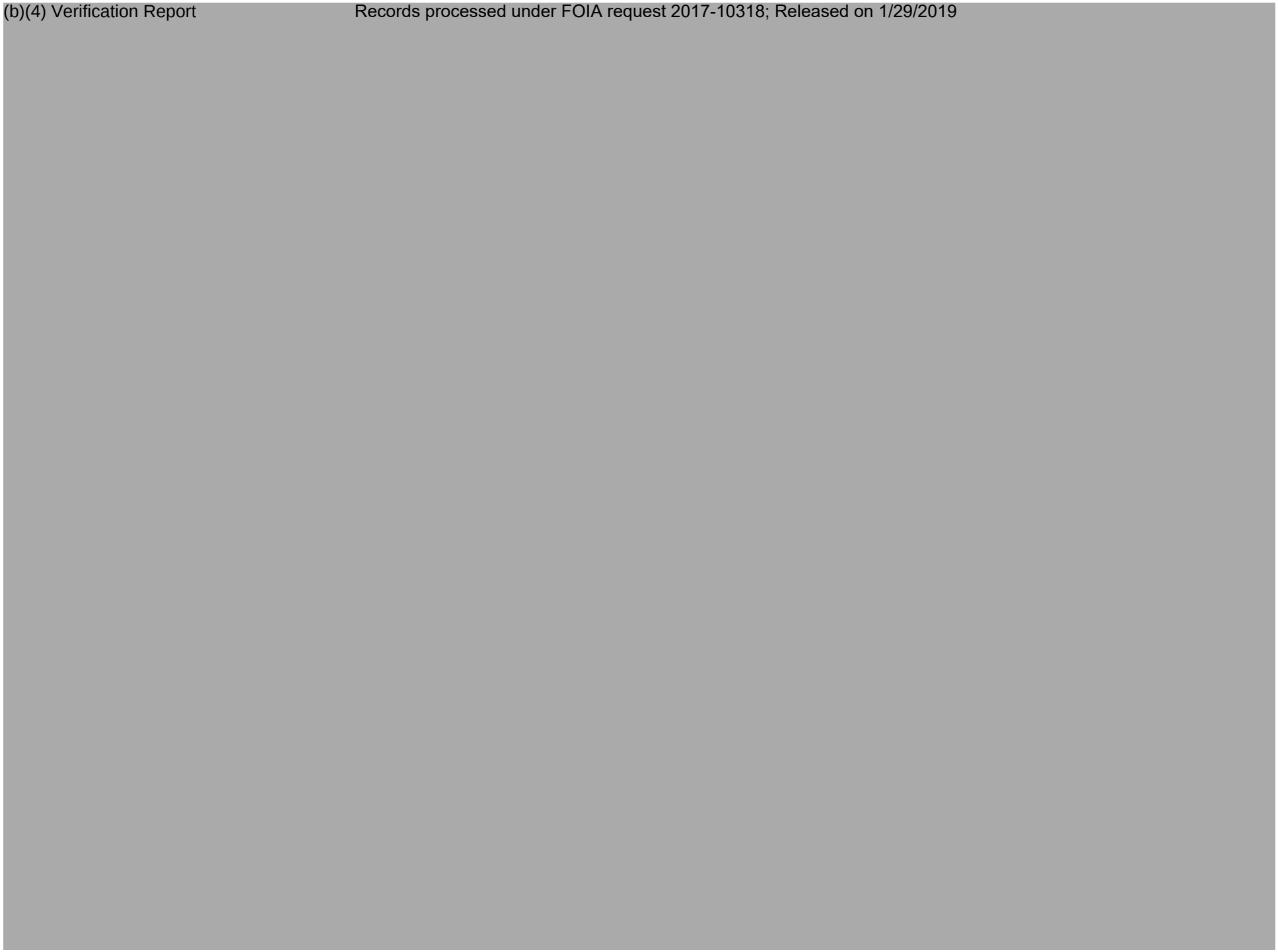

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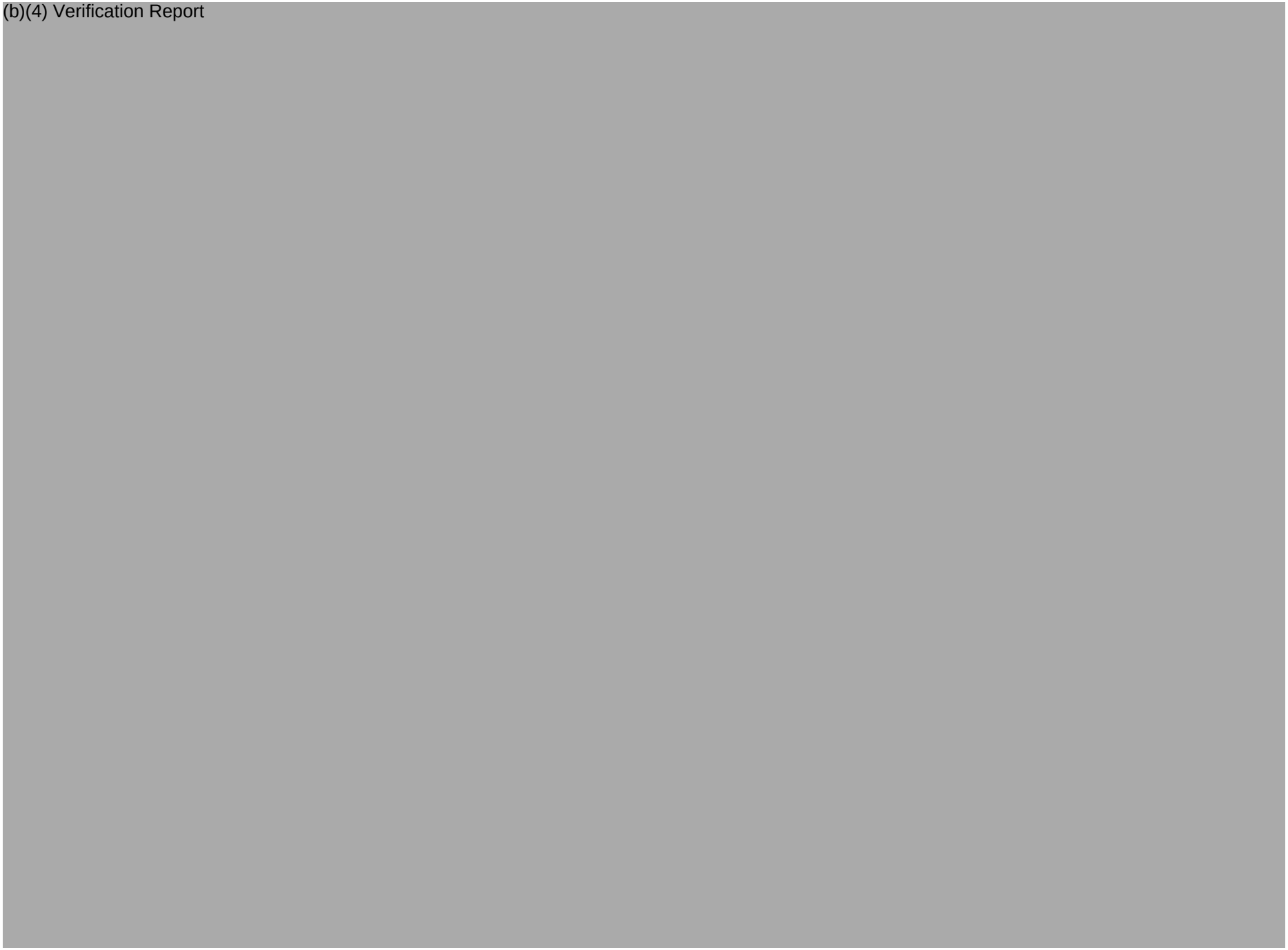

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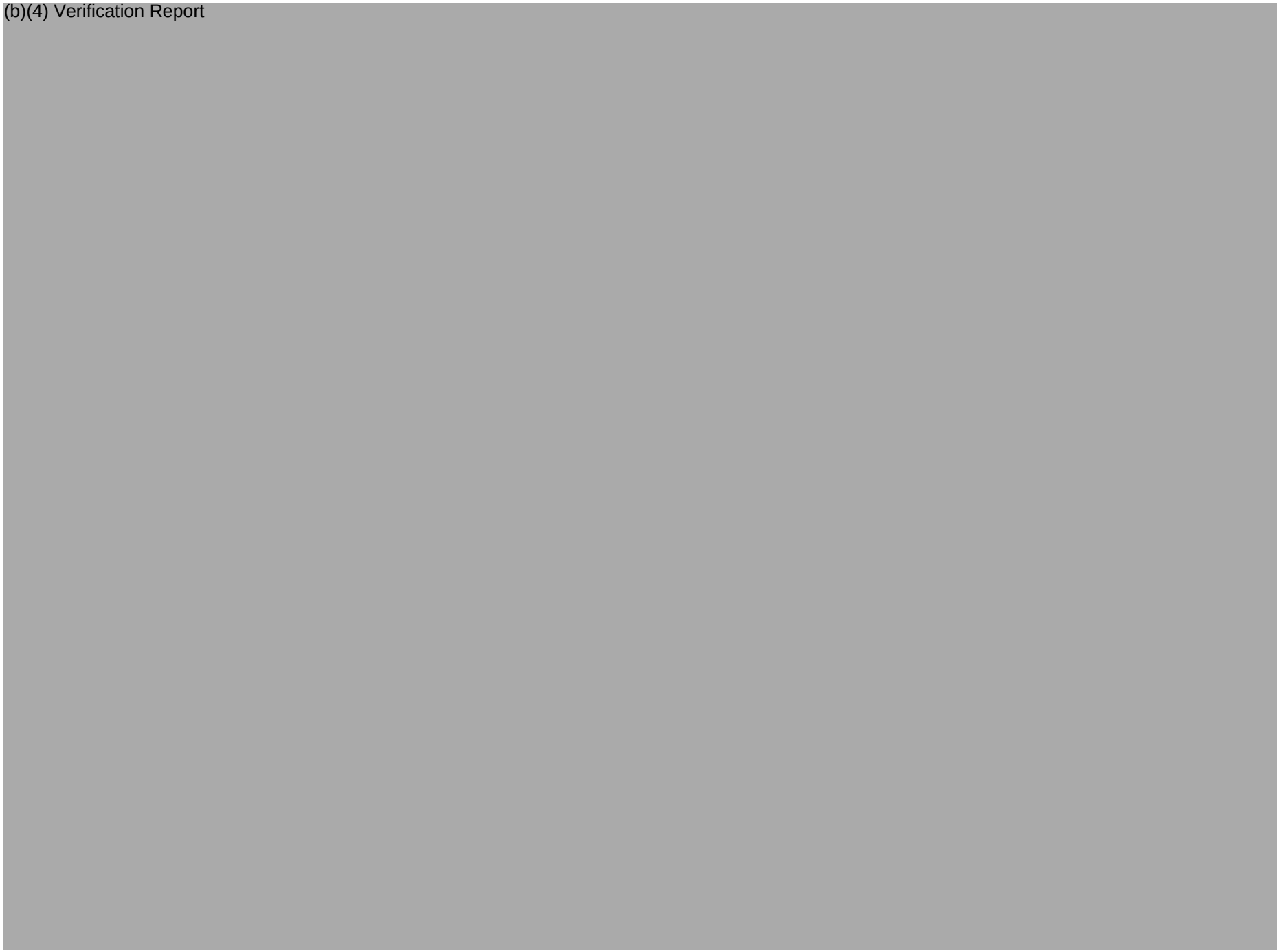

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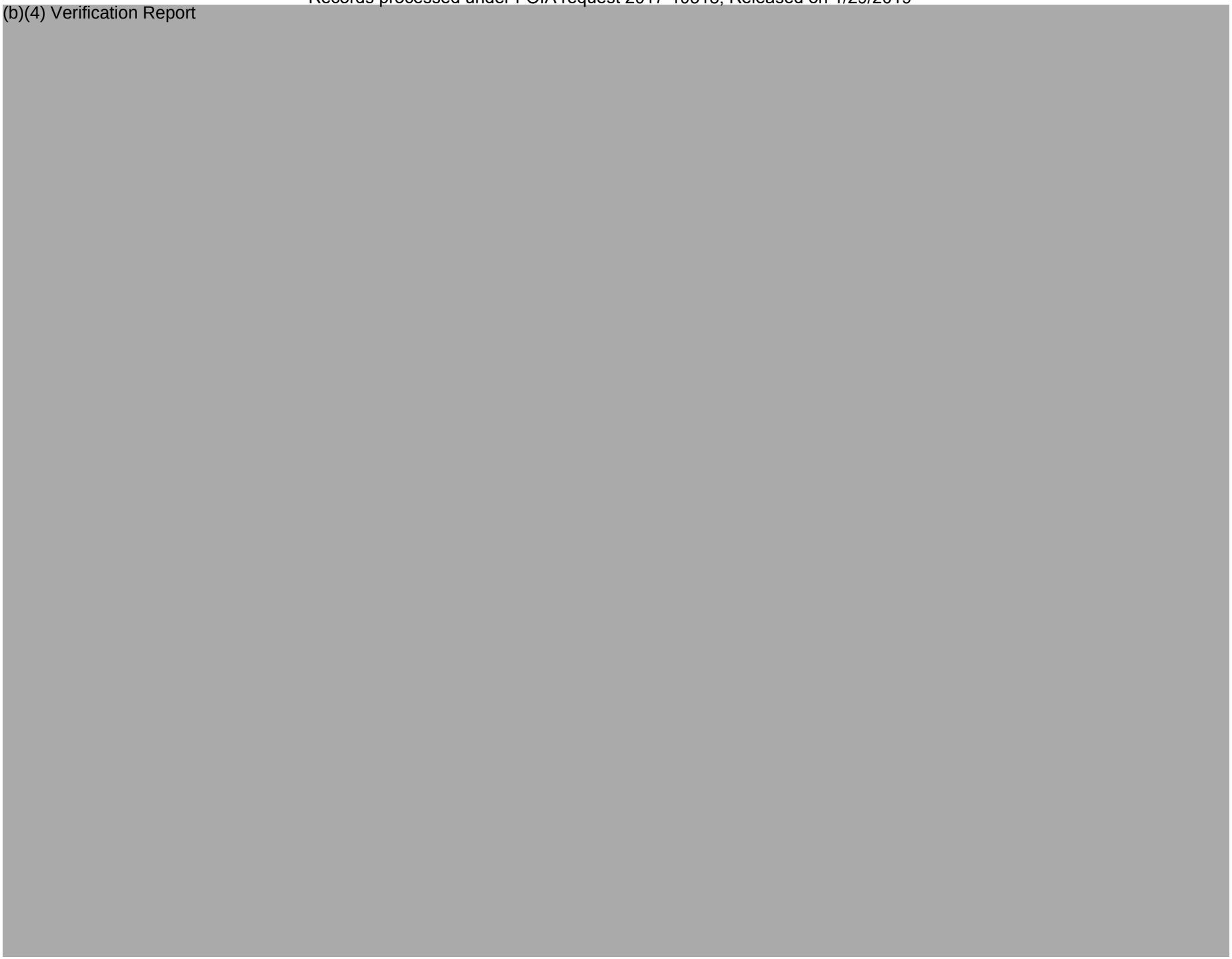

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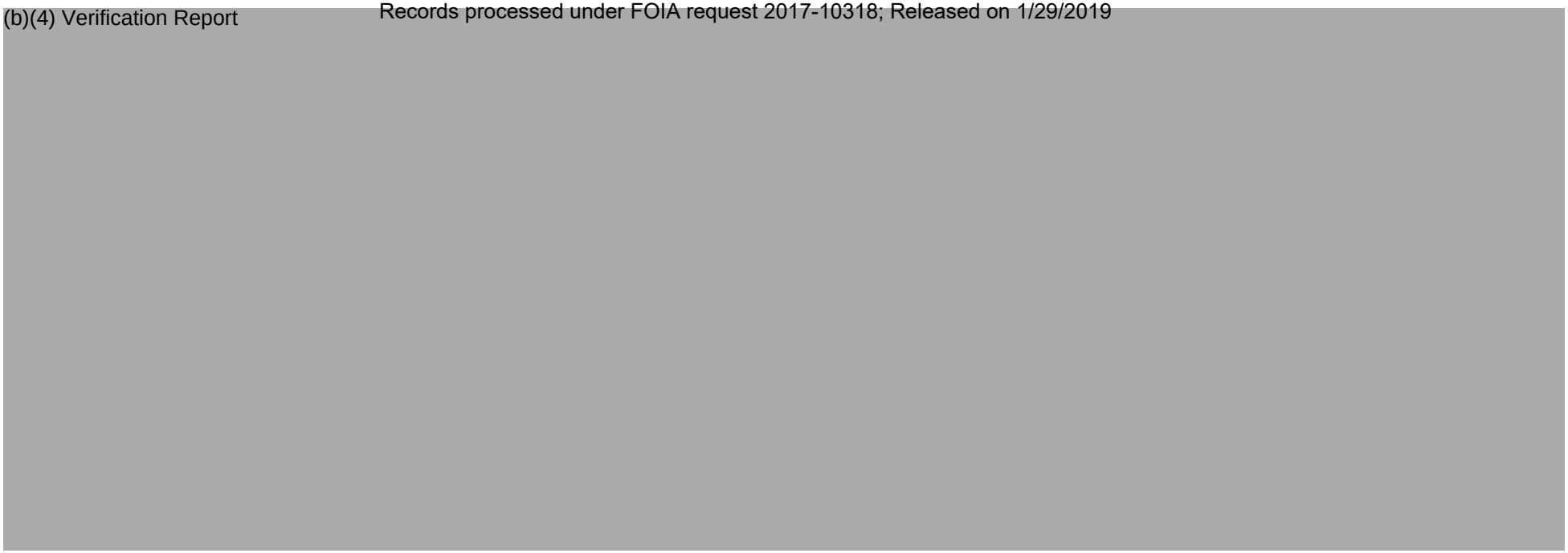

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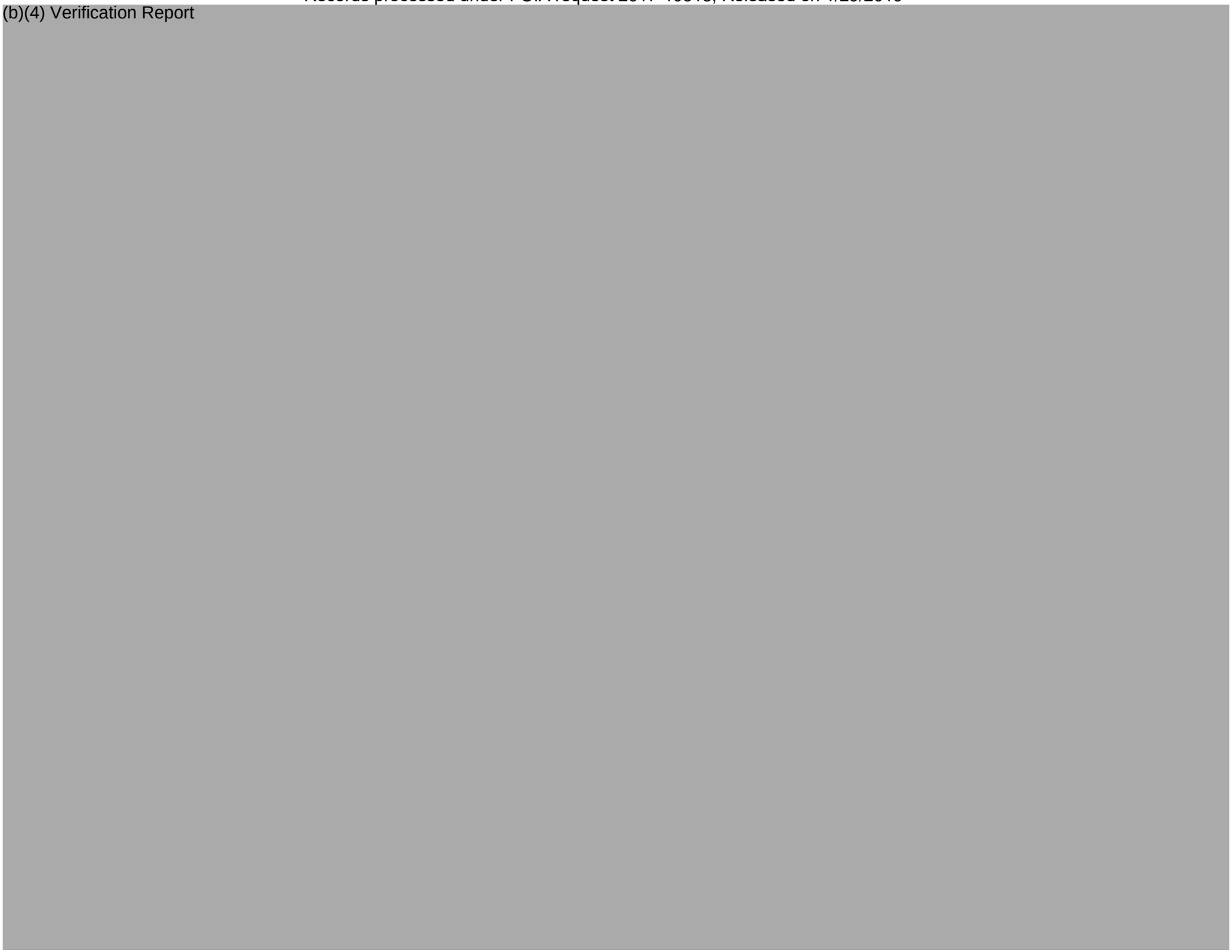

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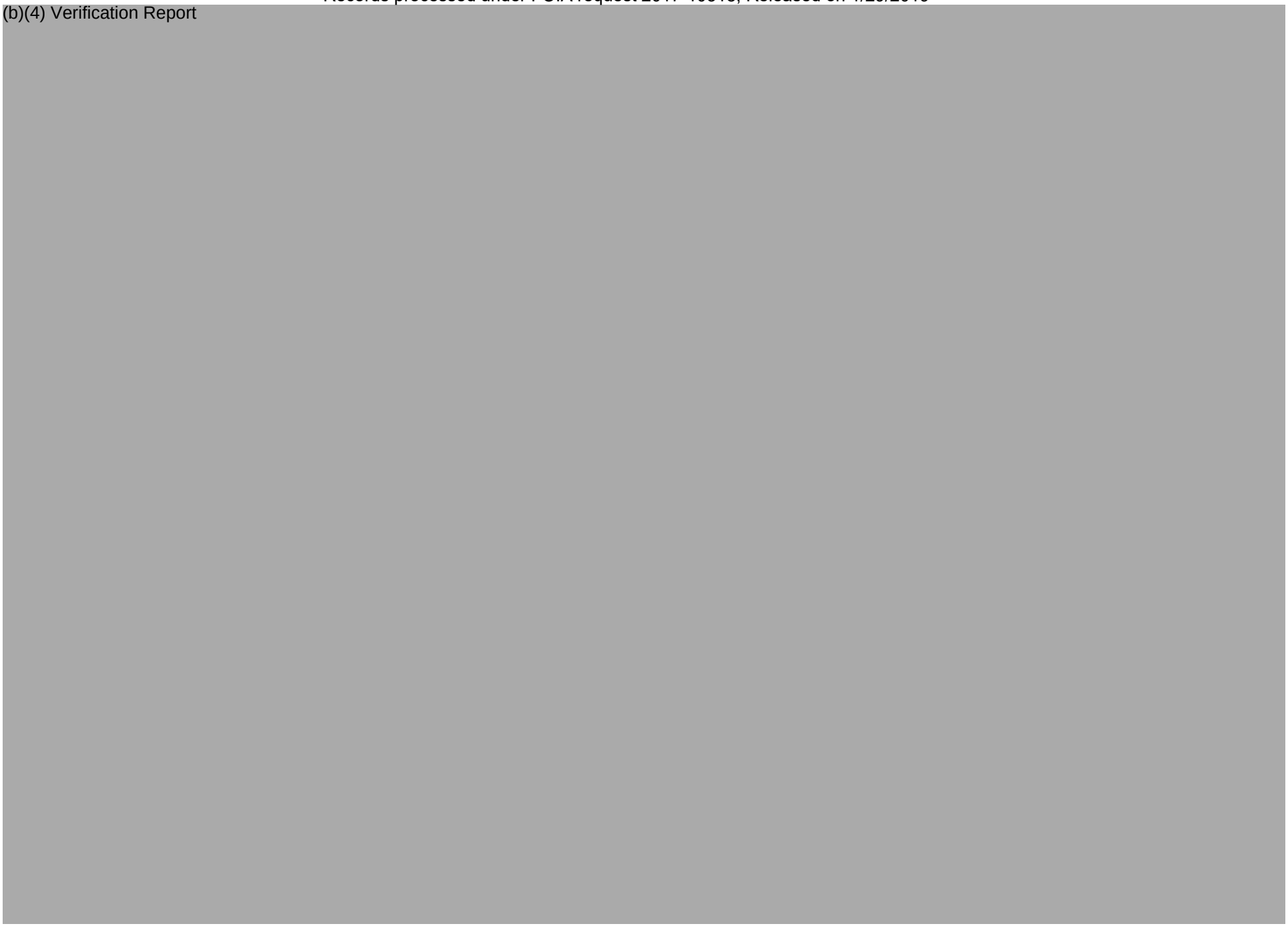

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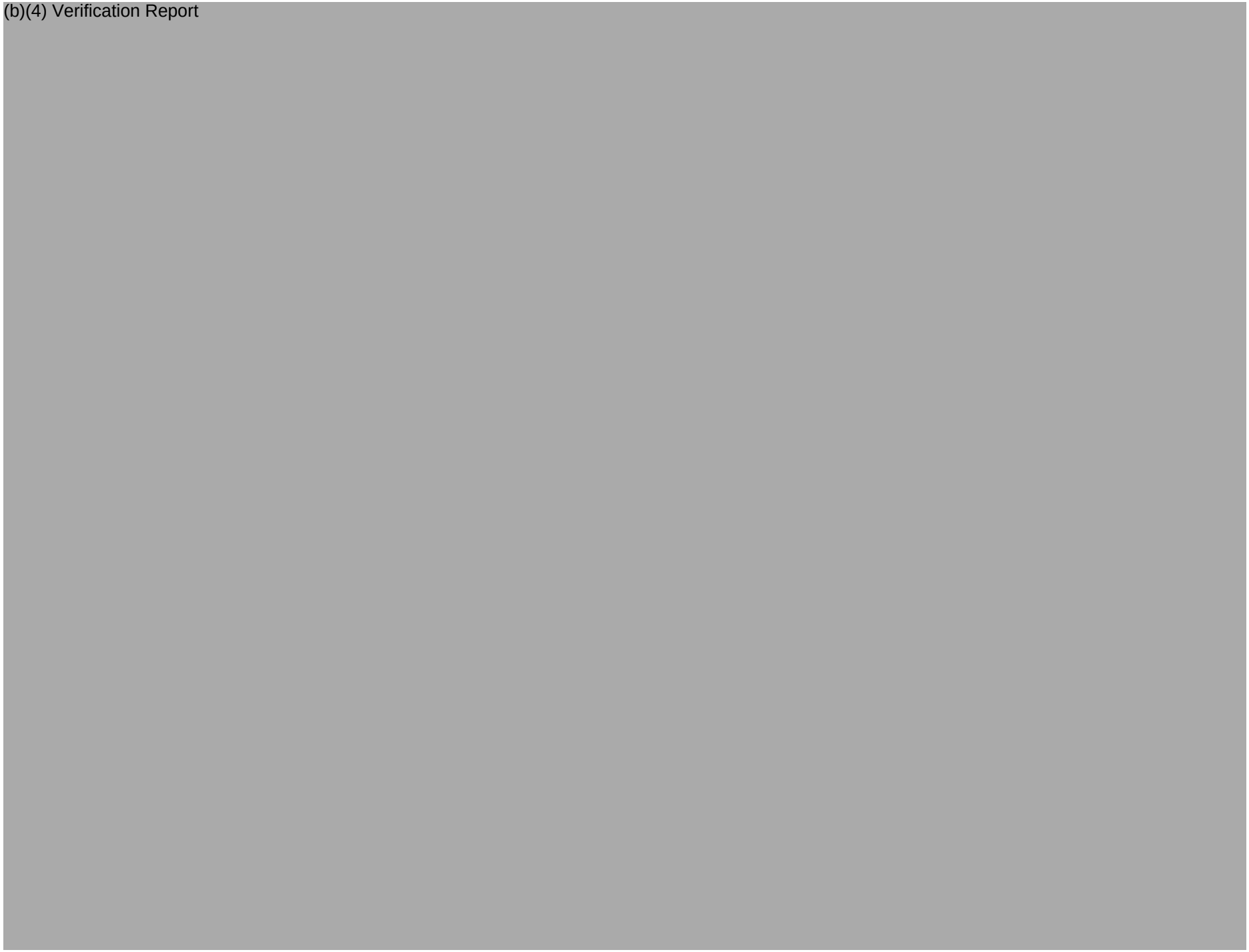

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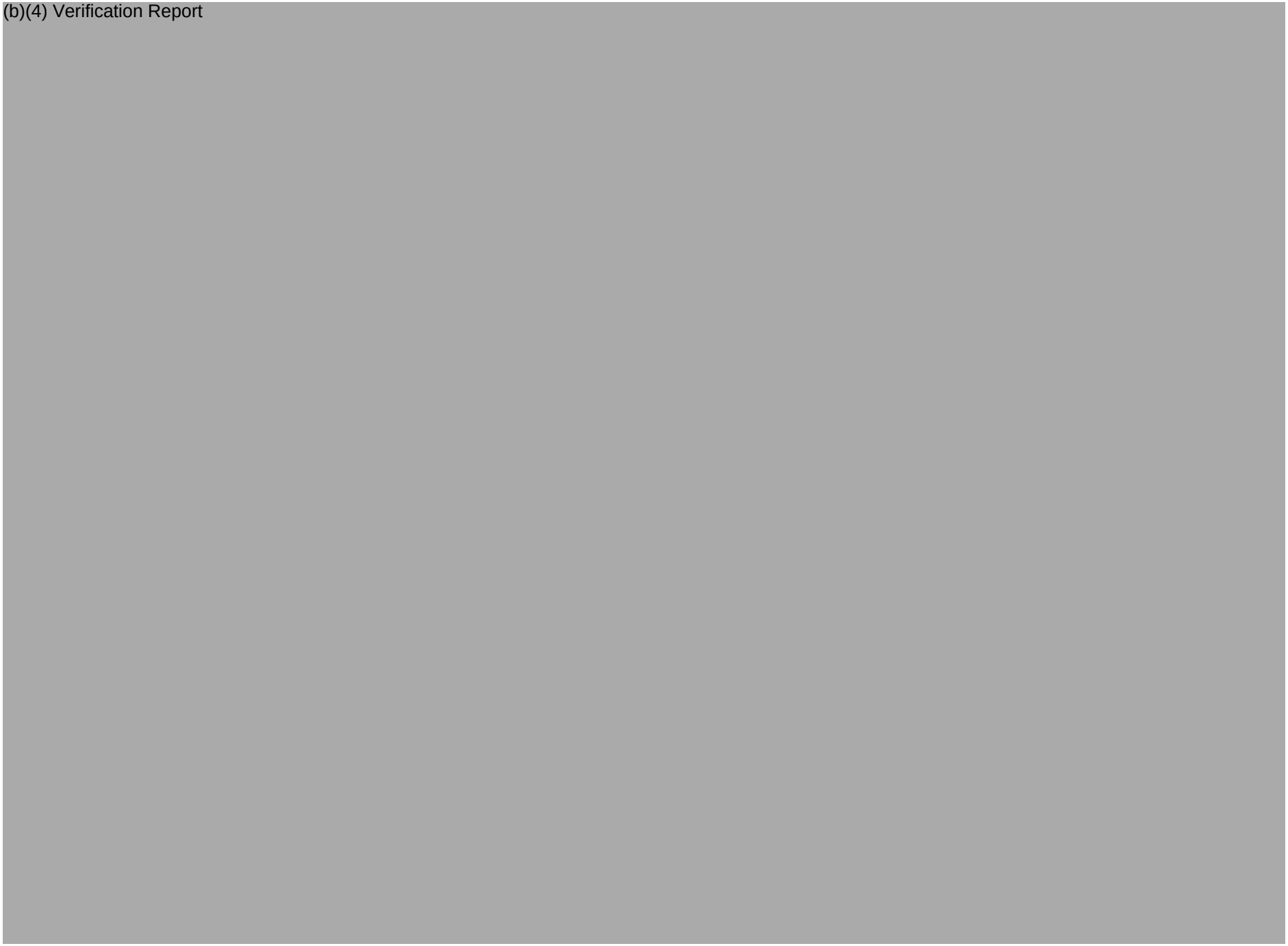

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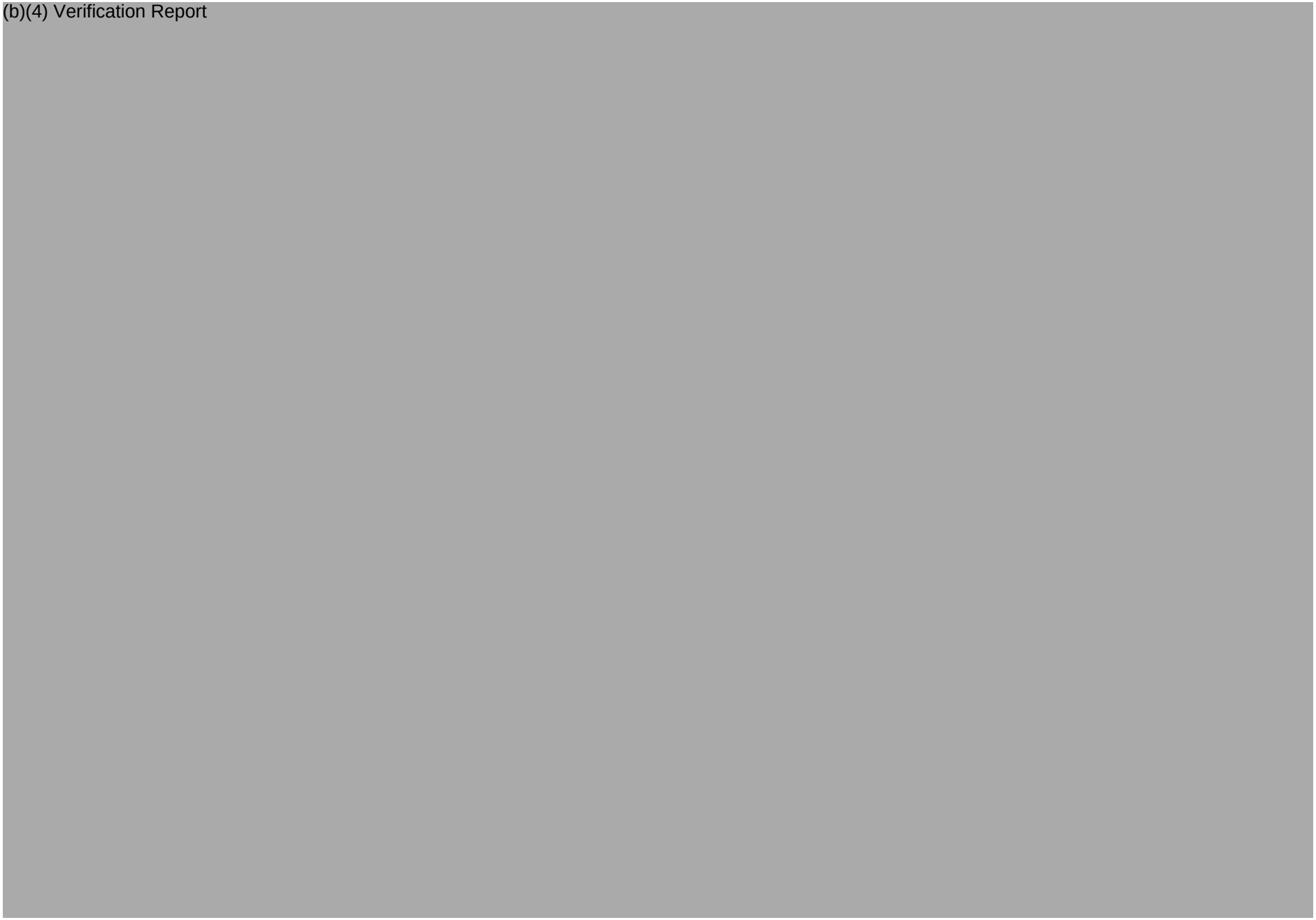

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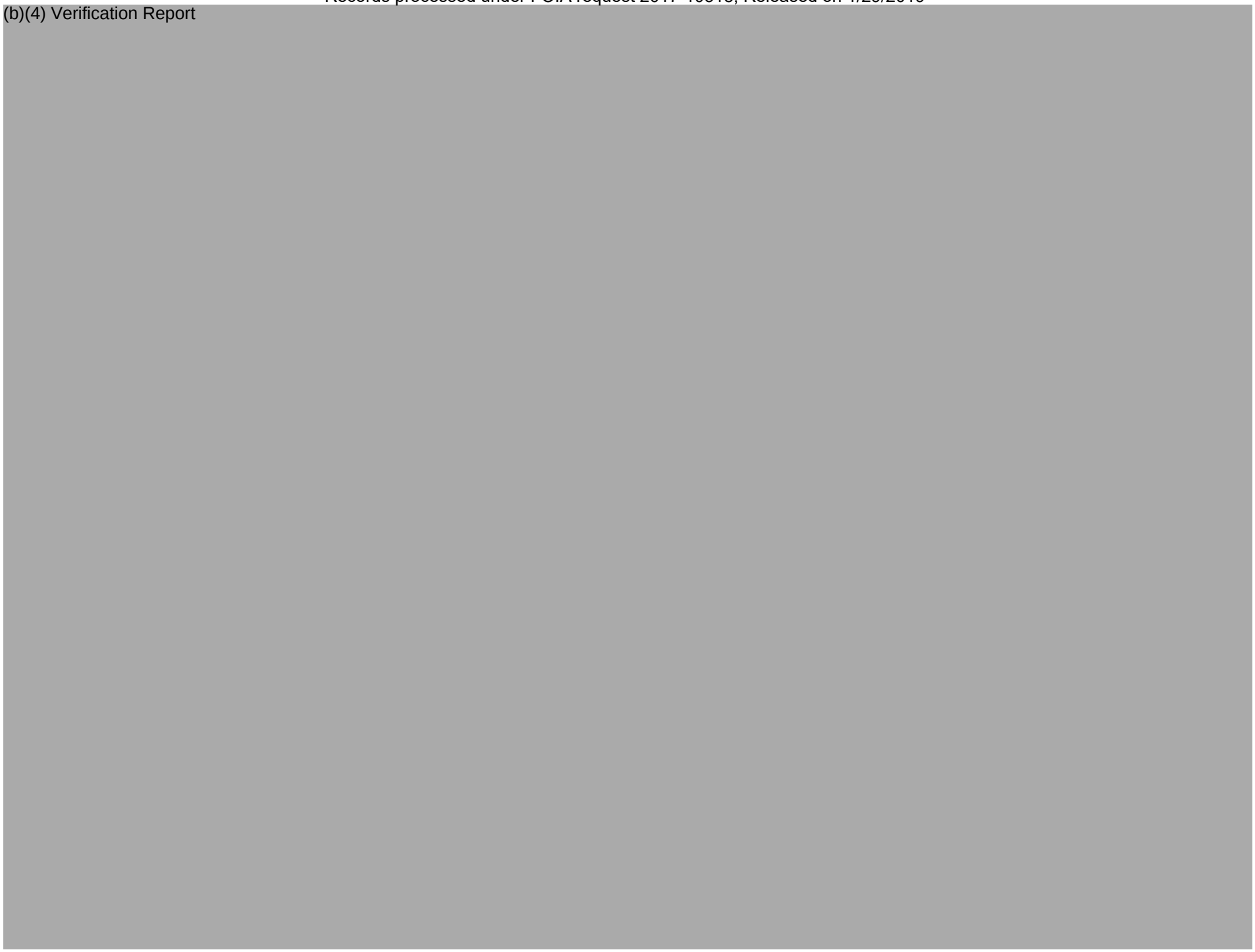

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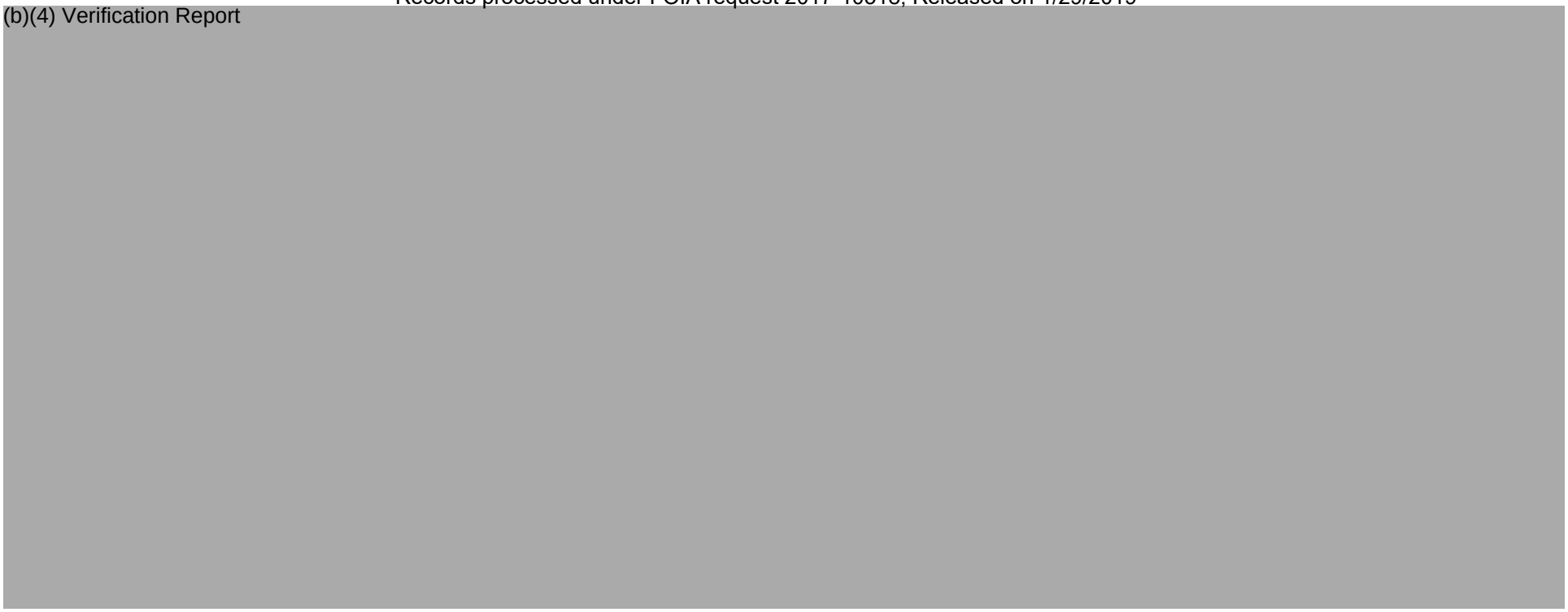

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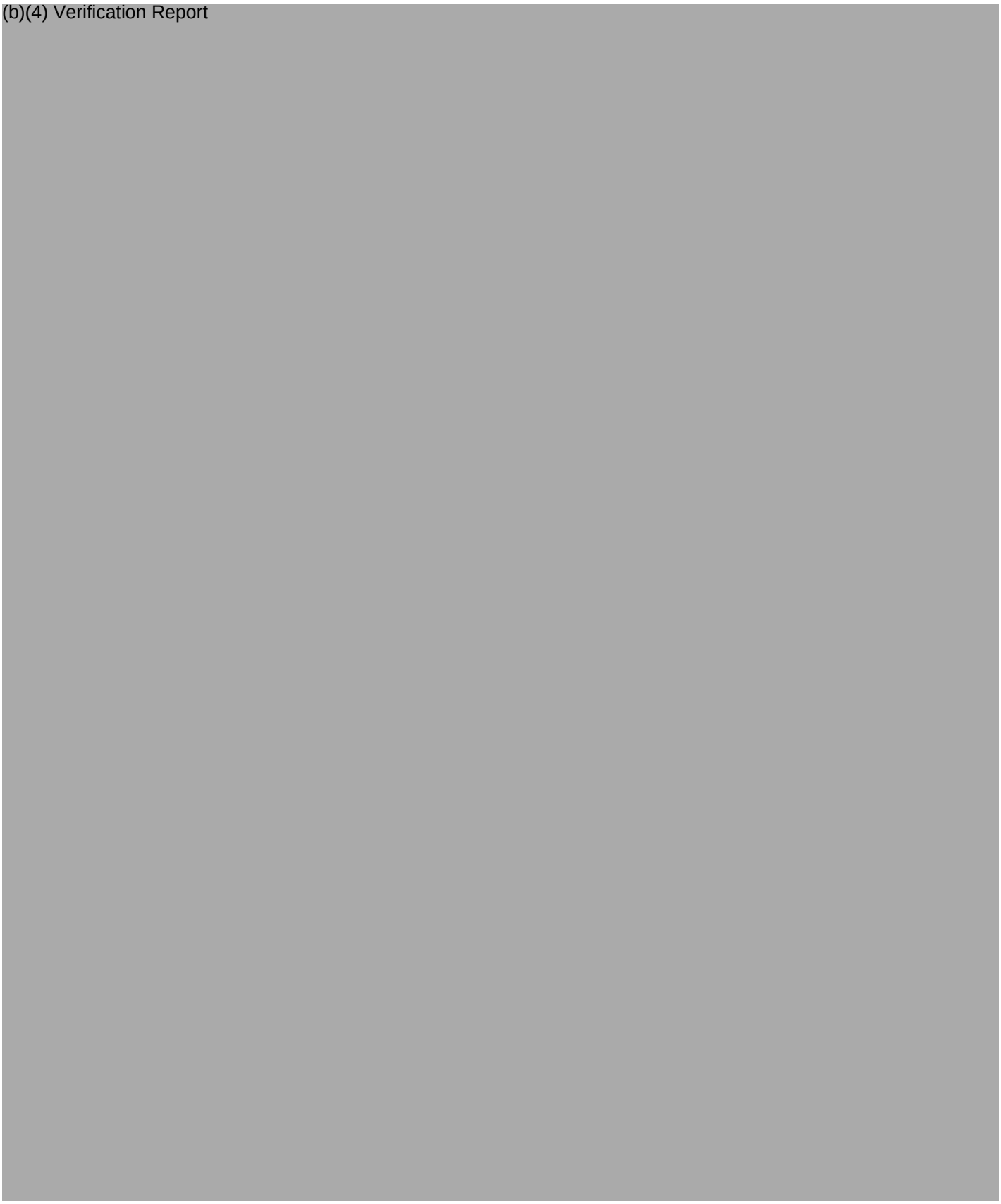

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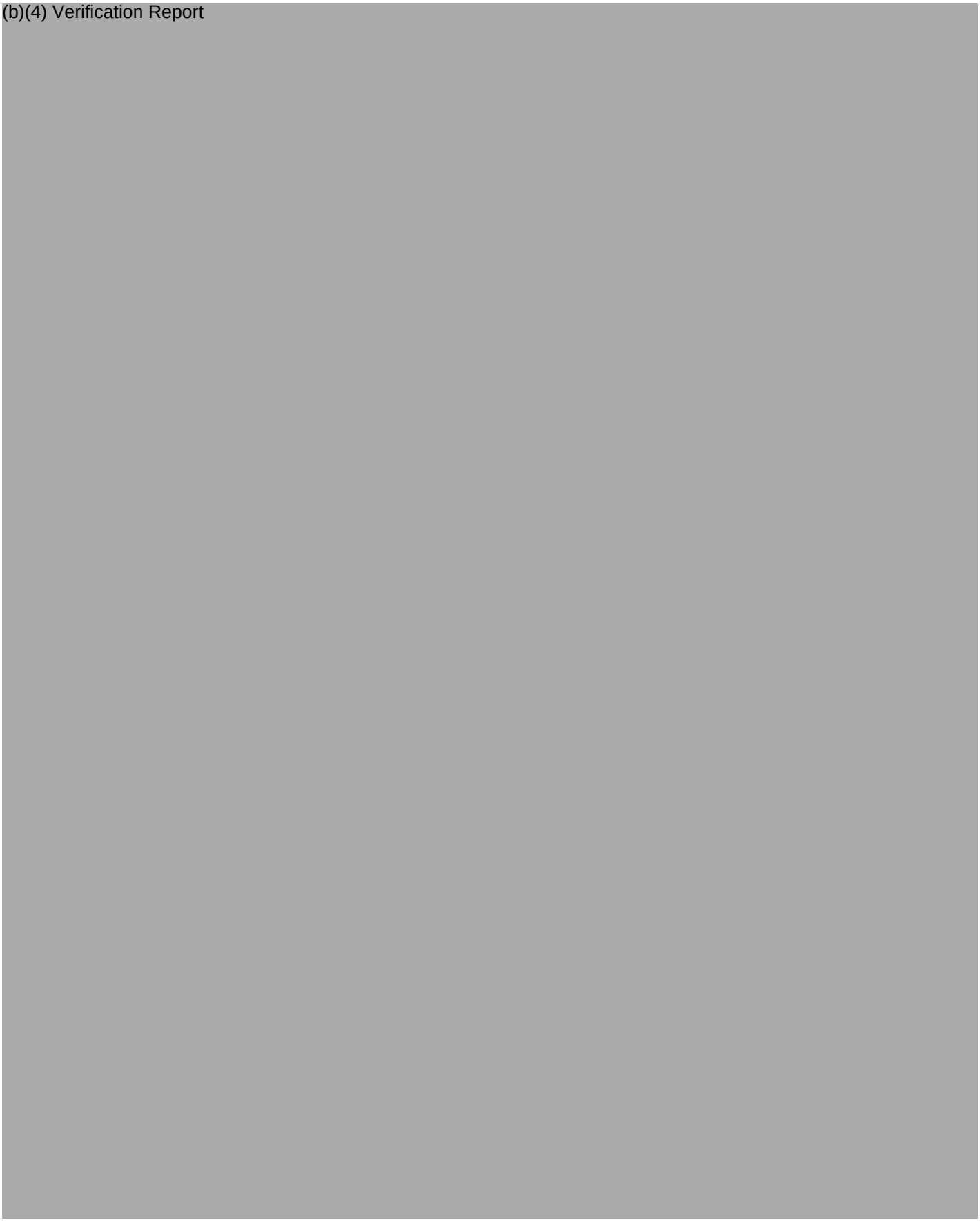

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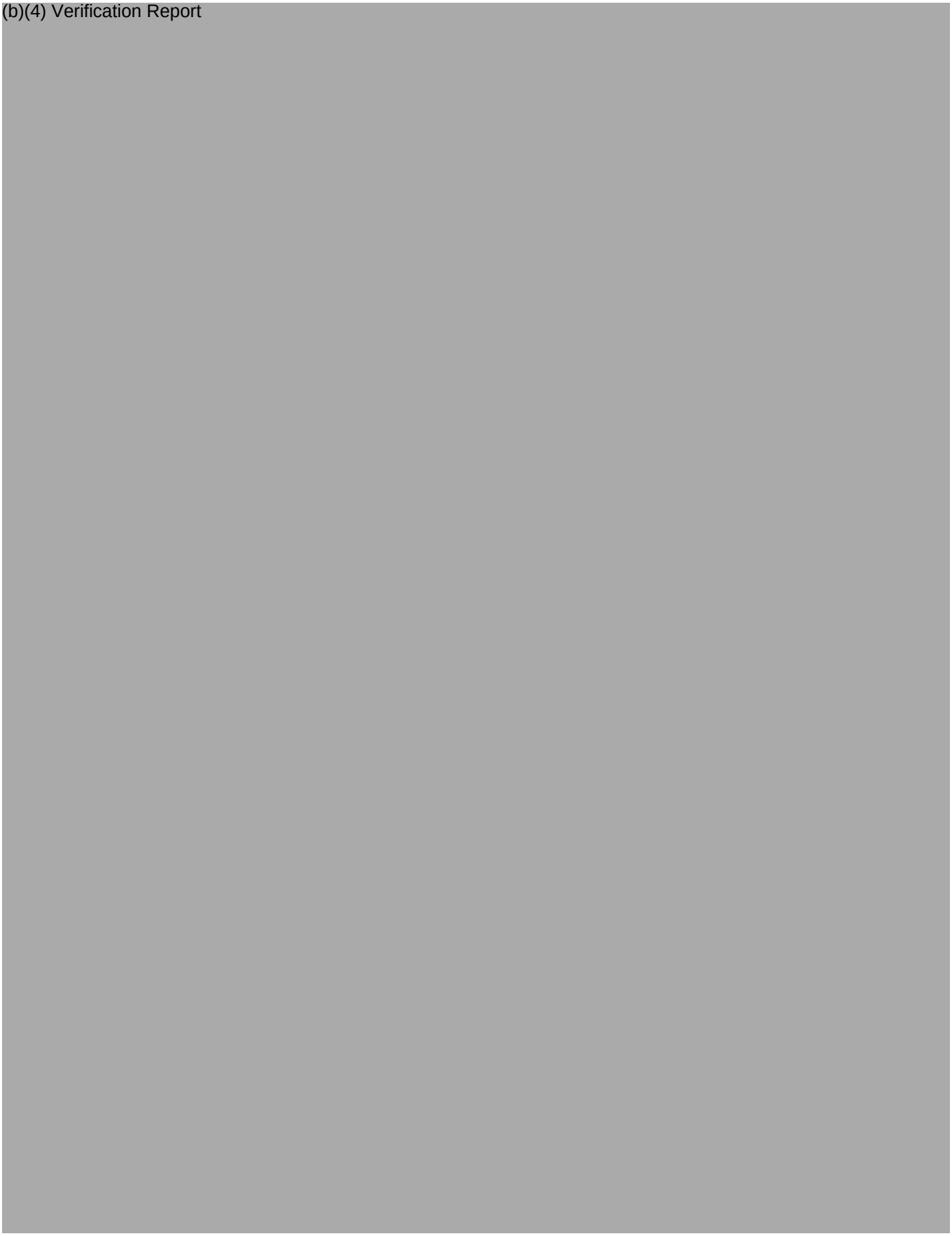

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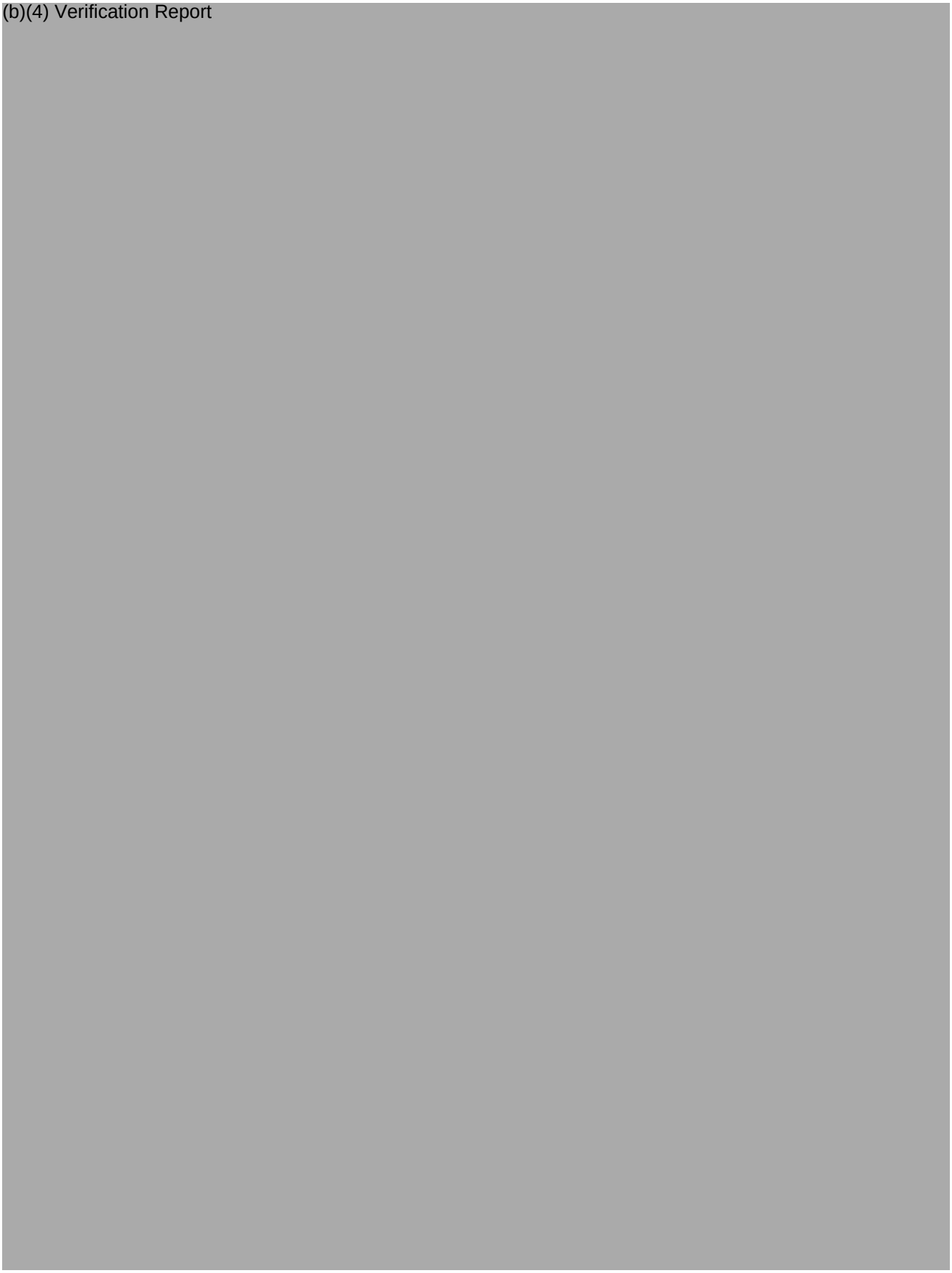

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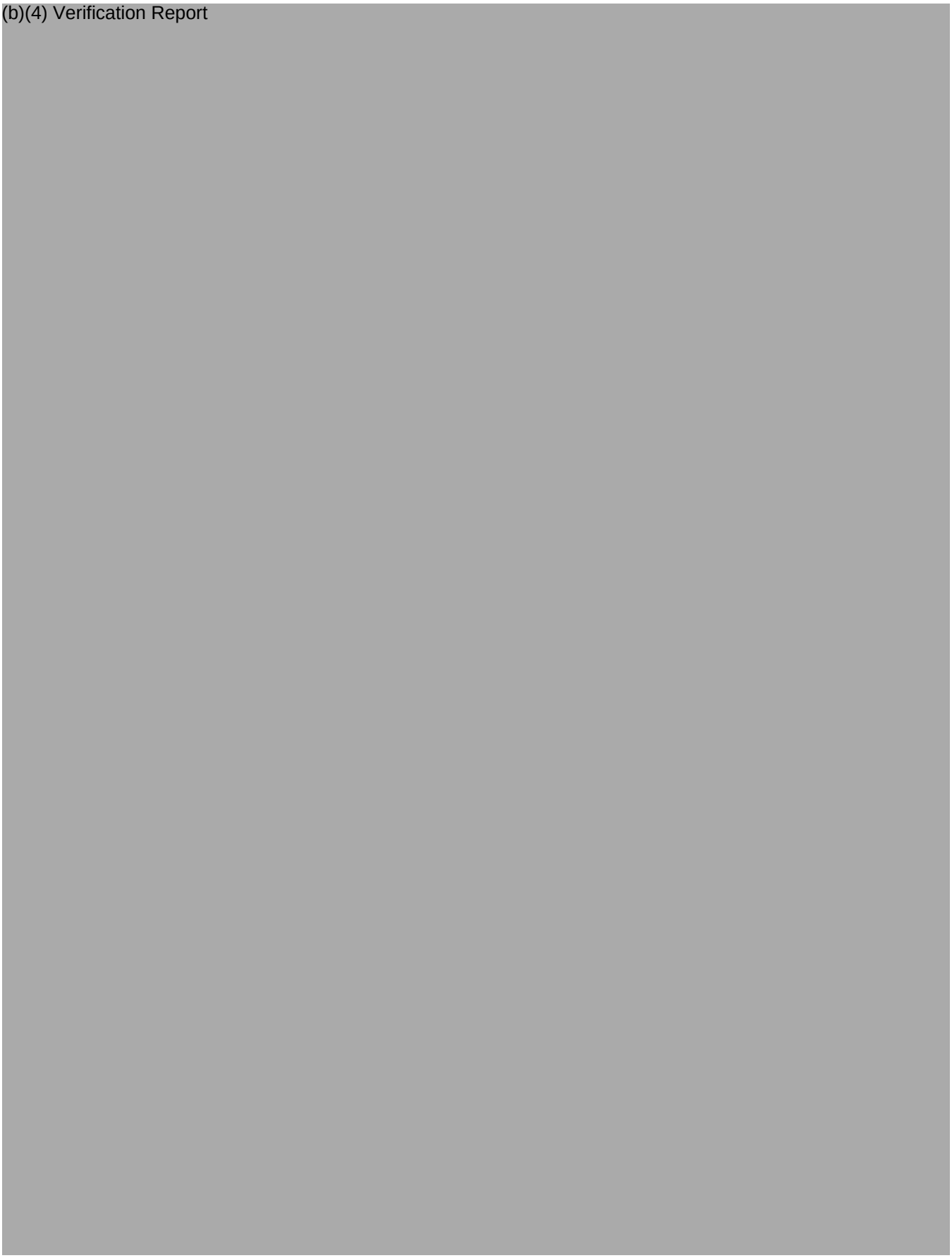

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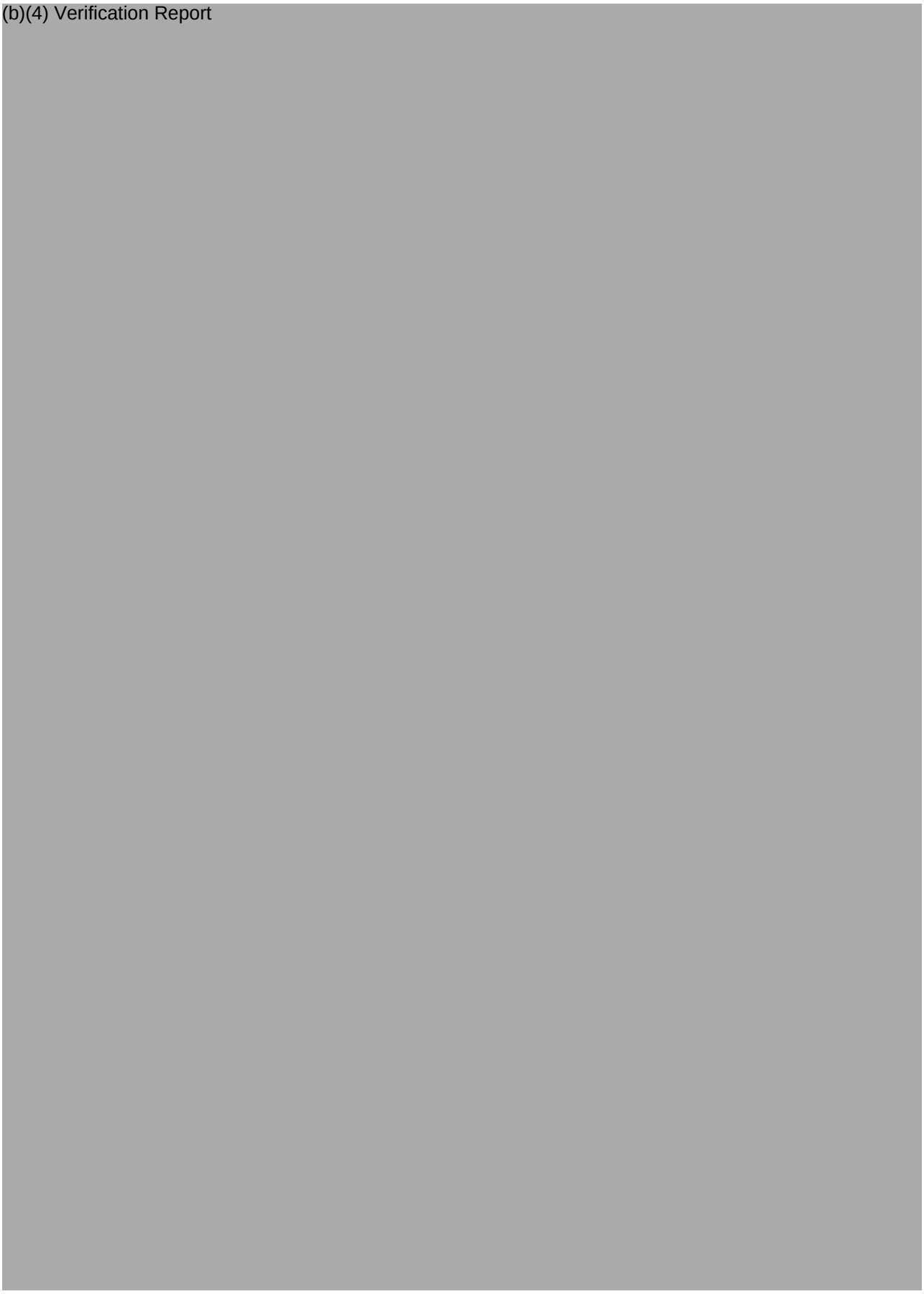

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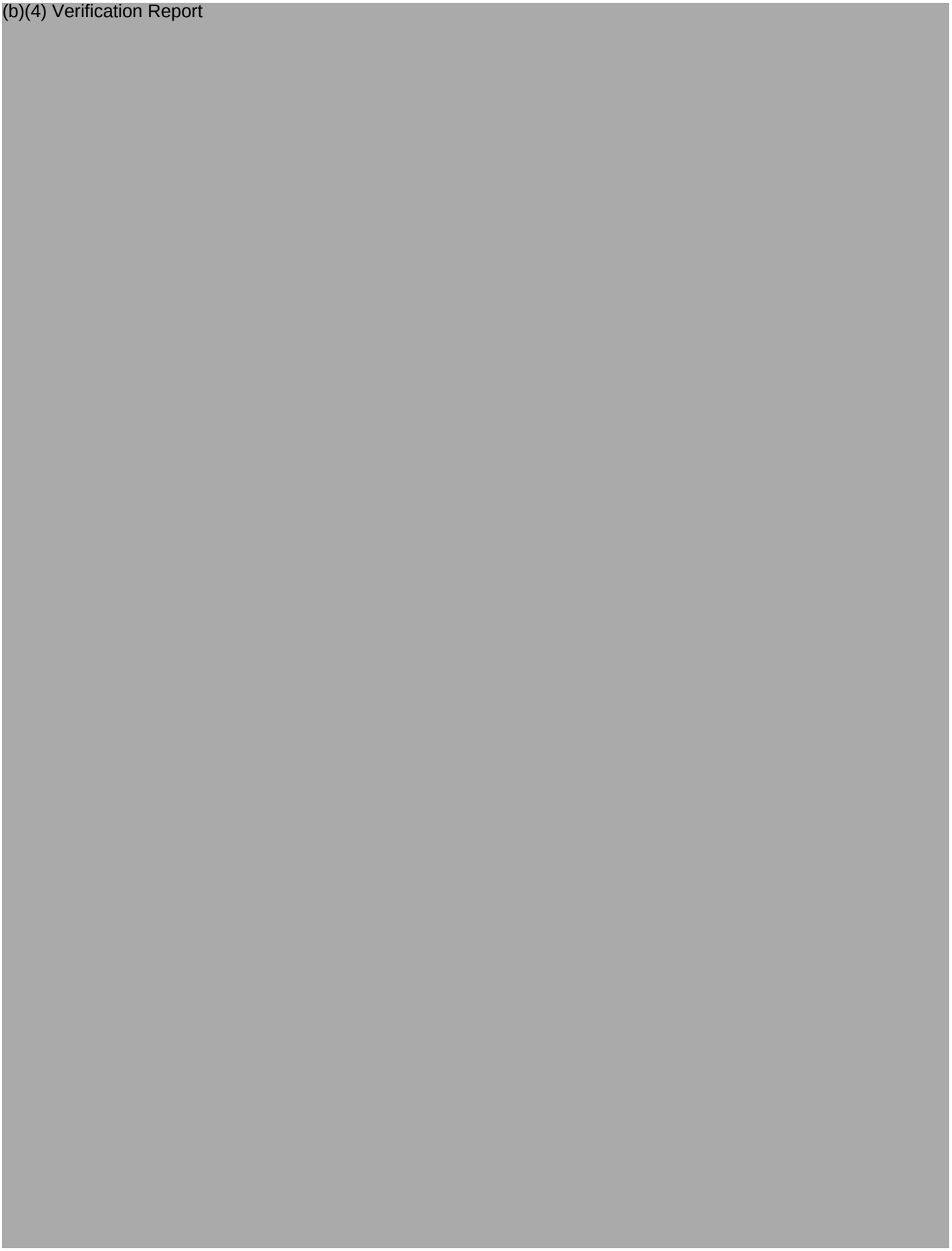

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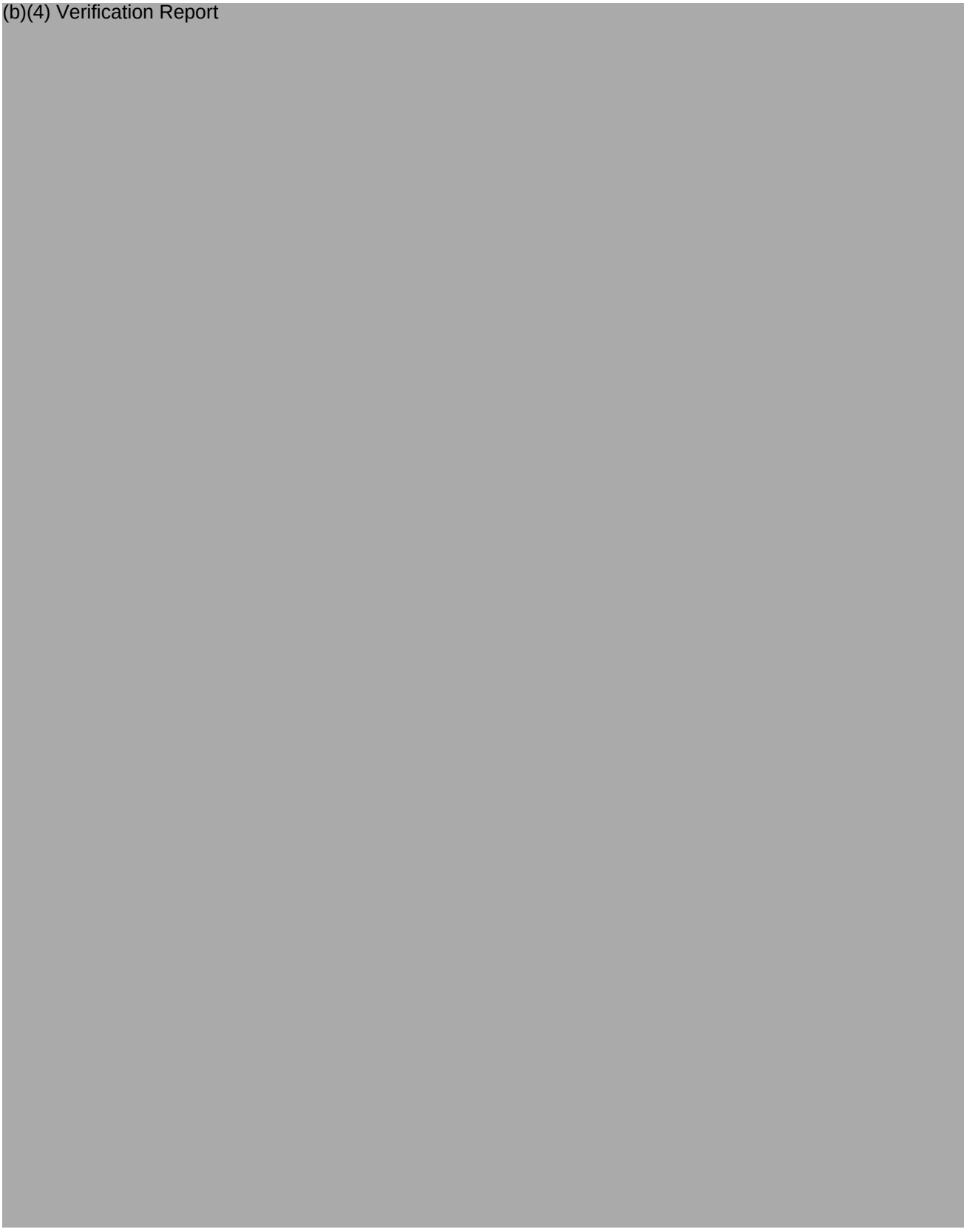

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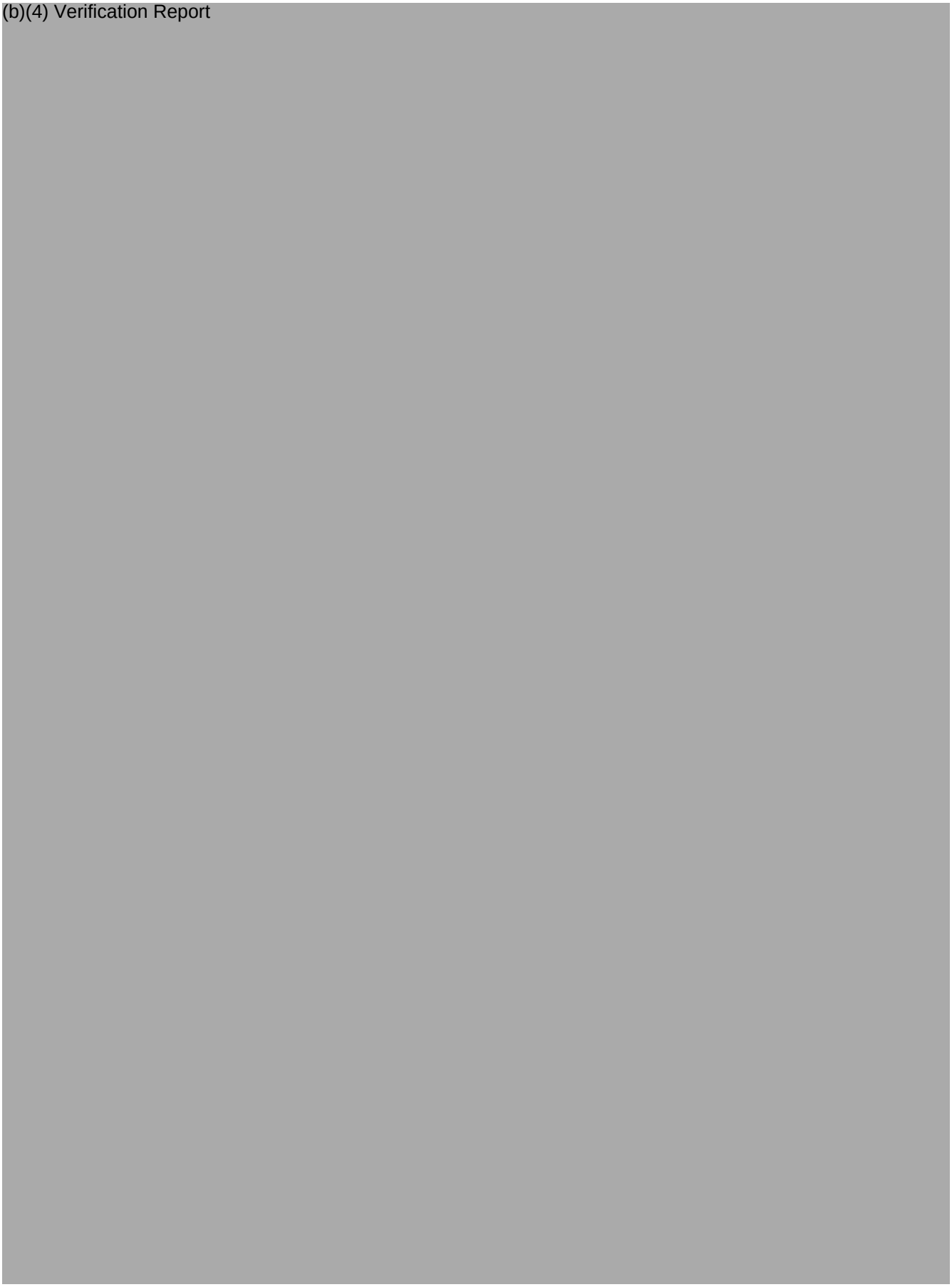

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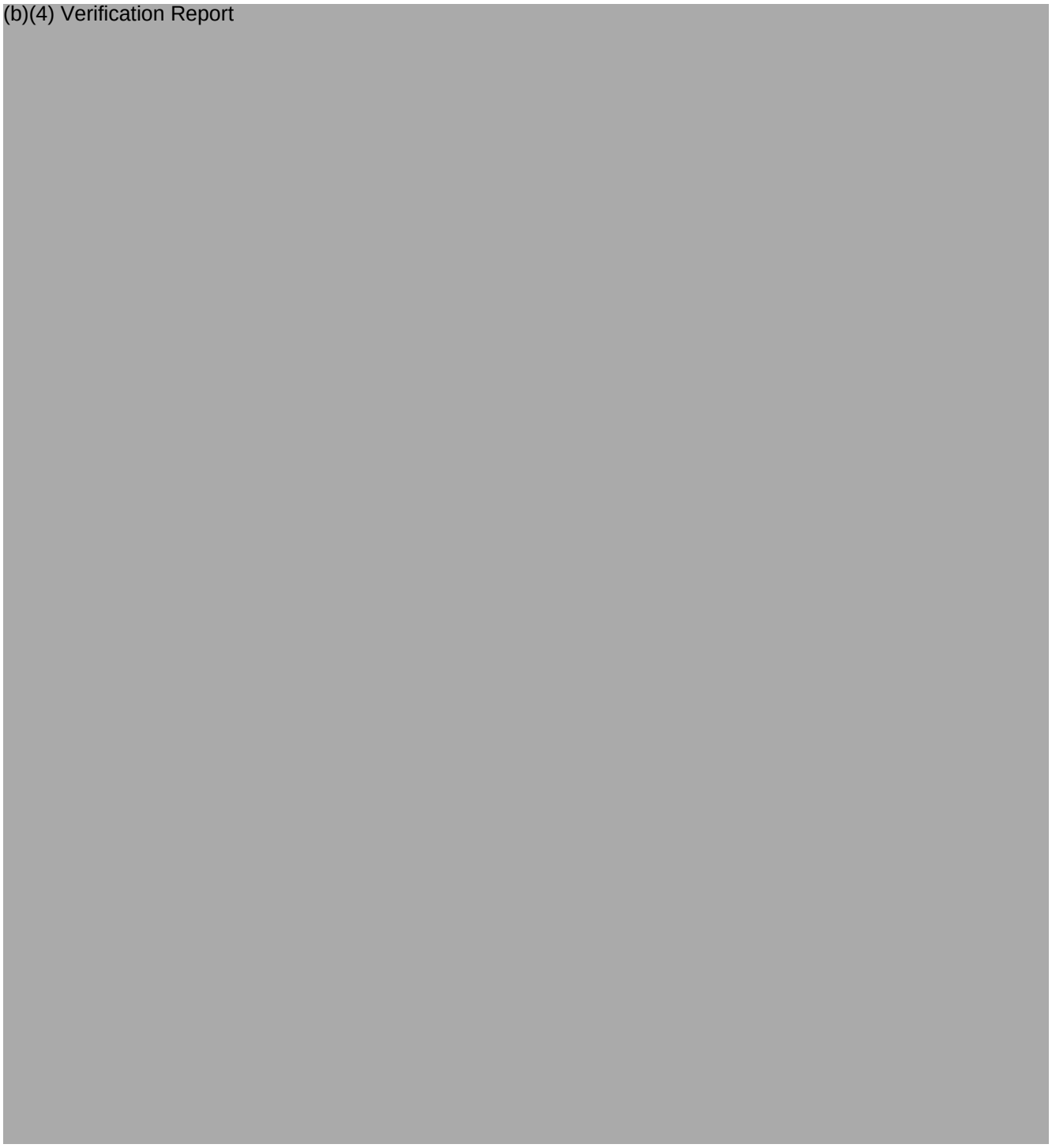

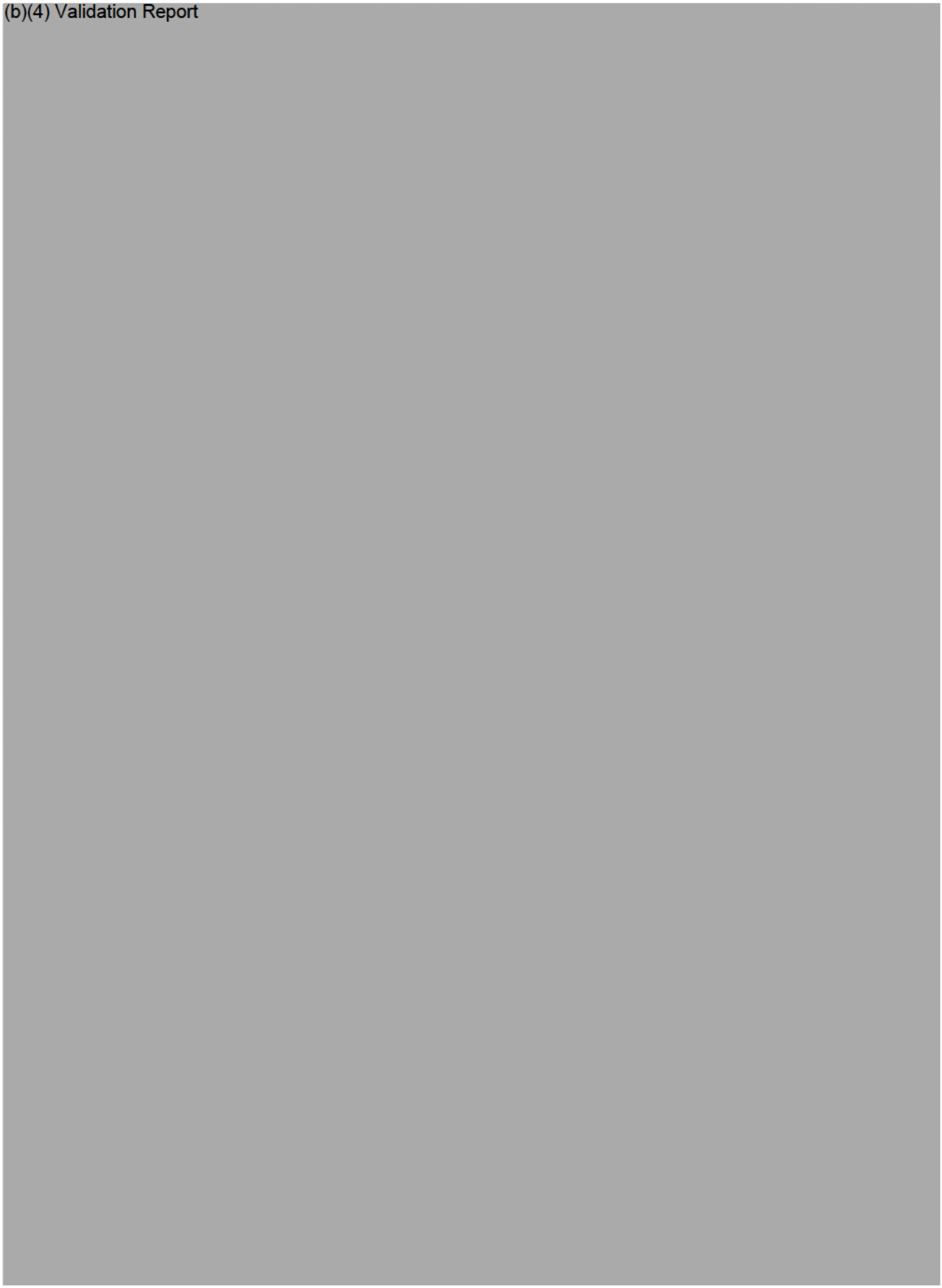

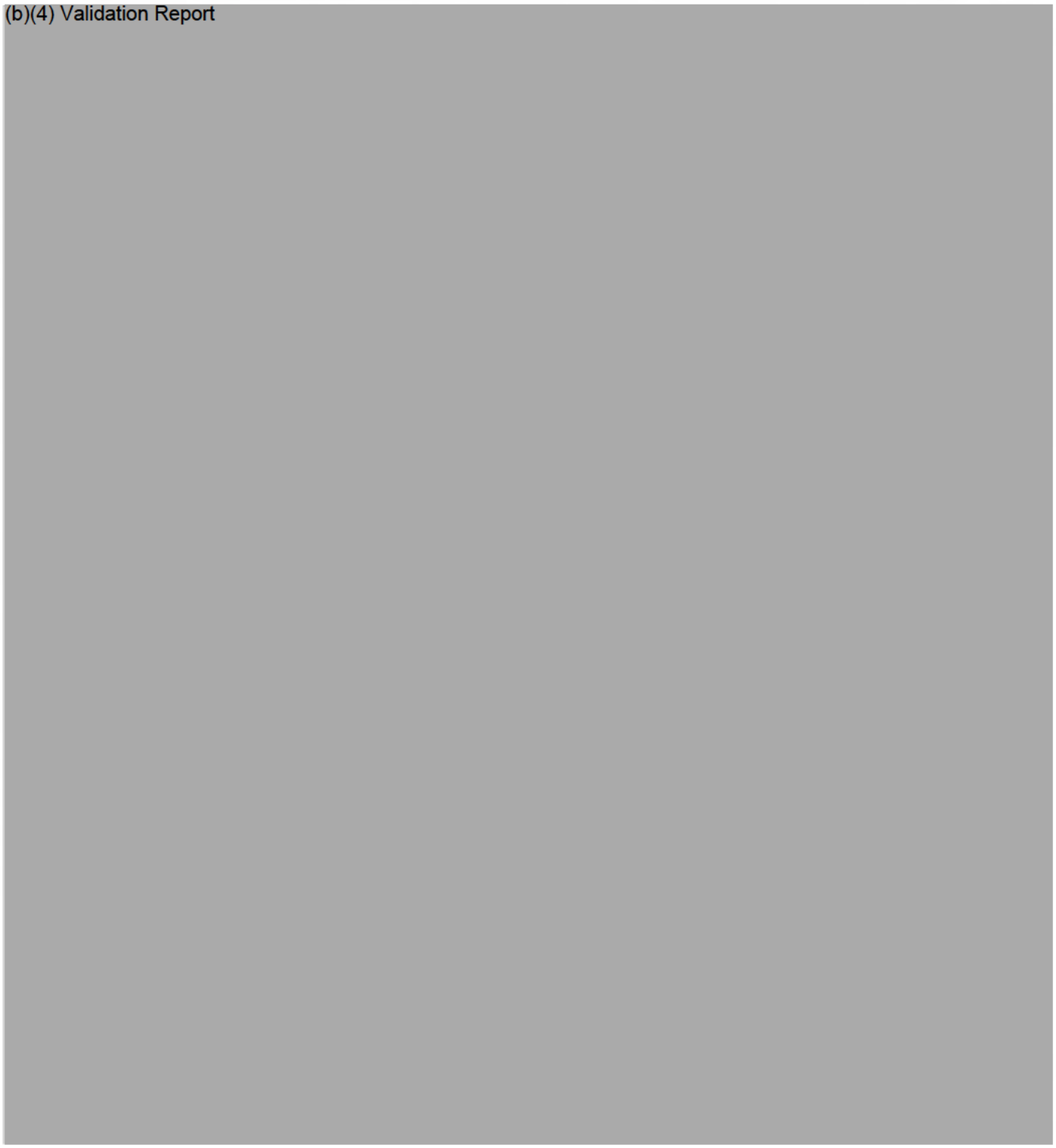

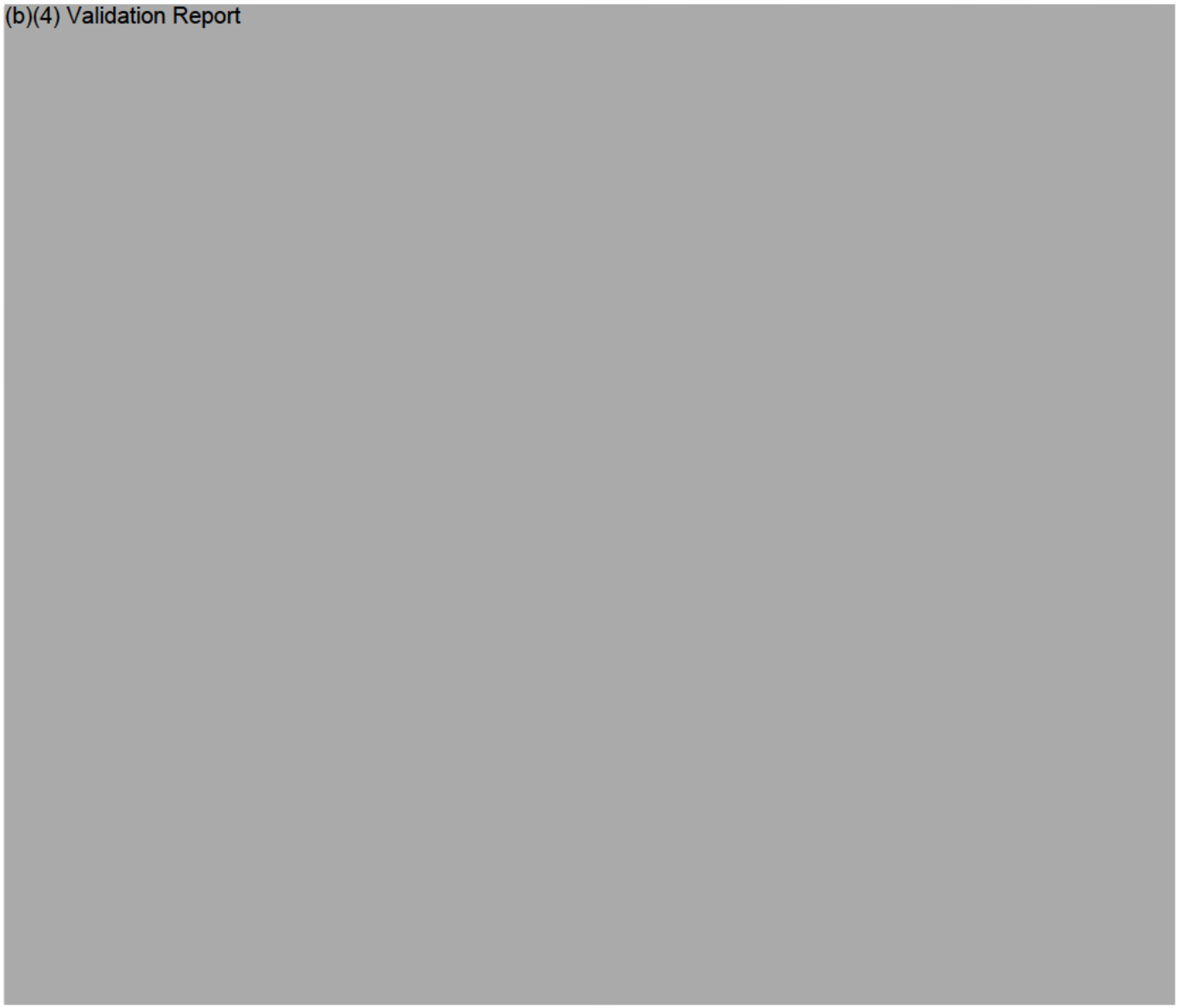

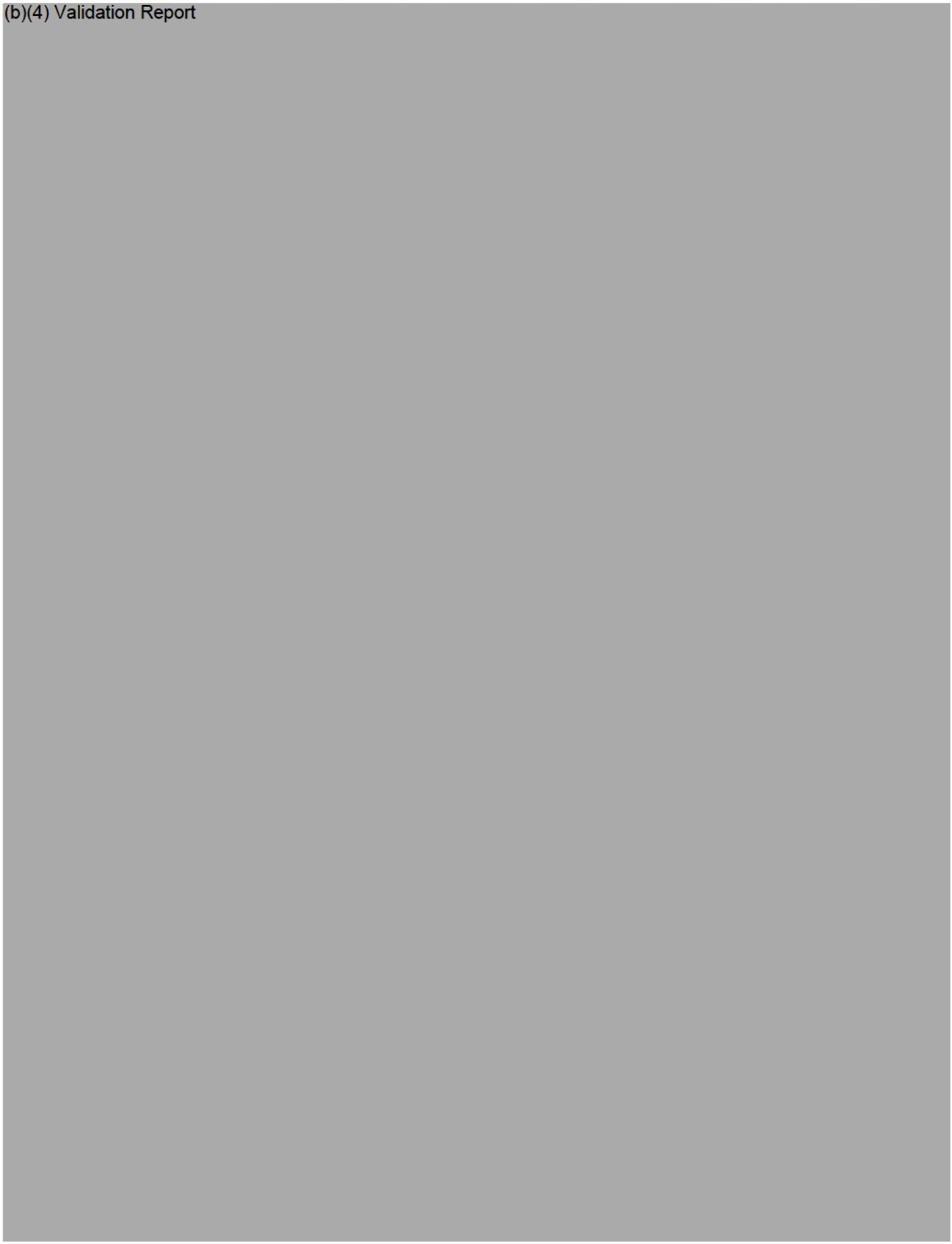

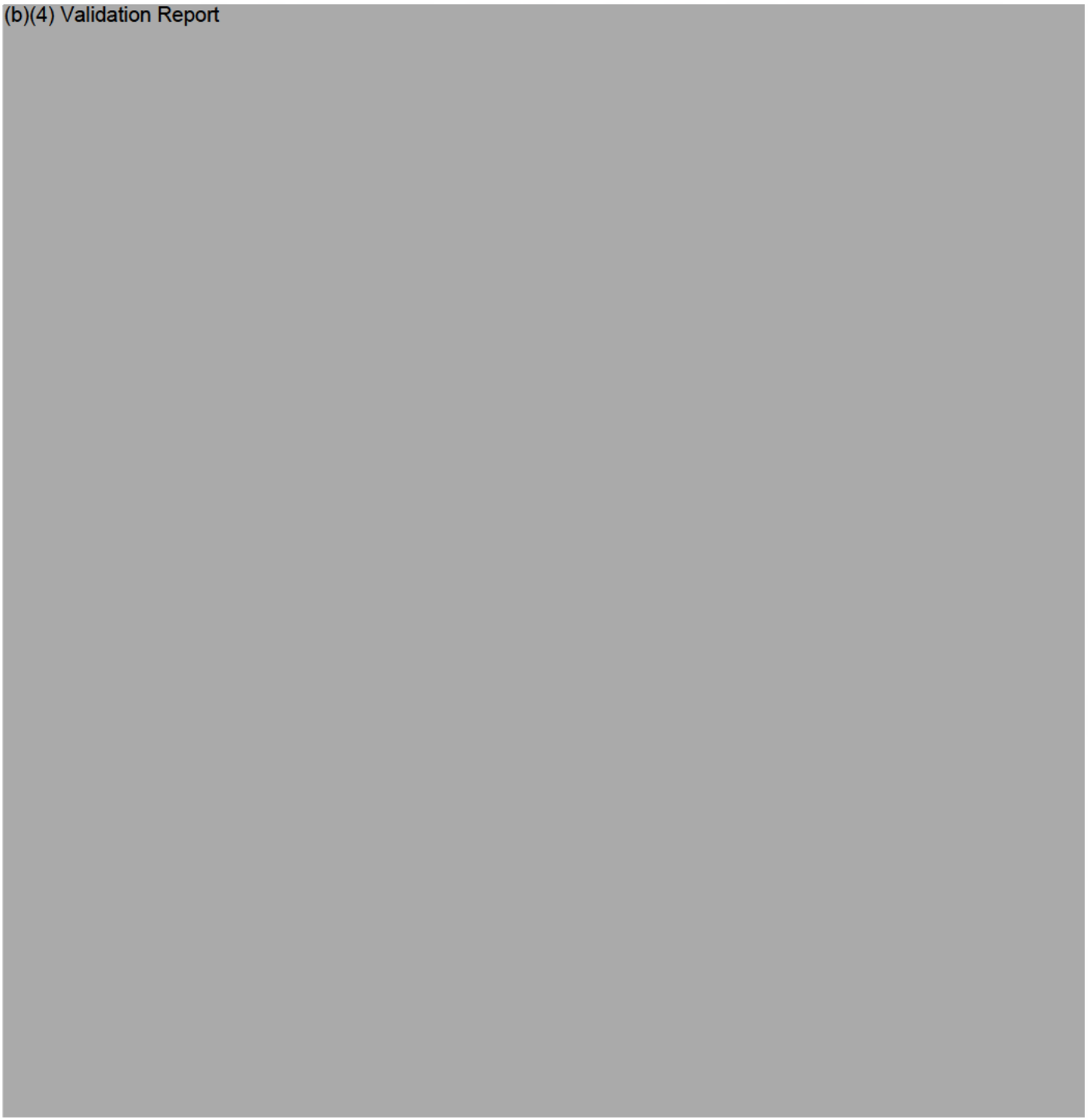

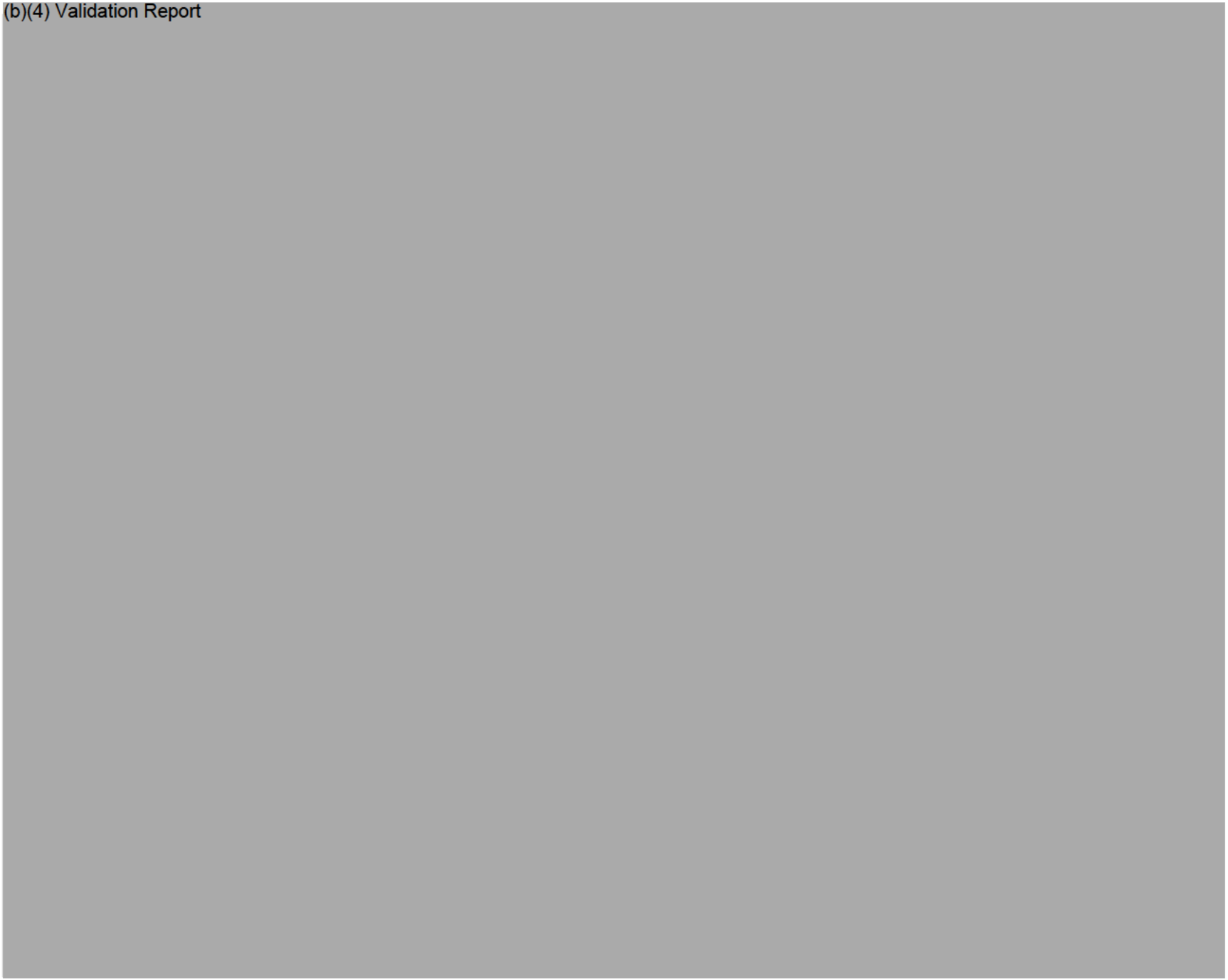

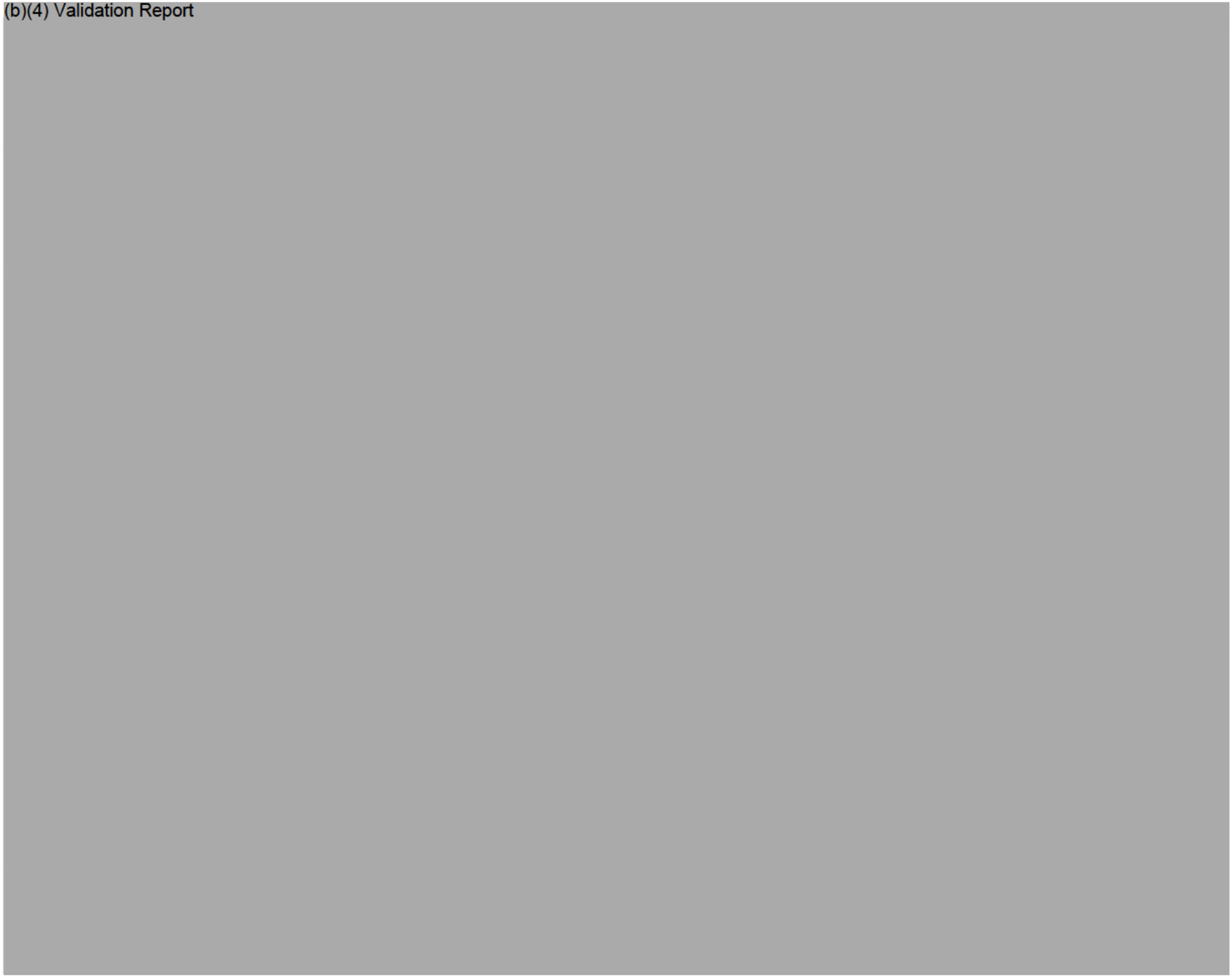

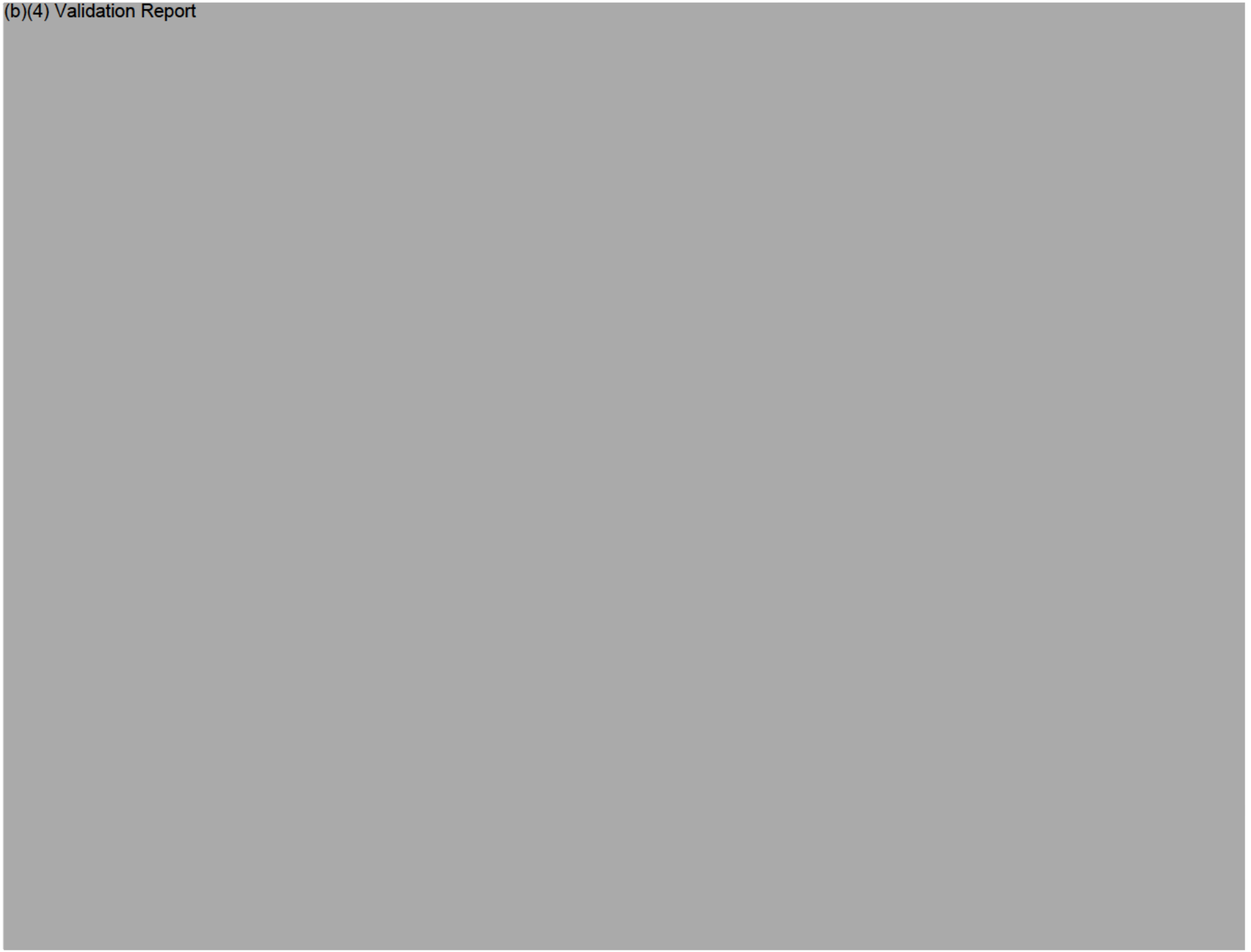

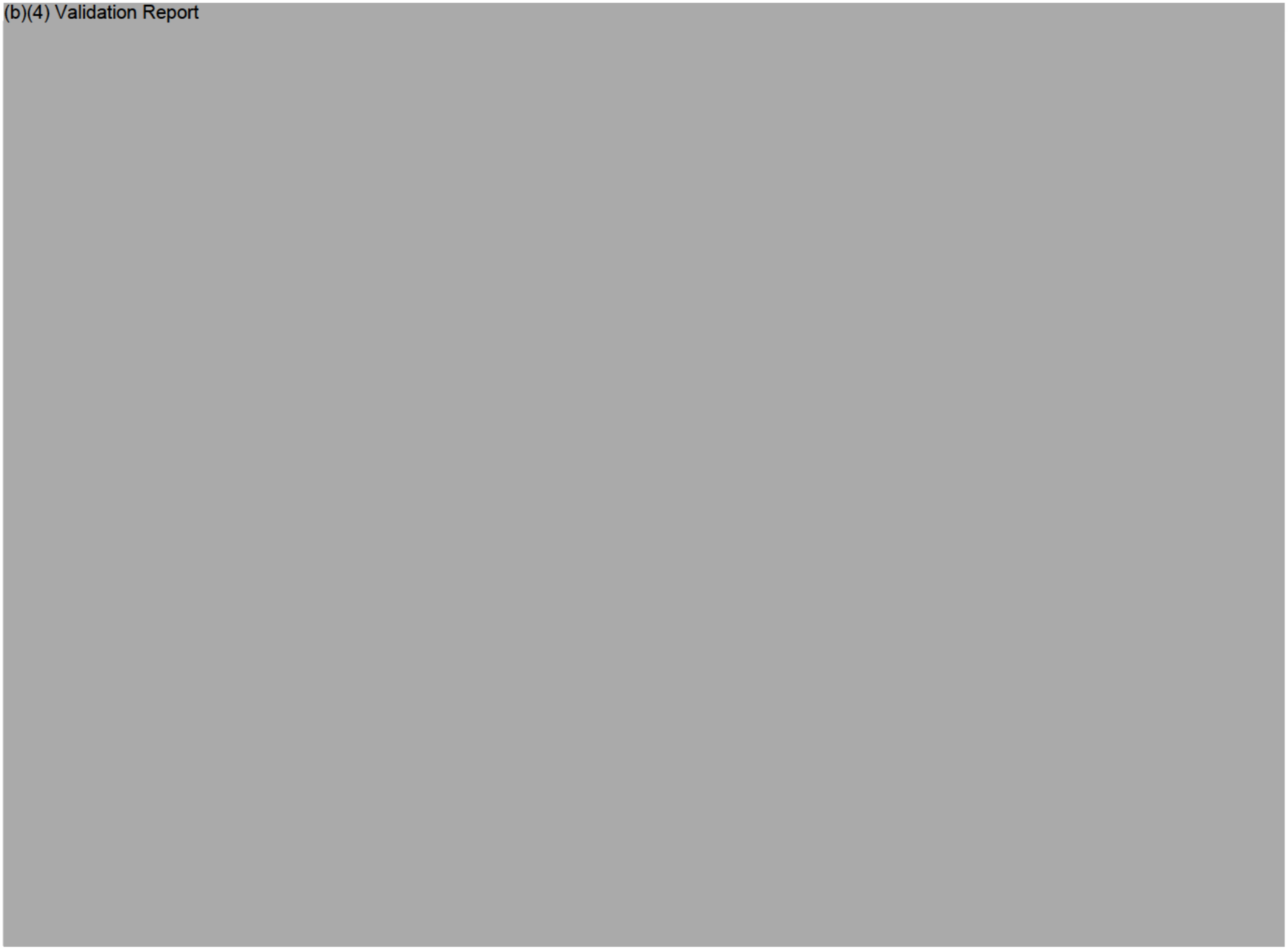

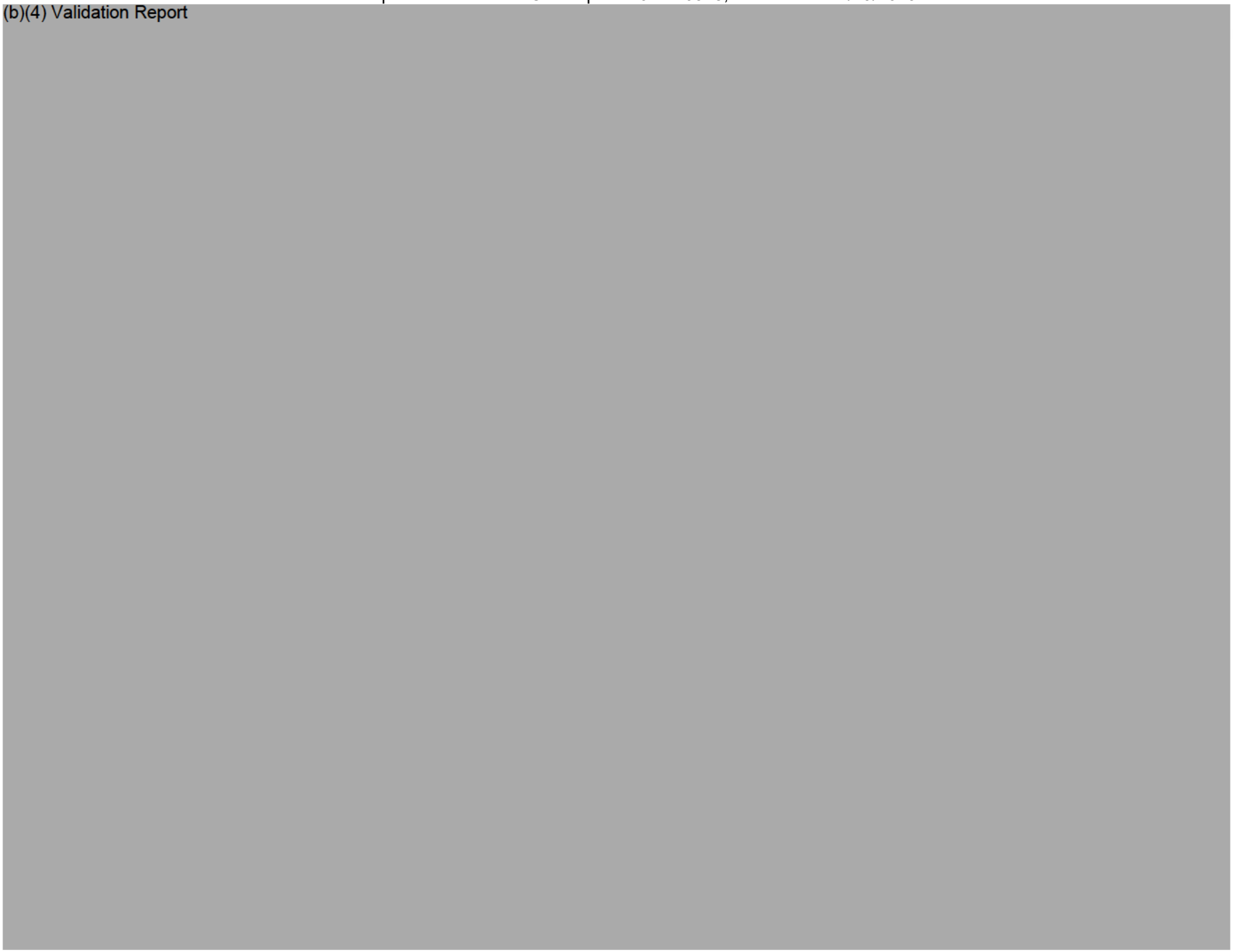

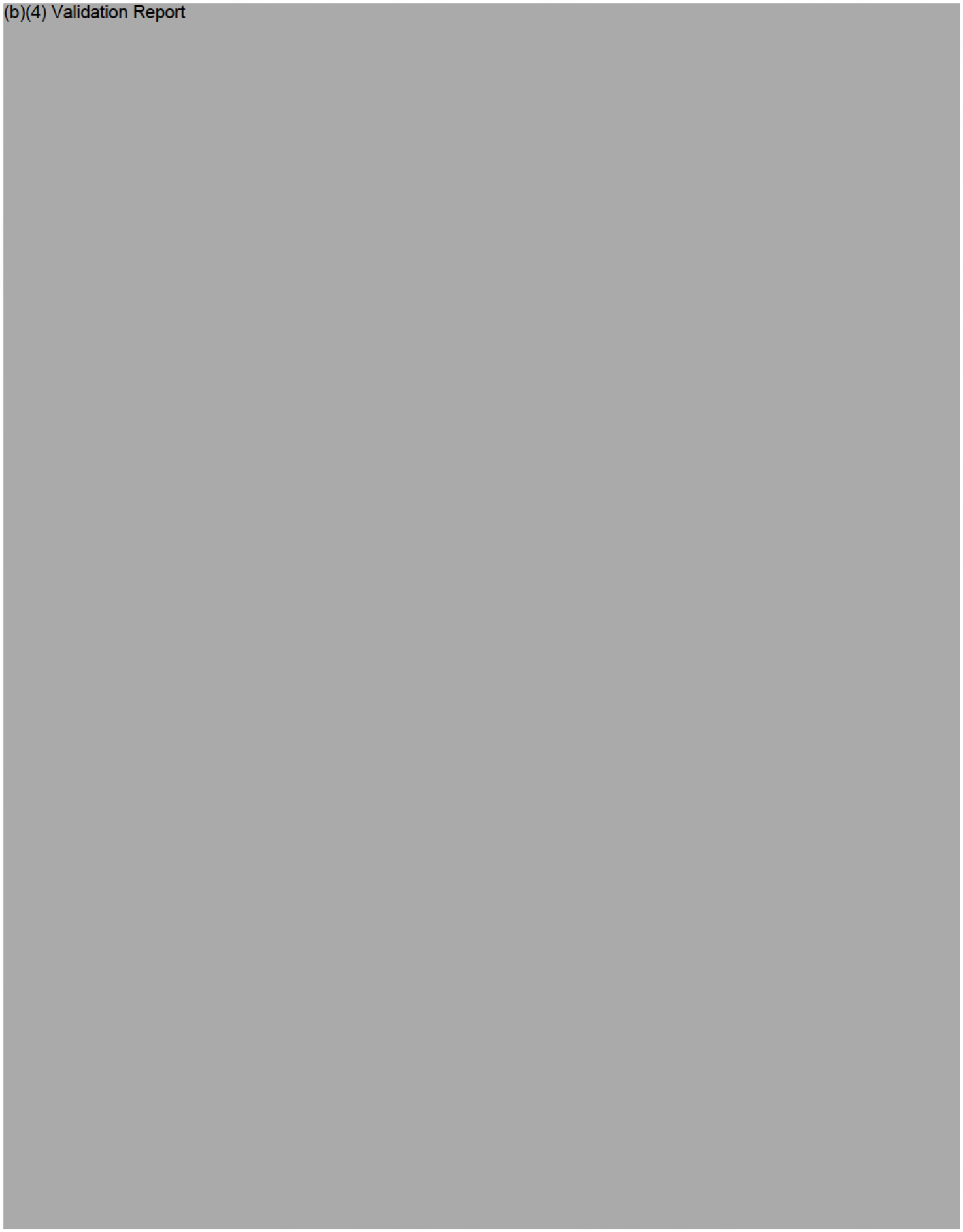

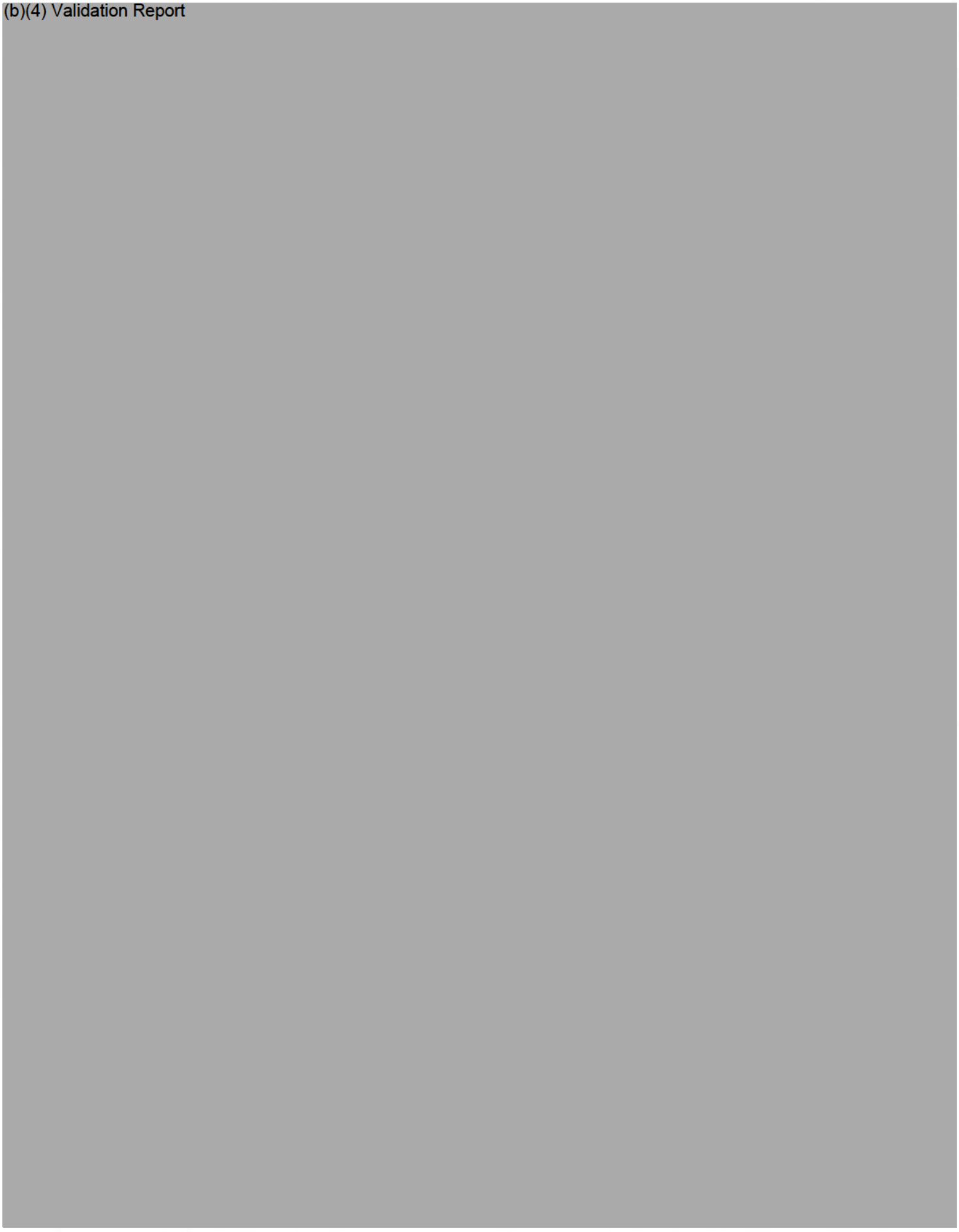

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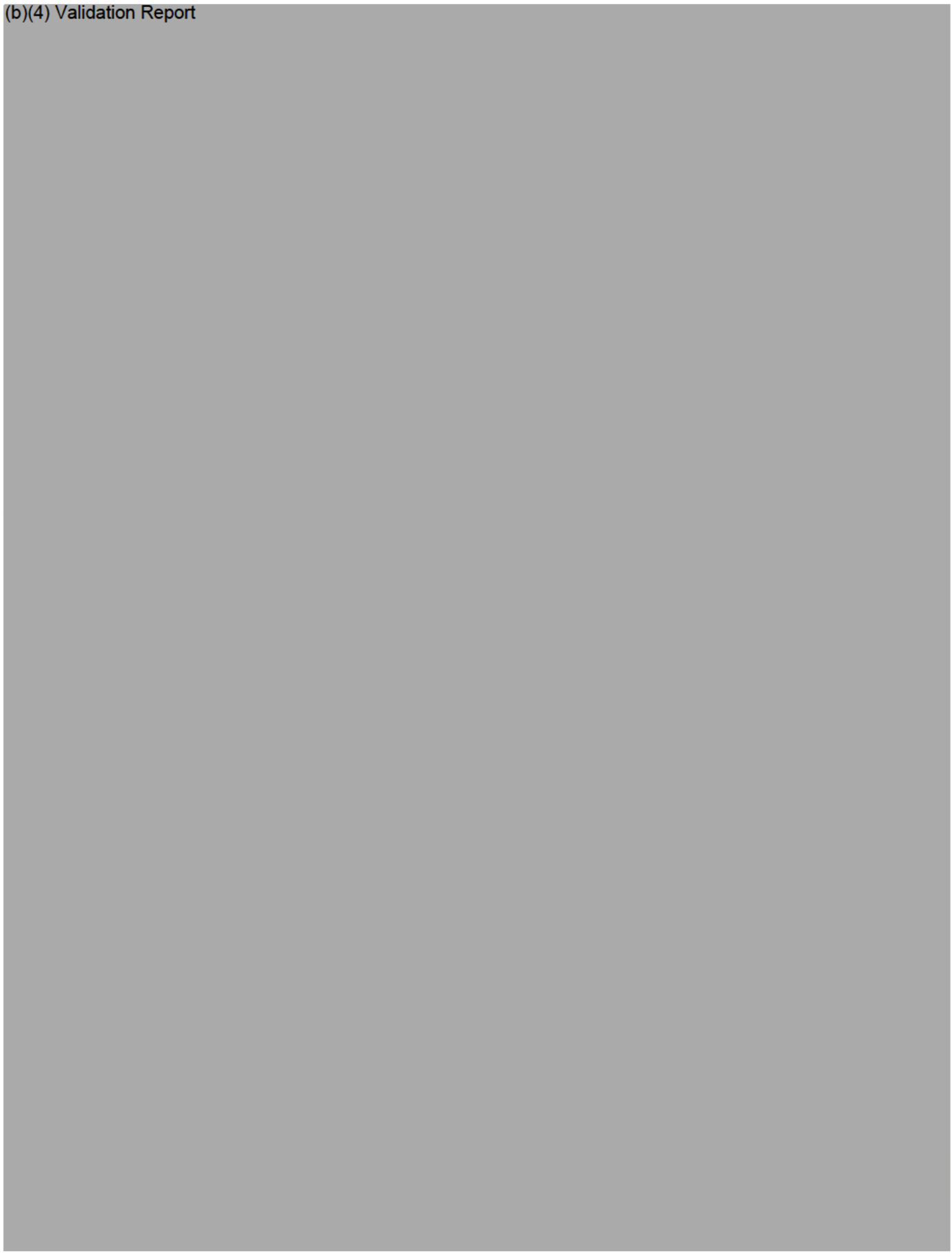

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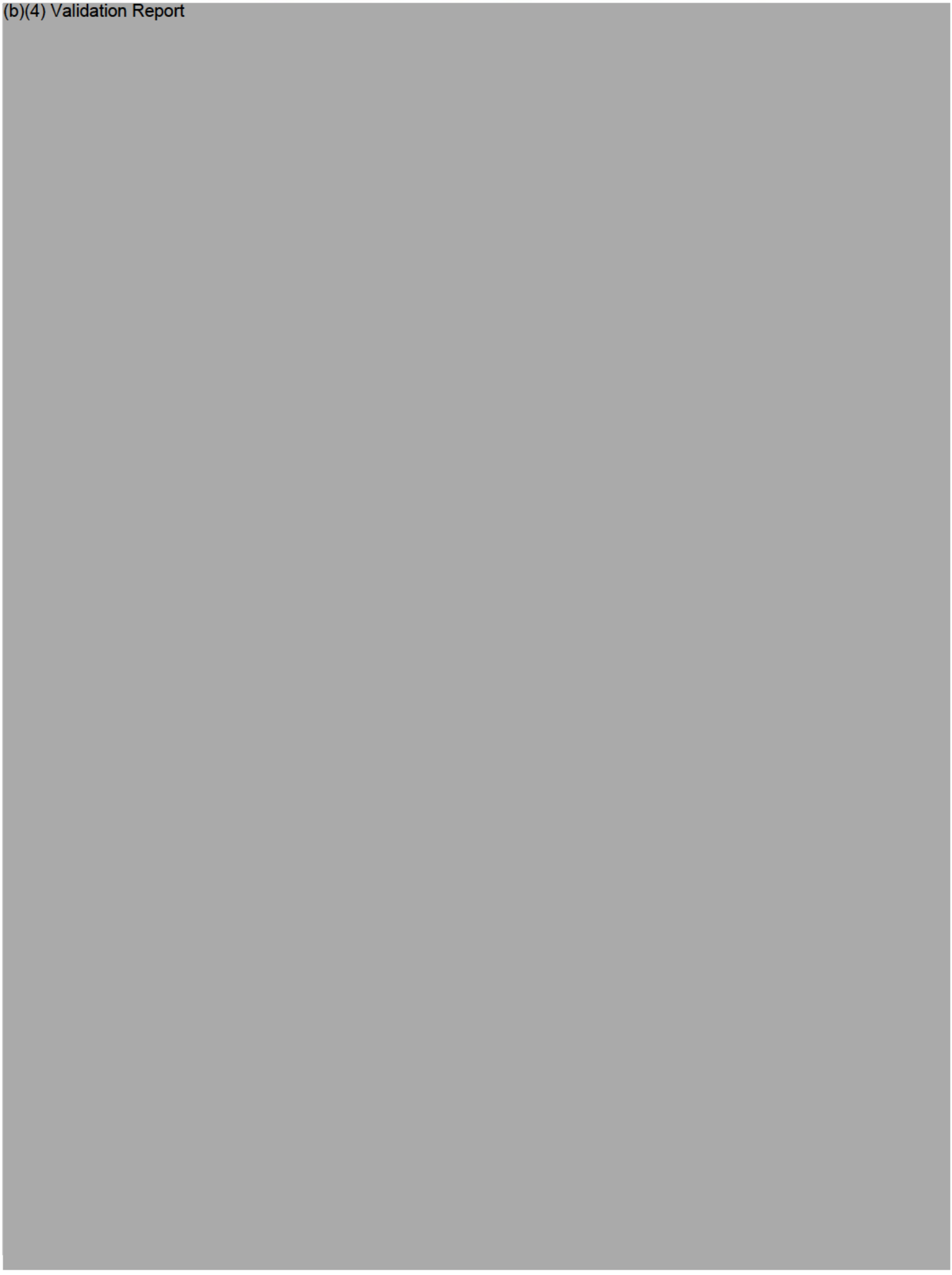

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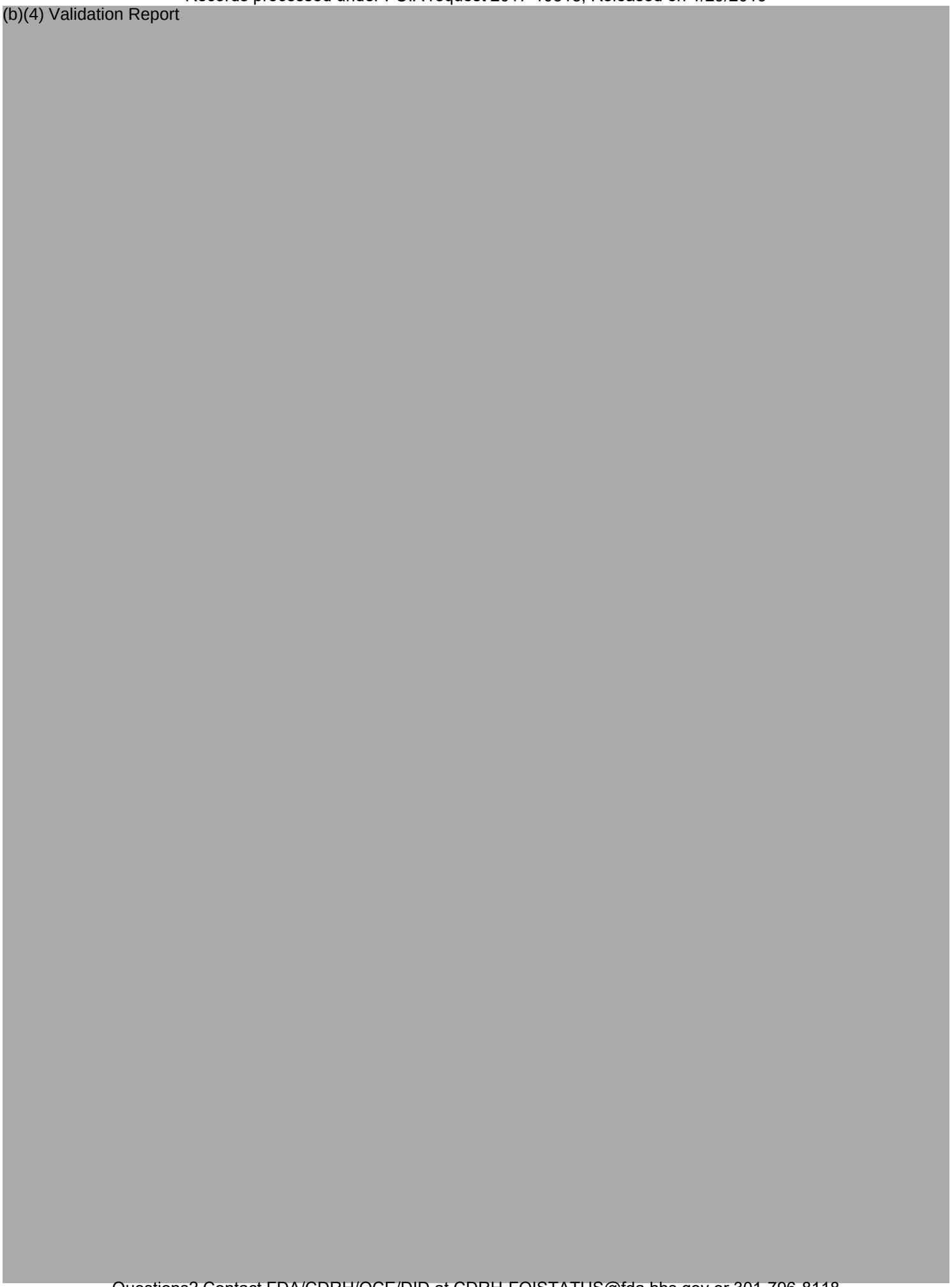

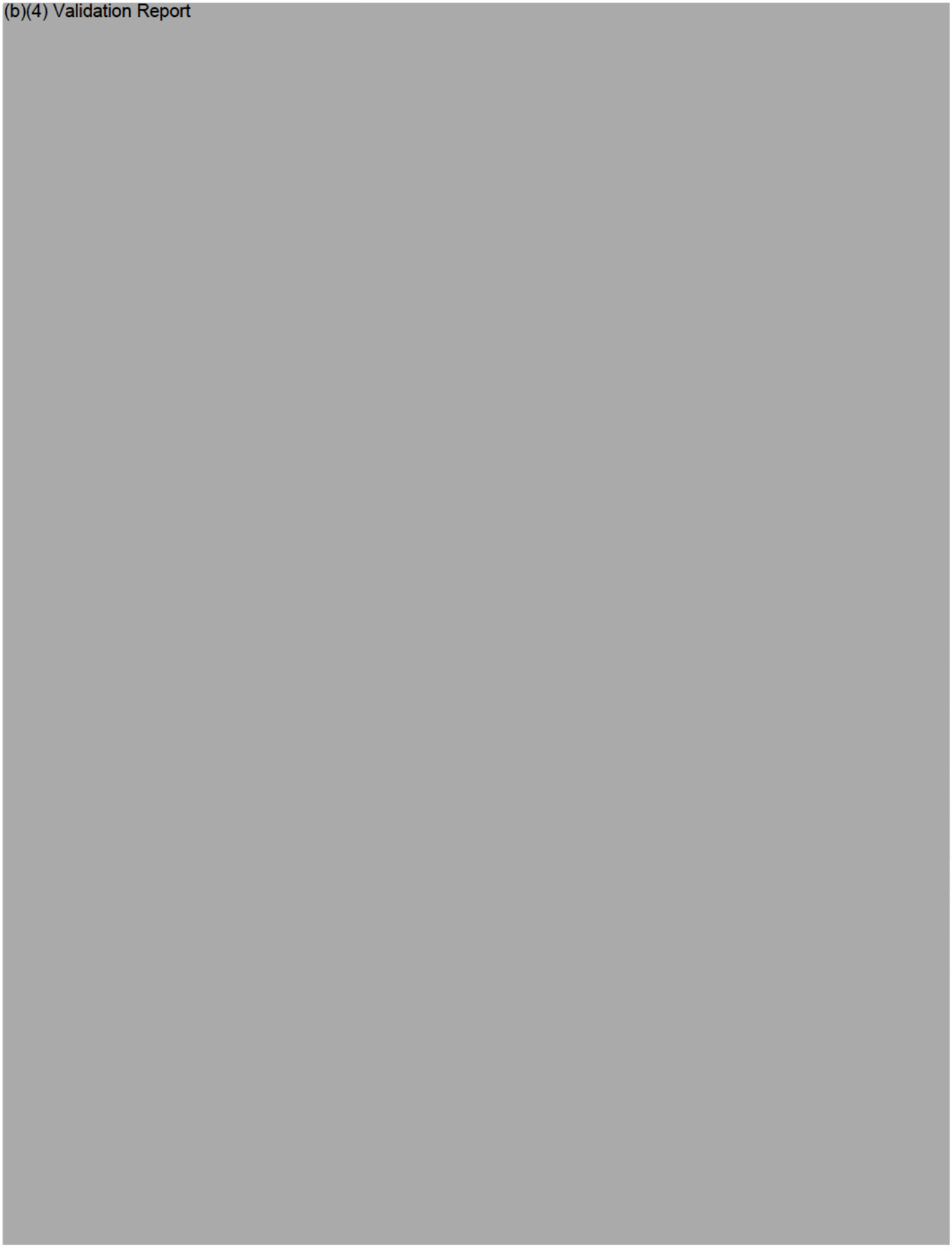

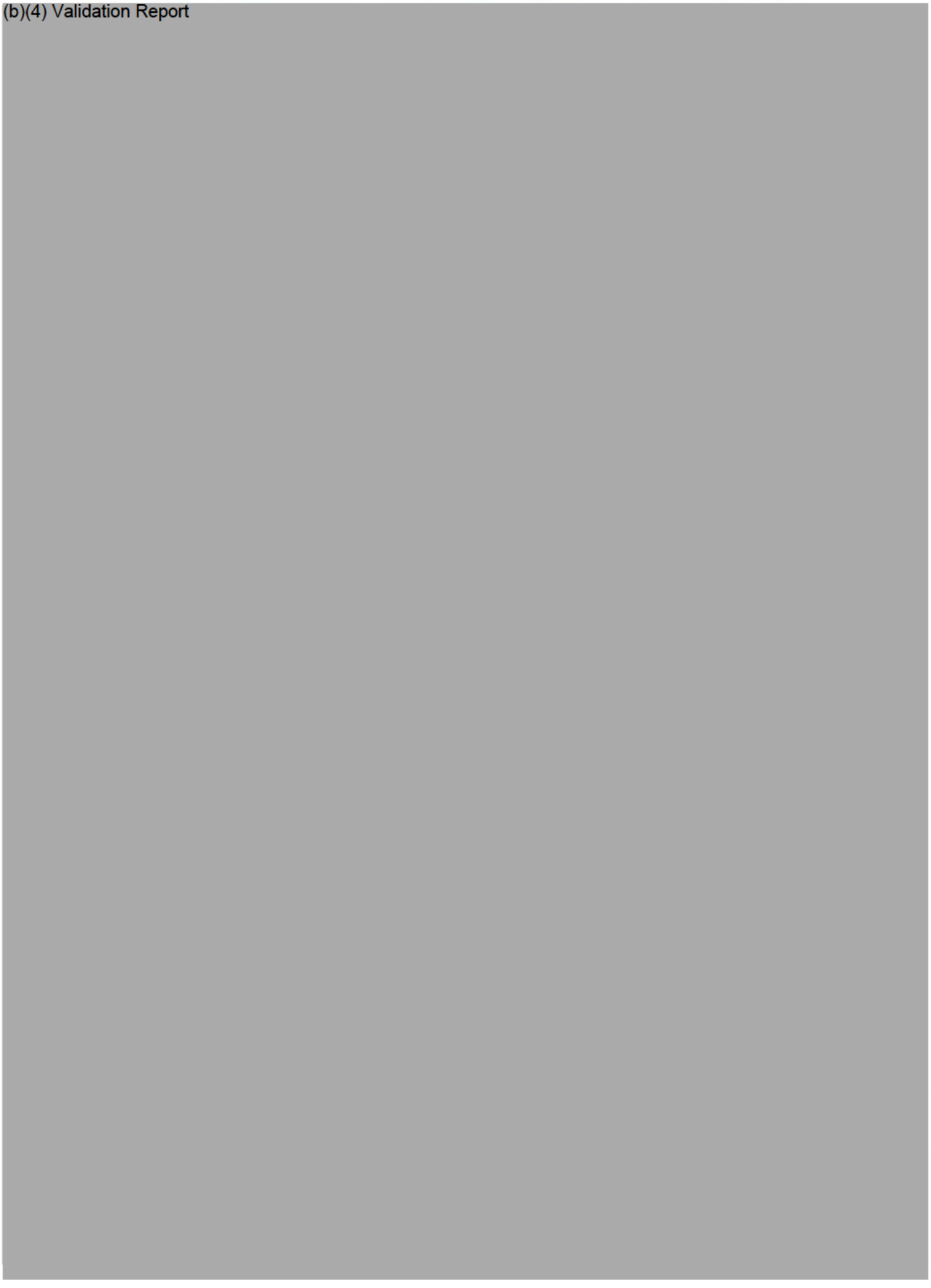

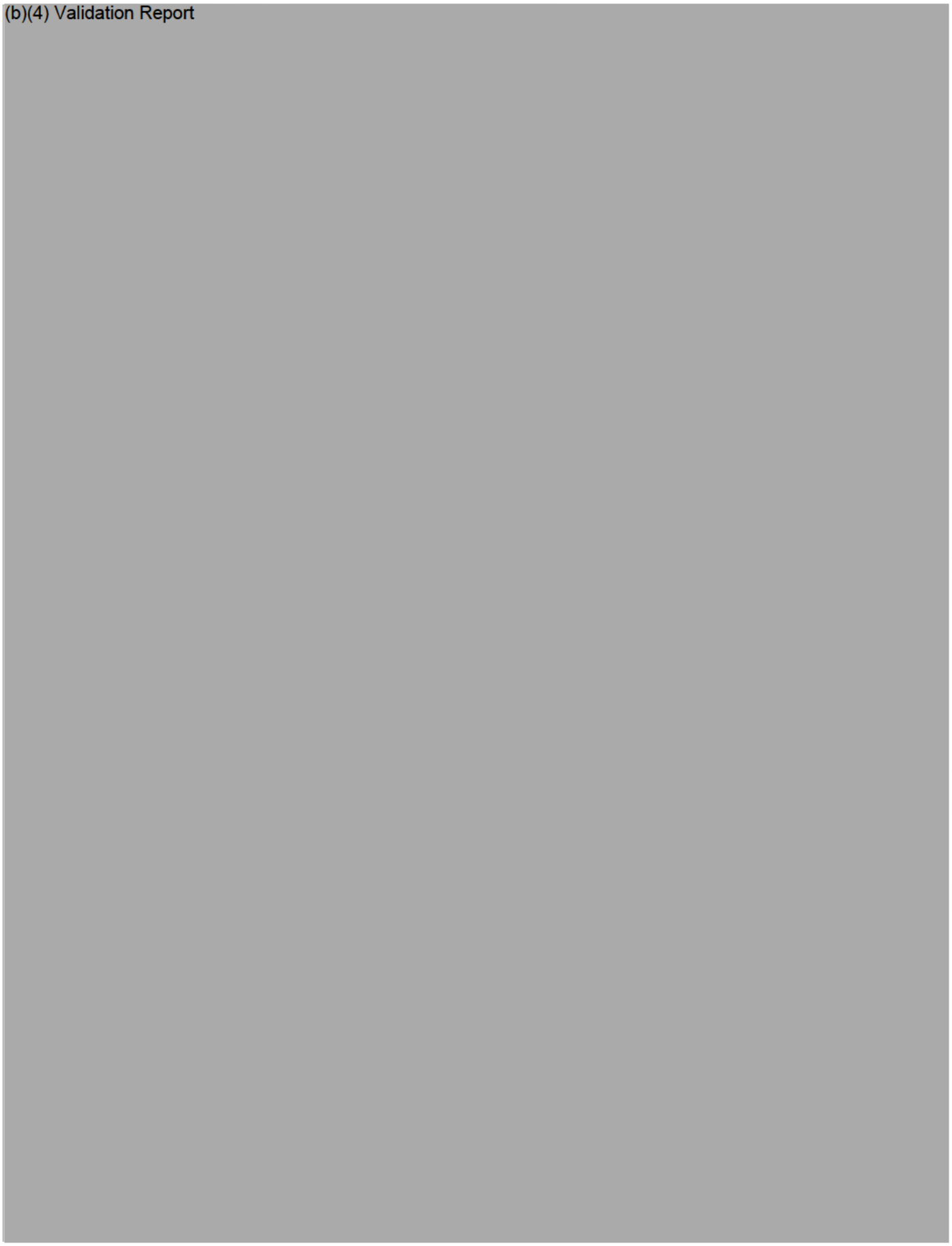

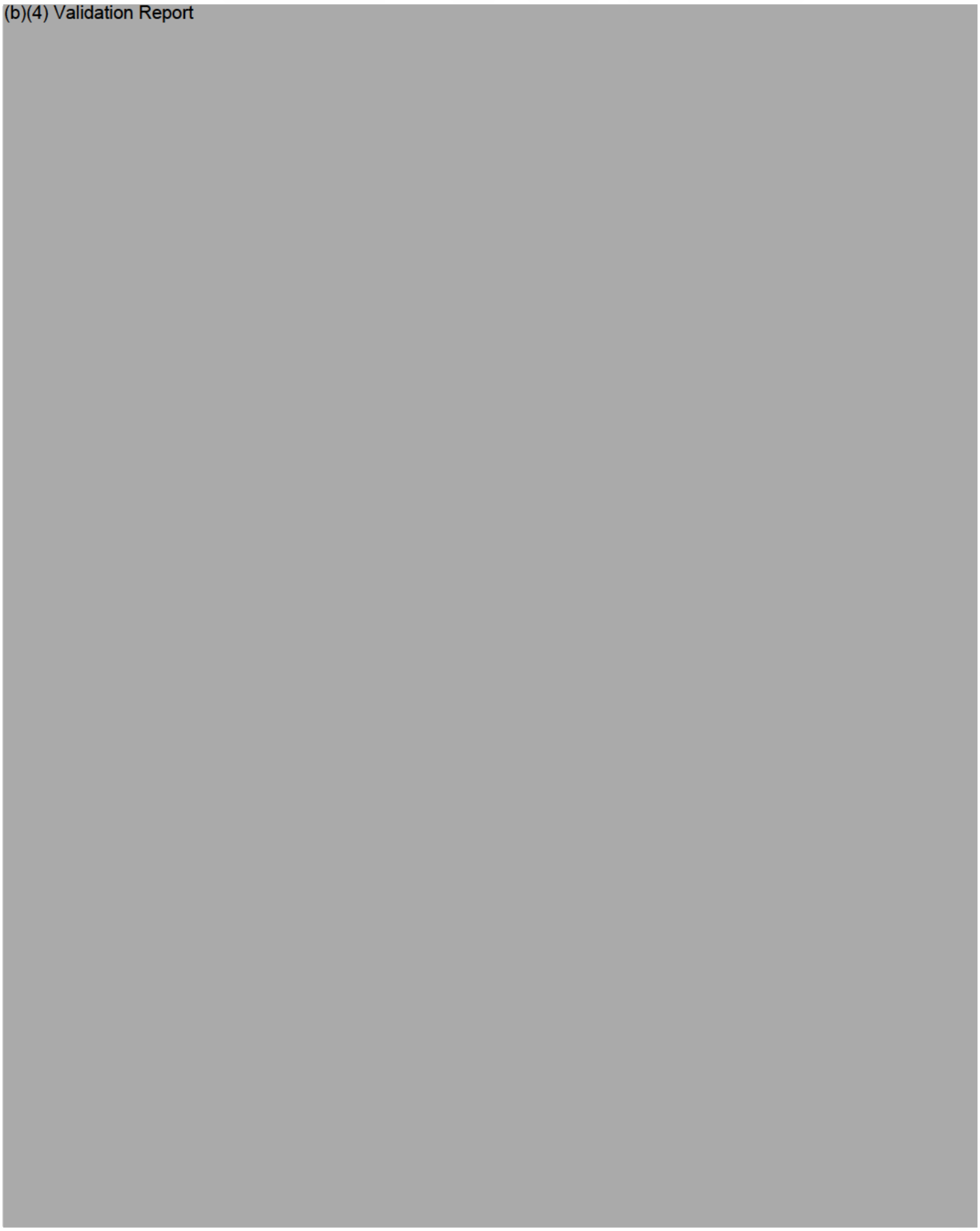

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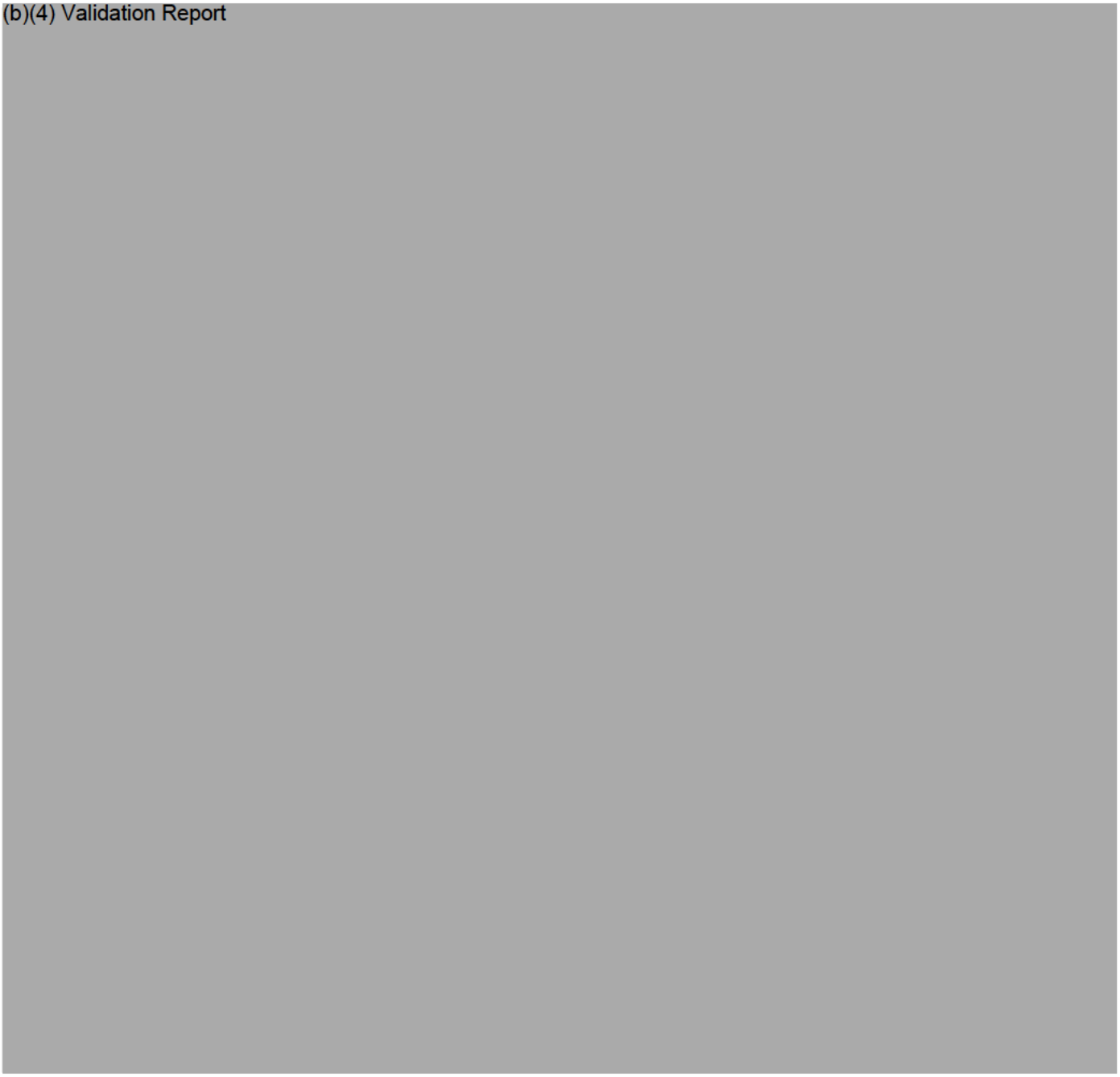

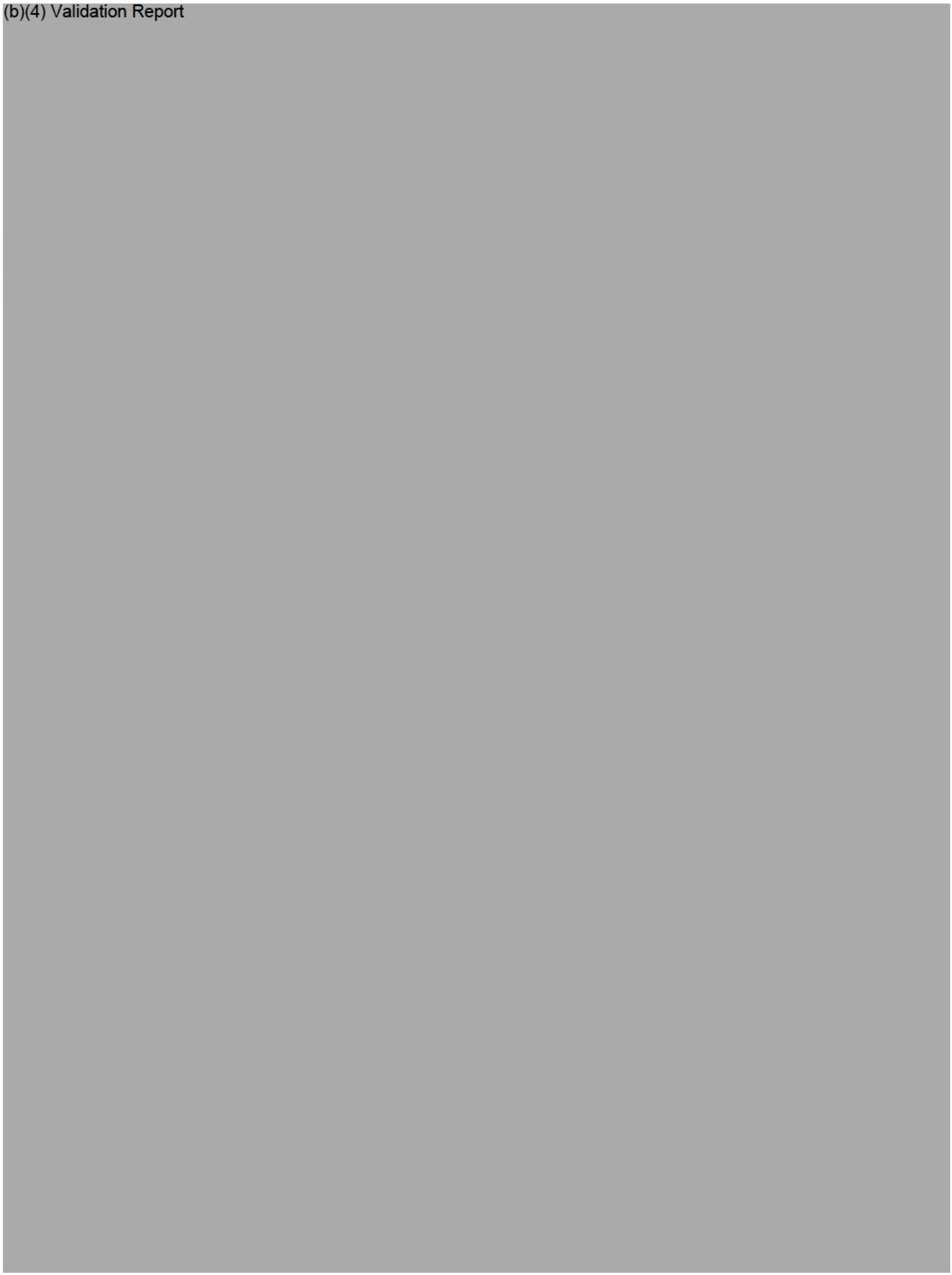

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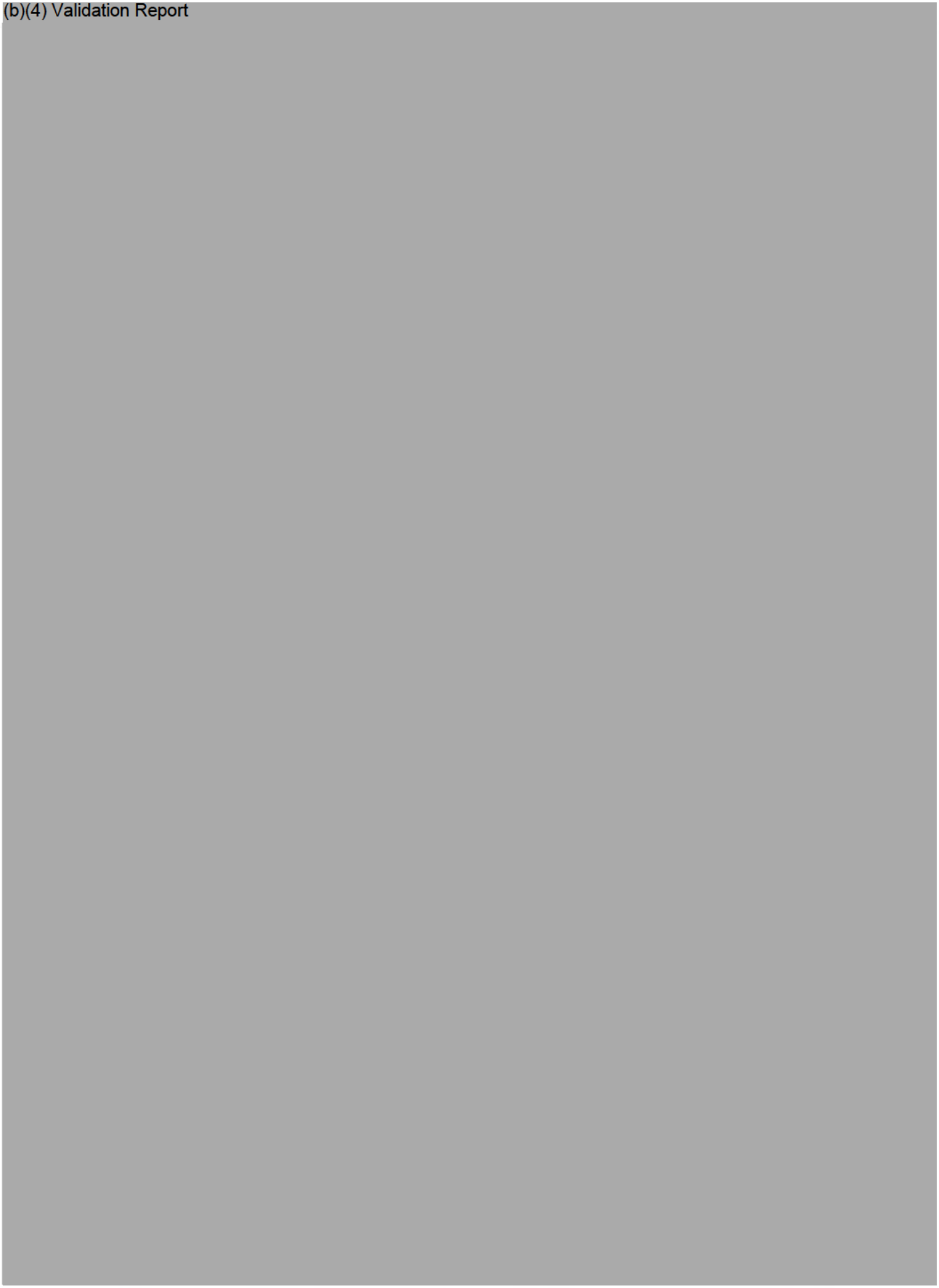

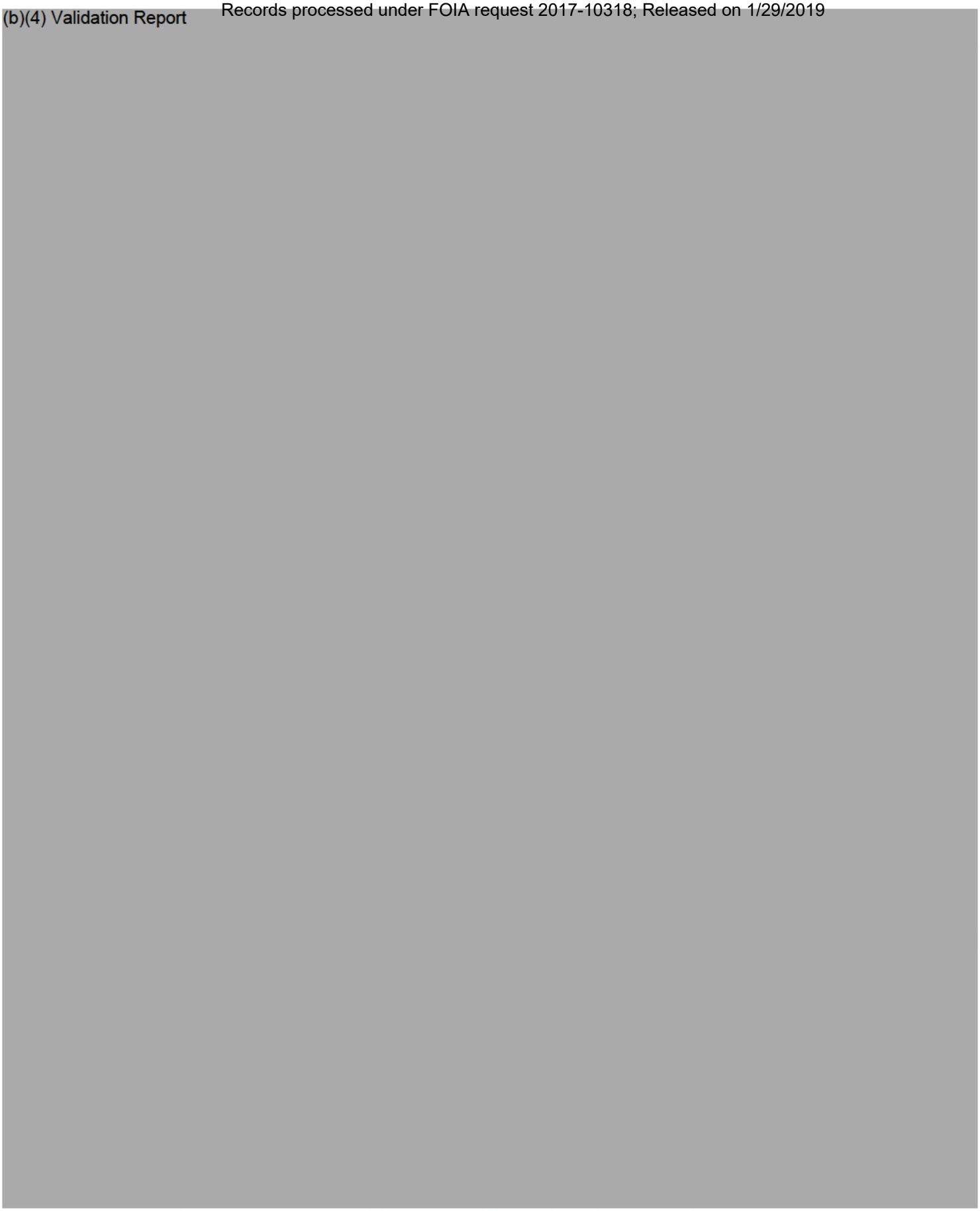

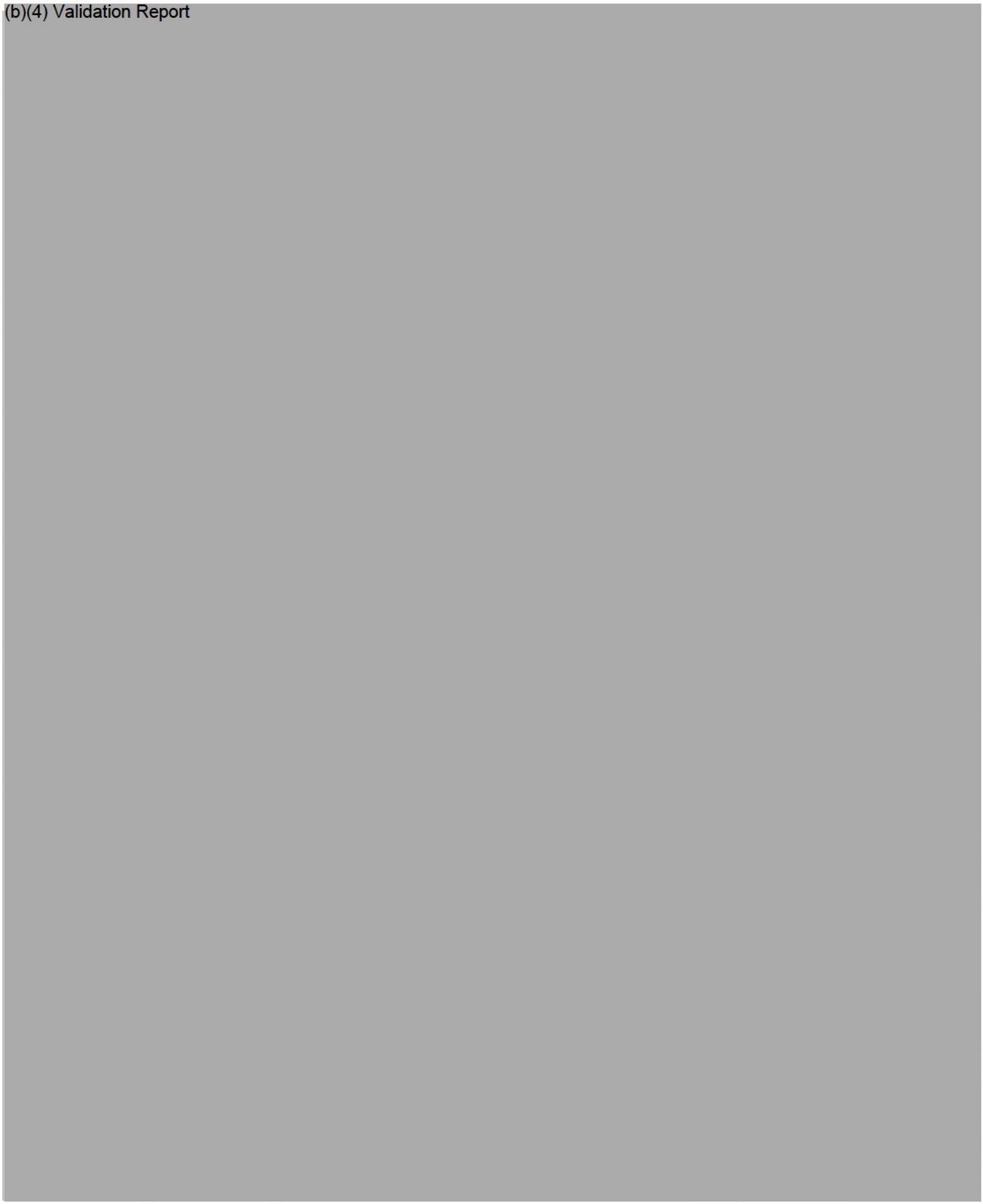

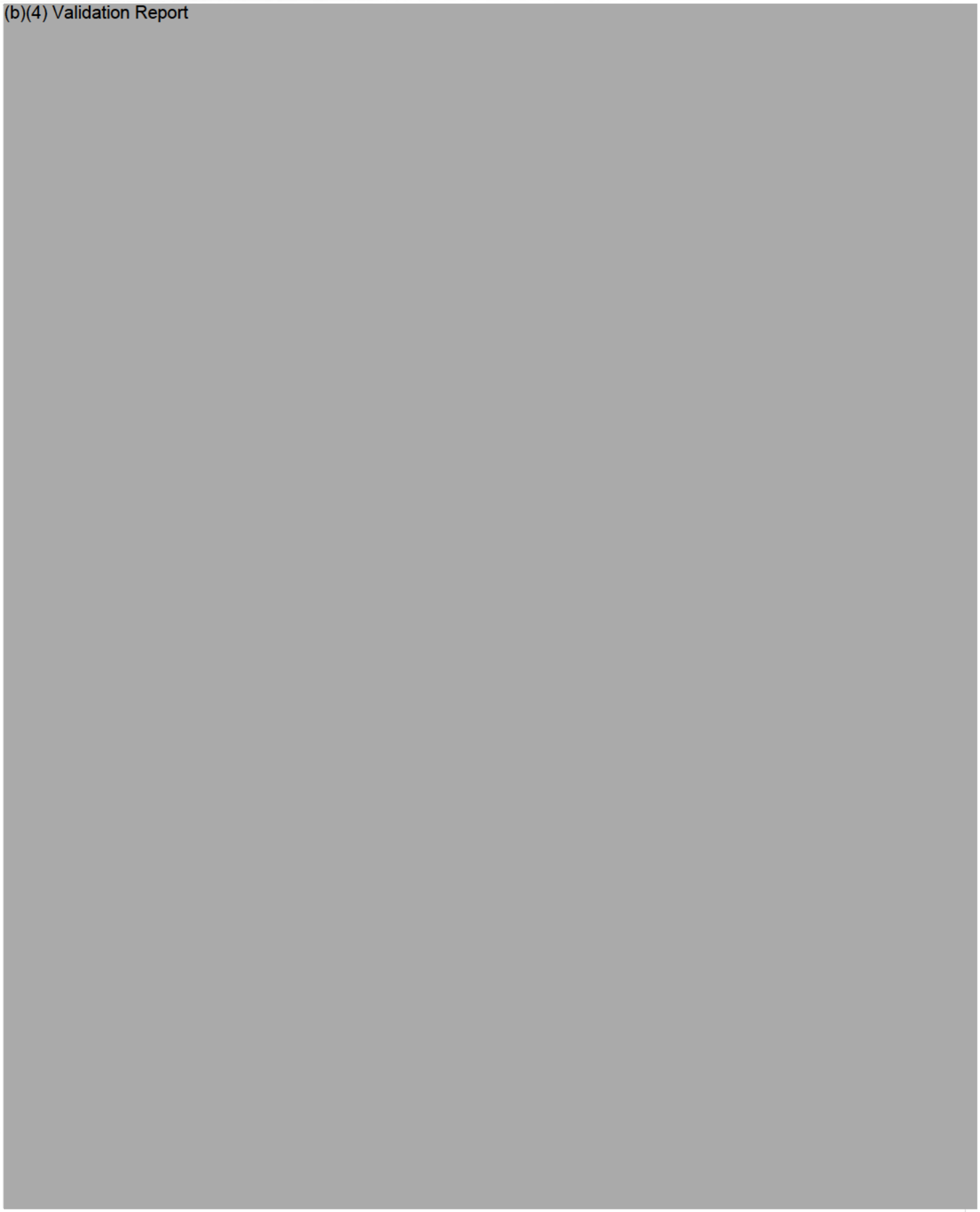

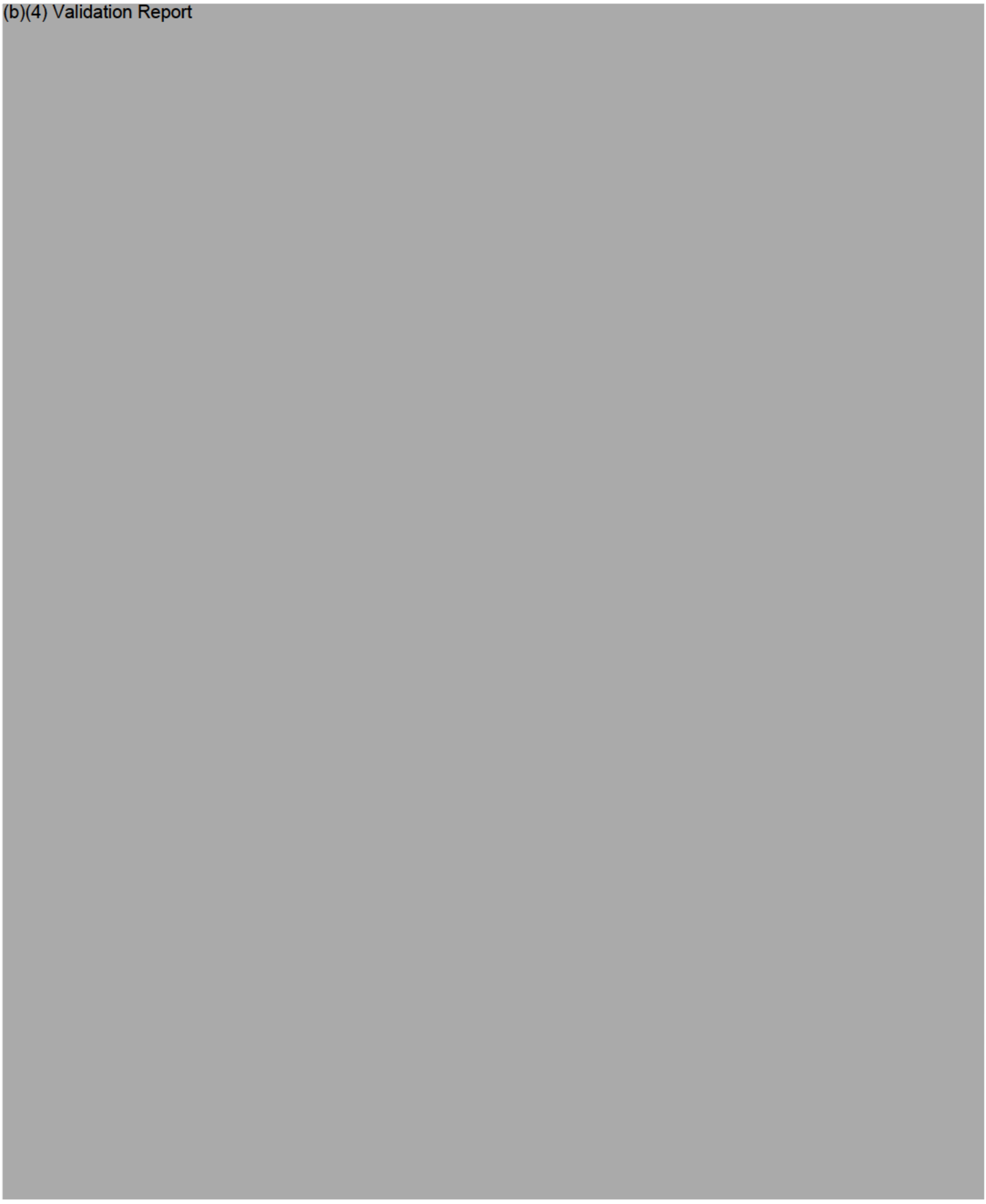

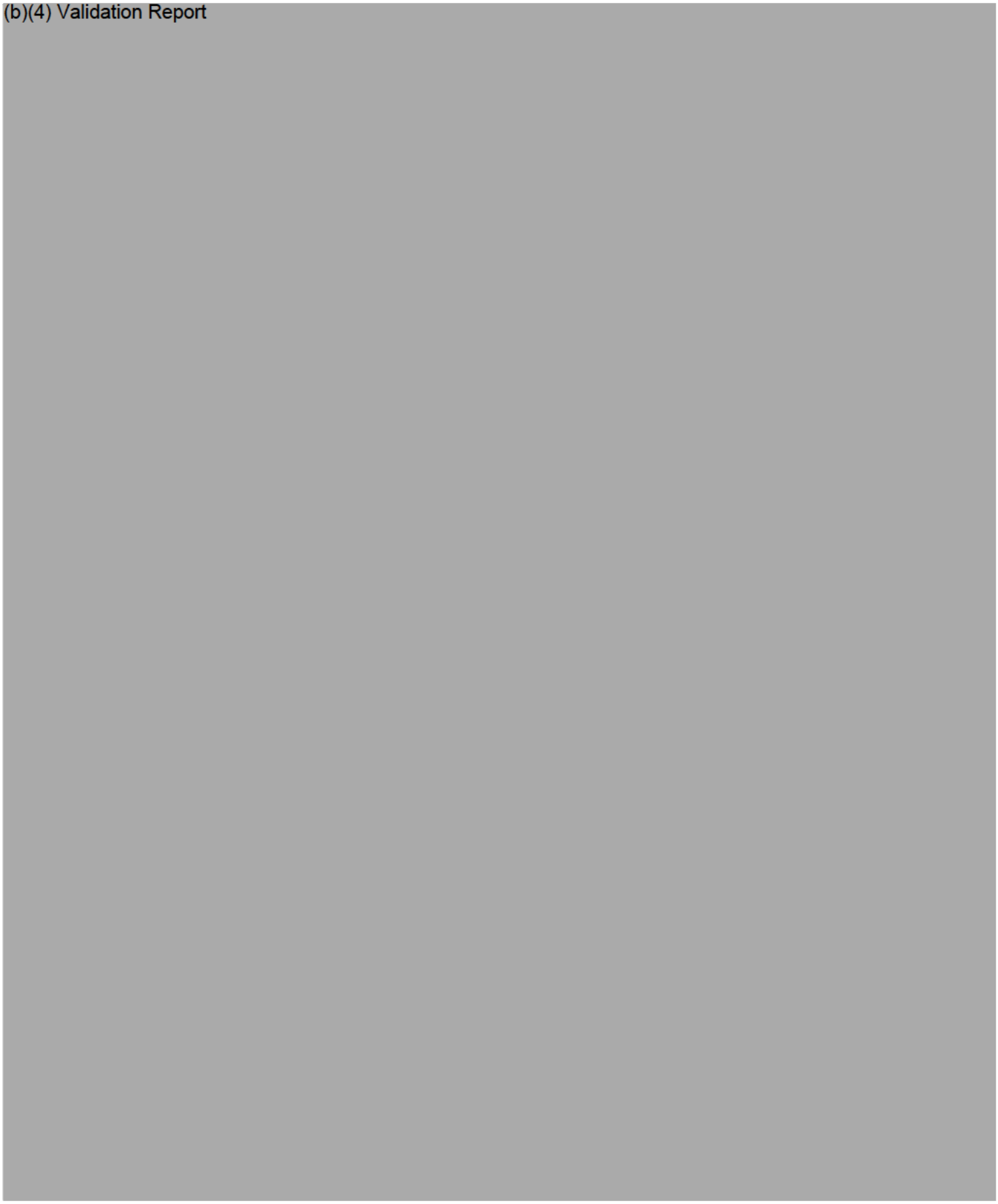

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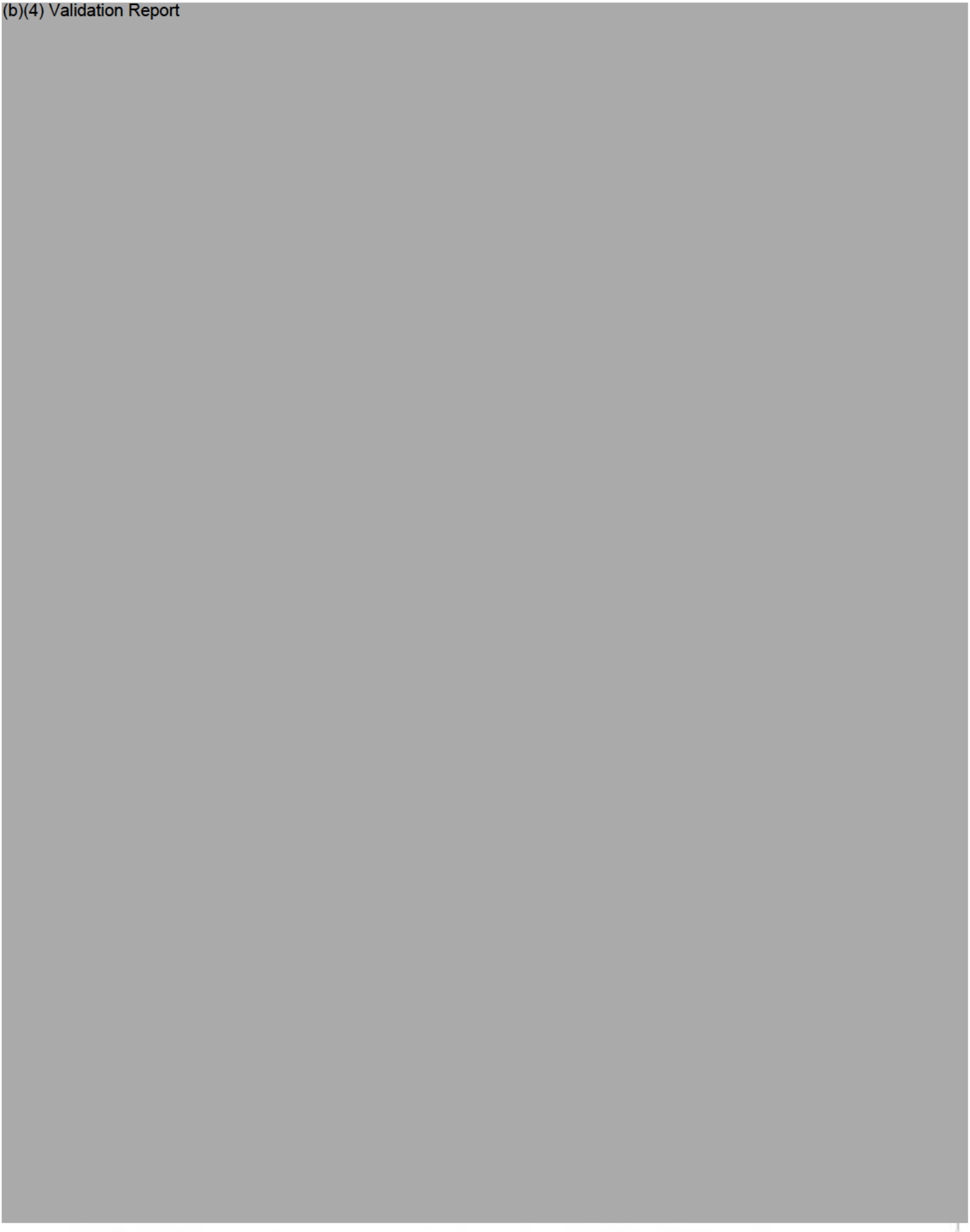

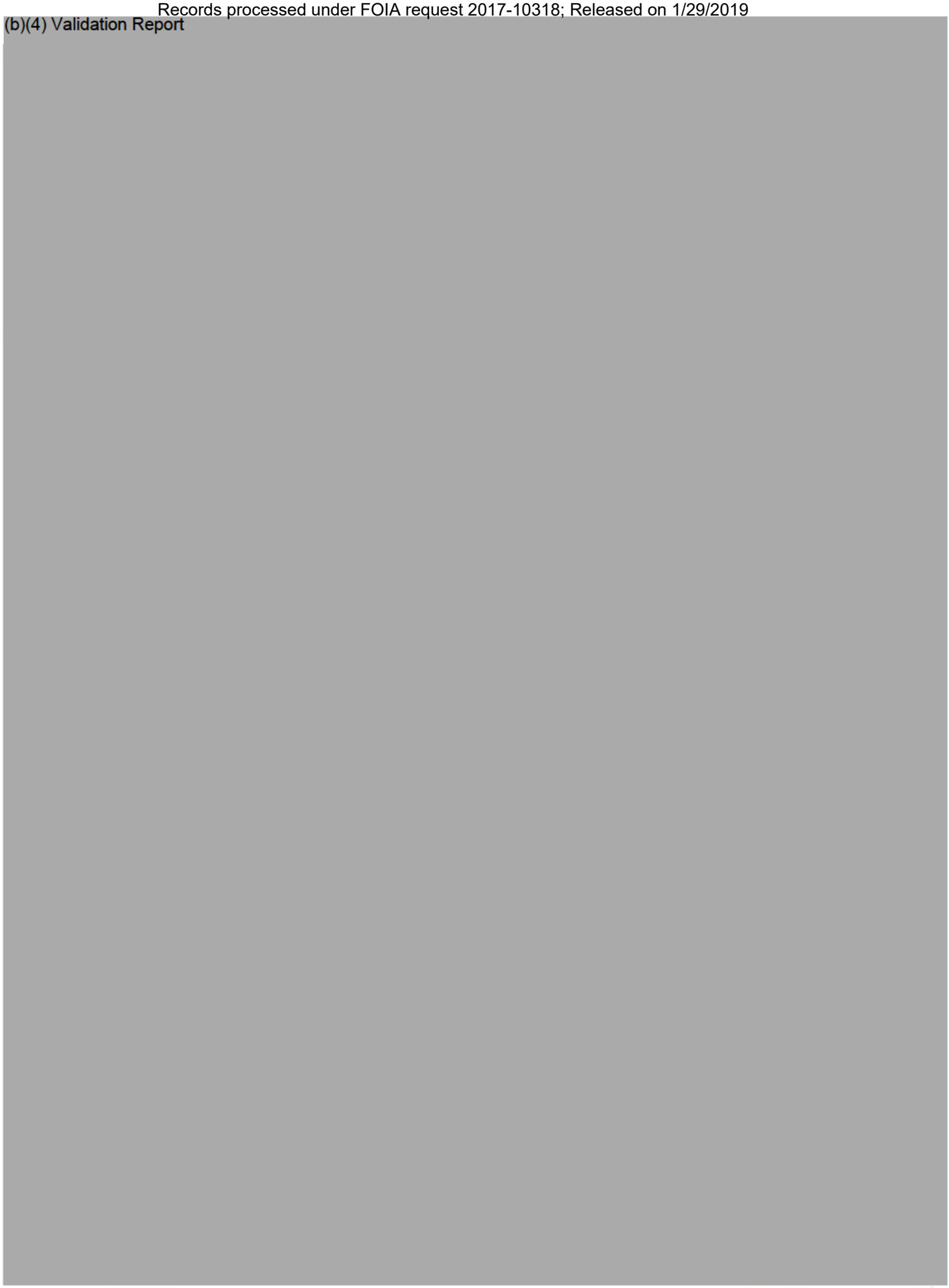

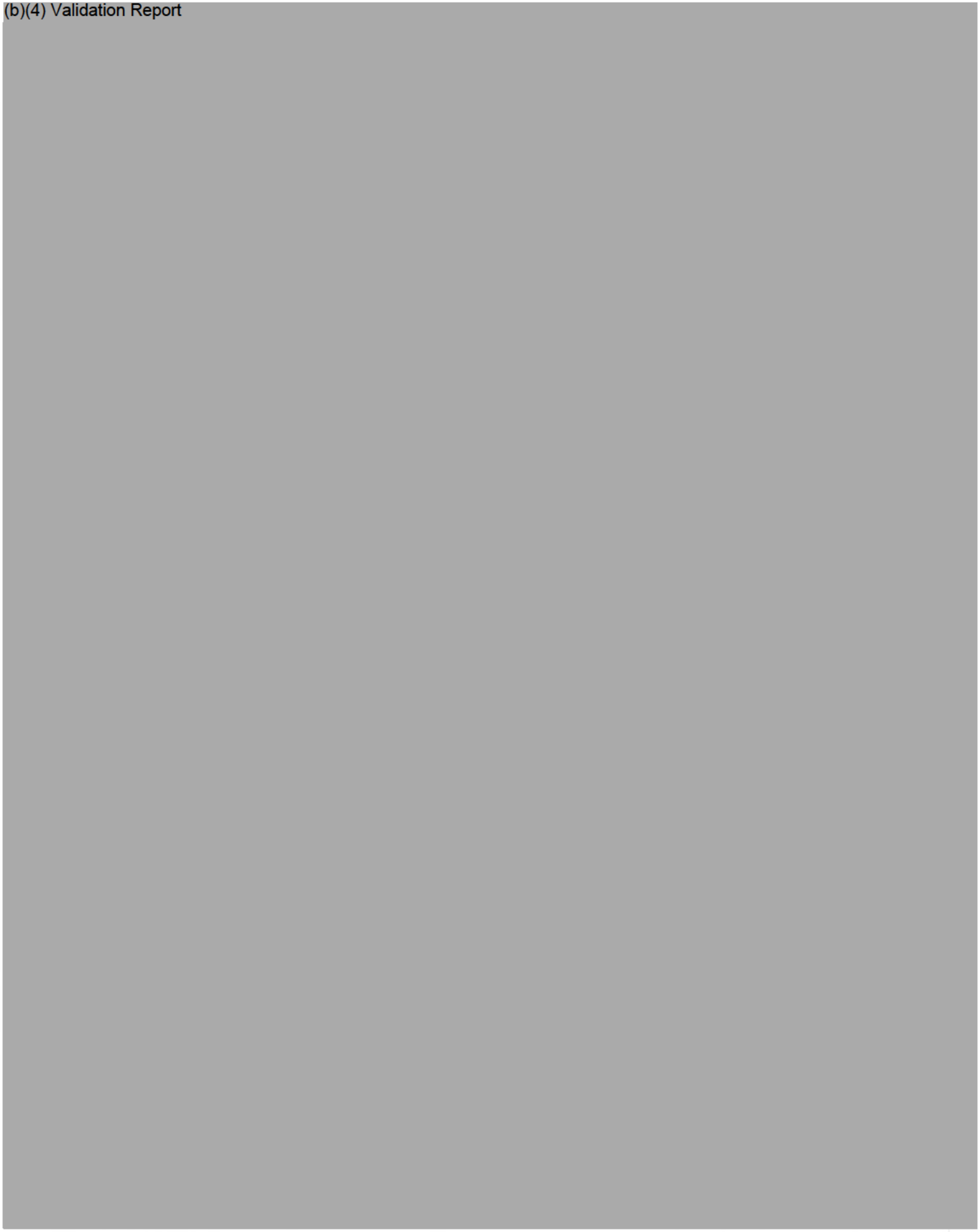

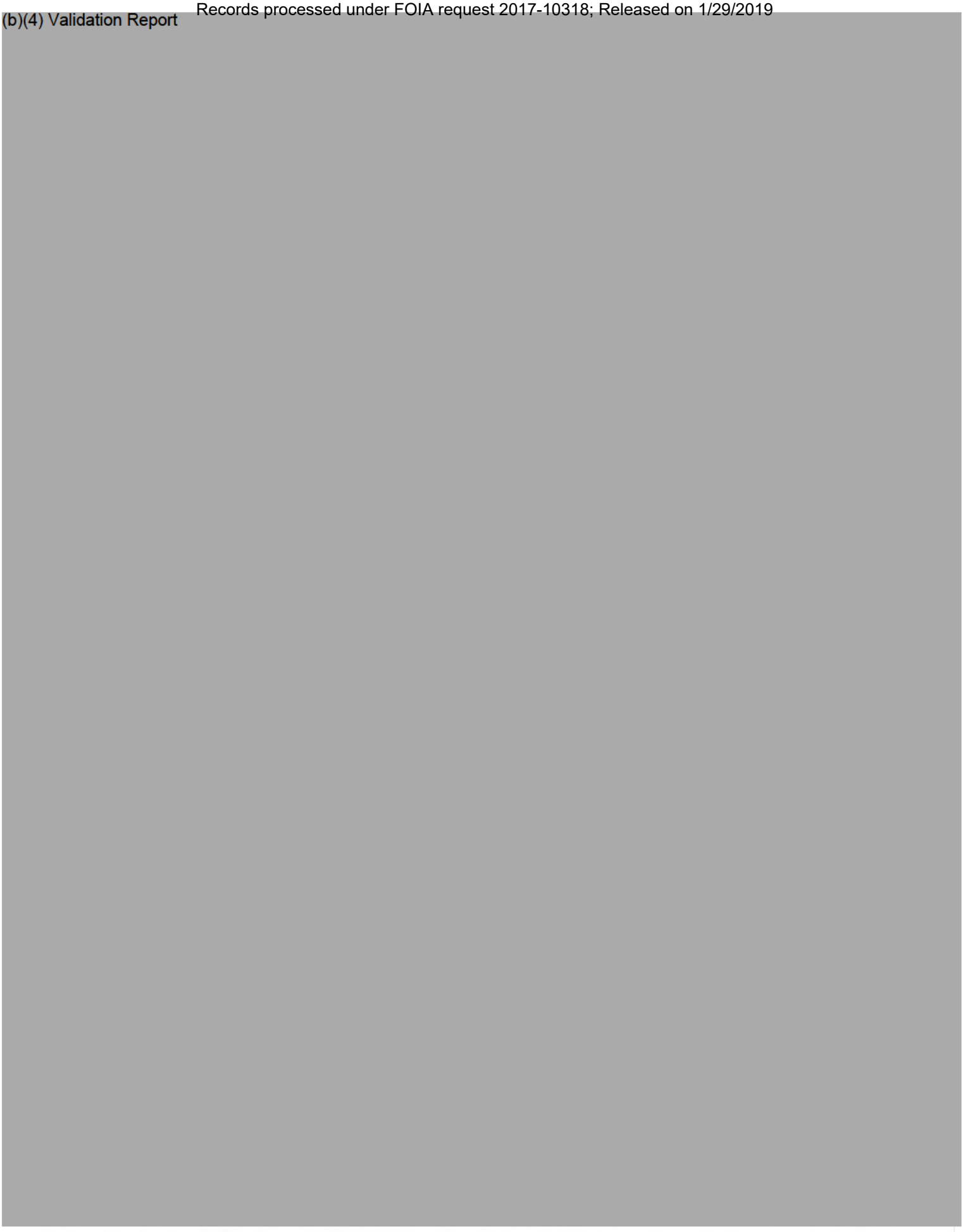

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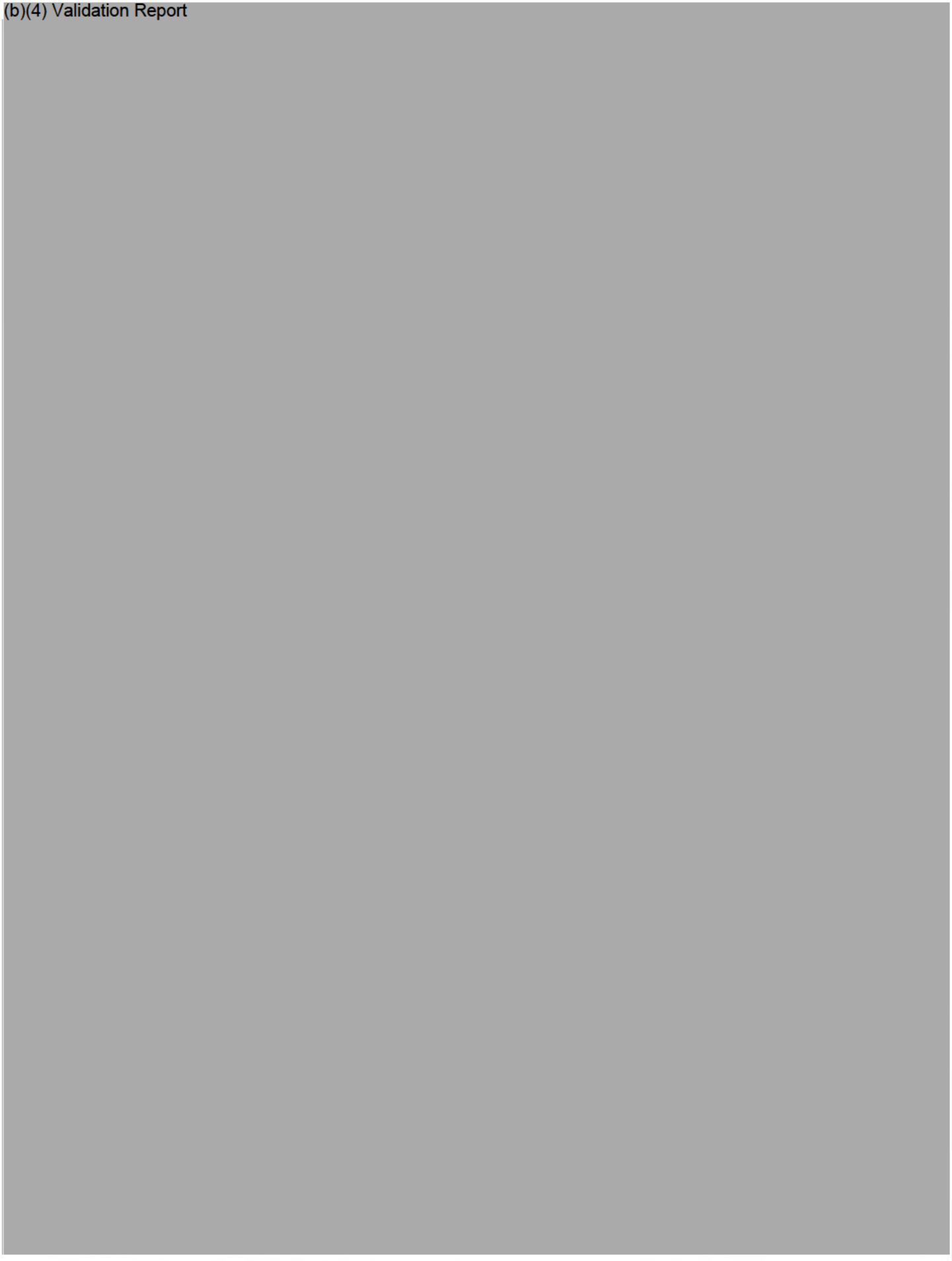
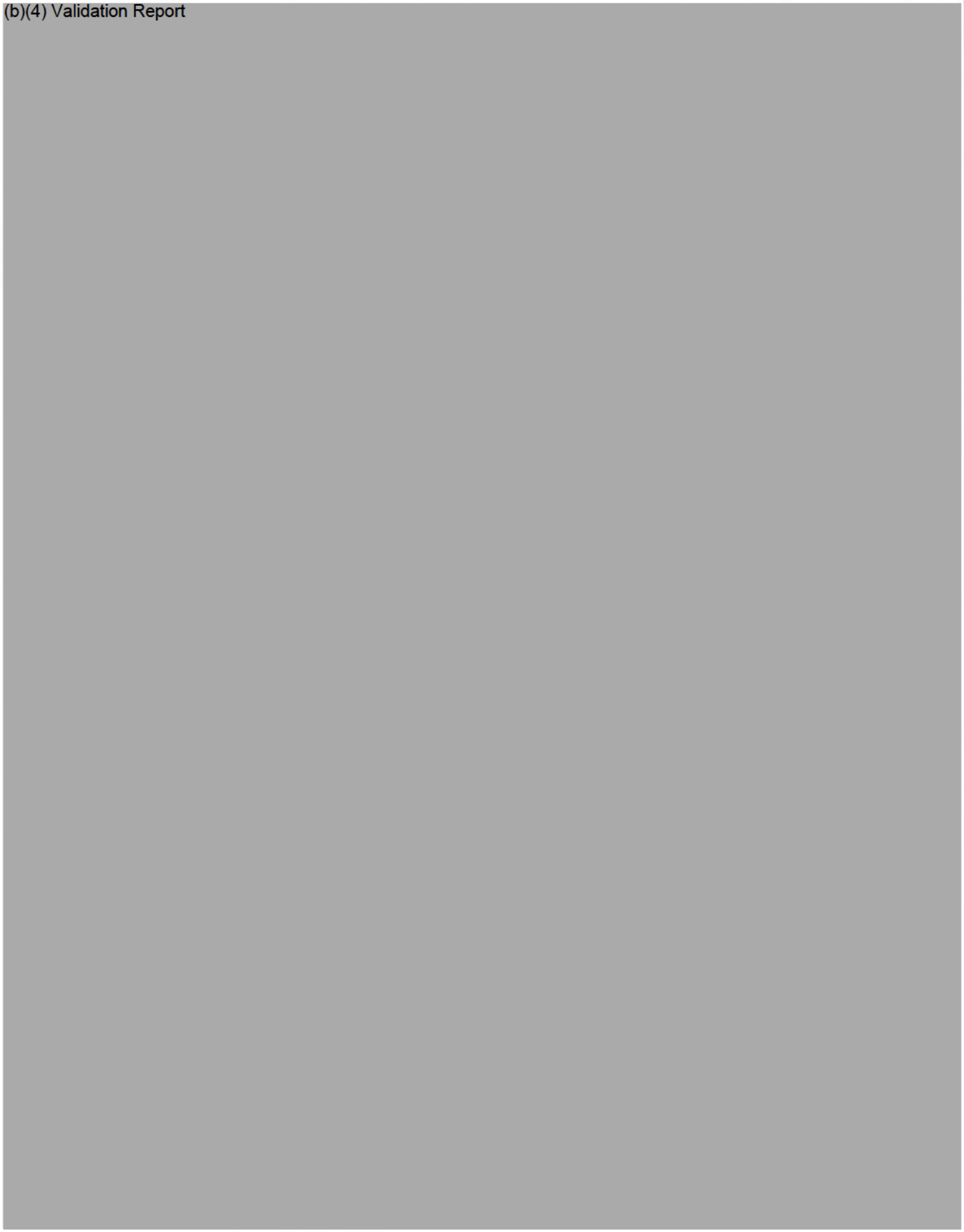
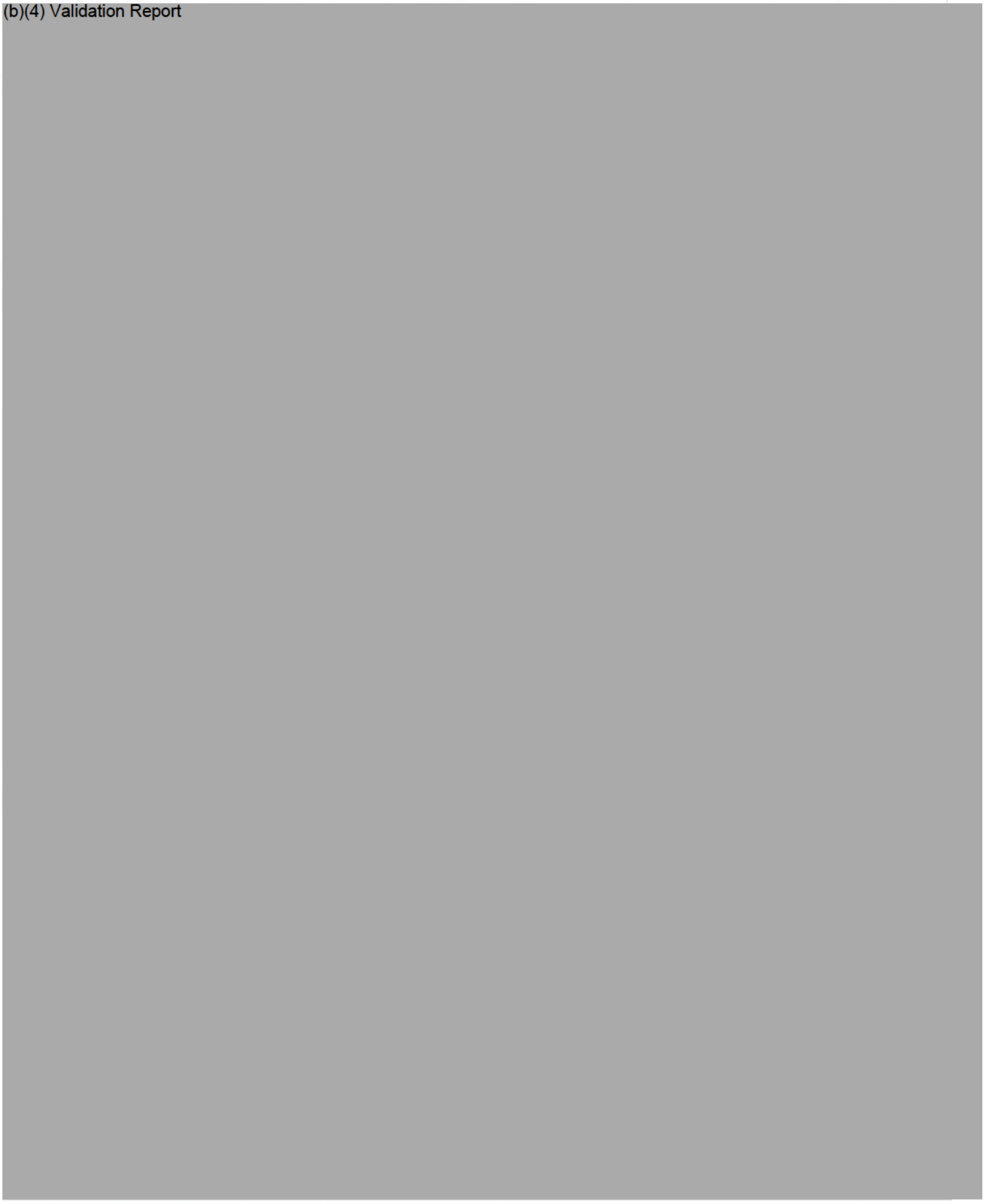
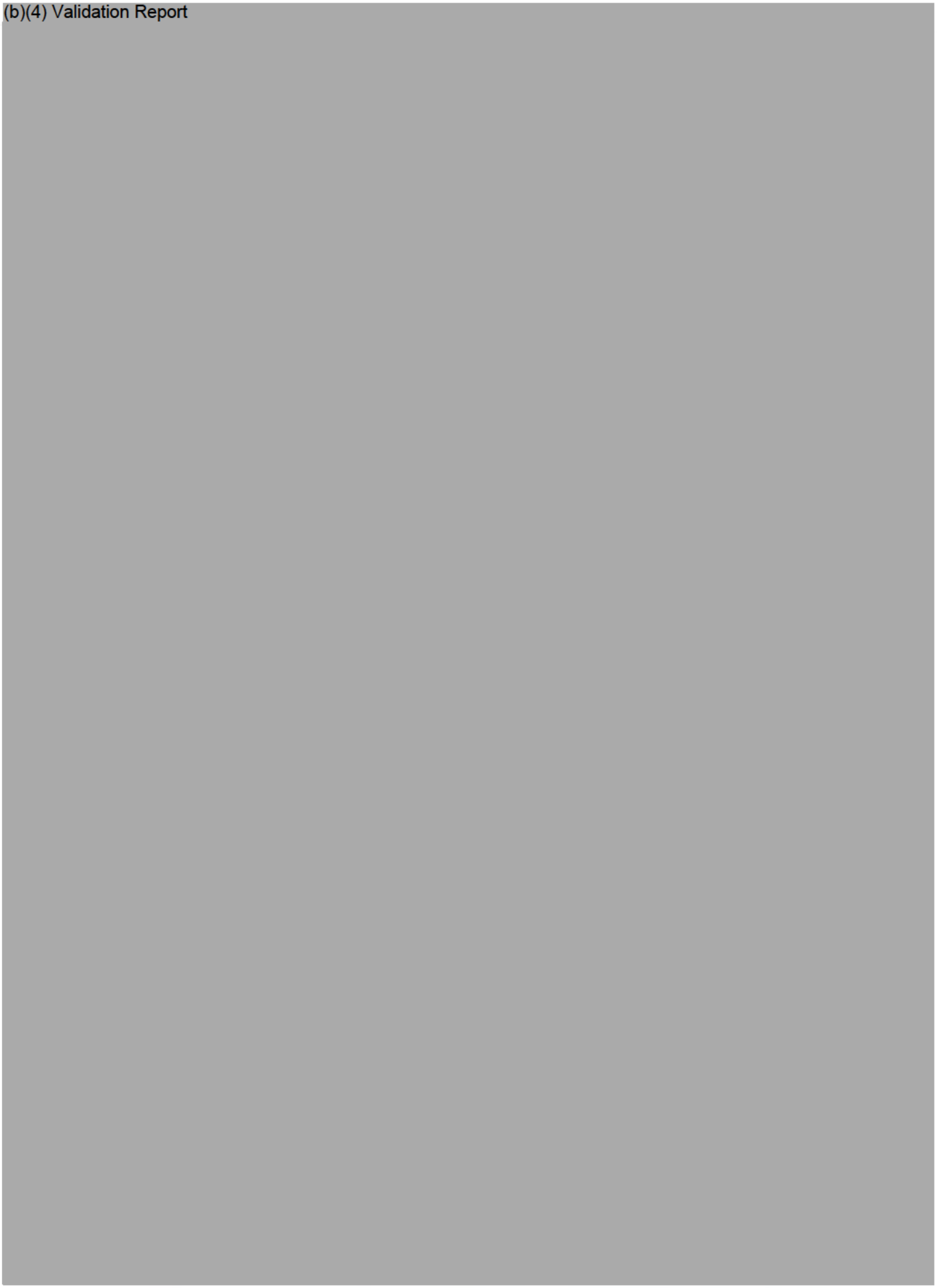
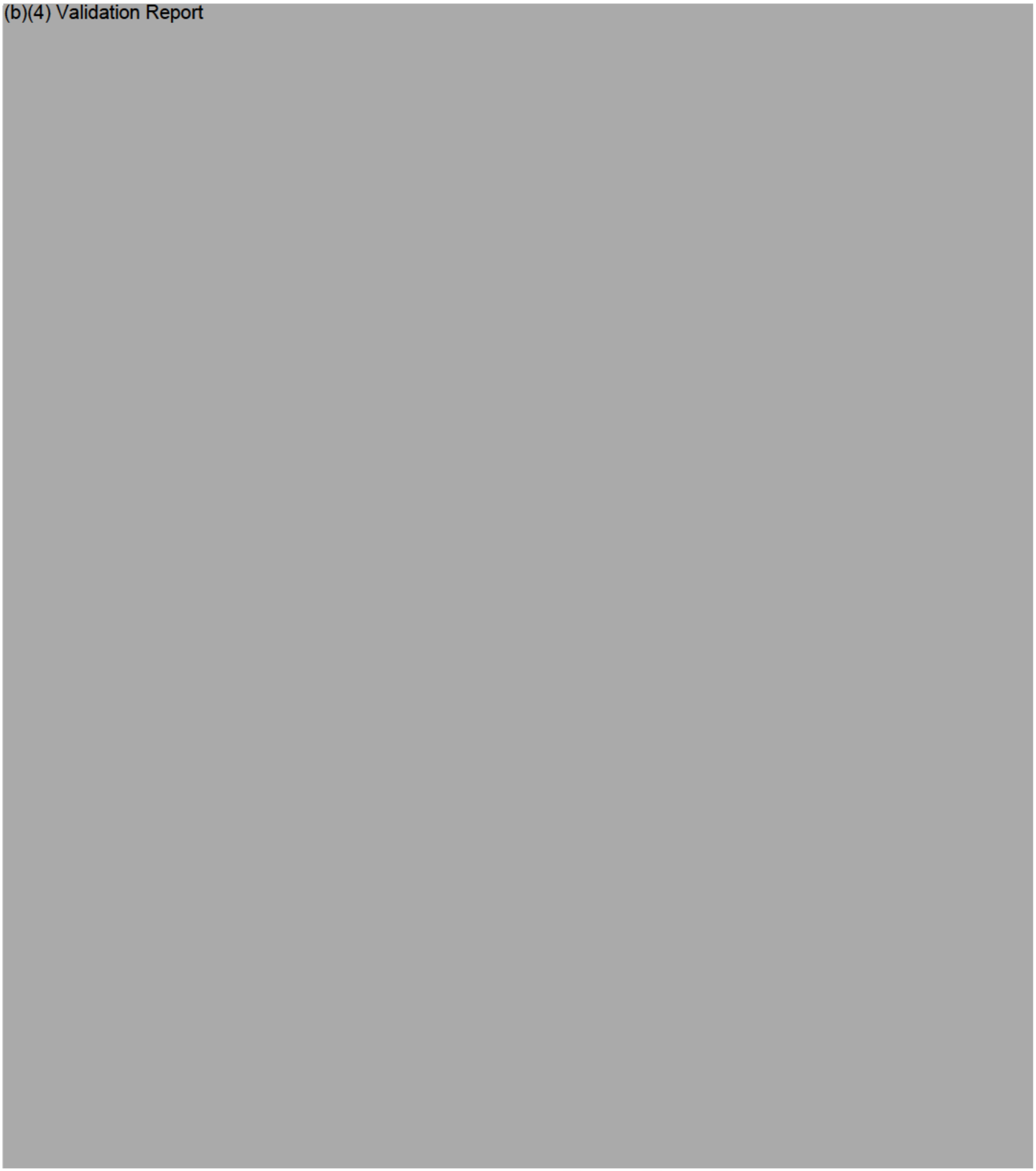
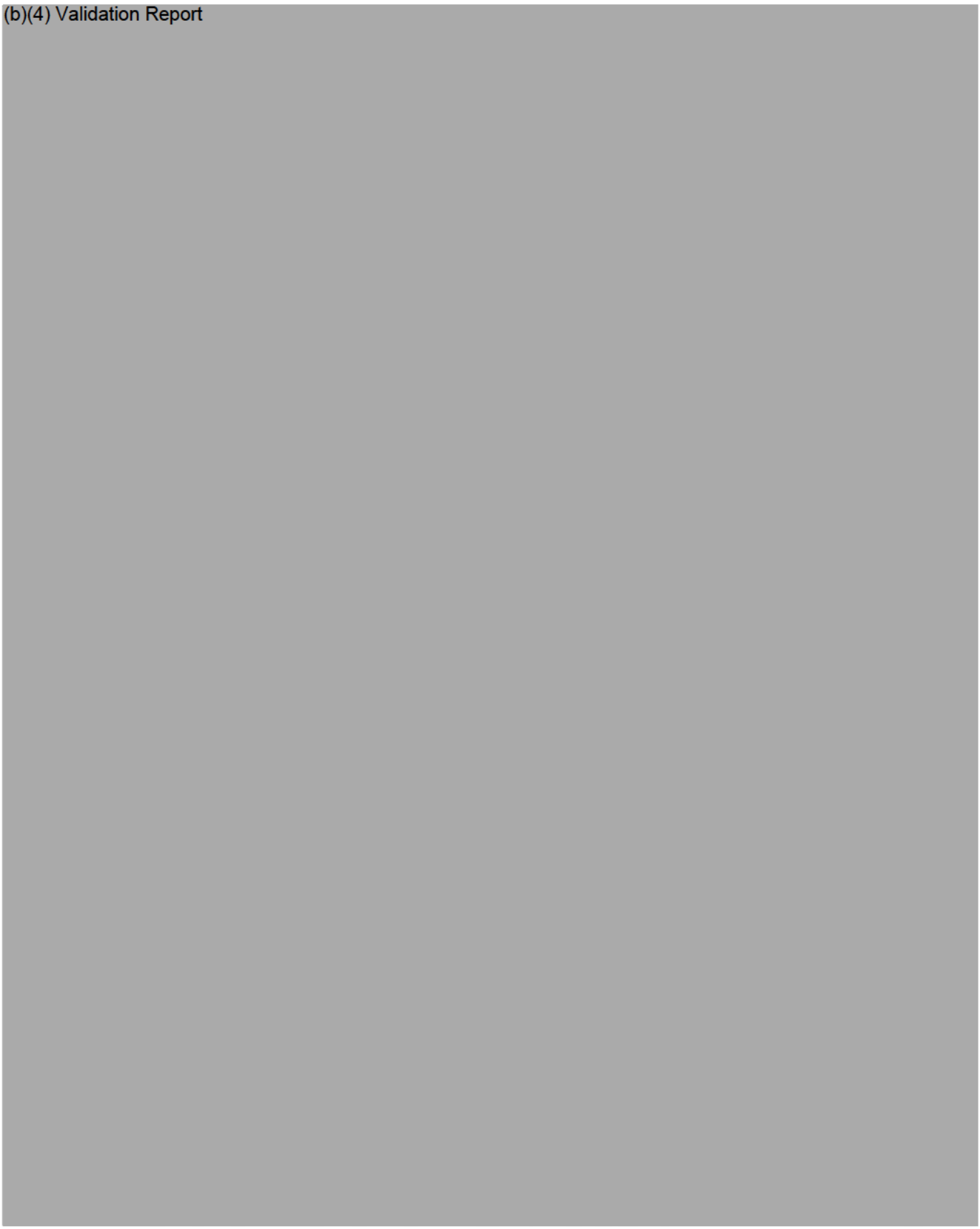


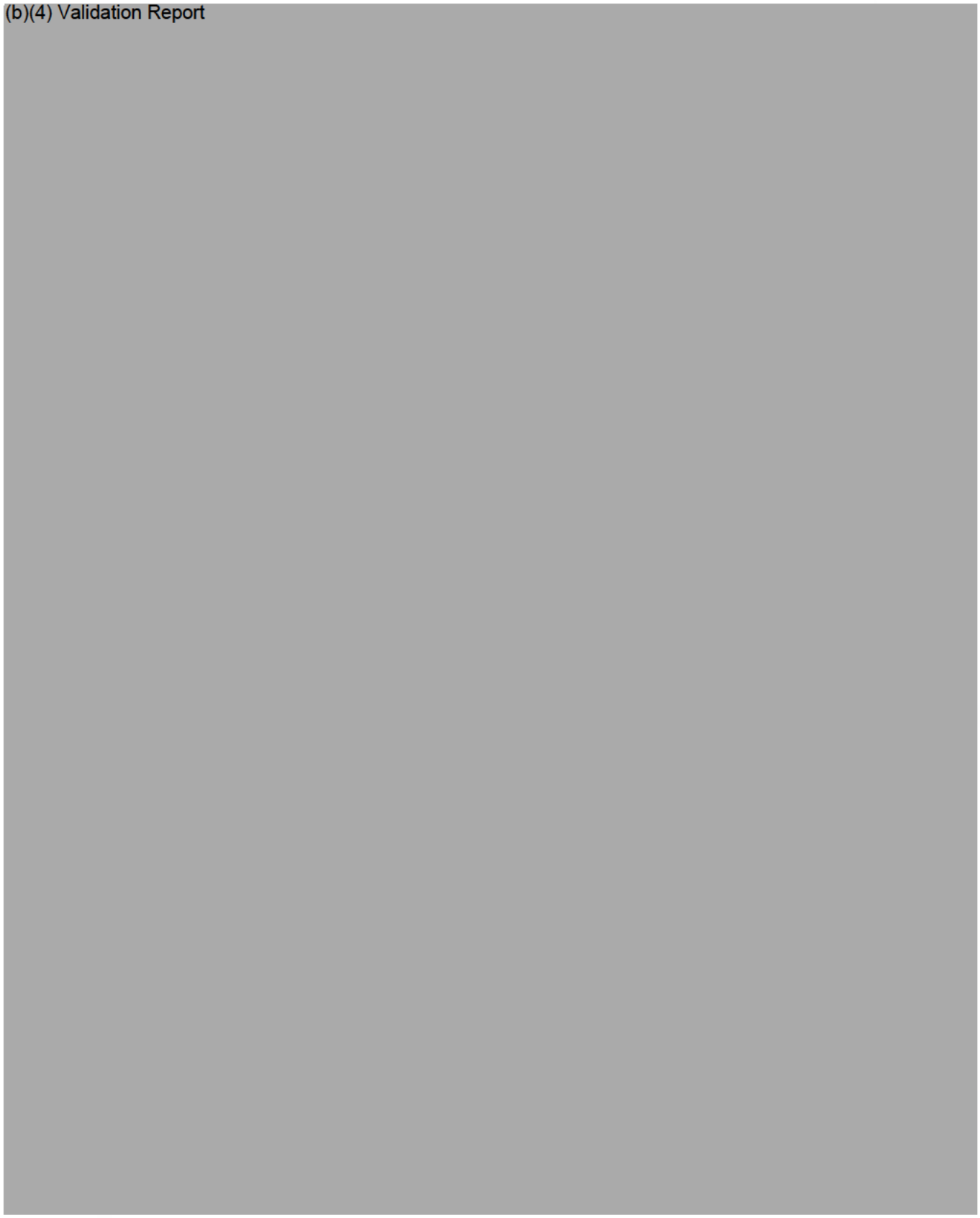


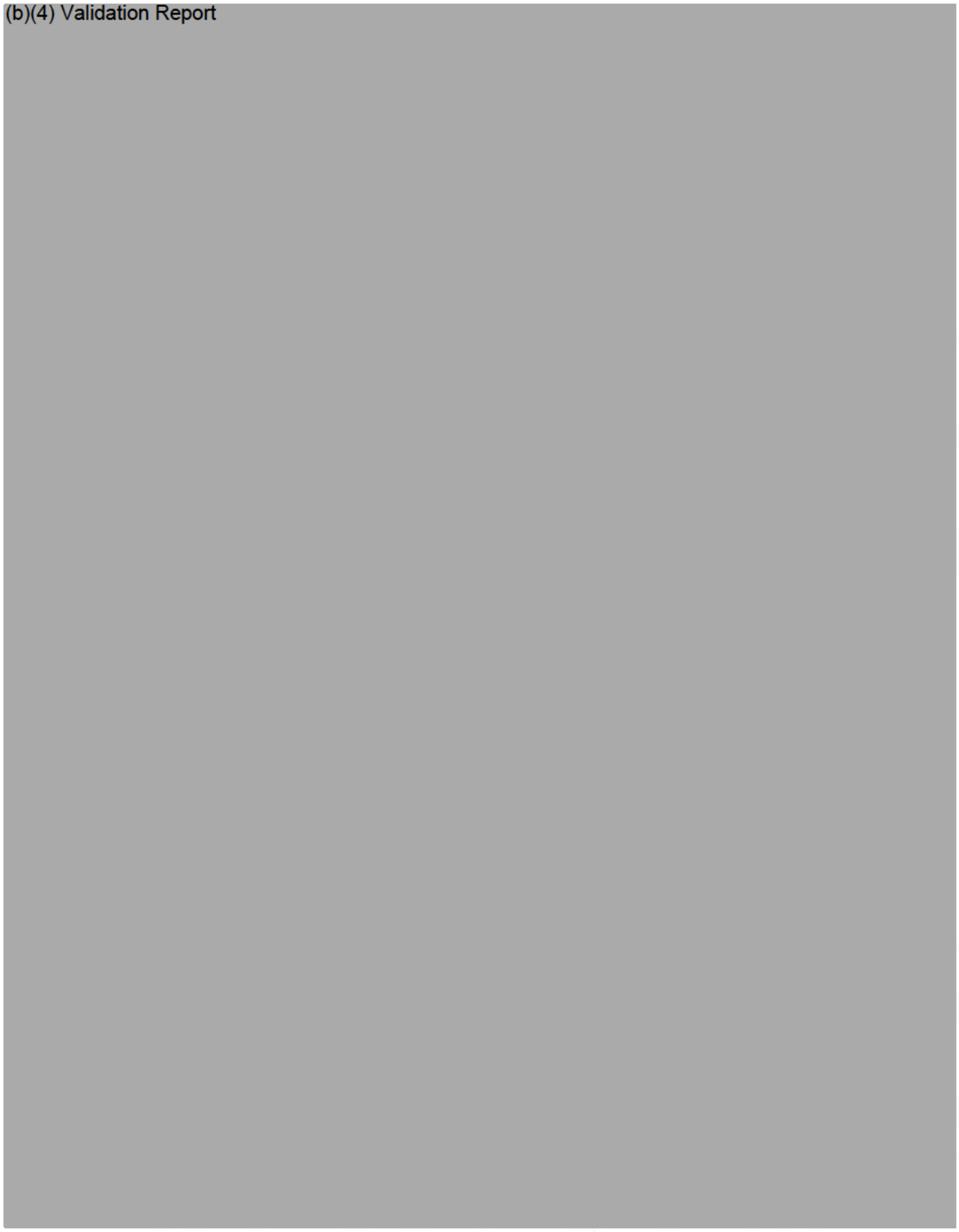


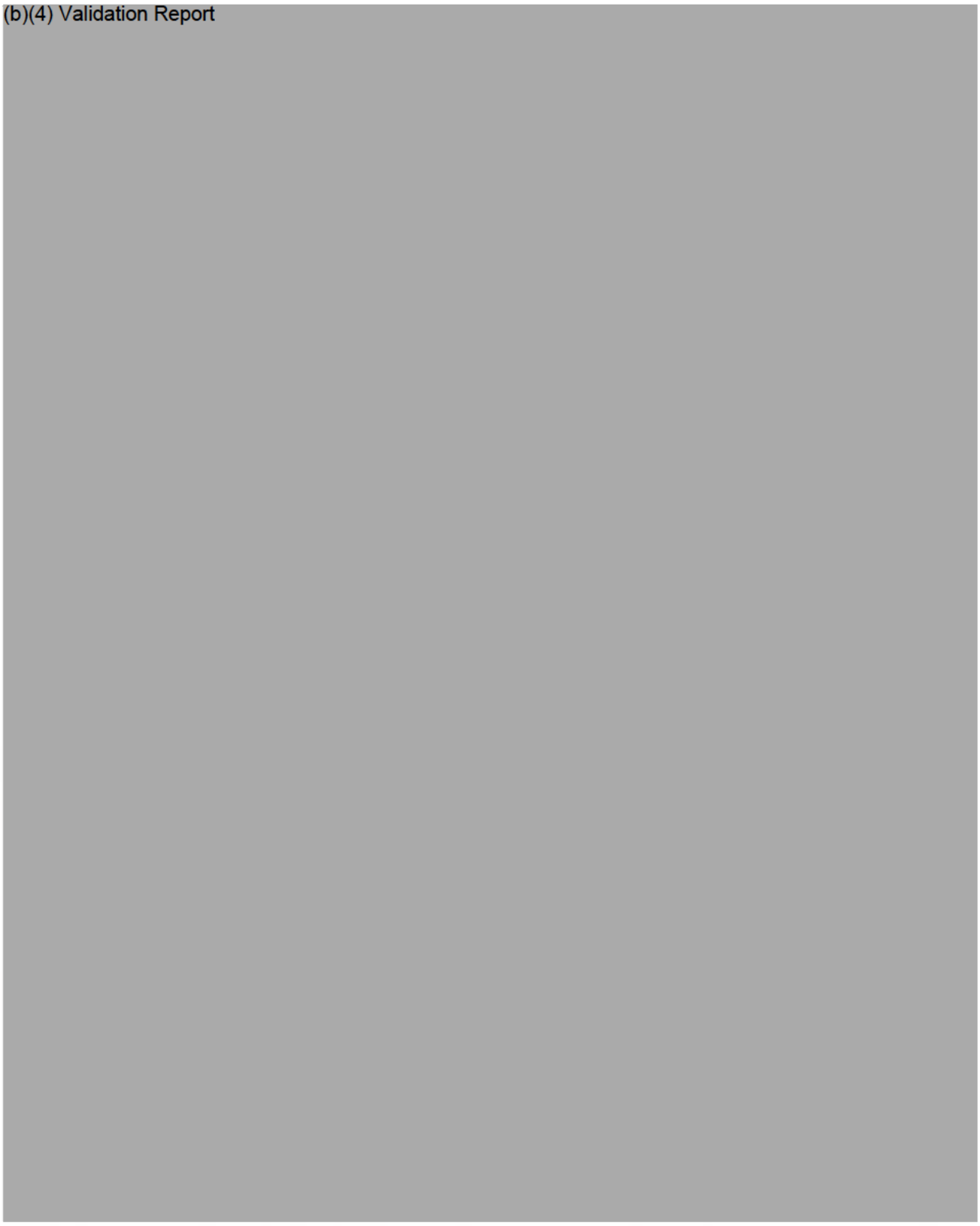


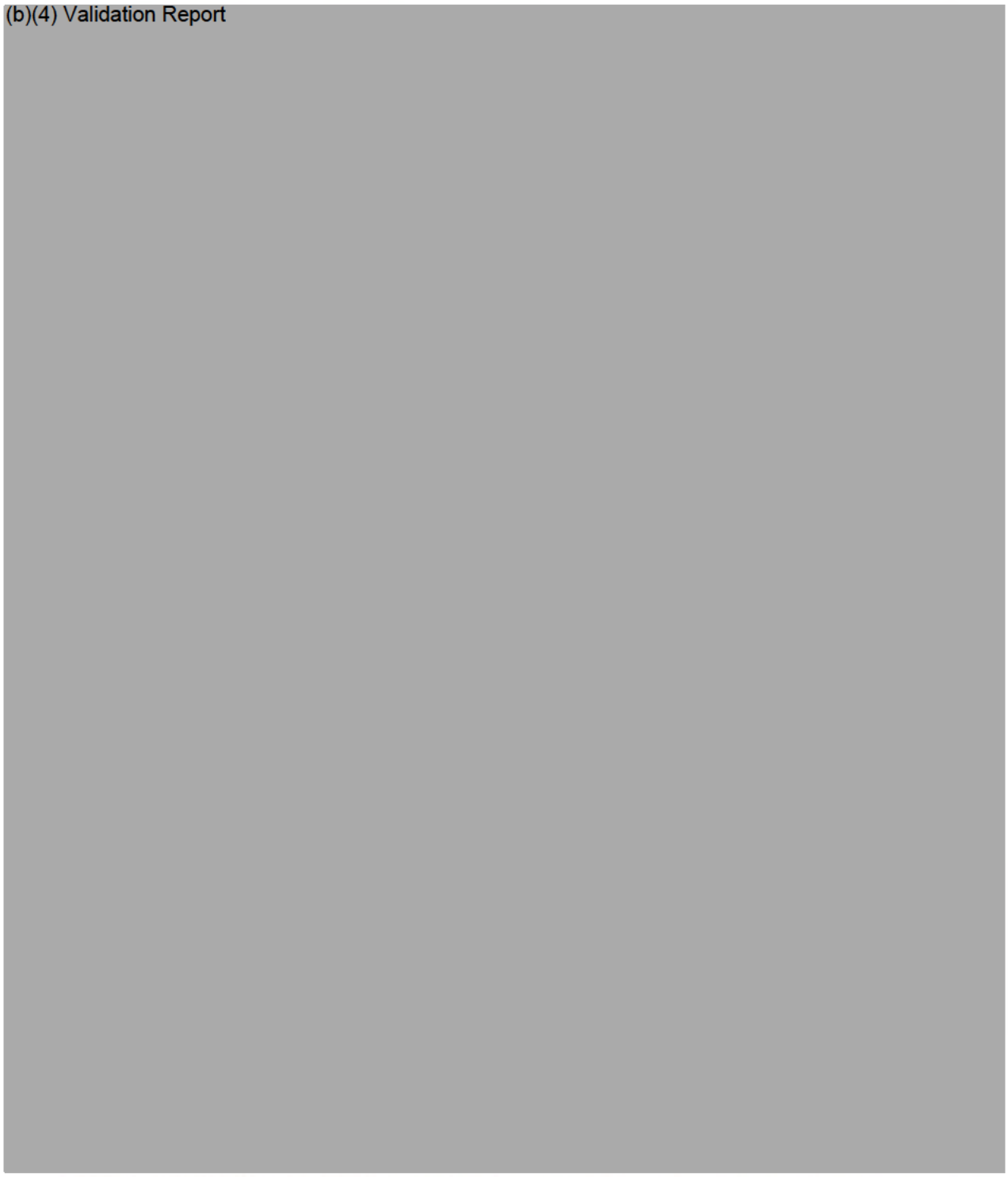


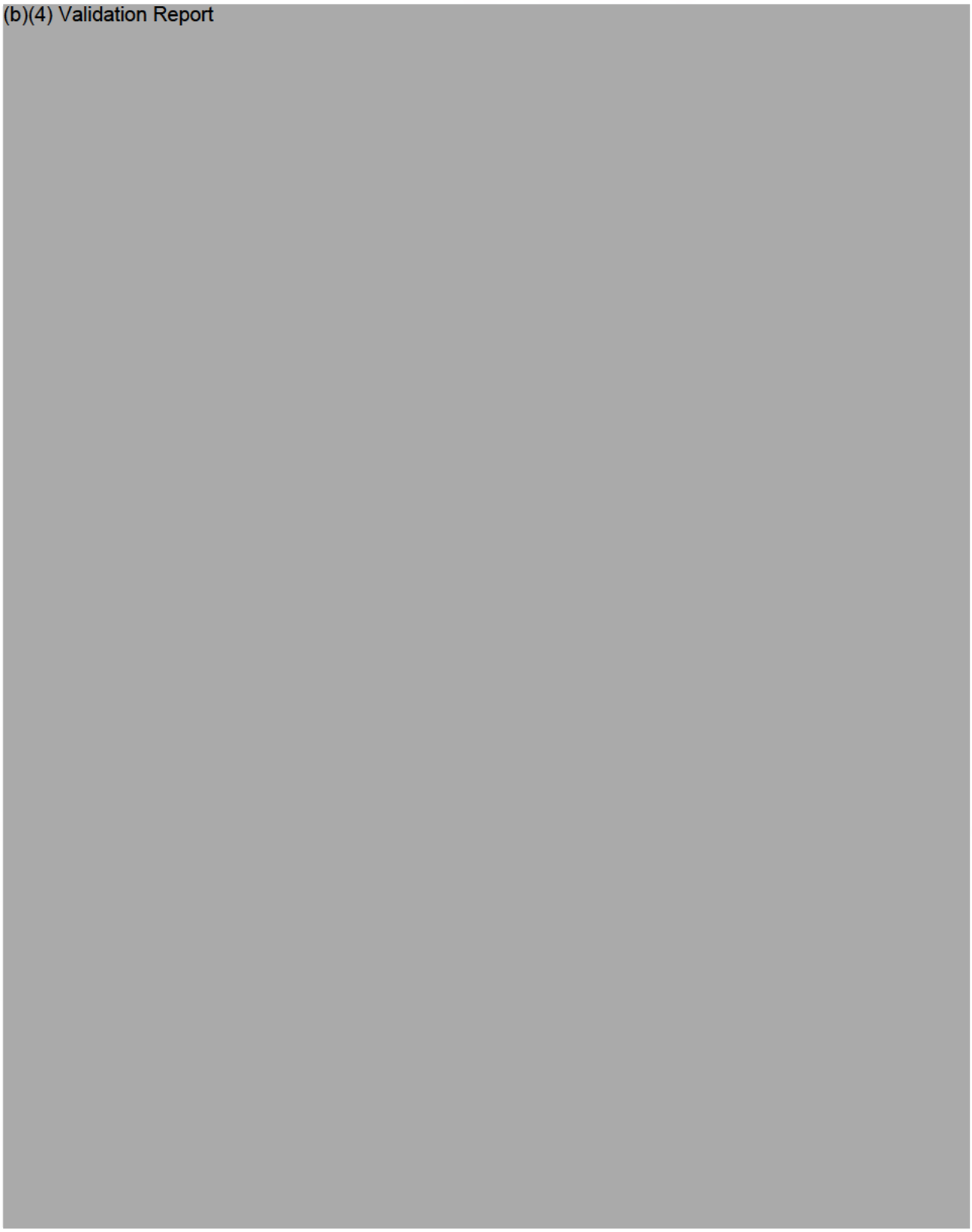






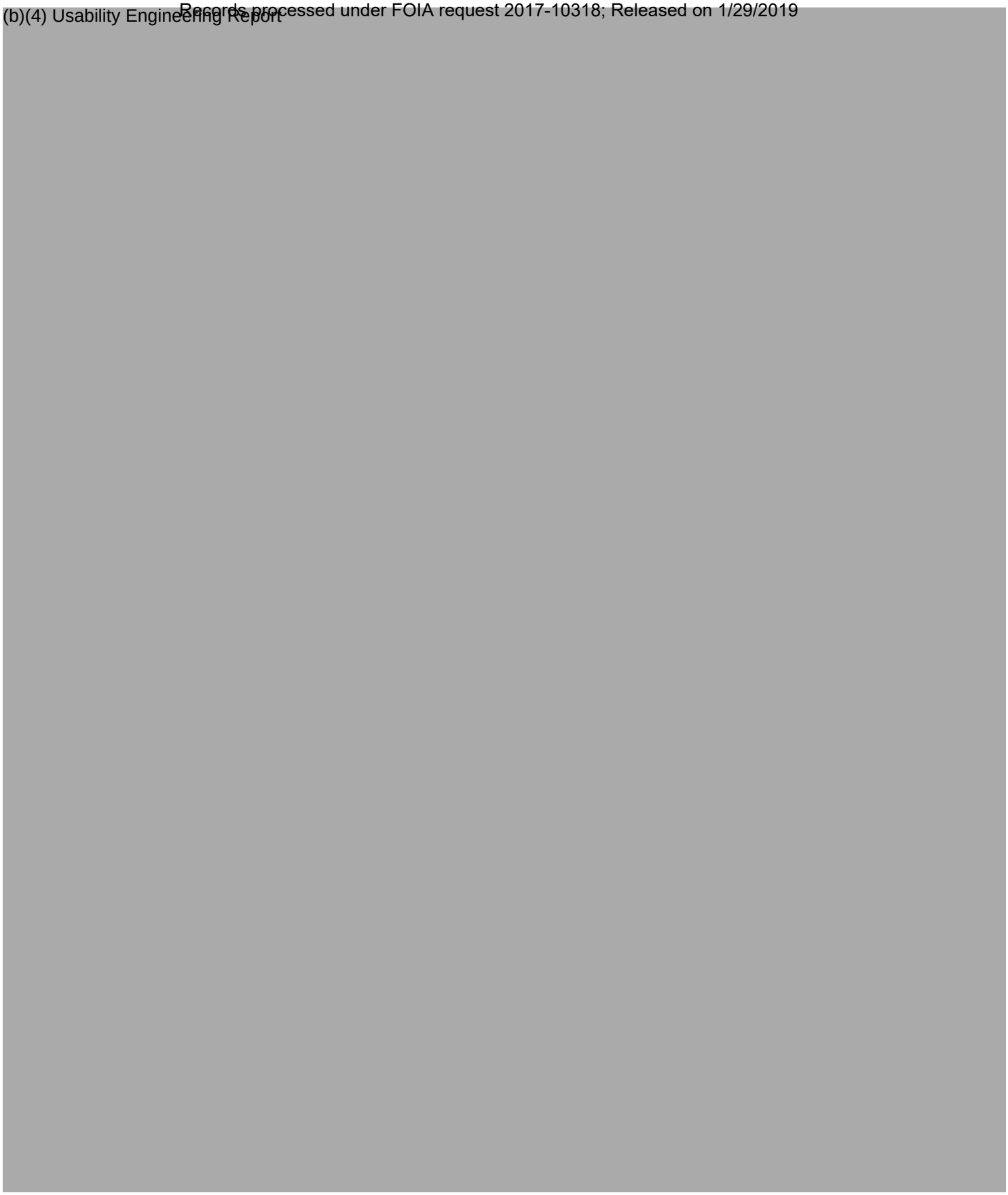


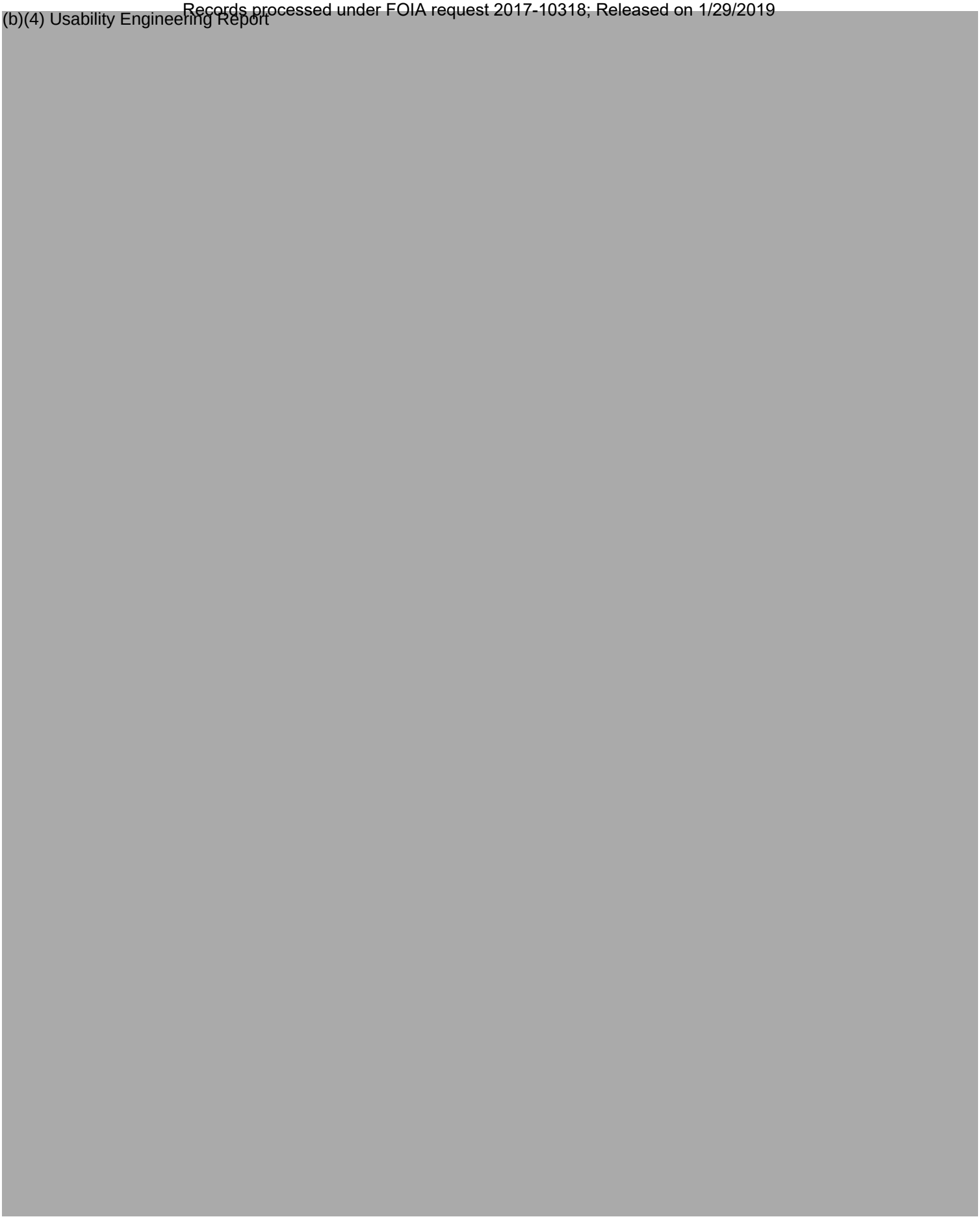


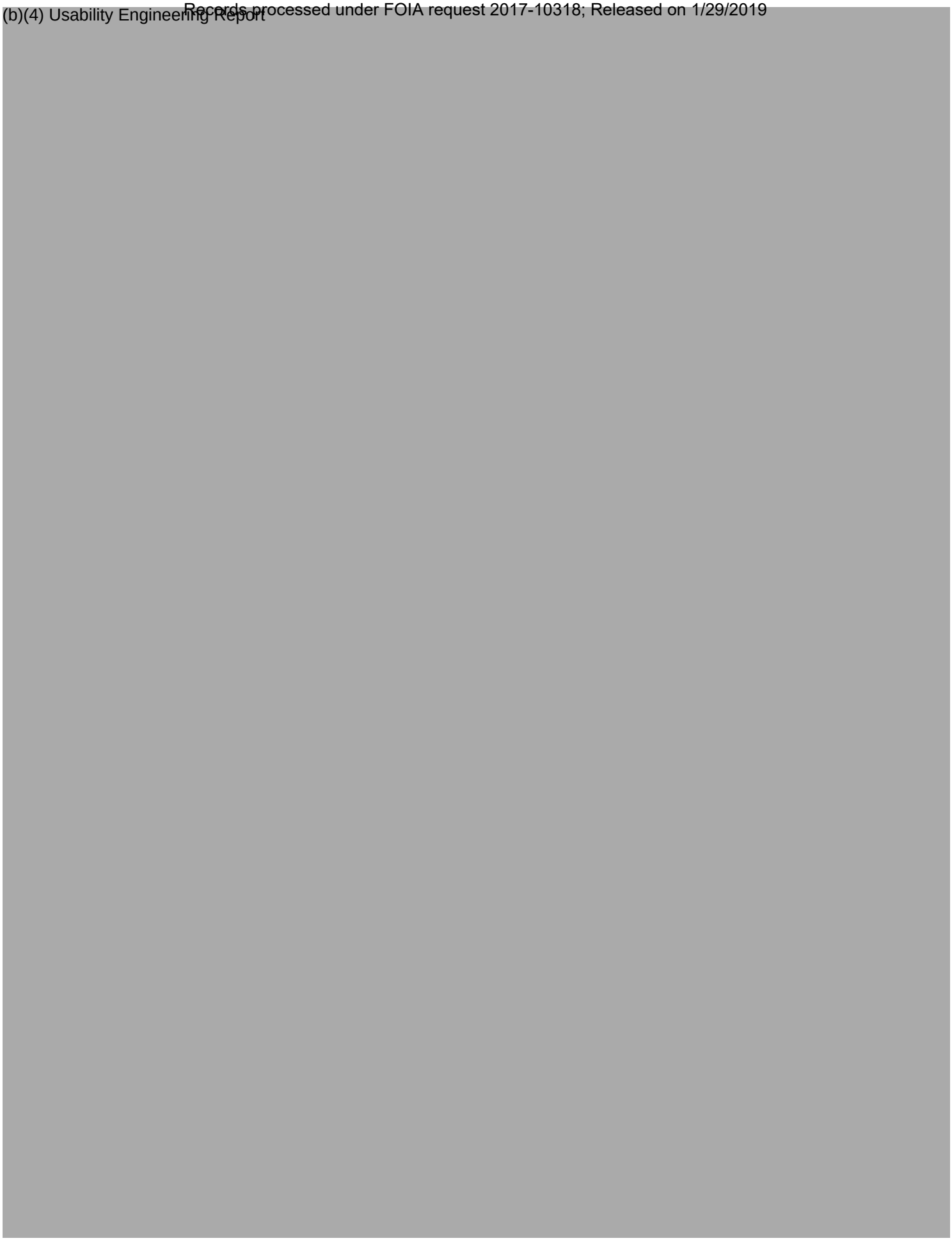


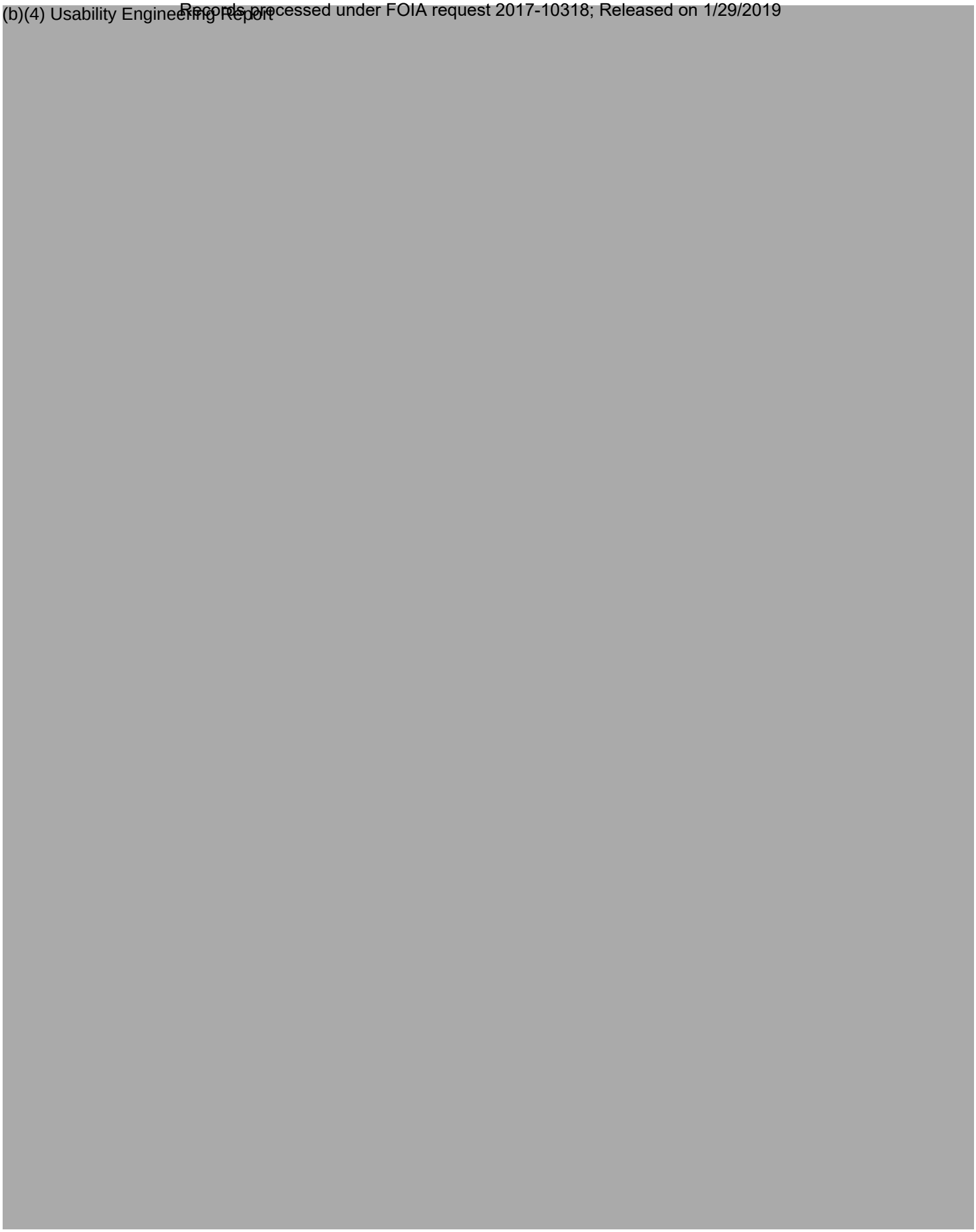
APPENDIX 9
USABILITY TESTING

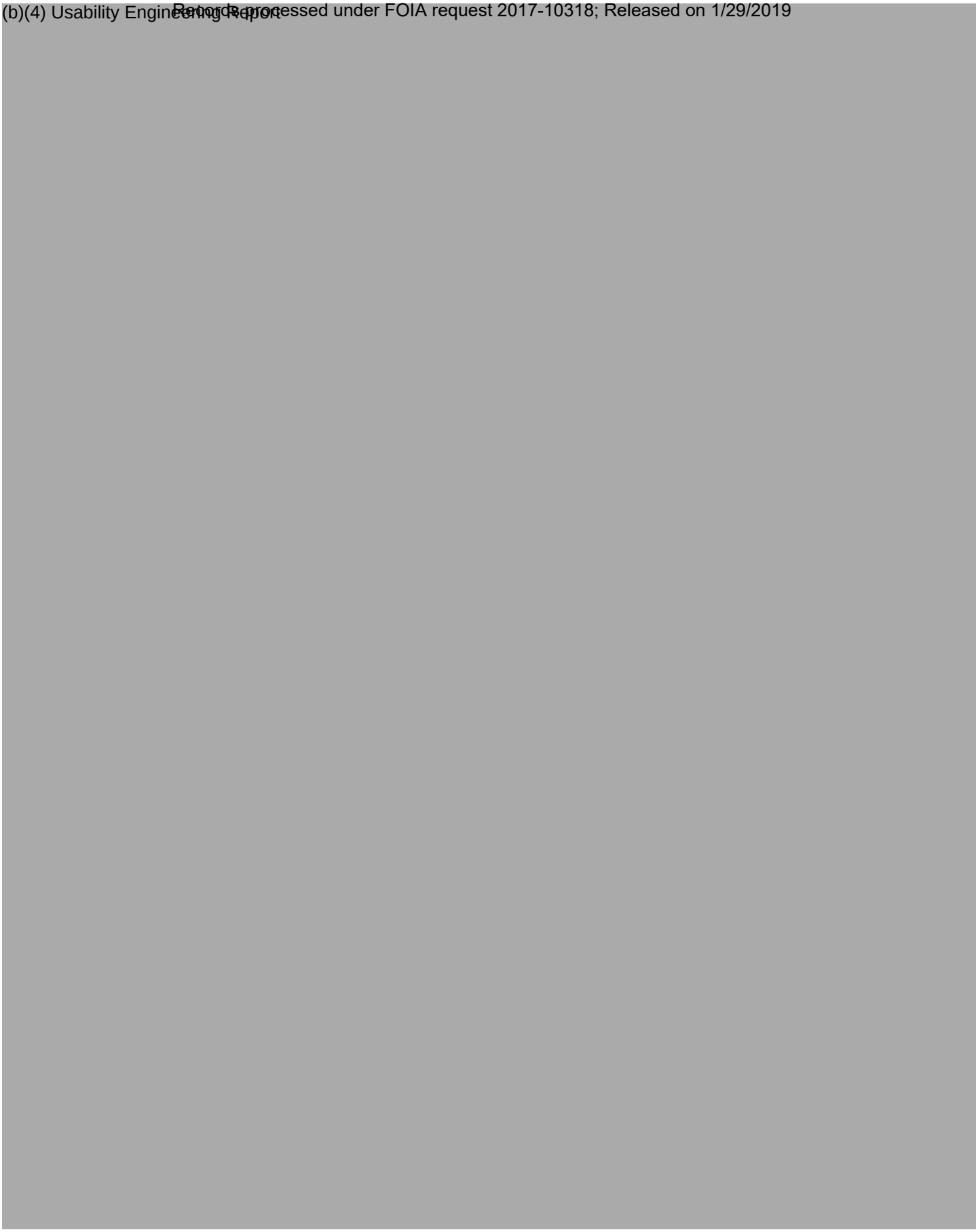
Provided in this appendix is the usability study, "Kardia Band Usability Engineering Report" (b) (4) performed on the Kardia Band System



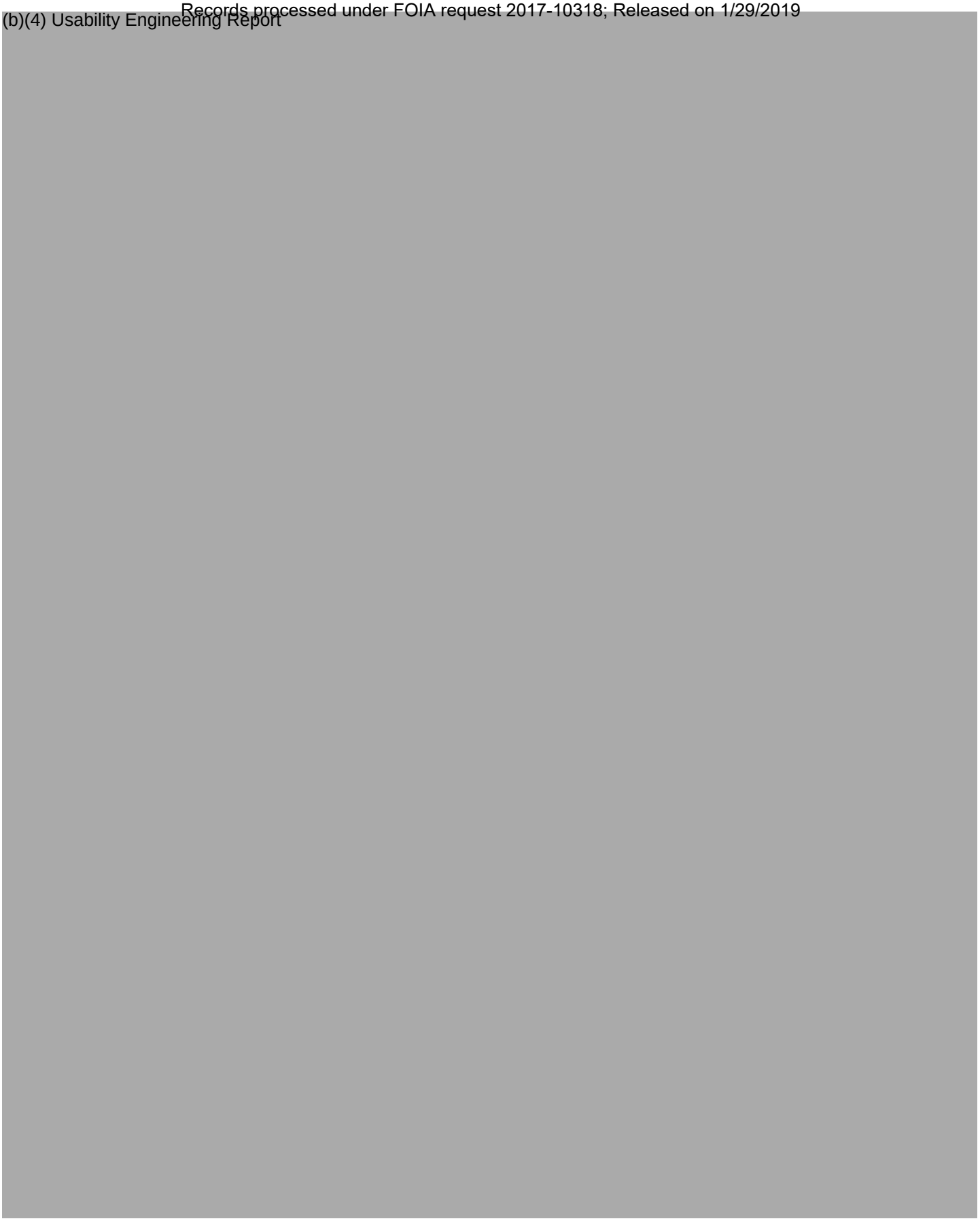


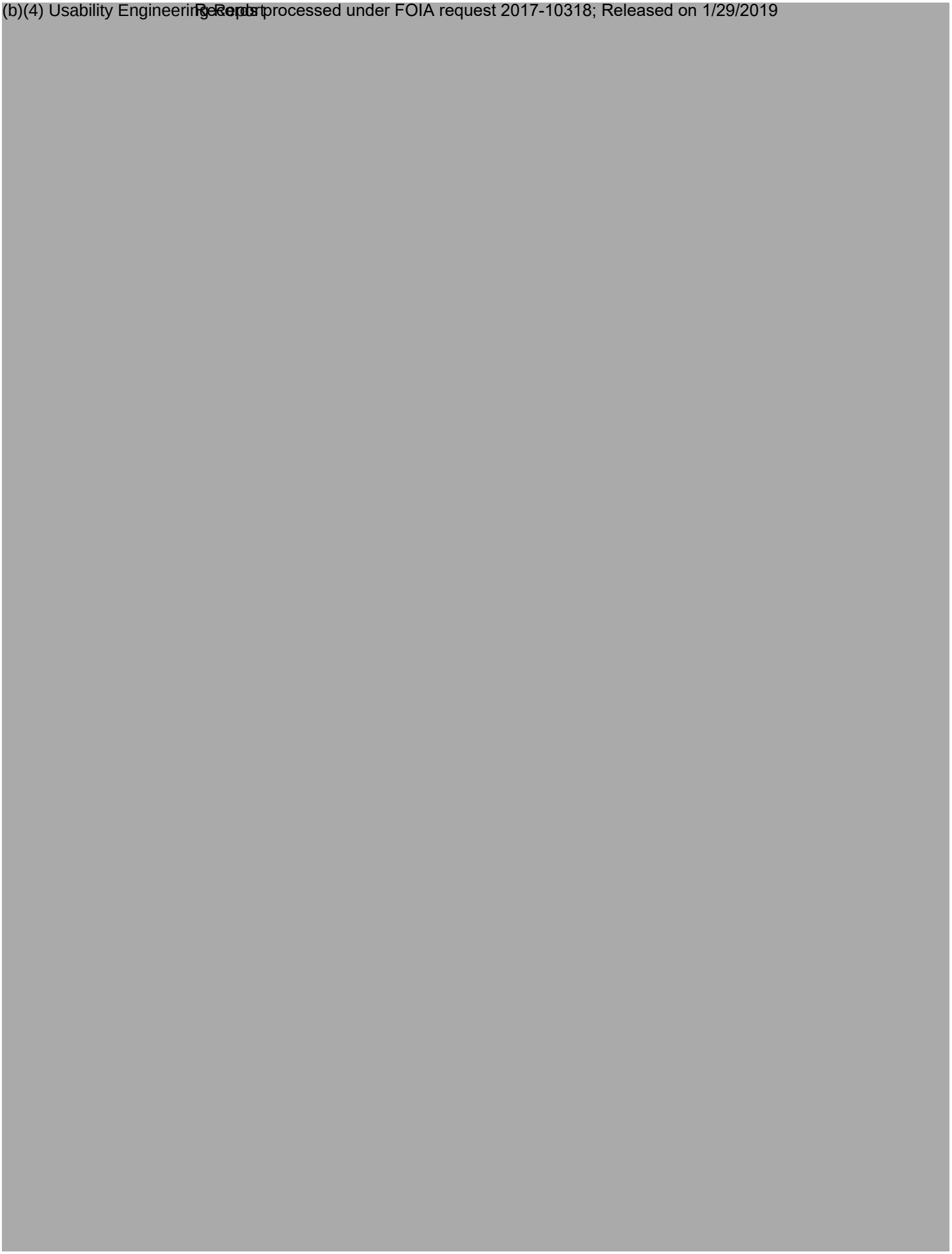


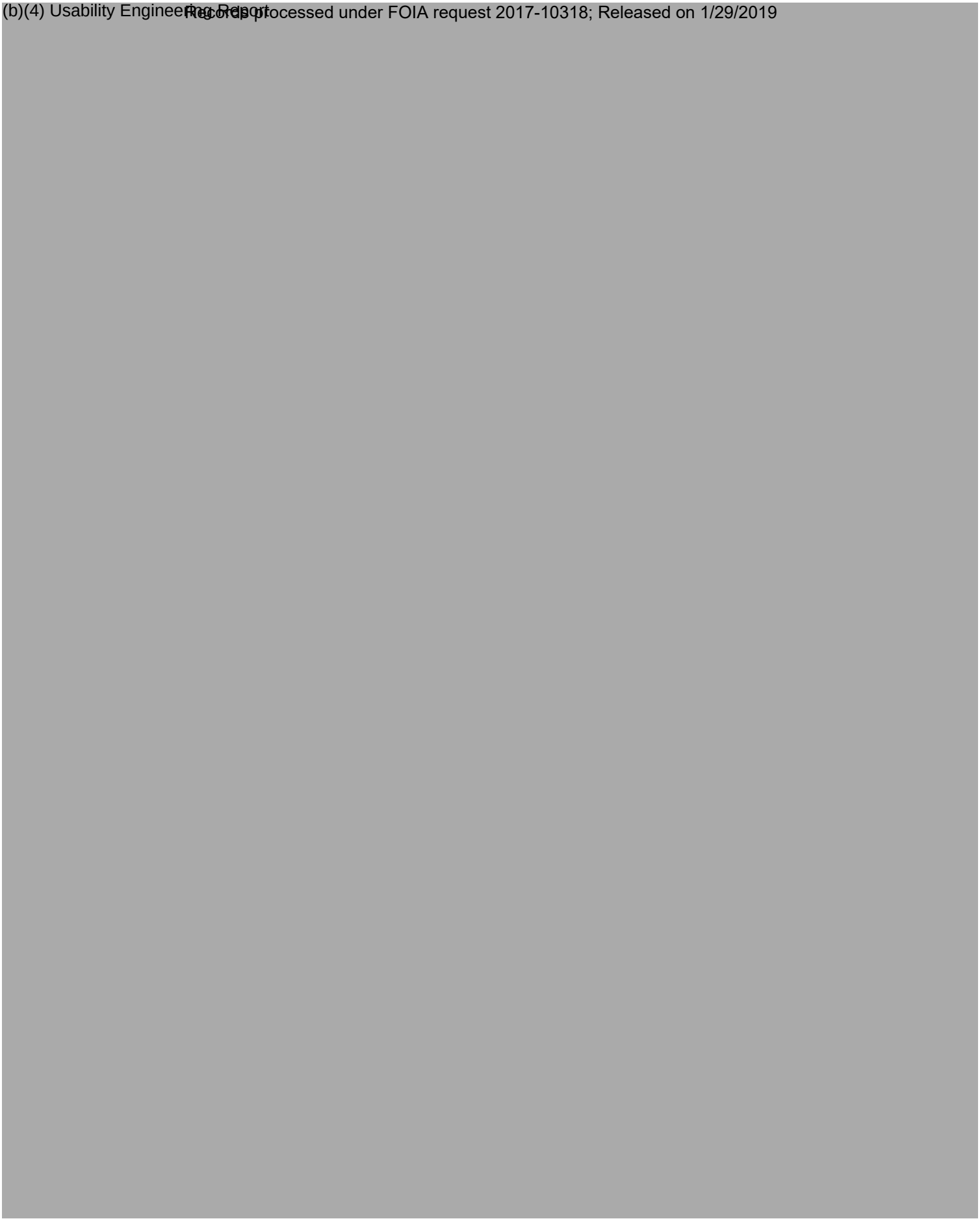


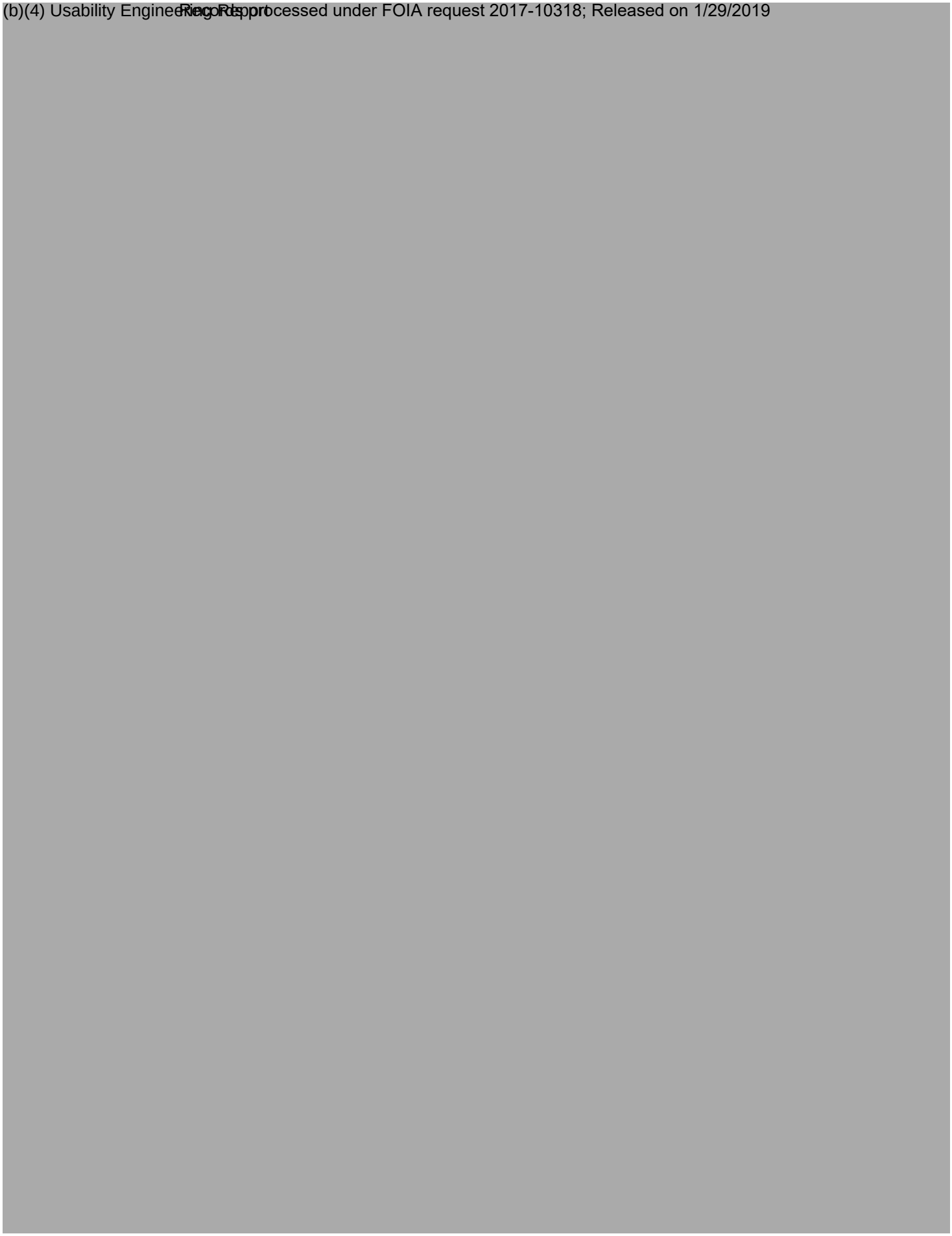


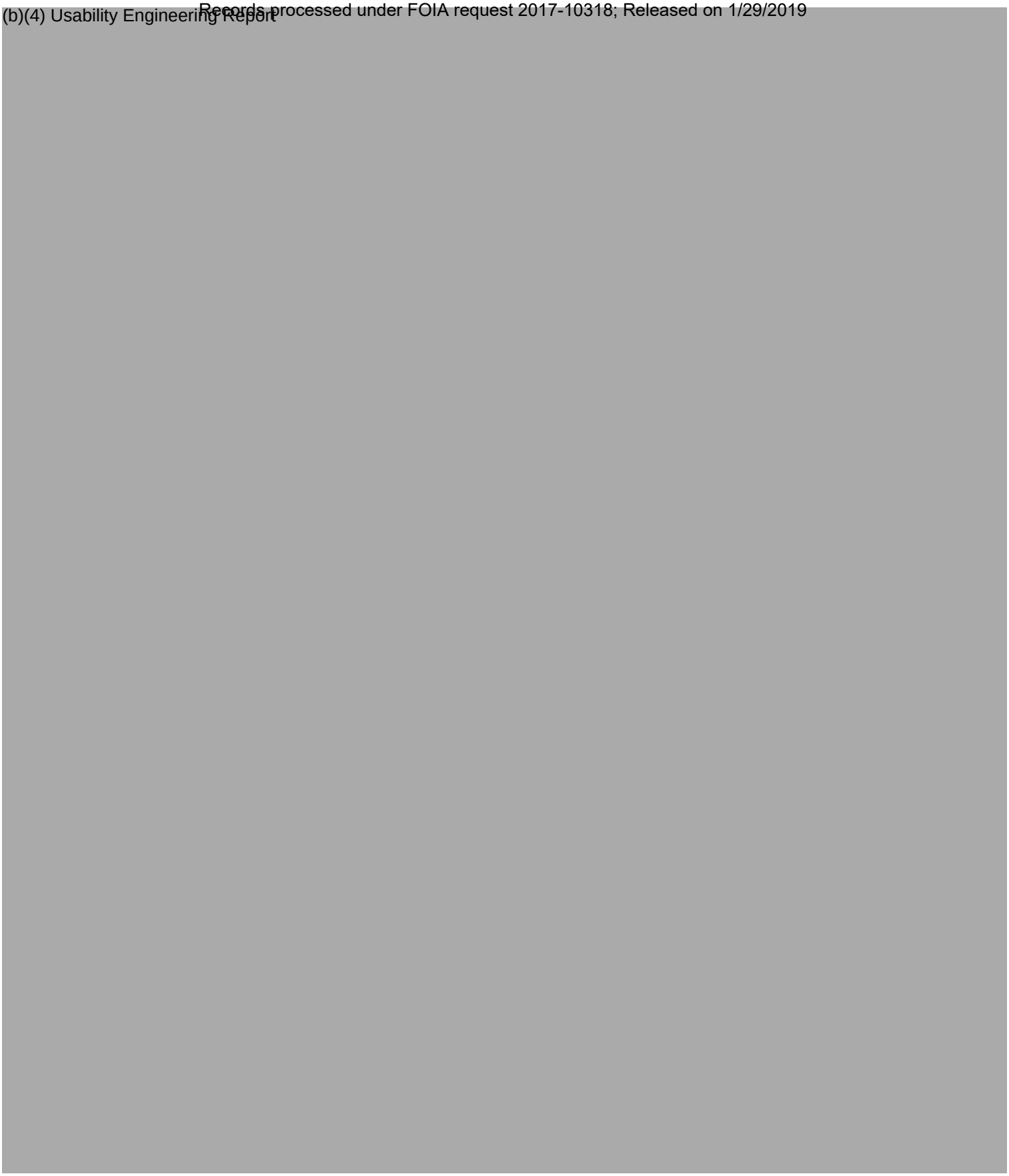
(b)(4) Usability Engineering Report

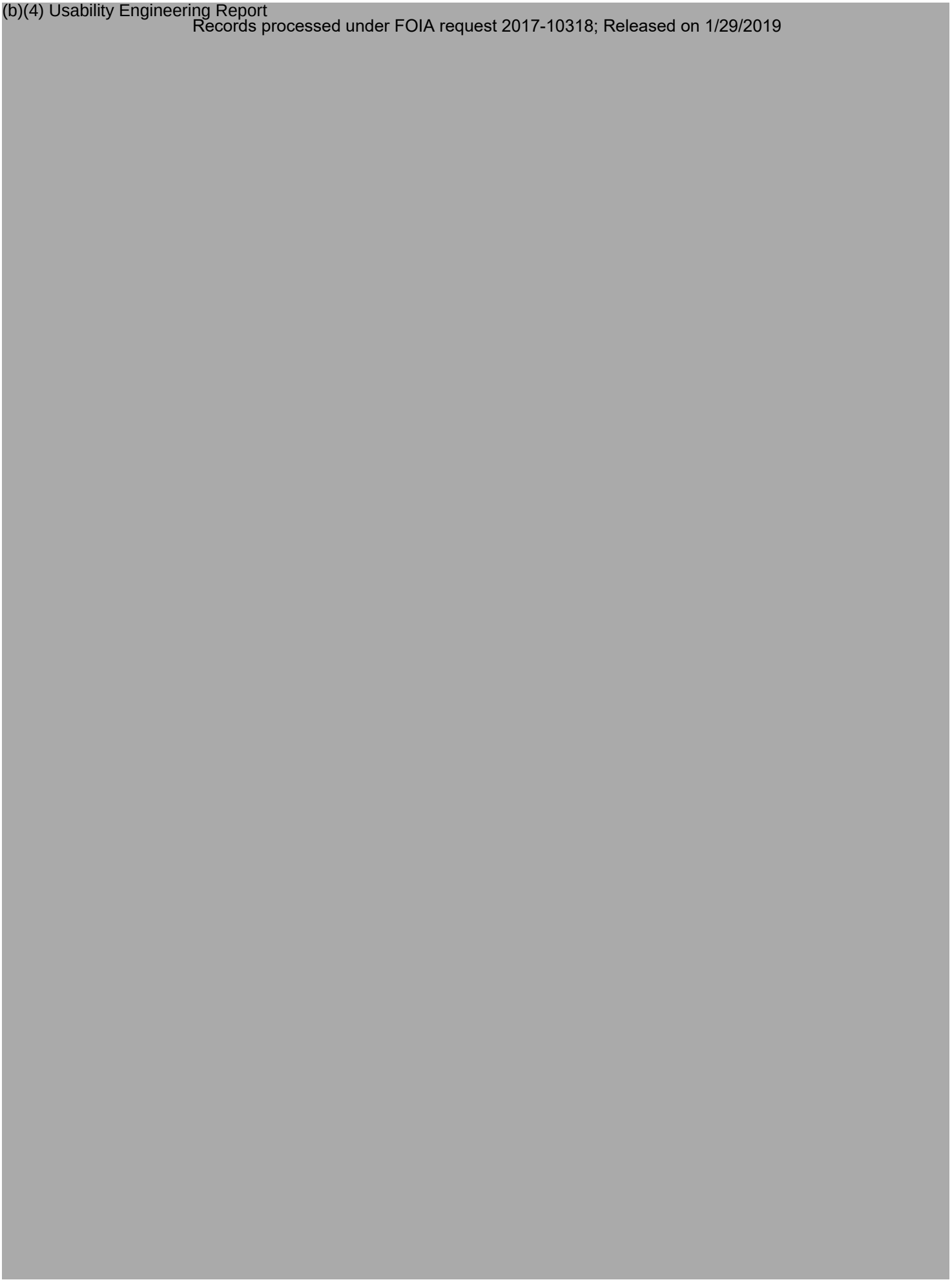


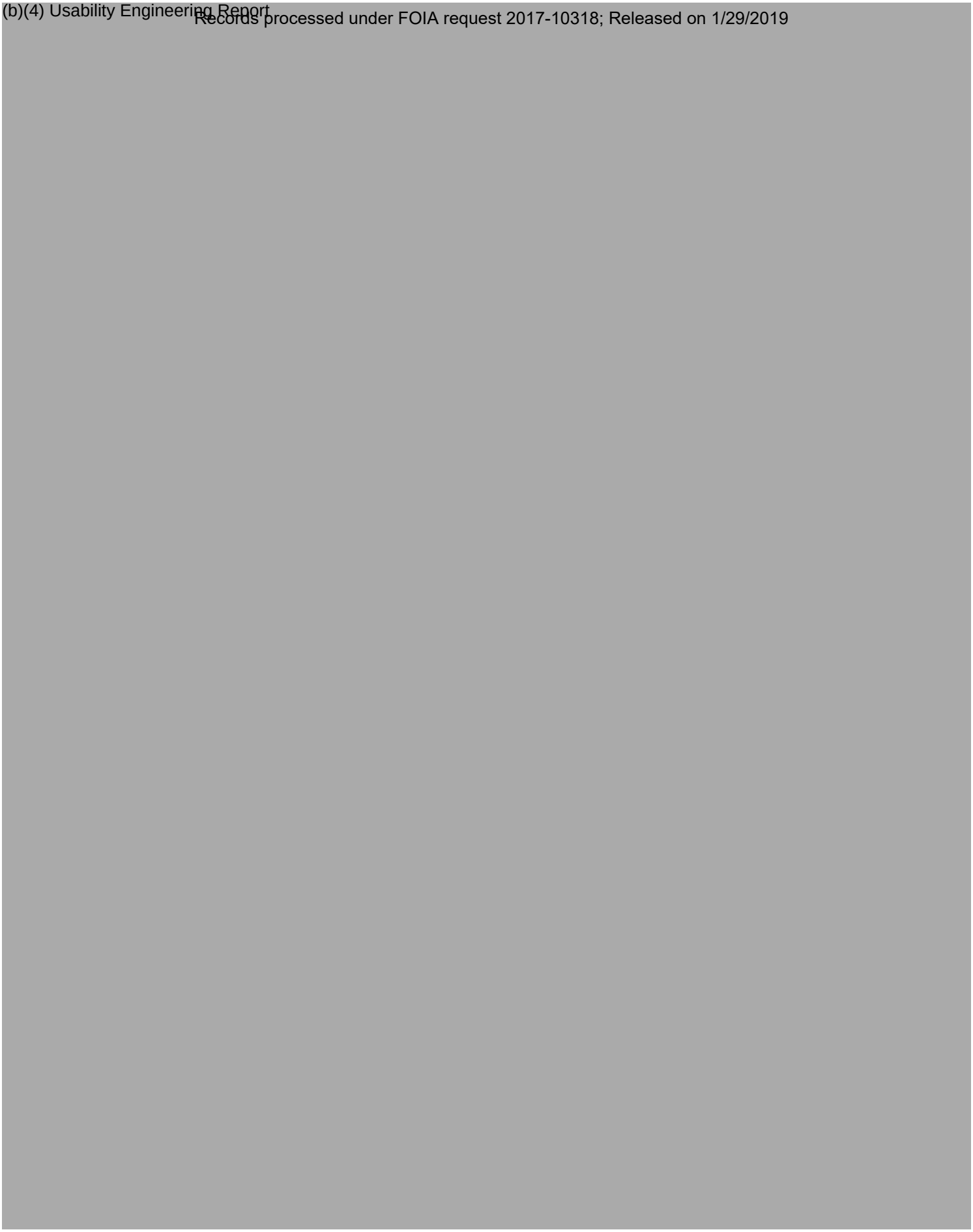


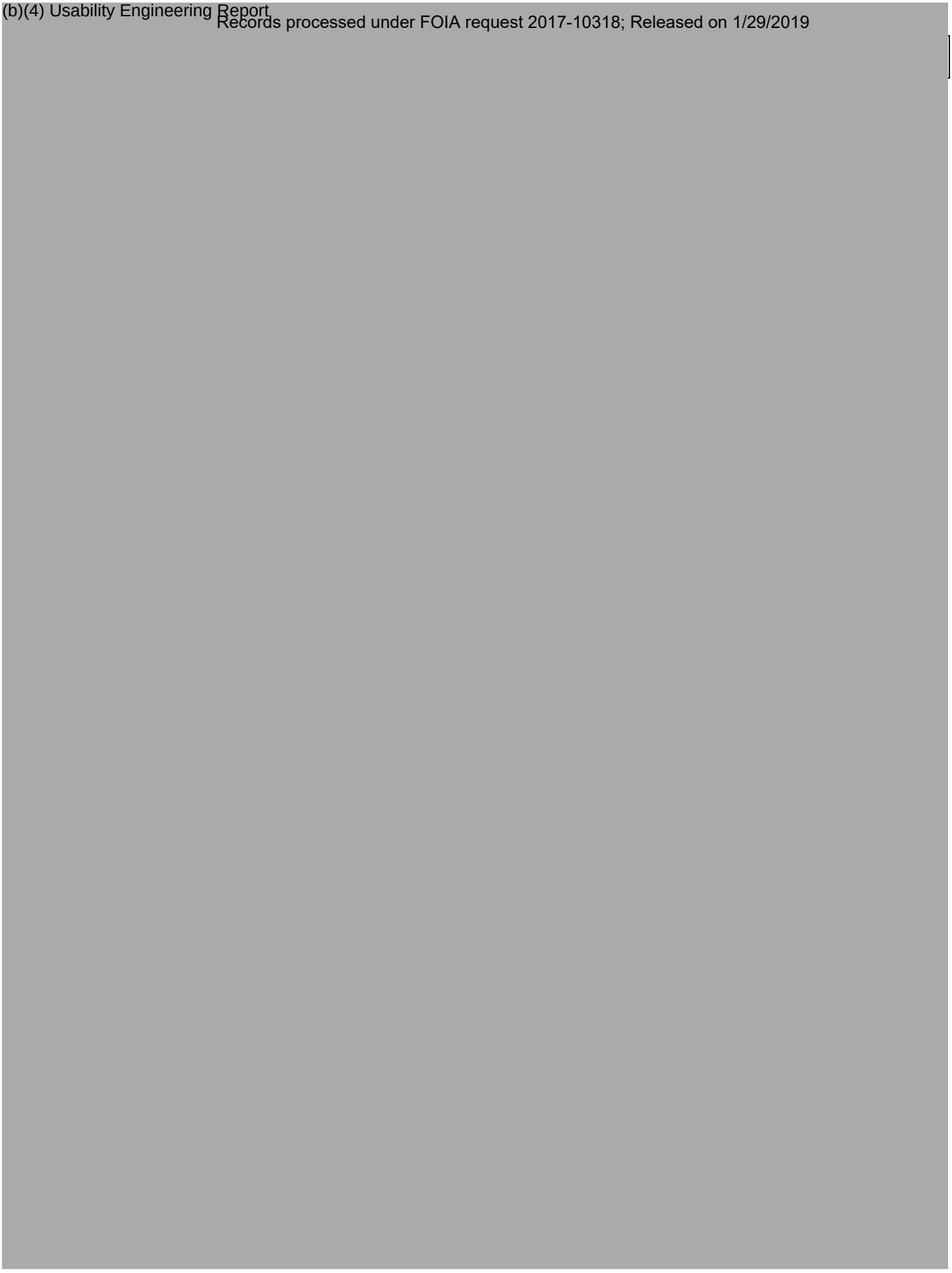


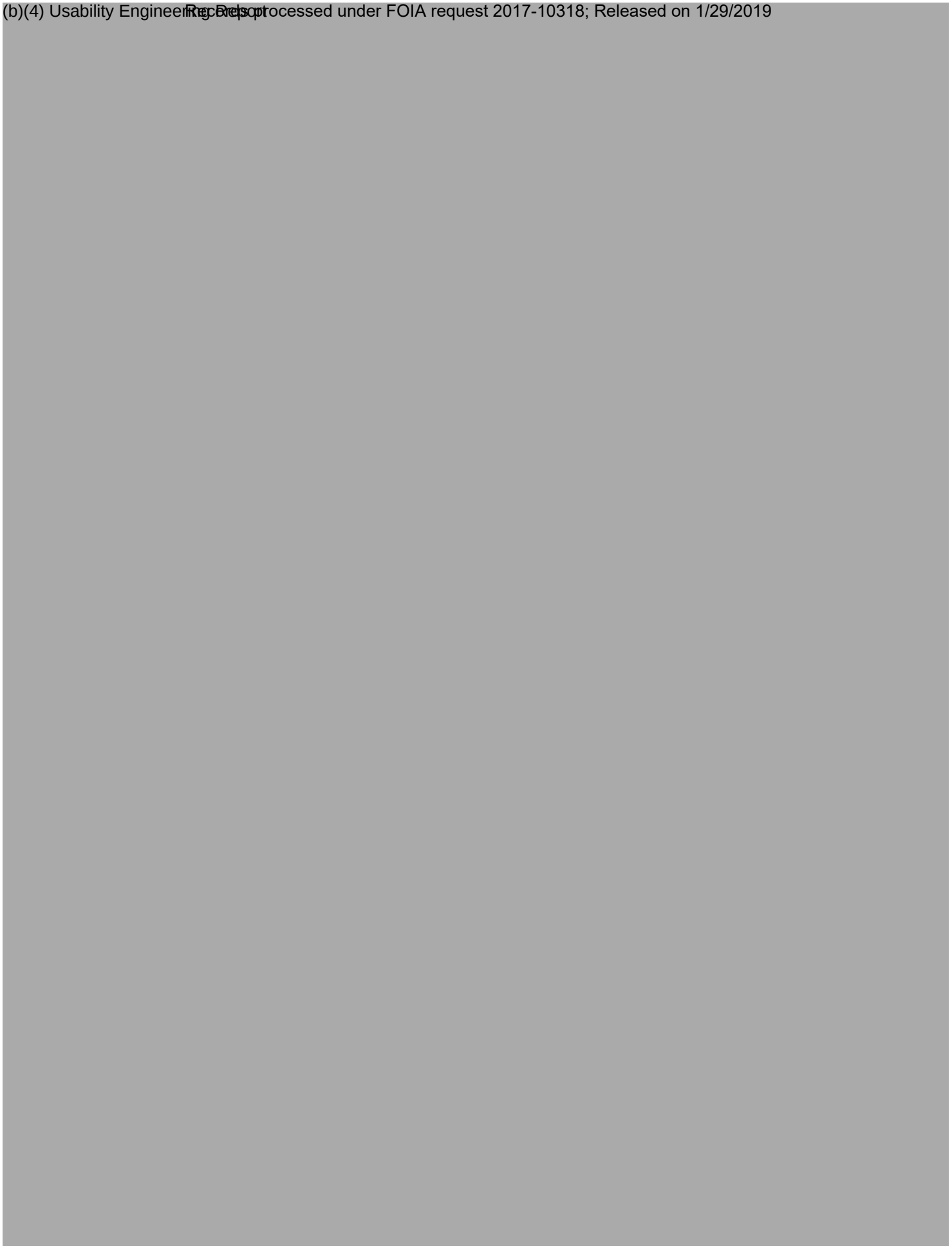


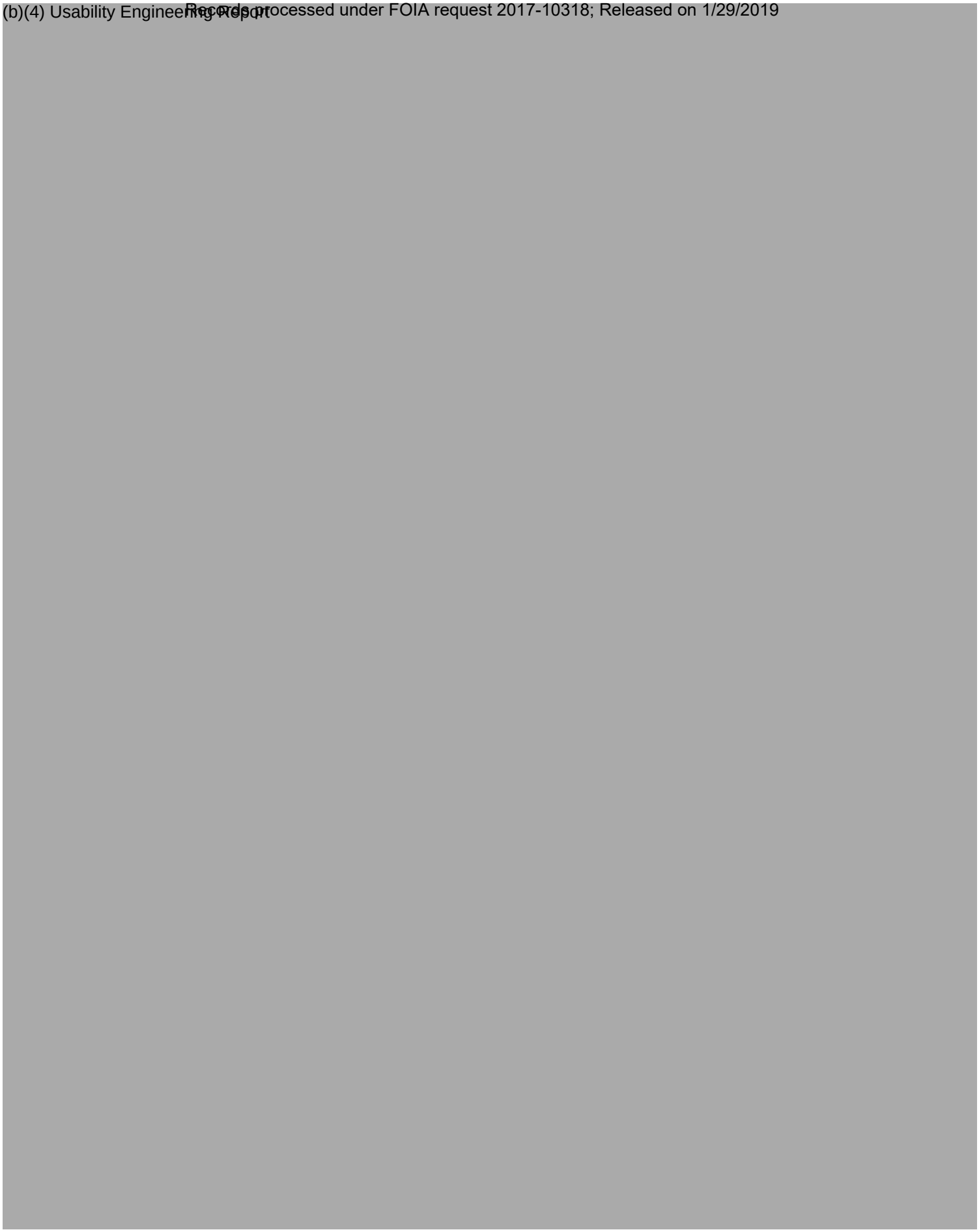


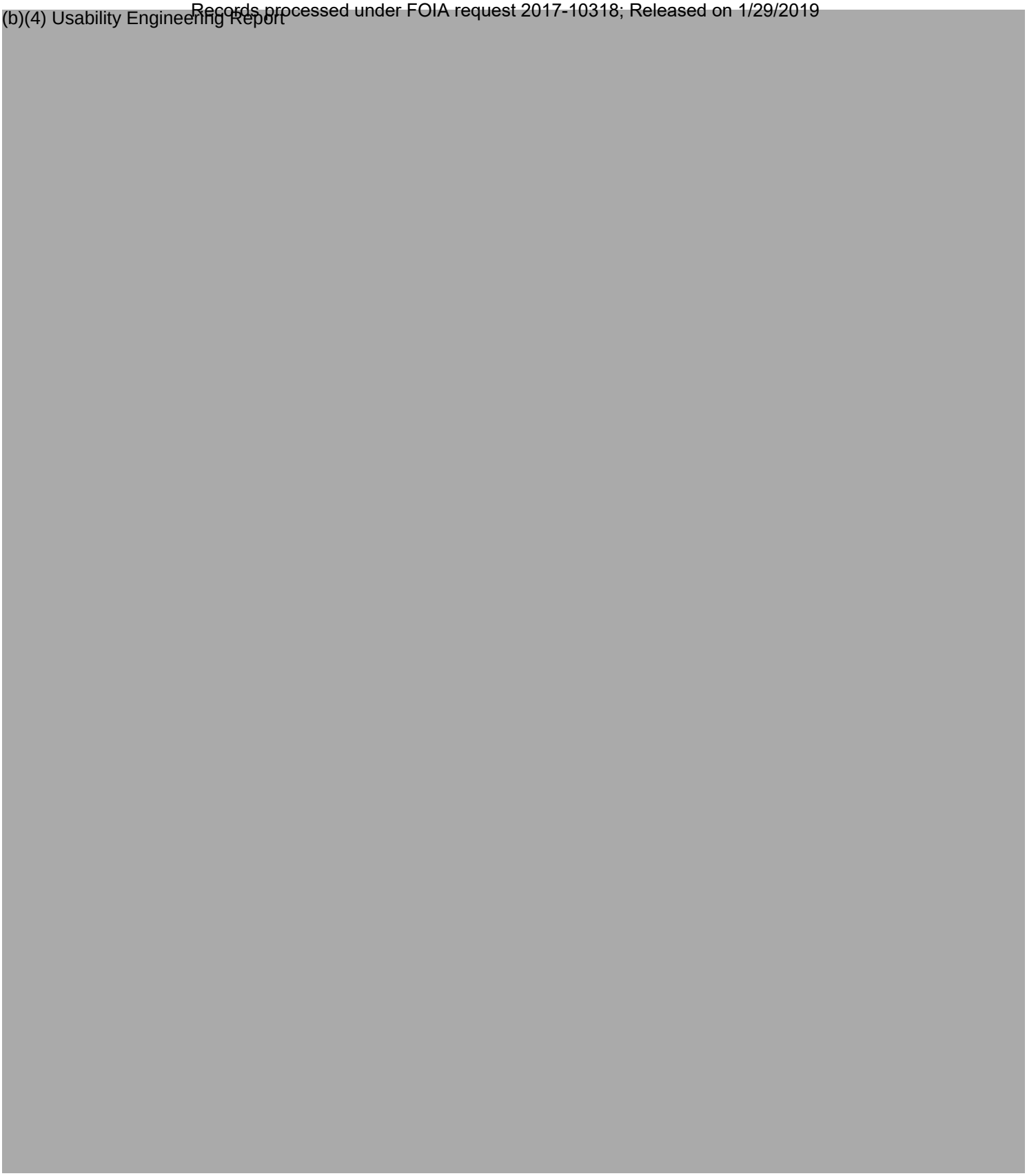












(b)(4) Usability Engineering Report

APPENDIX 10
CLINICAL TESTING

Provided in this appendix is the clinical testing, "Clinical Testing Report for the AliveCor Kardia Band" (b) (4), being submitted for the Kardia Band System.

(b)(4) Clinical Testing Report

CLINICAL EVALUATION REPORT

FOR THE

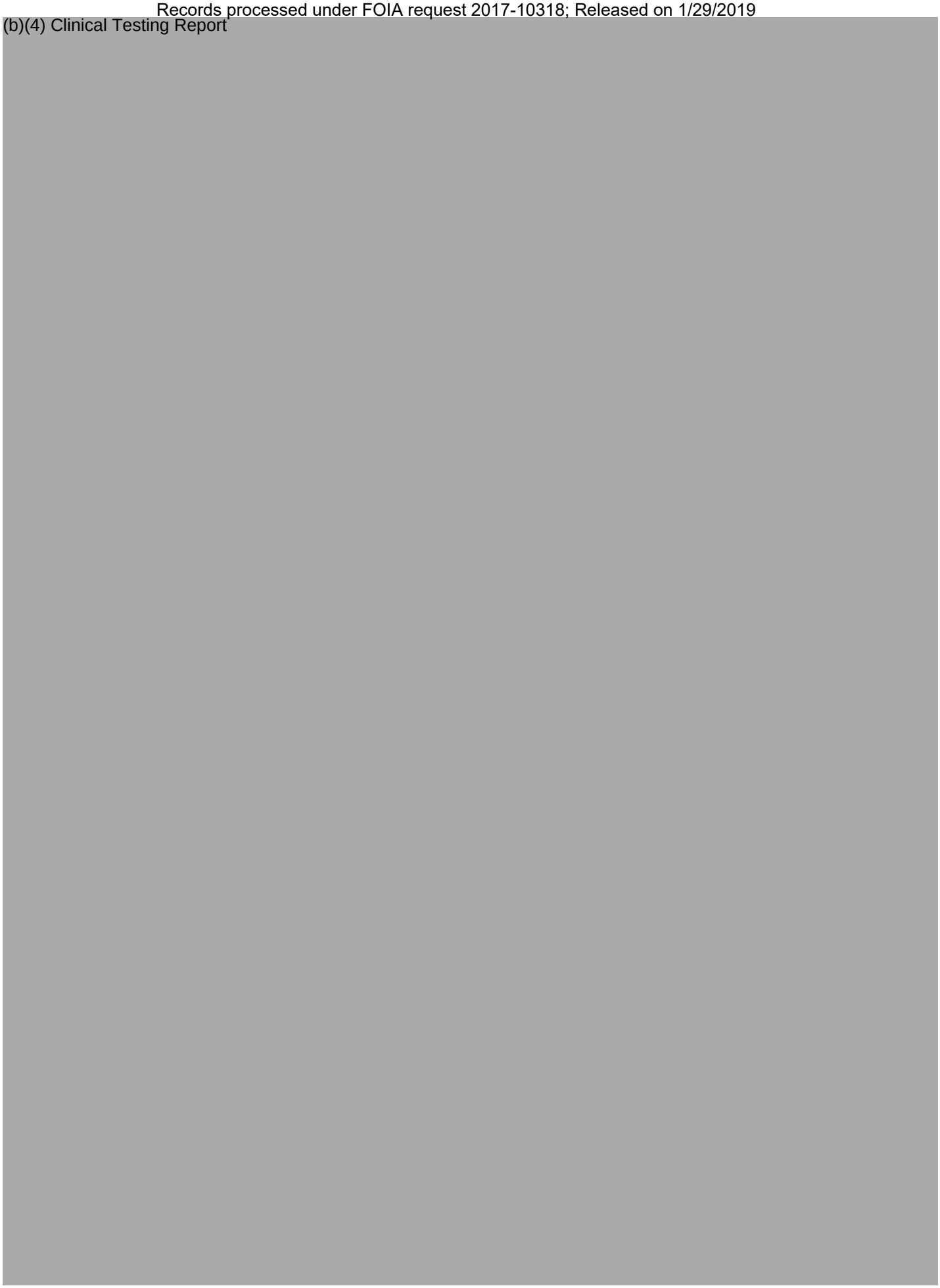
ALIVECOR KARDIA BAND

REPORT DATE: JANUARY 31, 2017

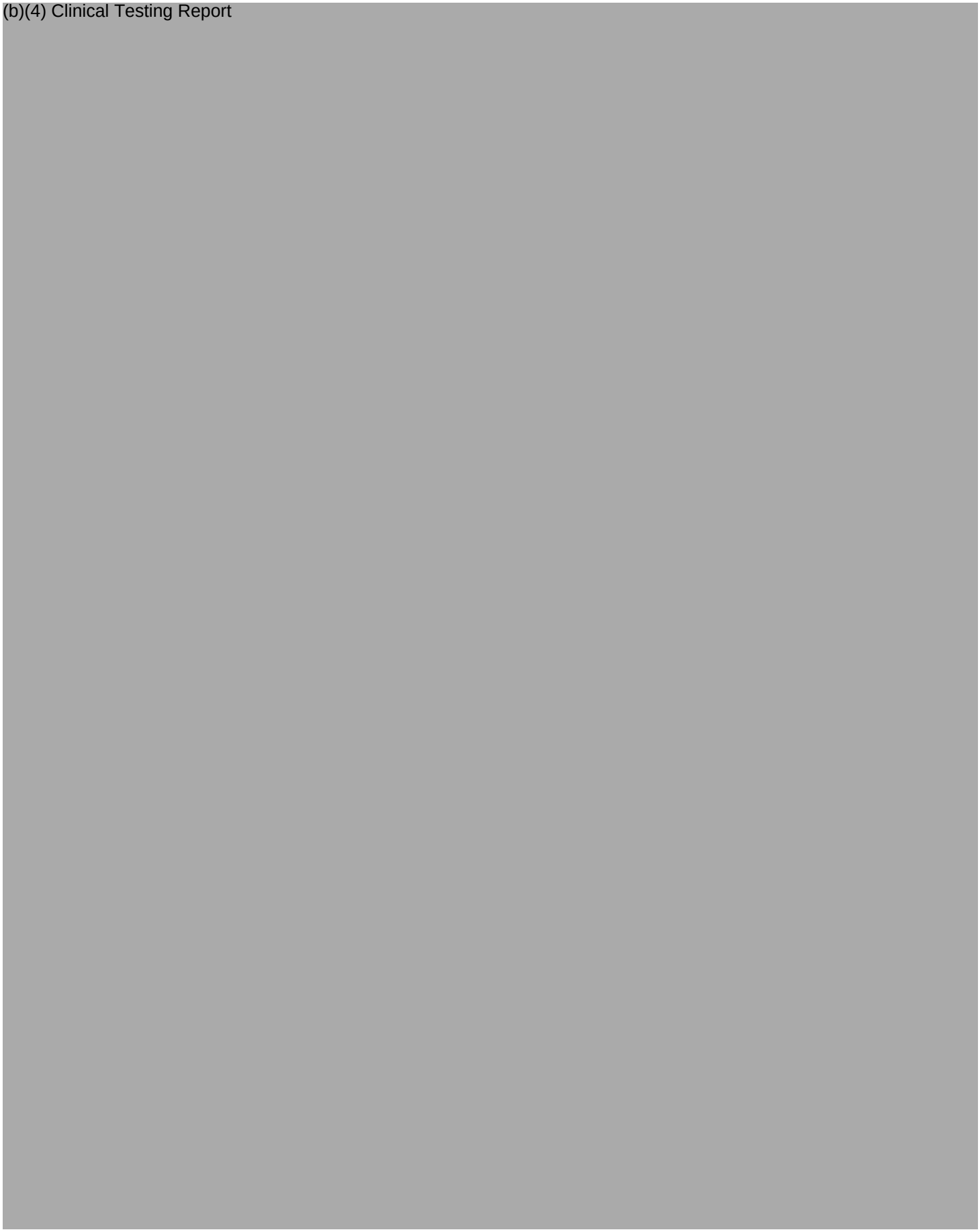
(b)(4) Clinical Testing Report

(b)(4) Clinical Testing Report

(b)(4) Clinical Testing Report



(b)(4) Clinical Testing Report



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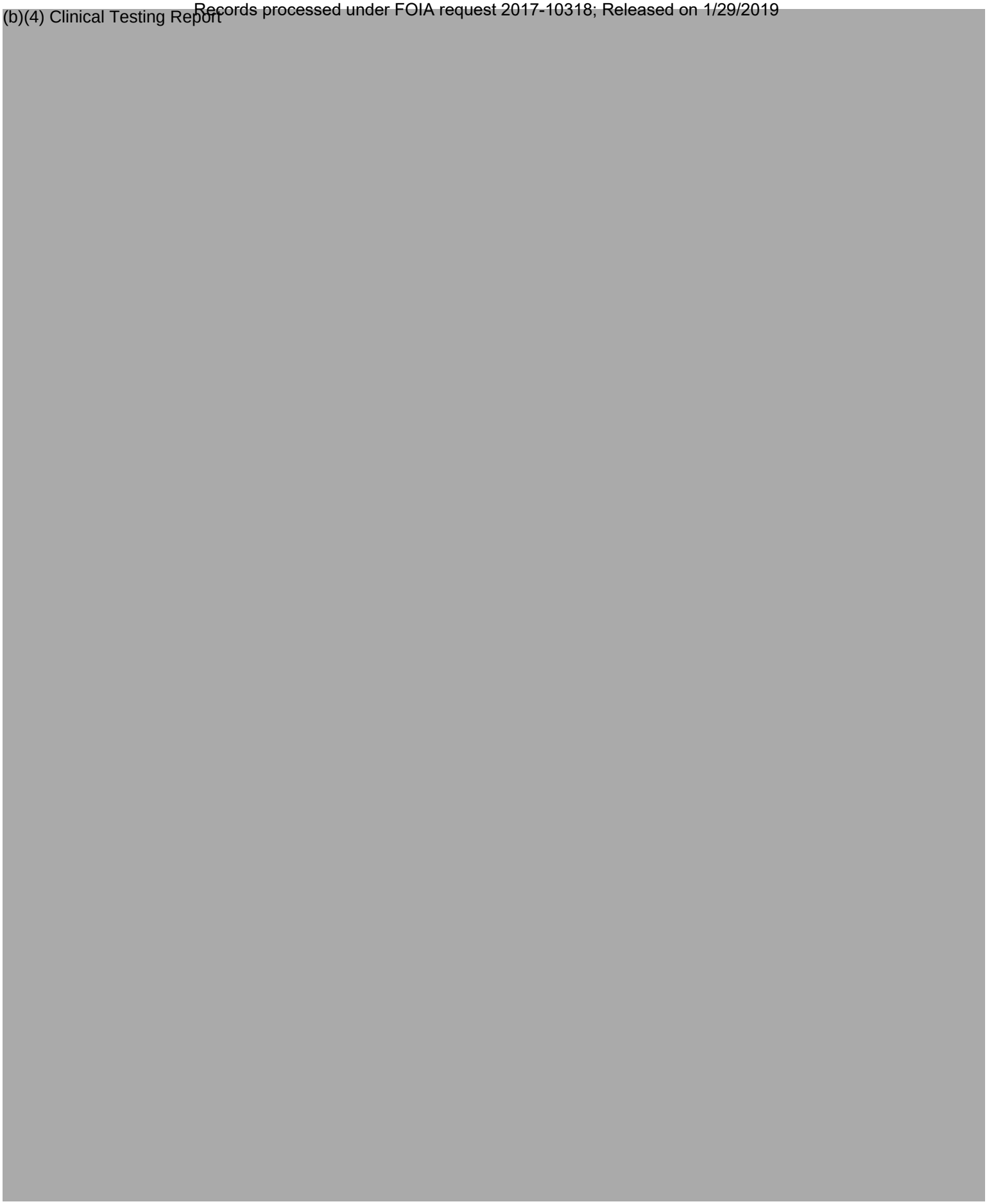

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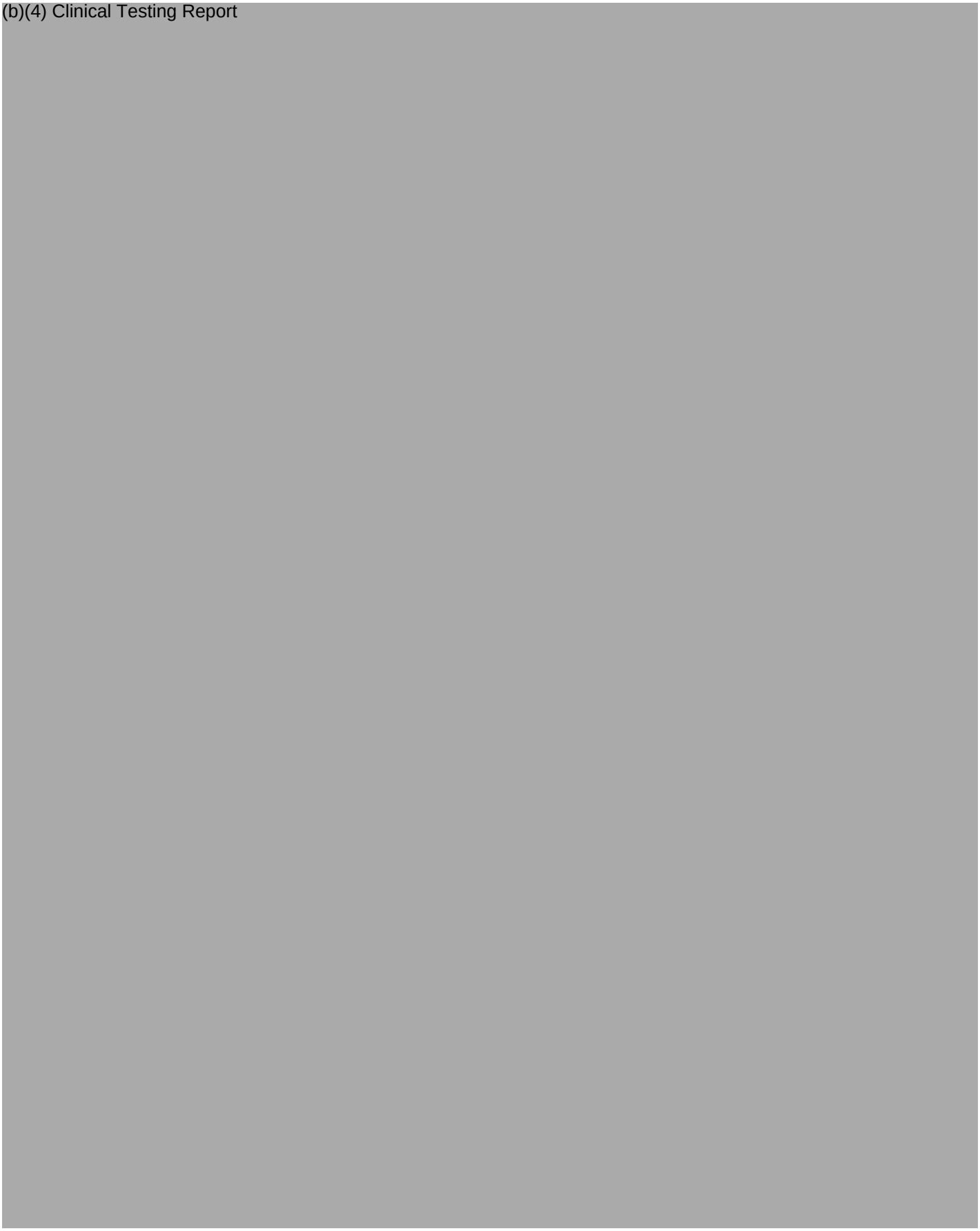

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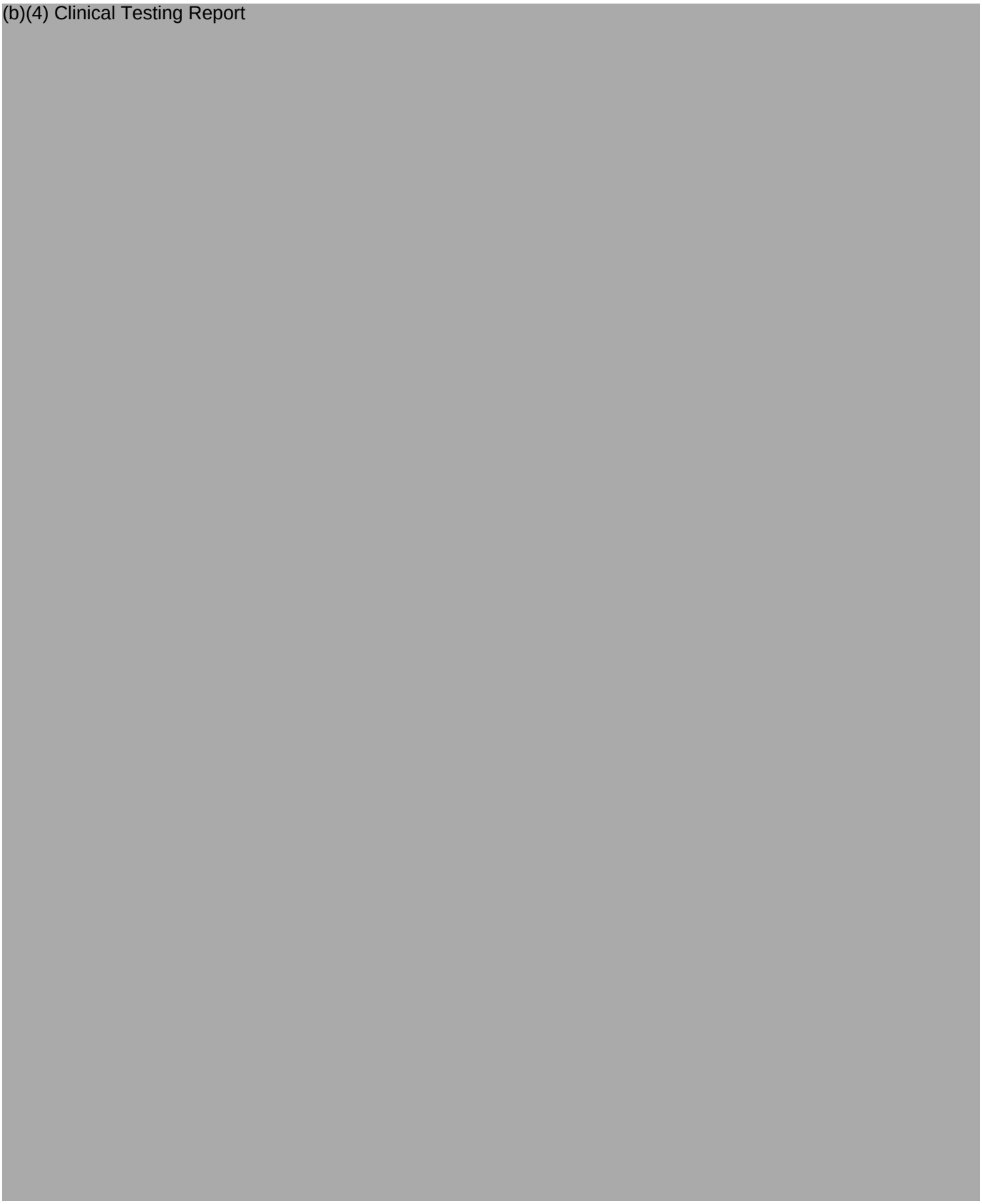

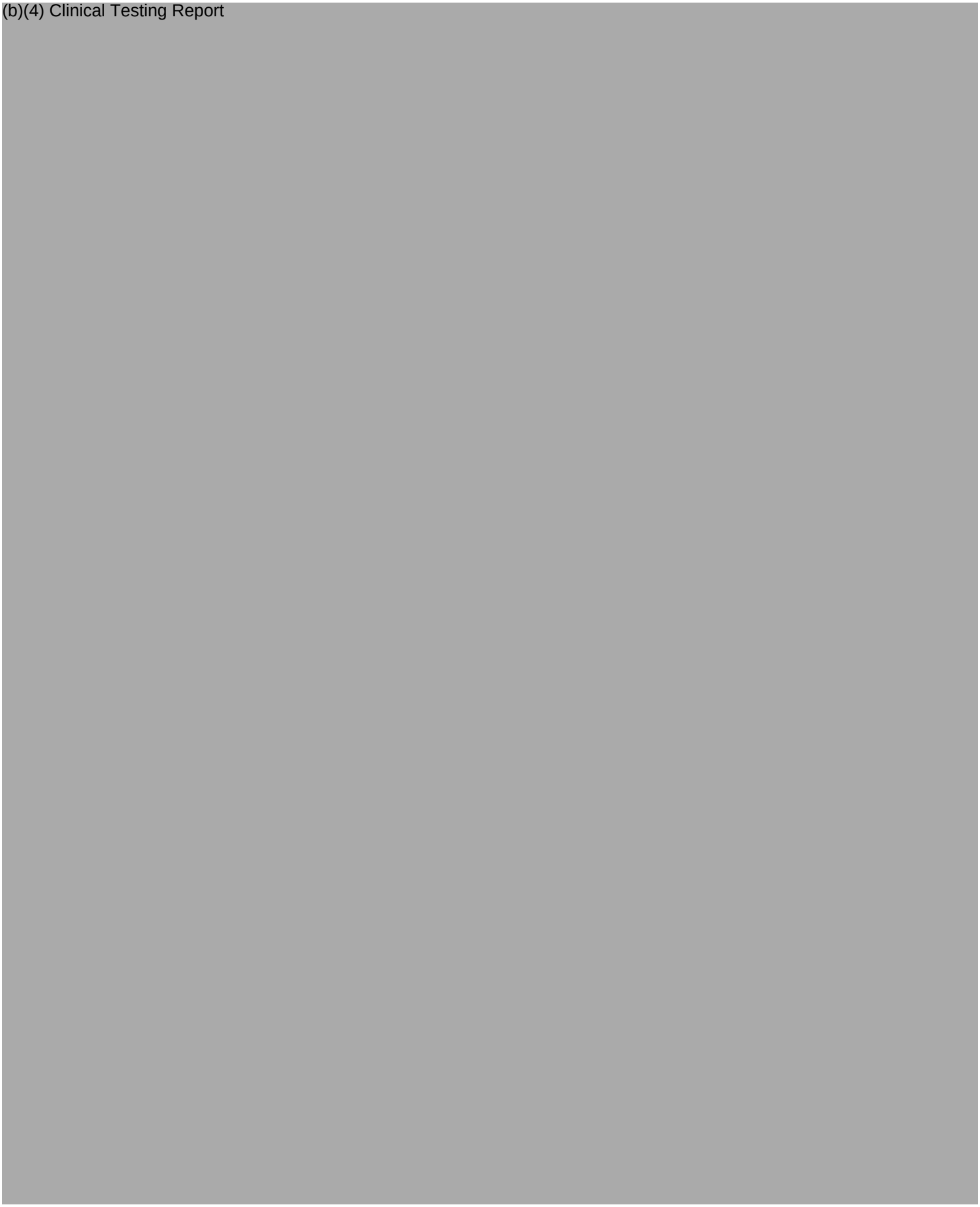

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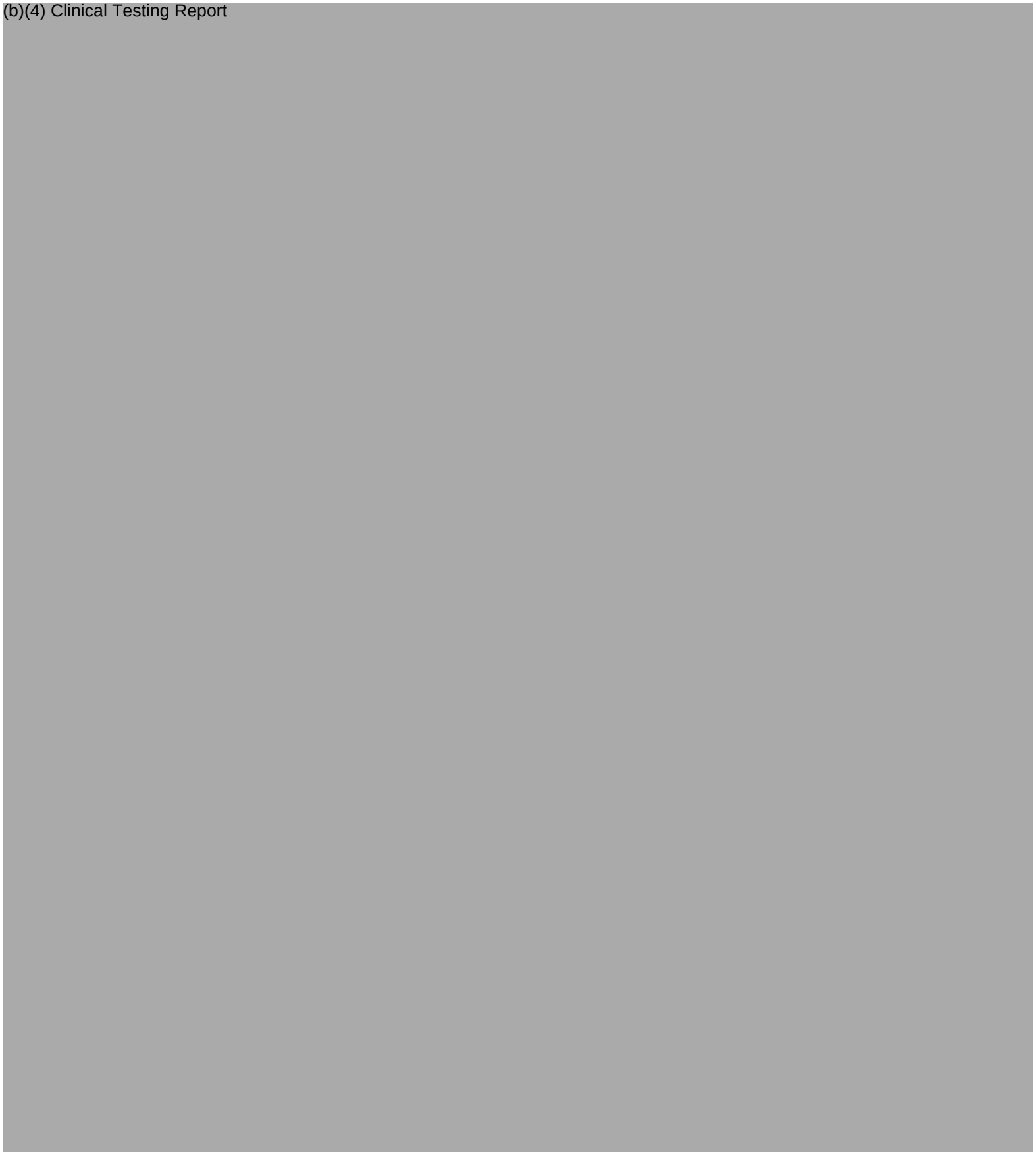
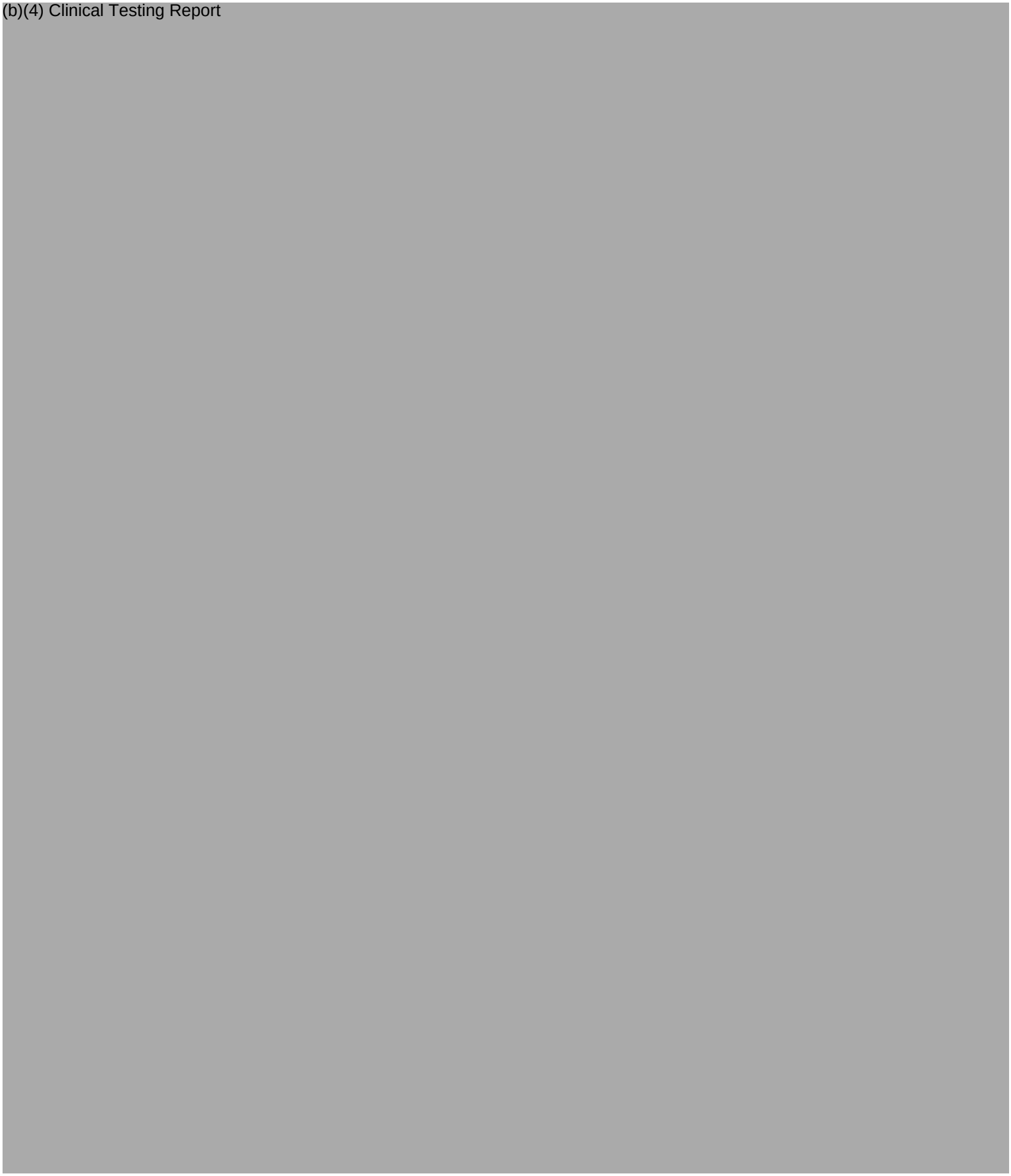


(b)(4) Clinical Testing Report

(b)(4) Clinical Testing Report



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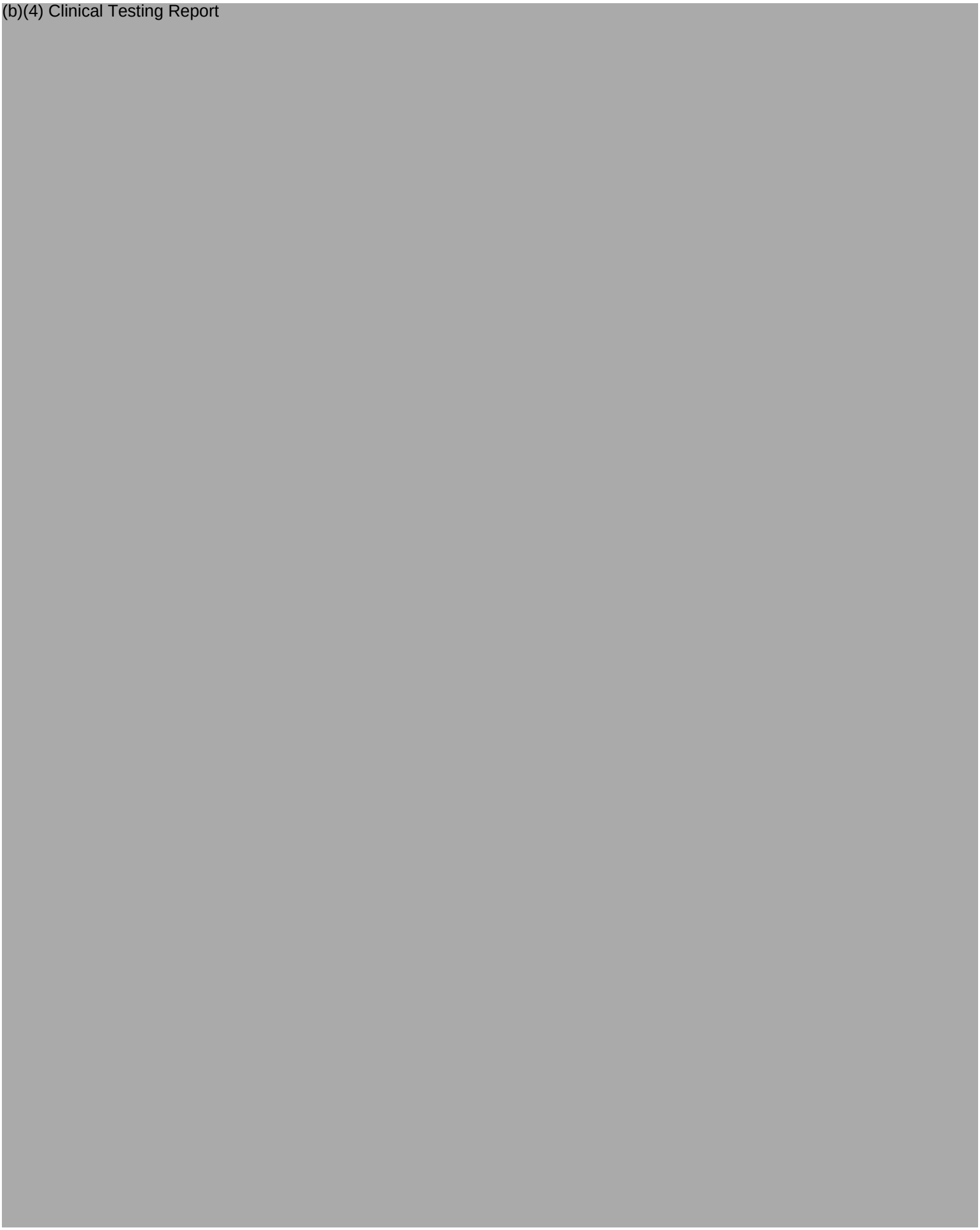

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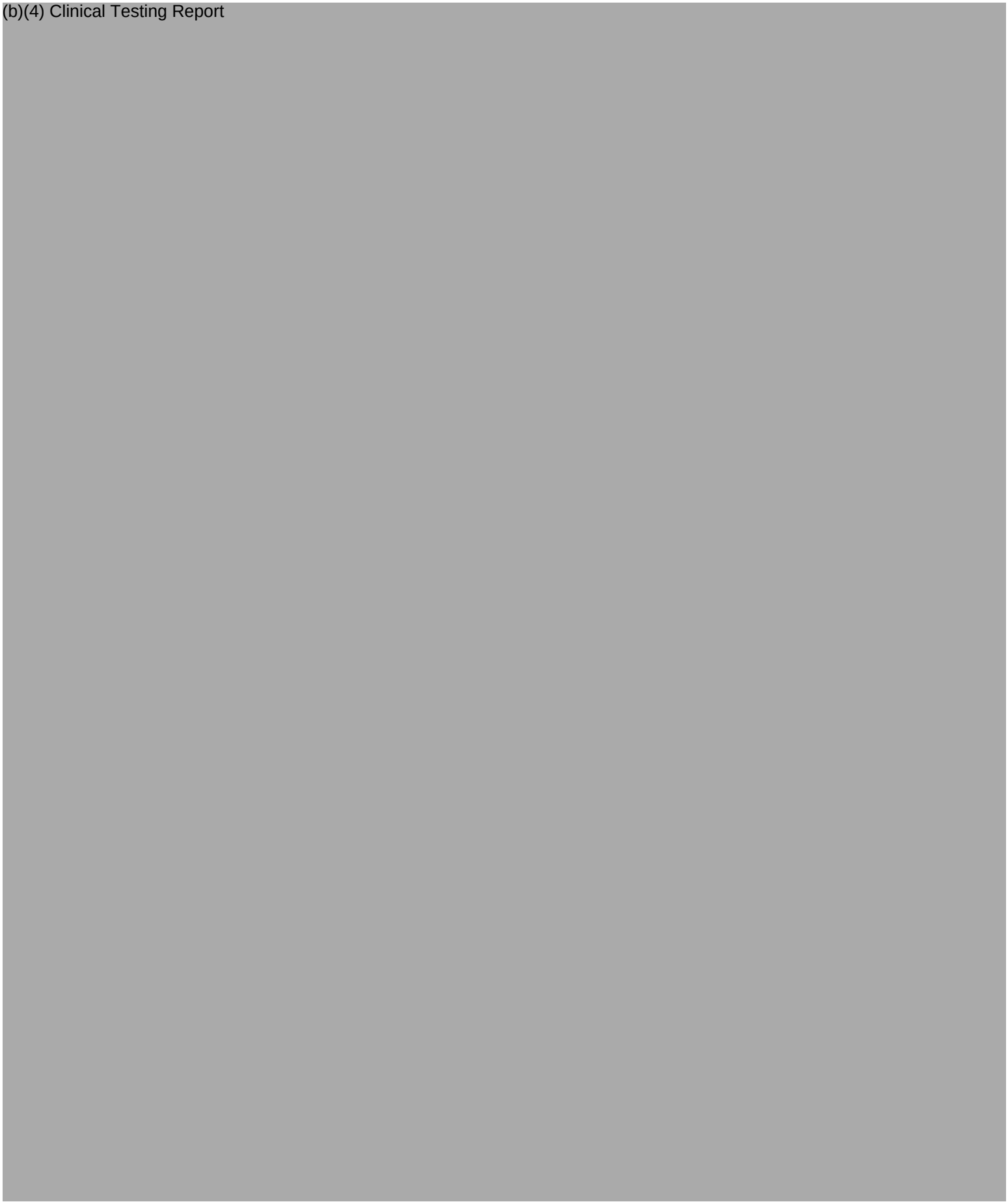

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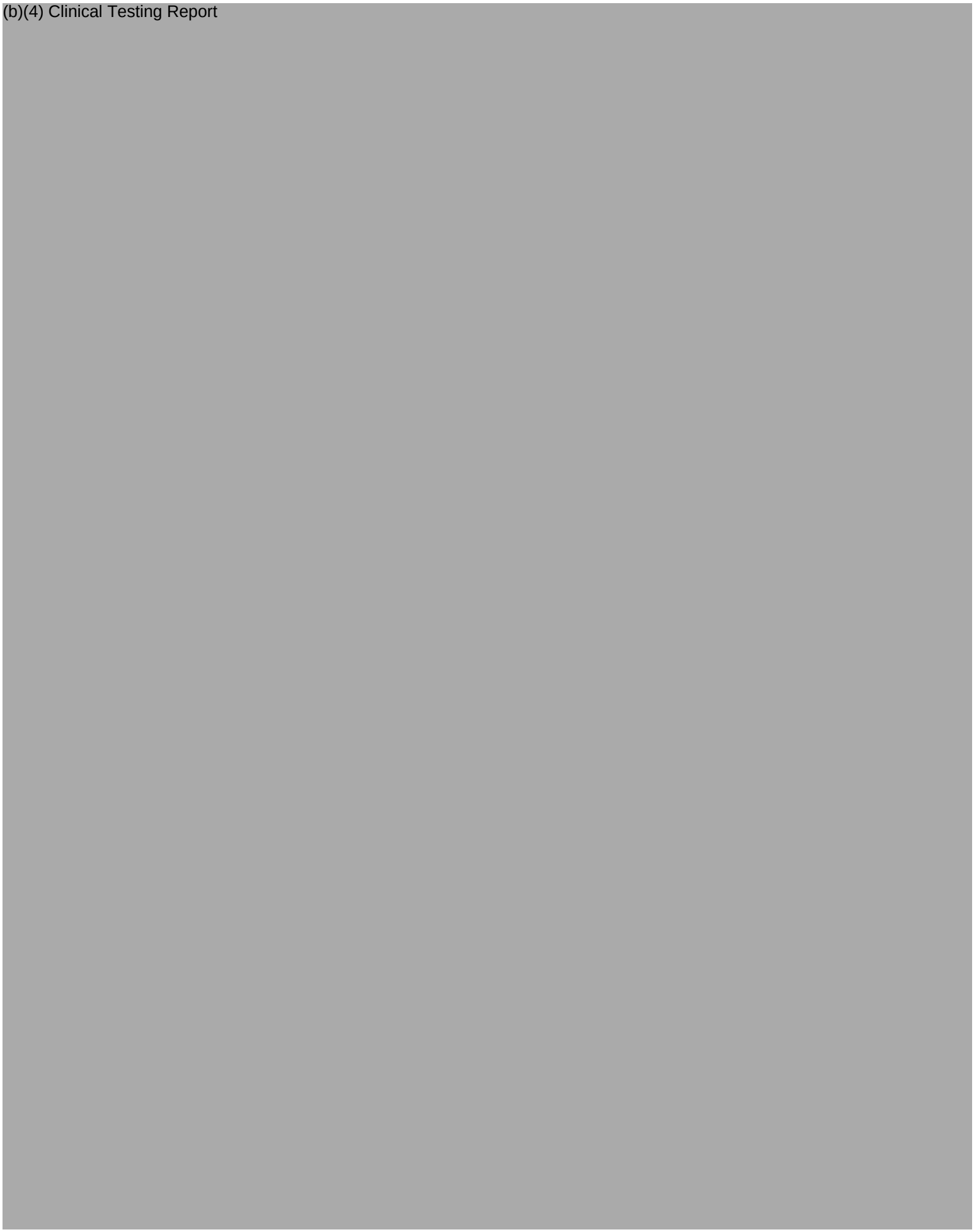

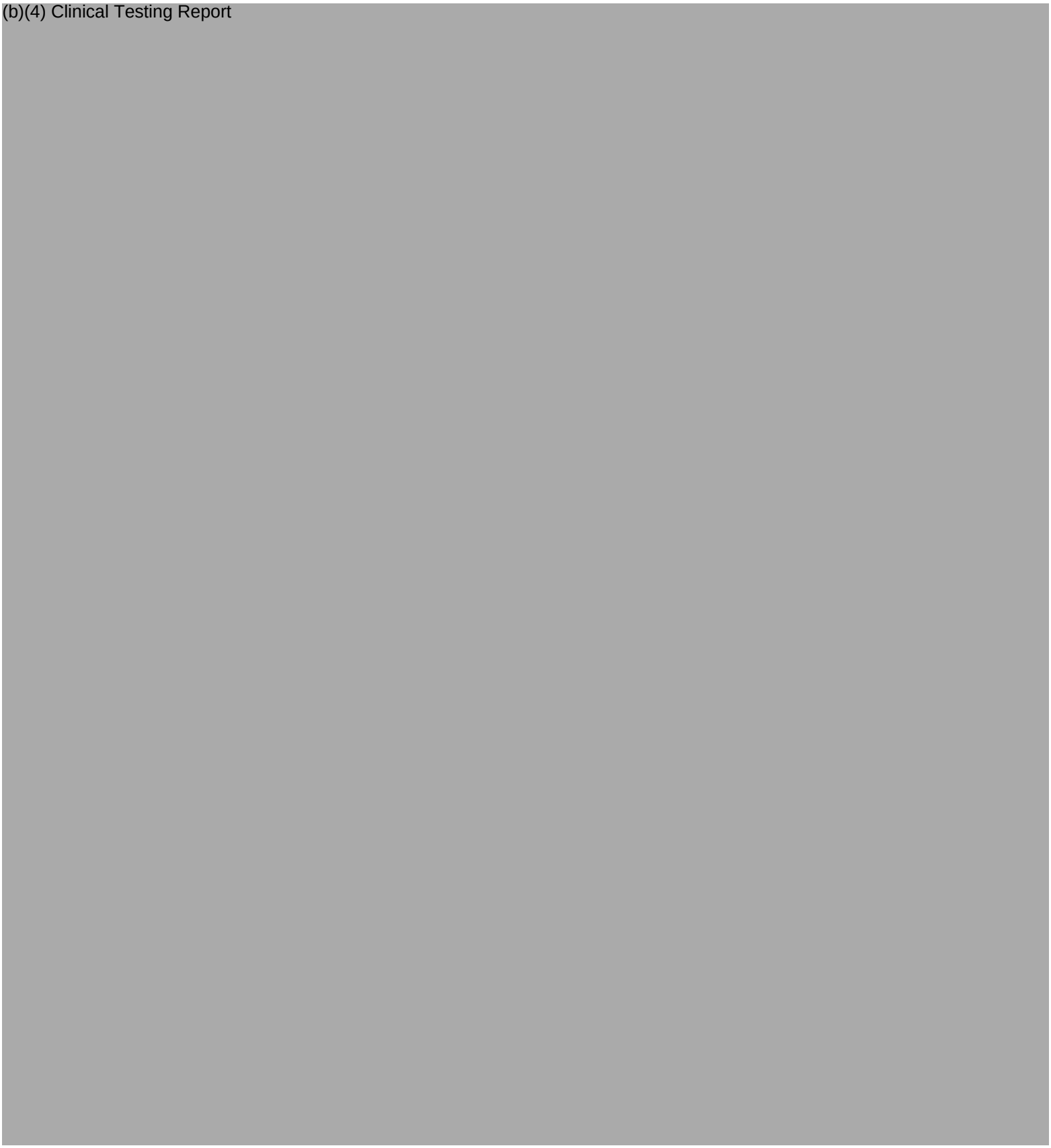

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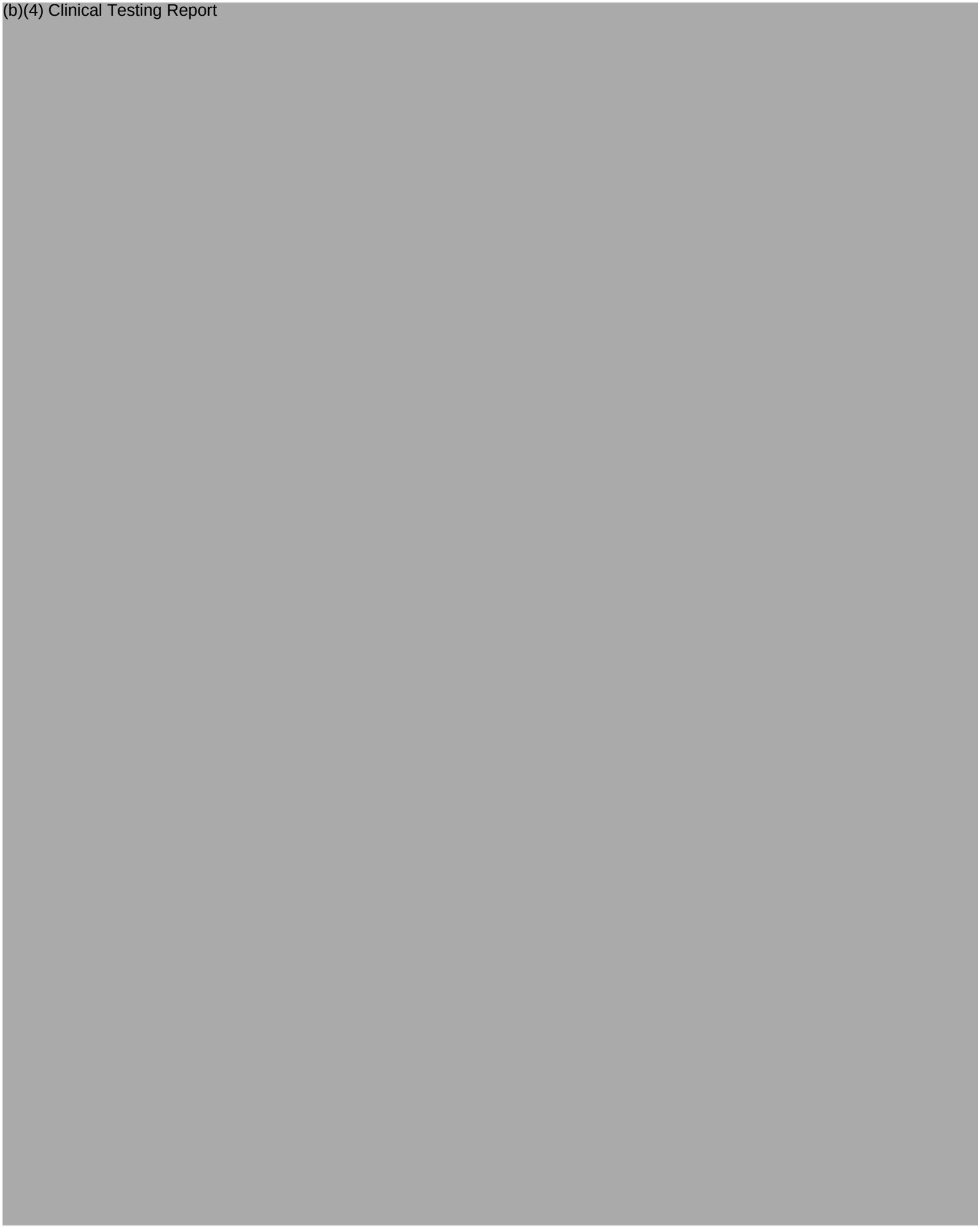

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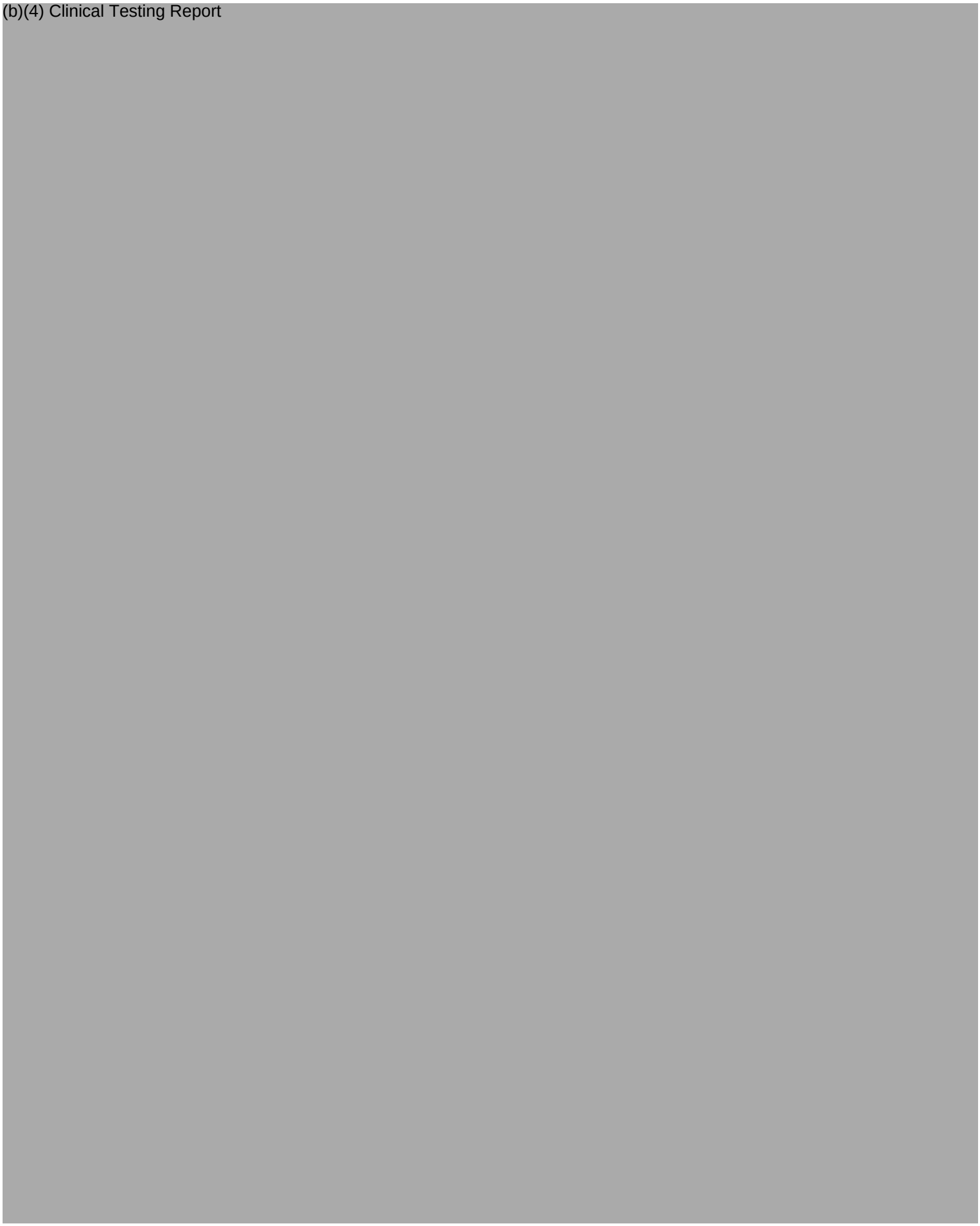

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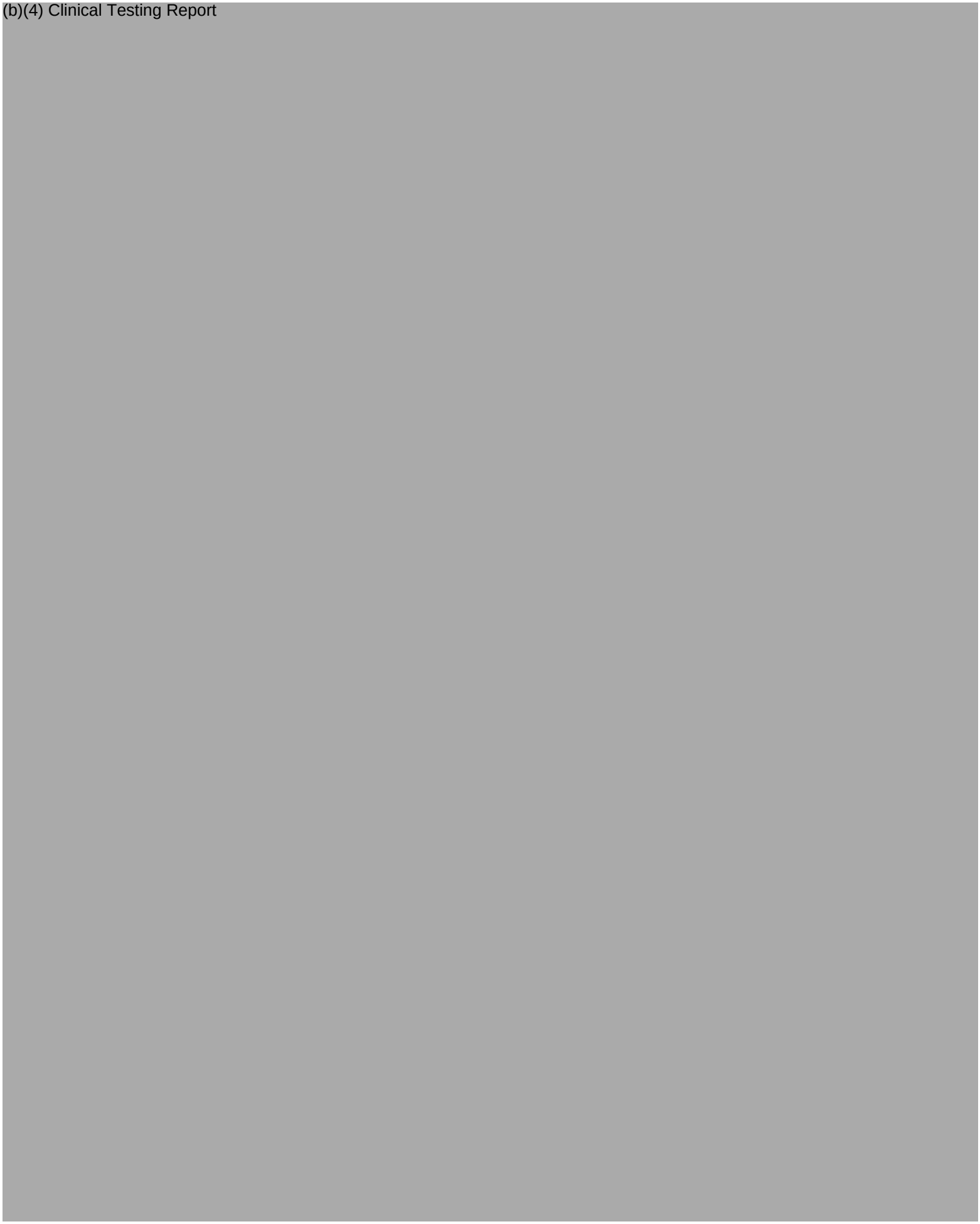

(b)(4) Clinical Testing Report

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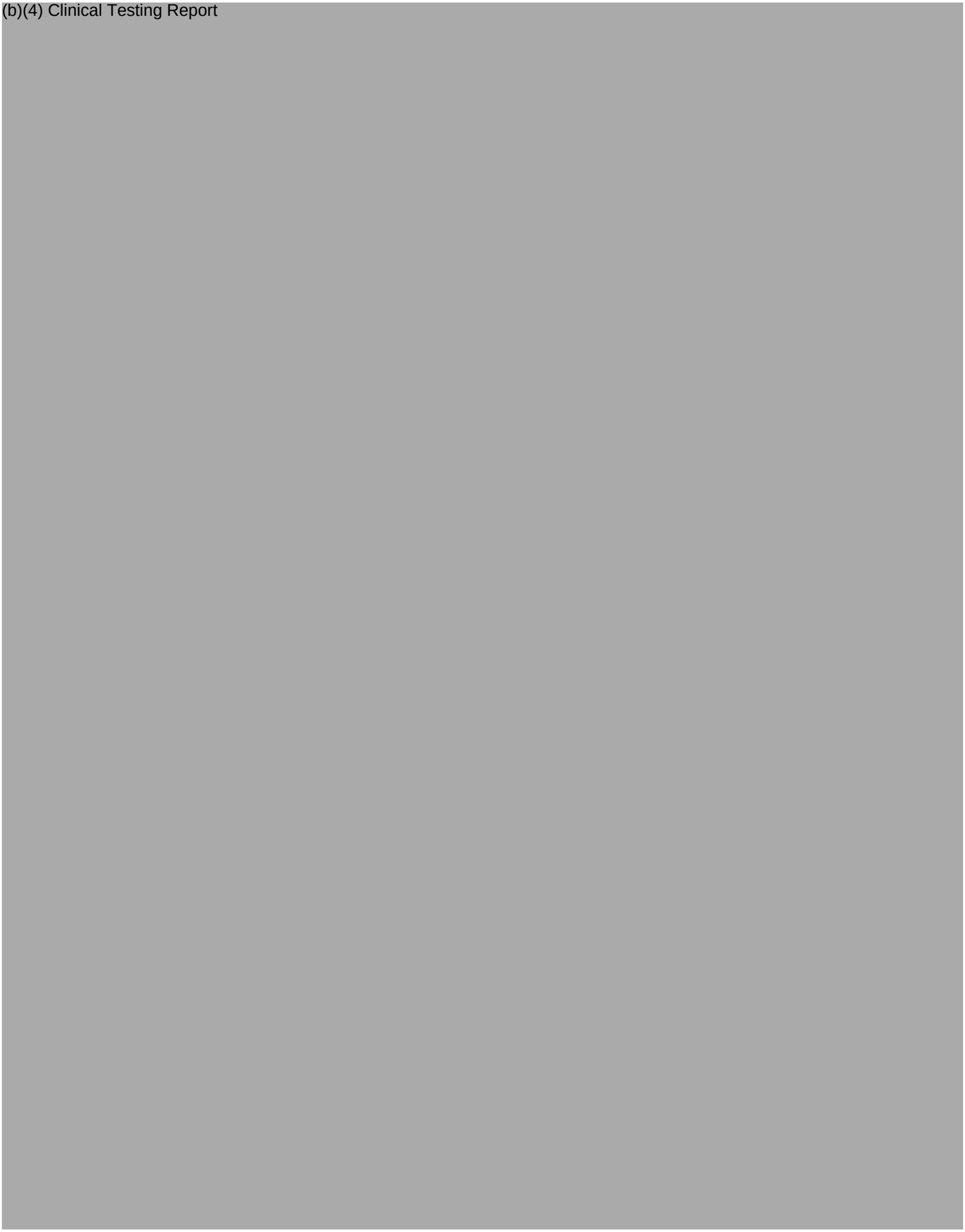

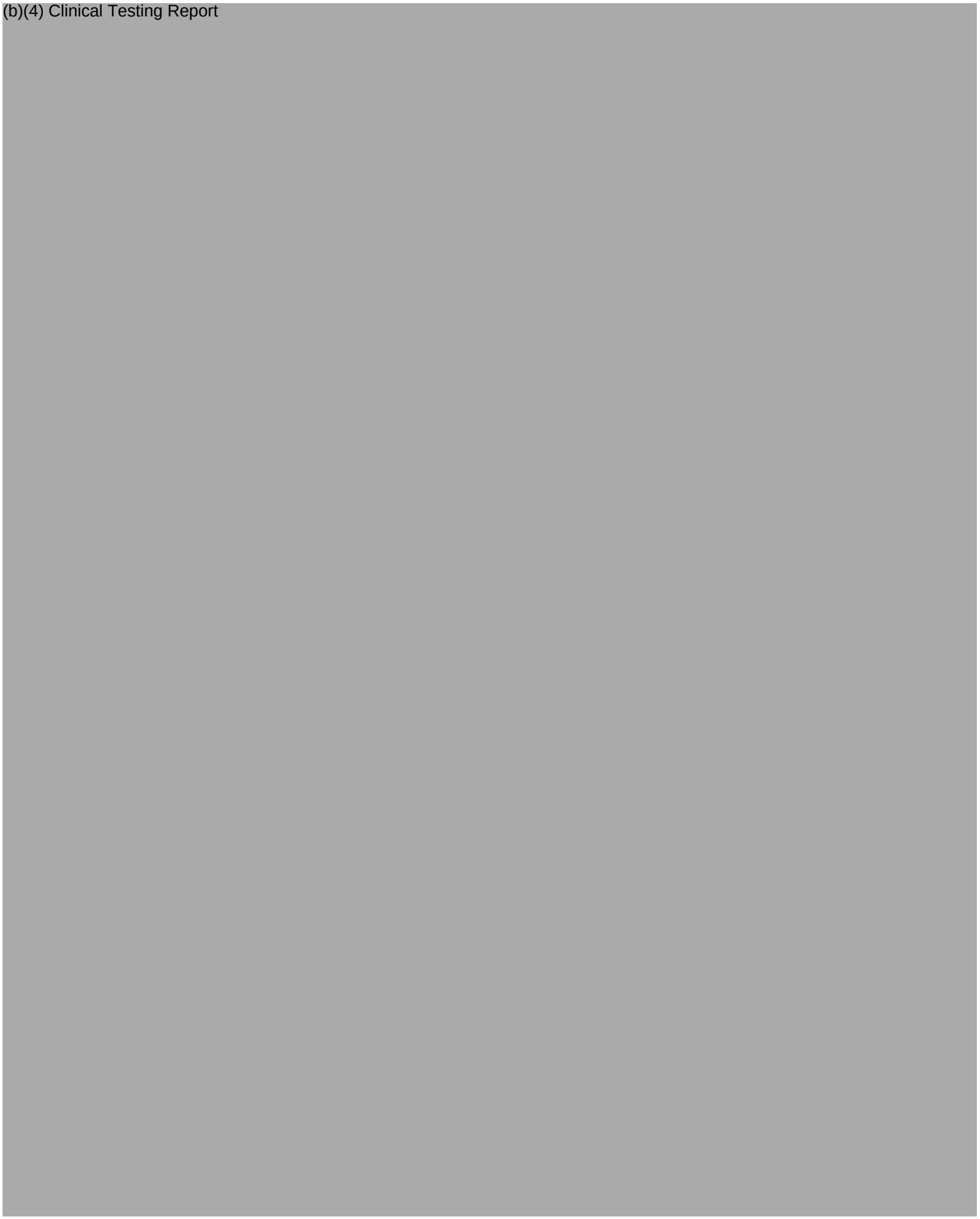

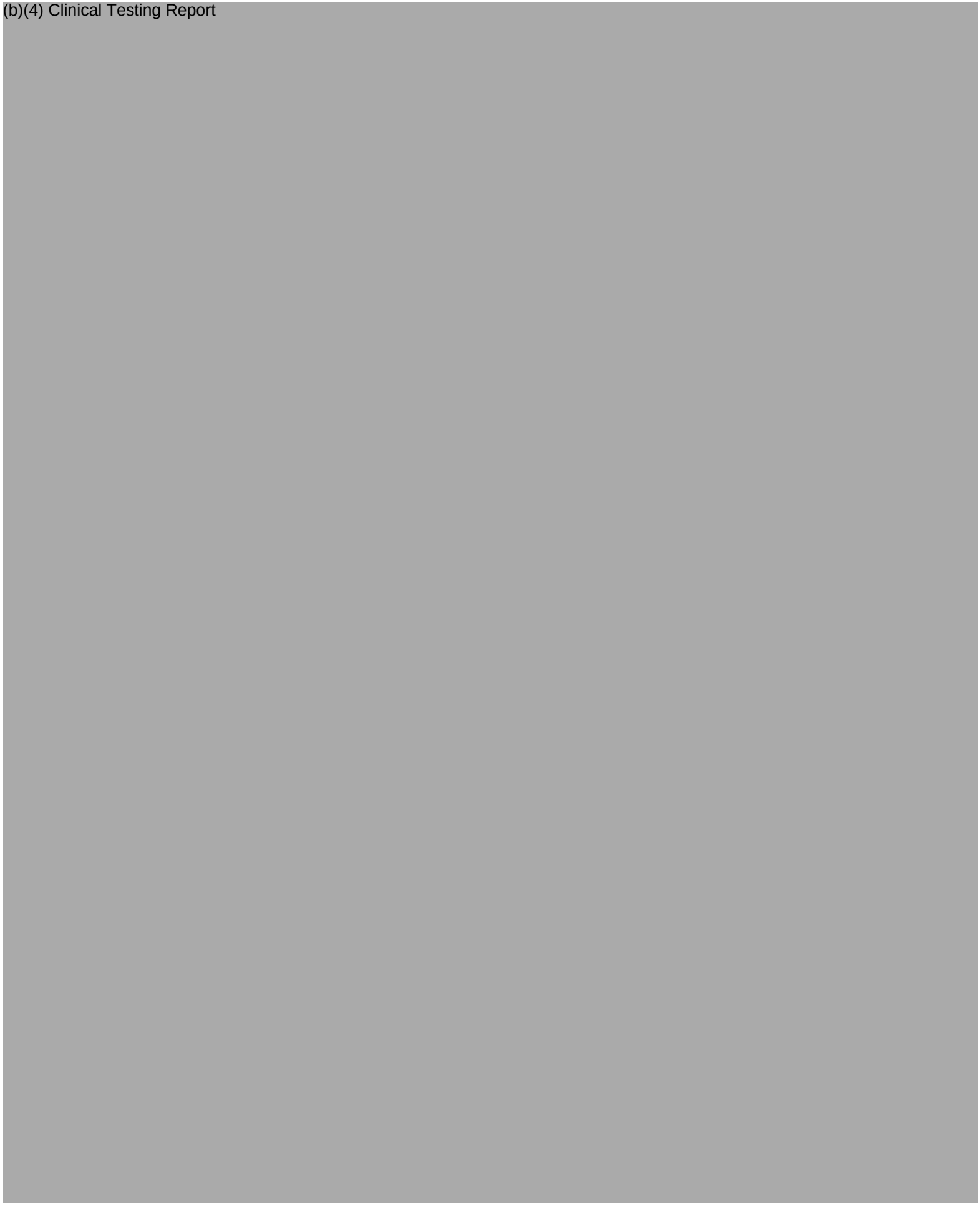

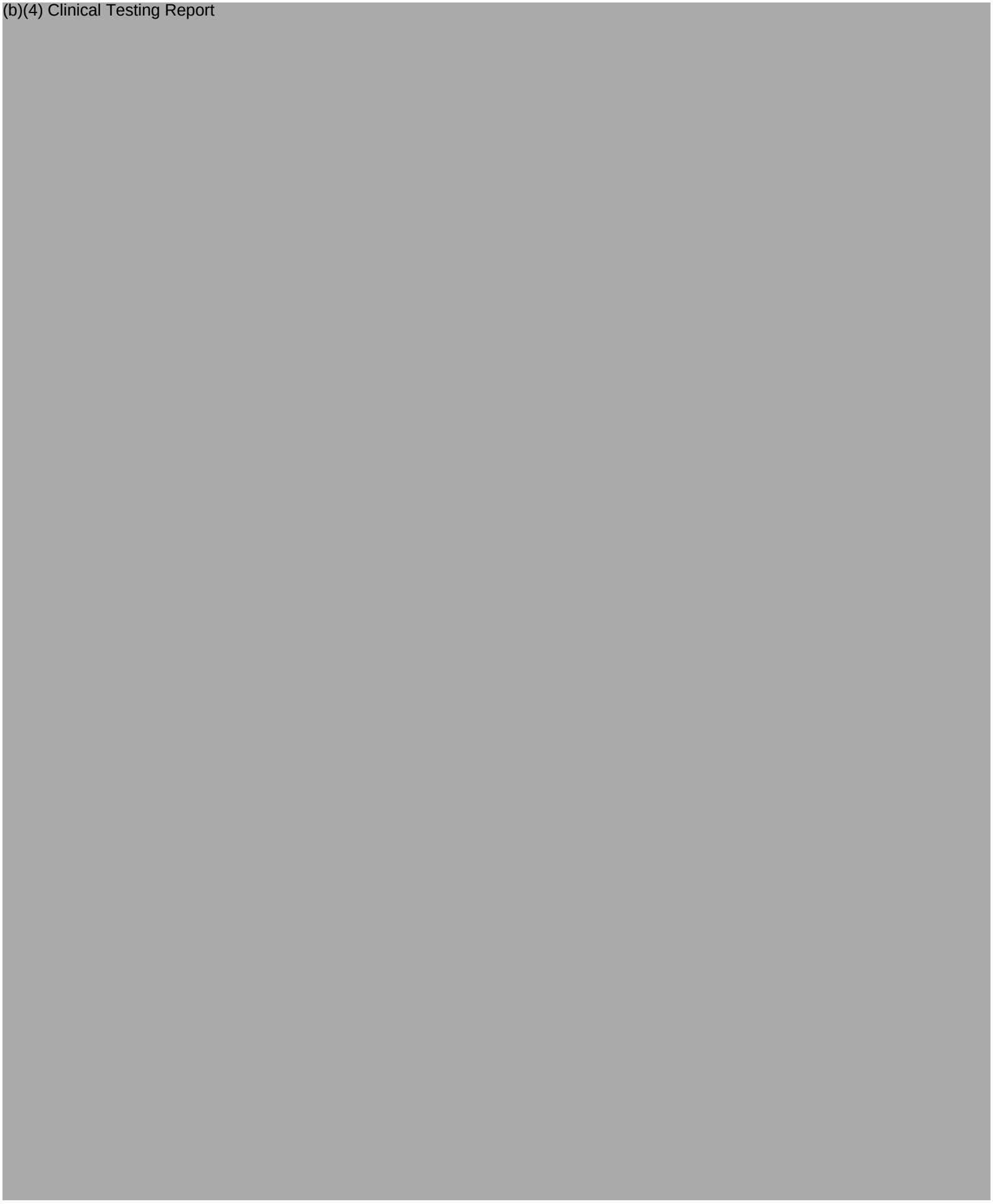

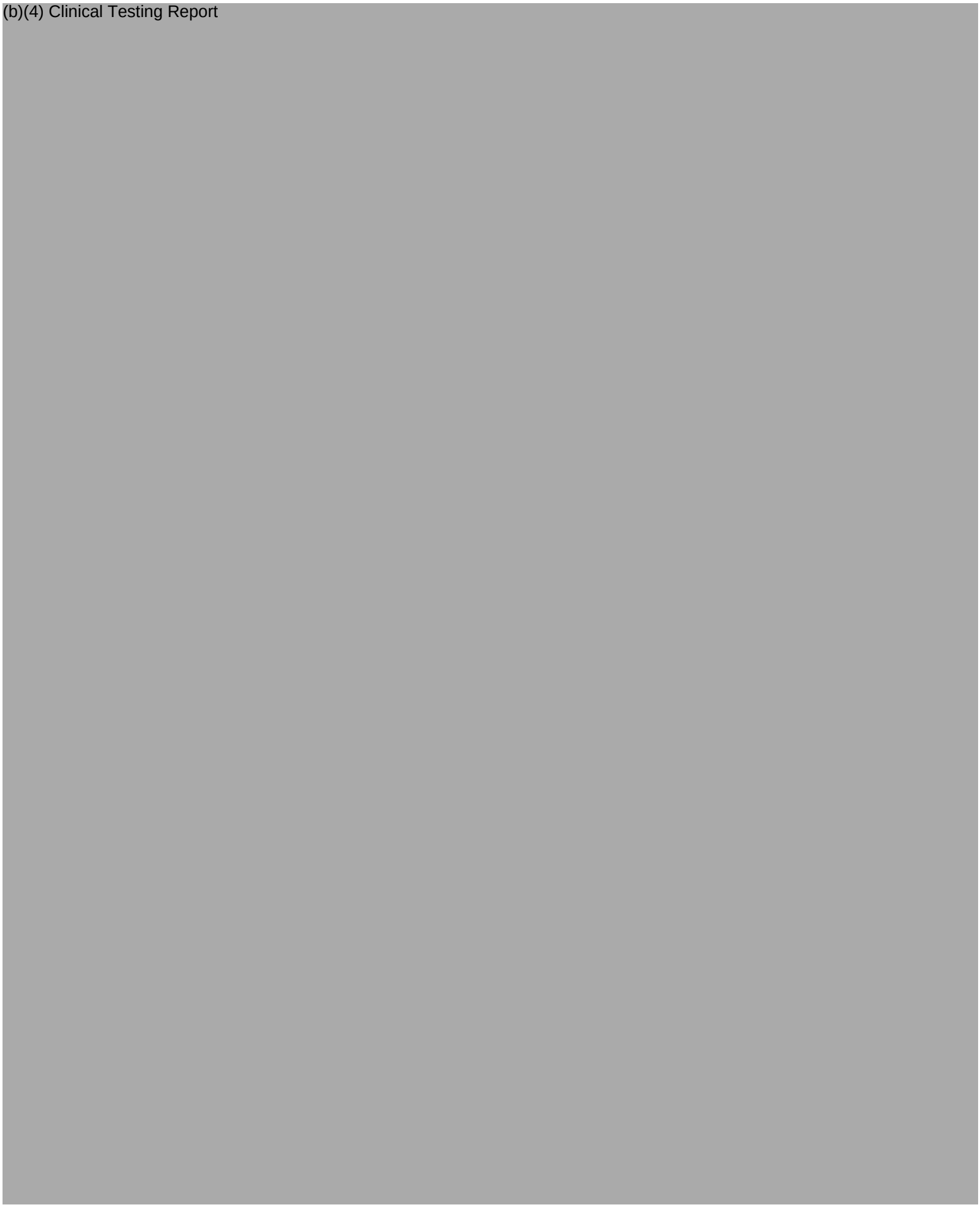

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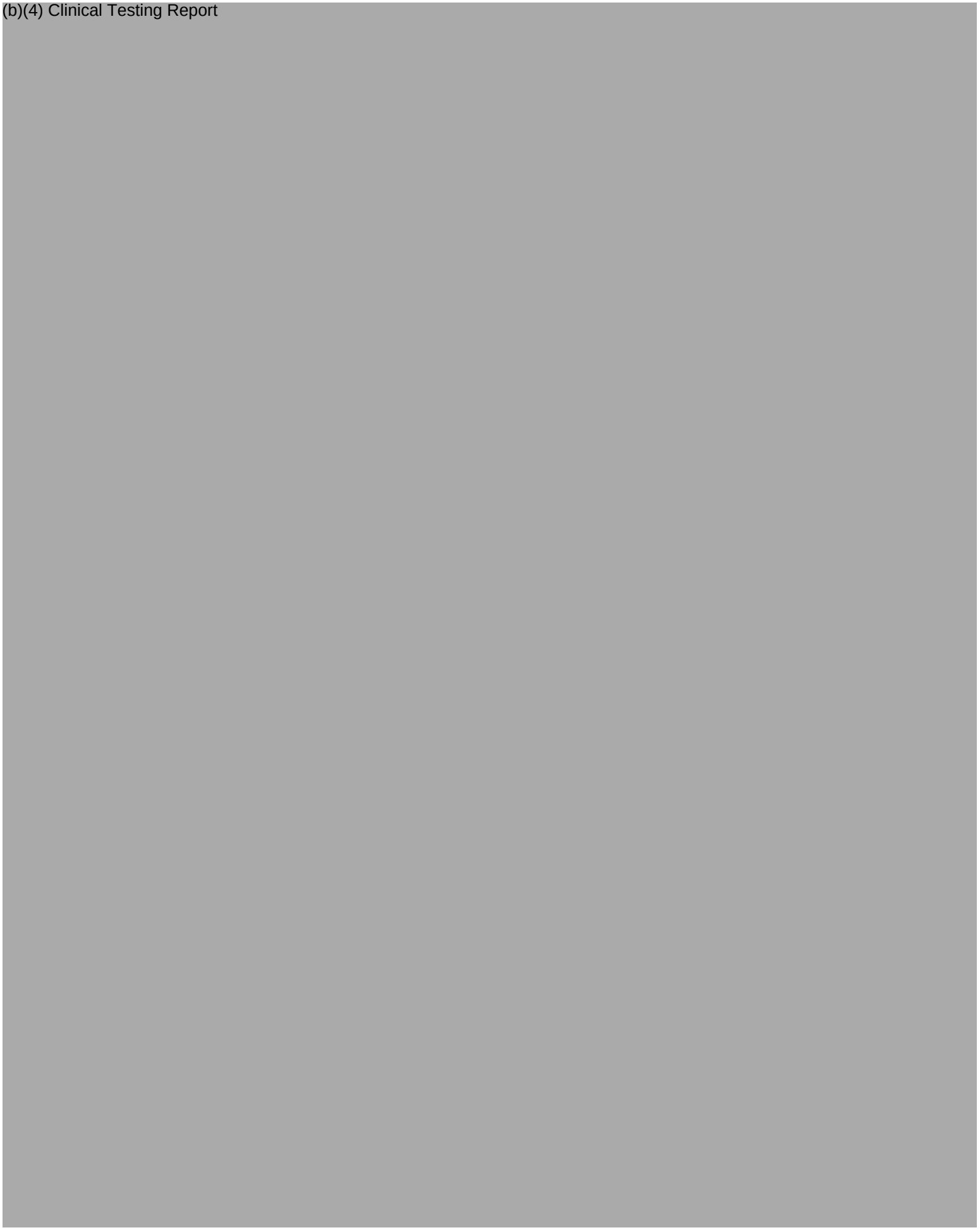

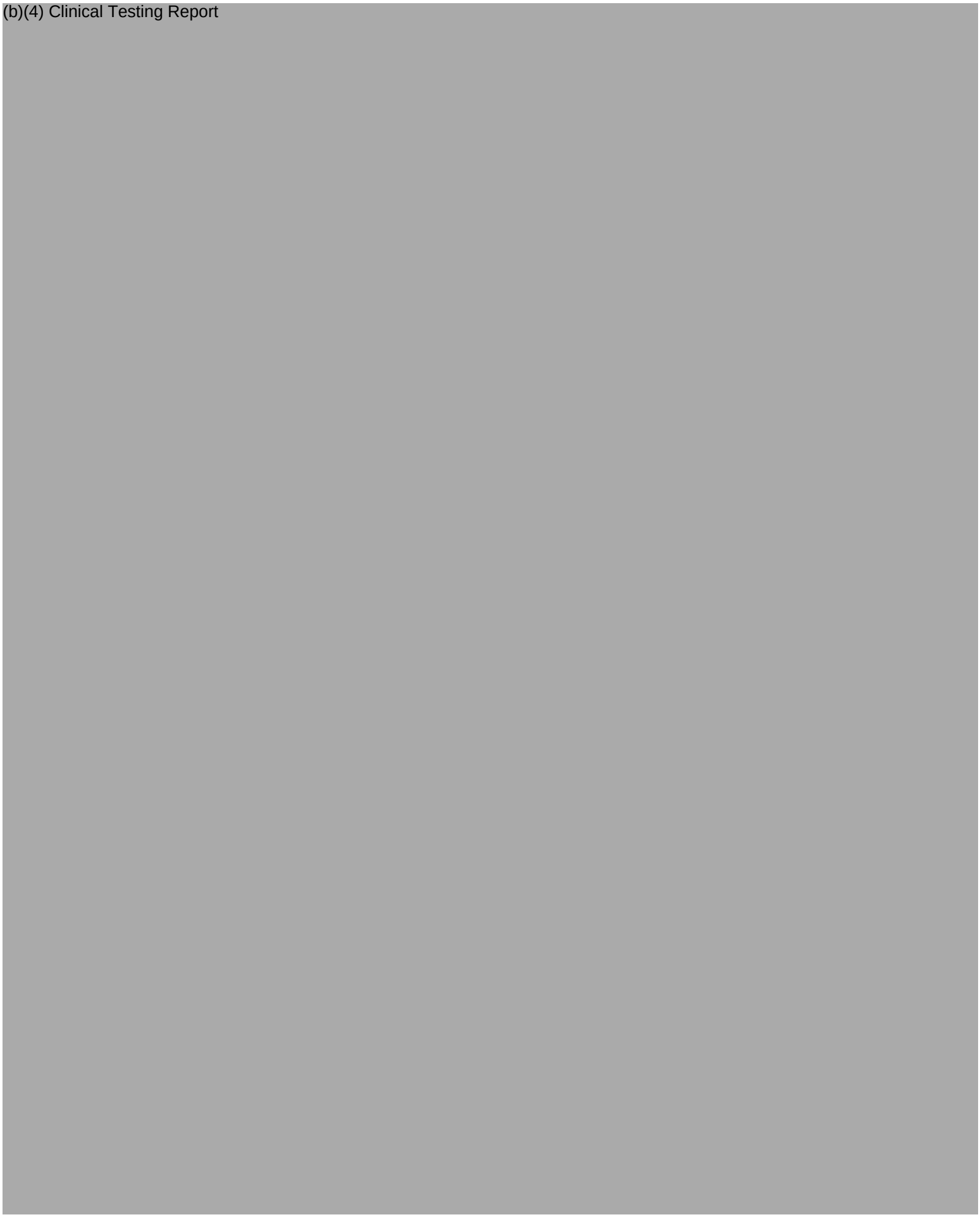

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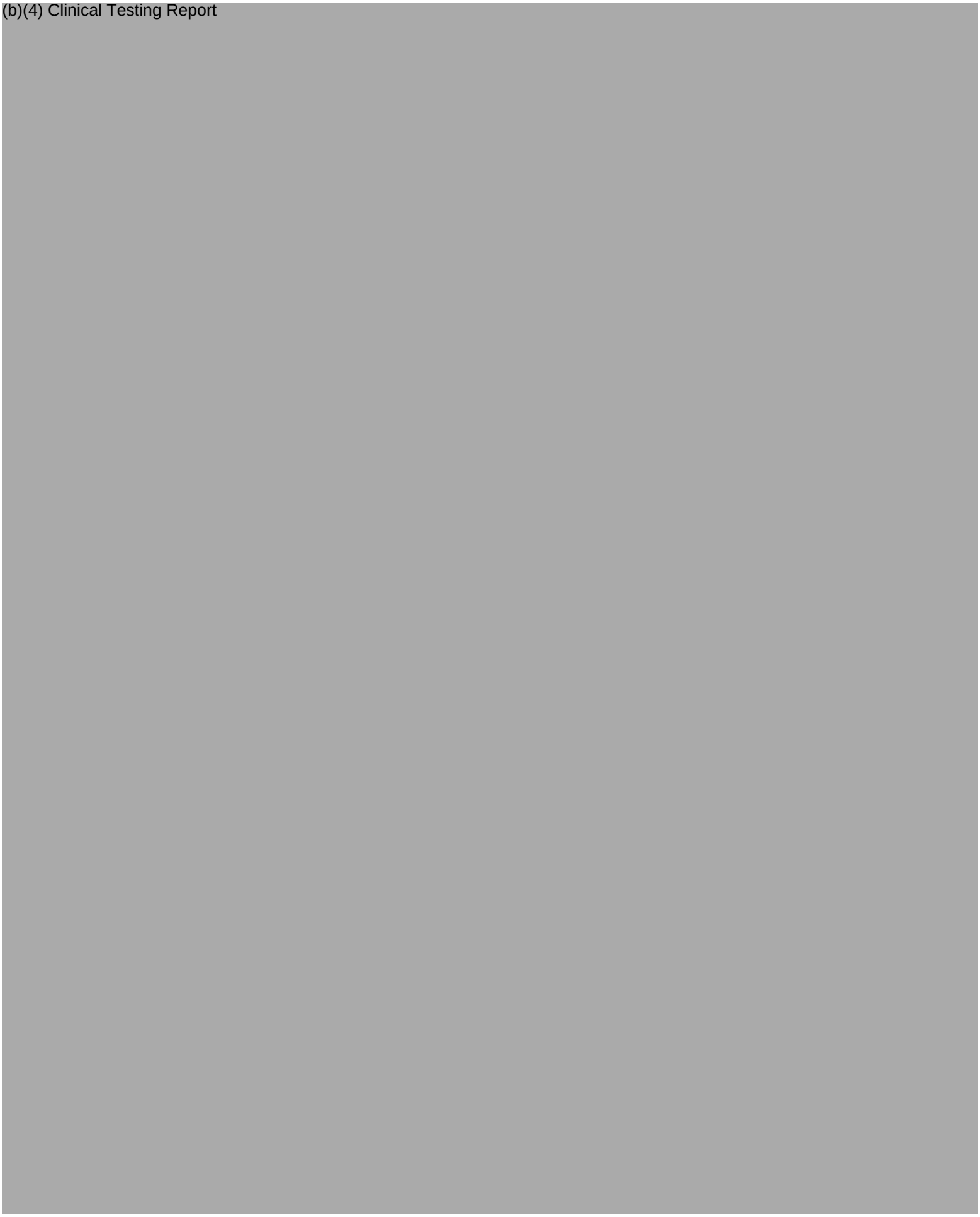

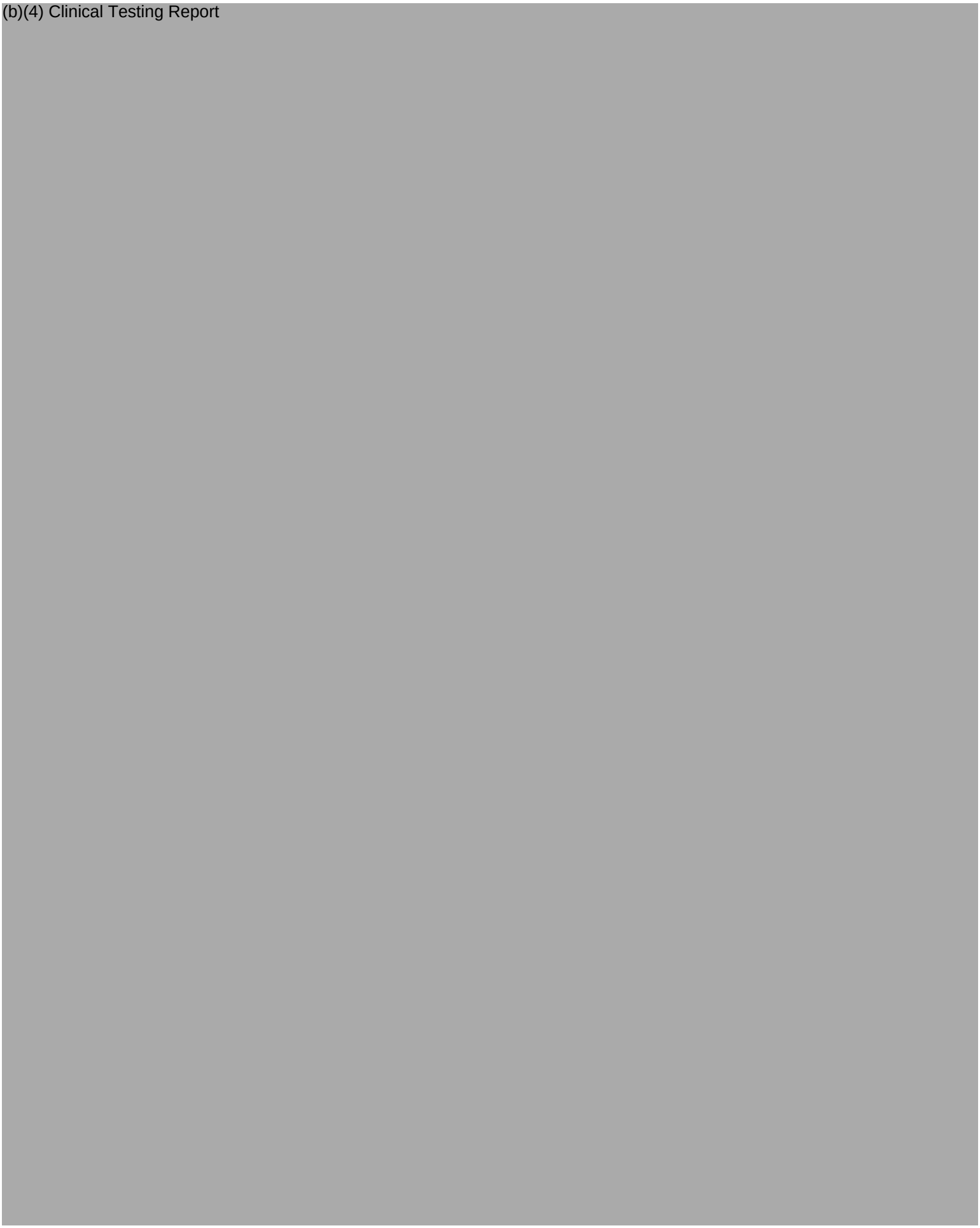

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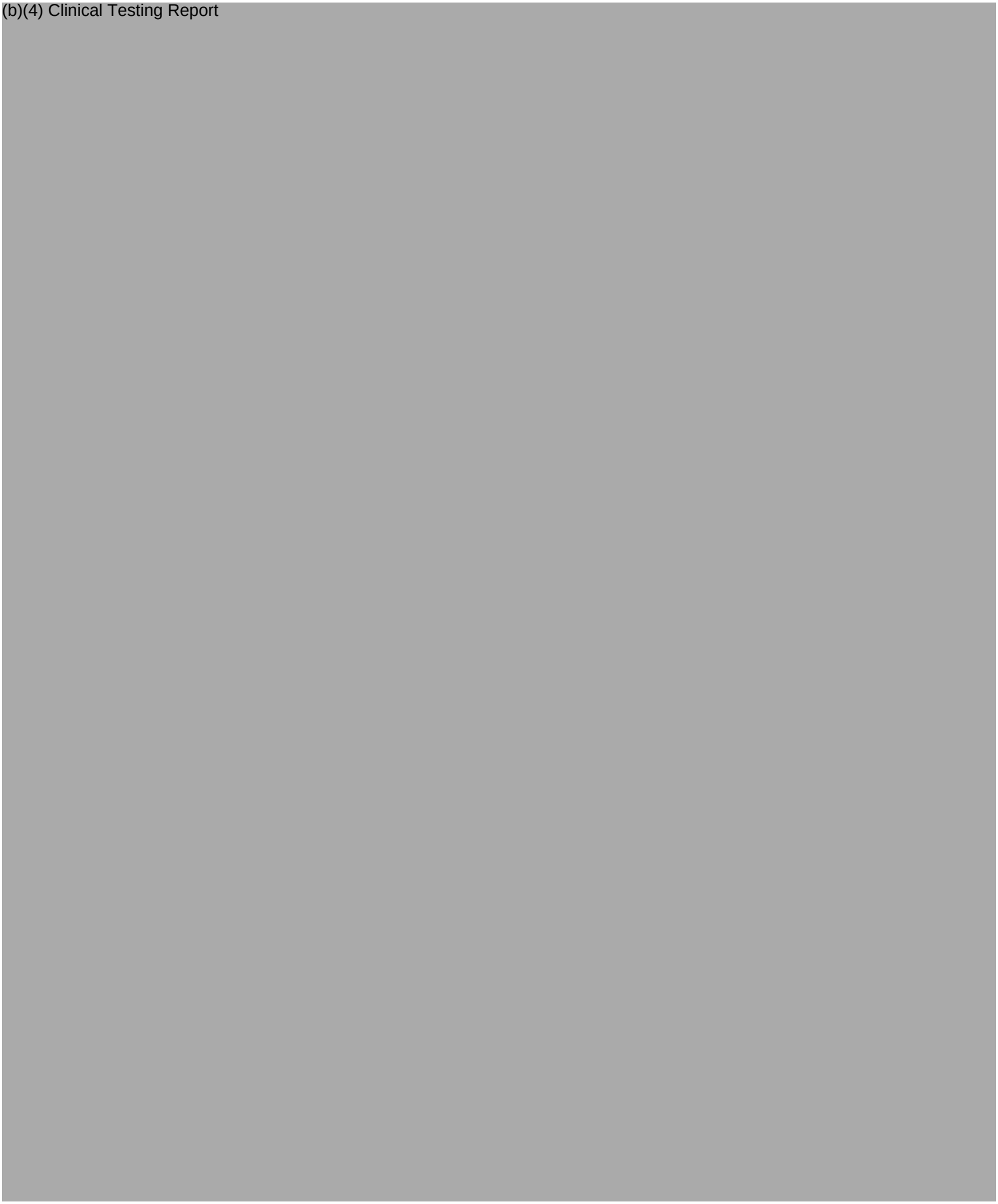

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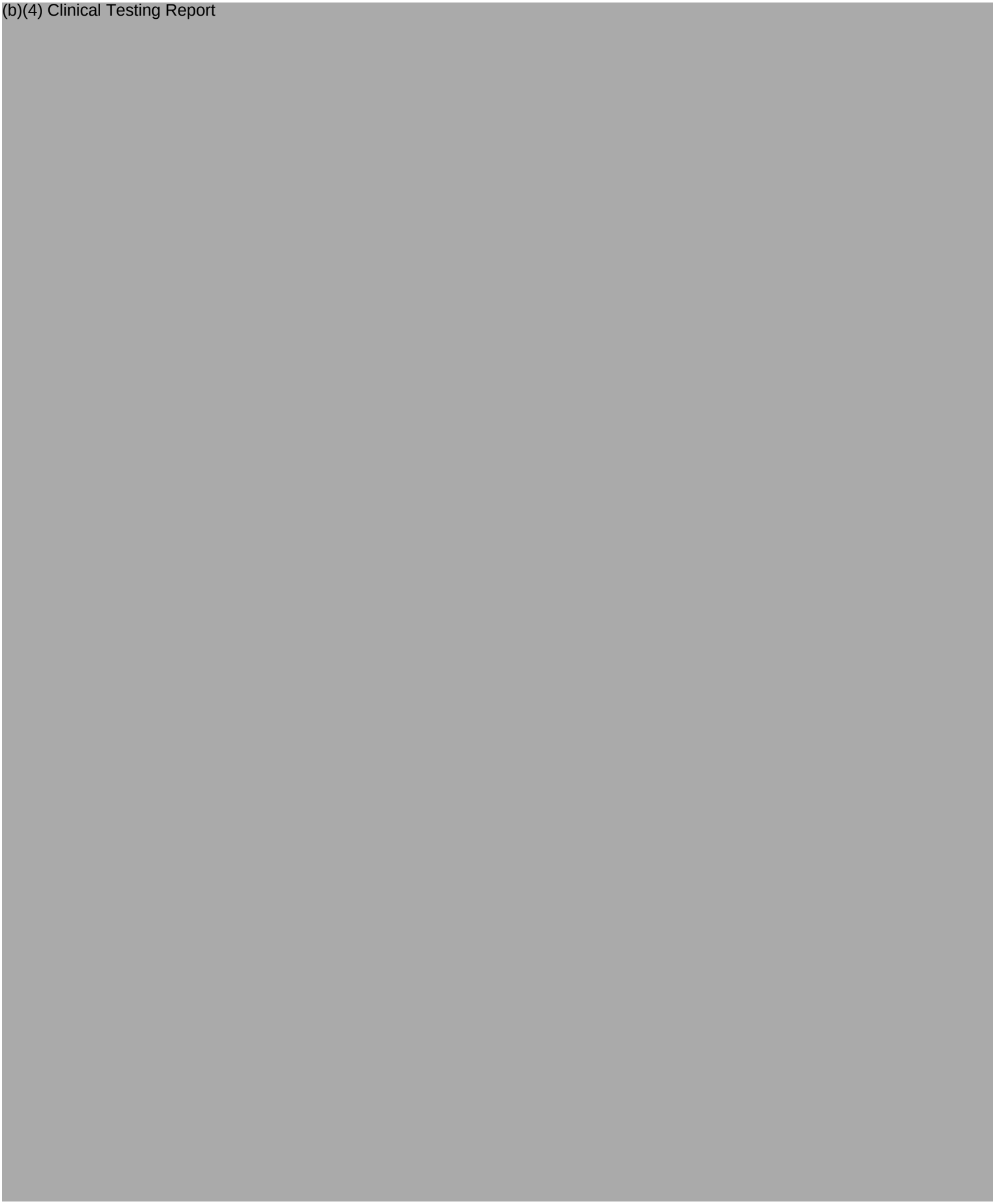

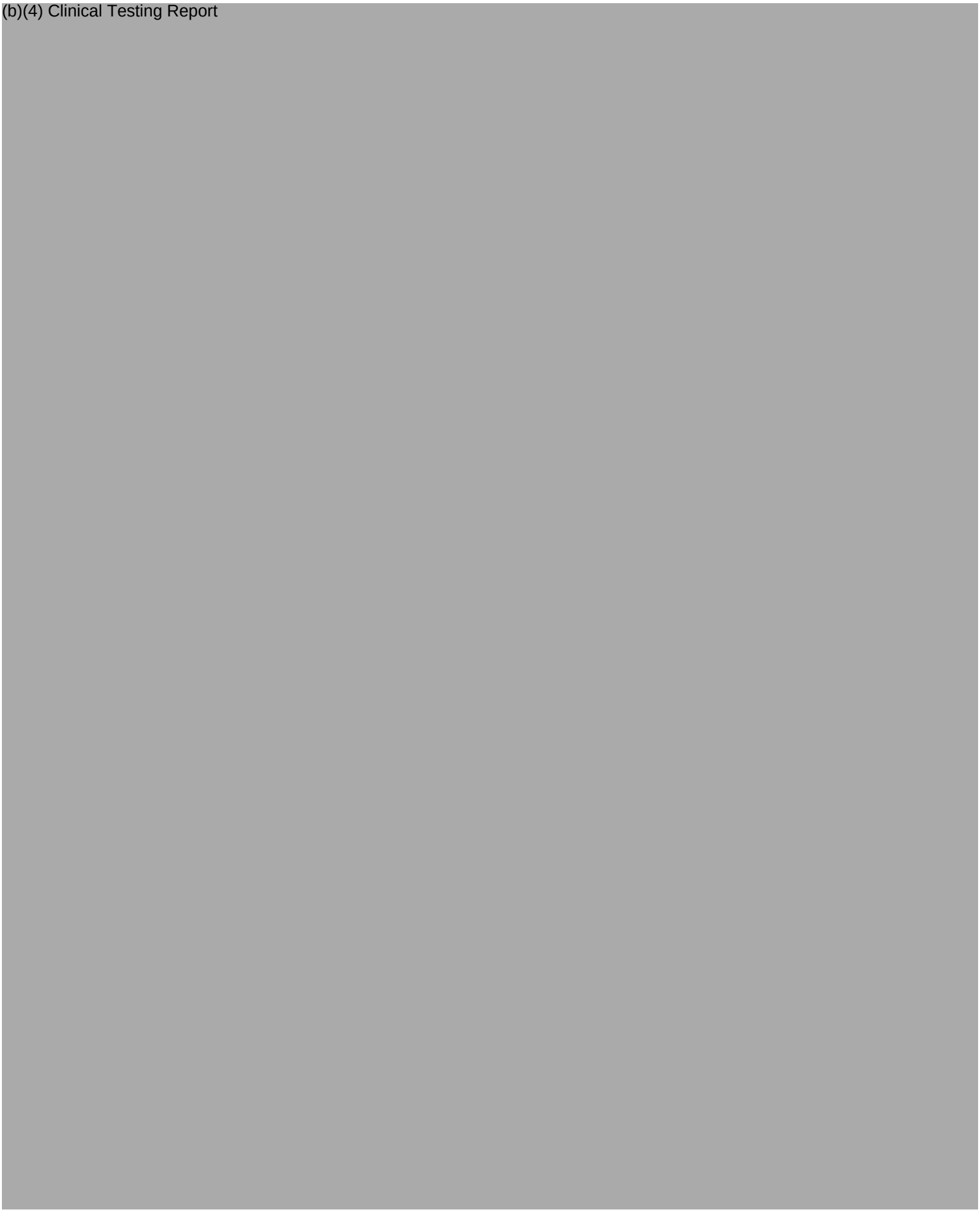

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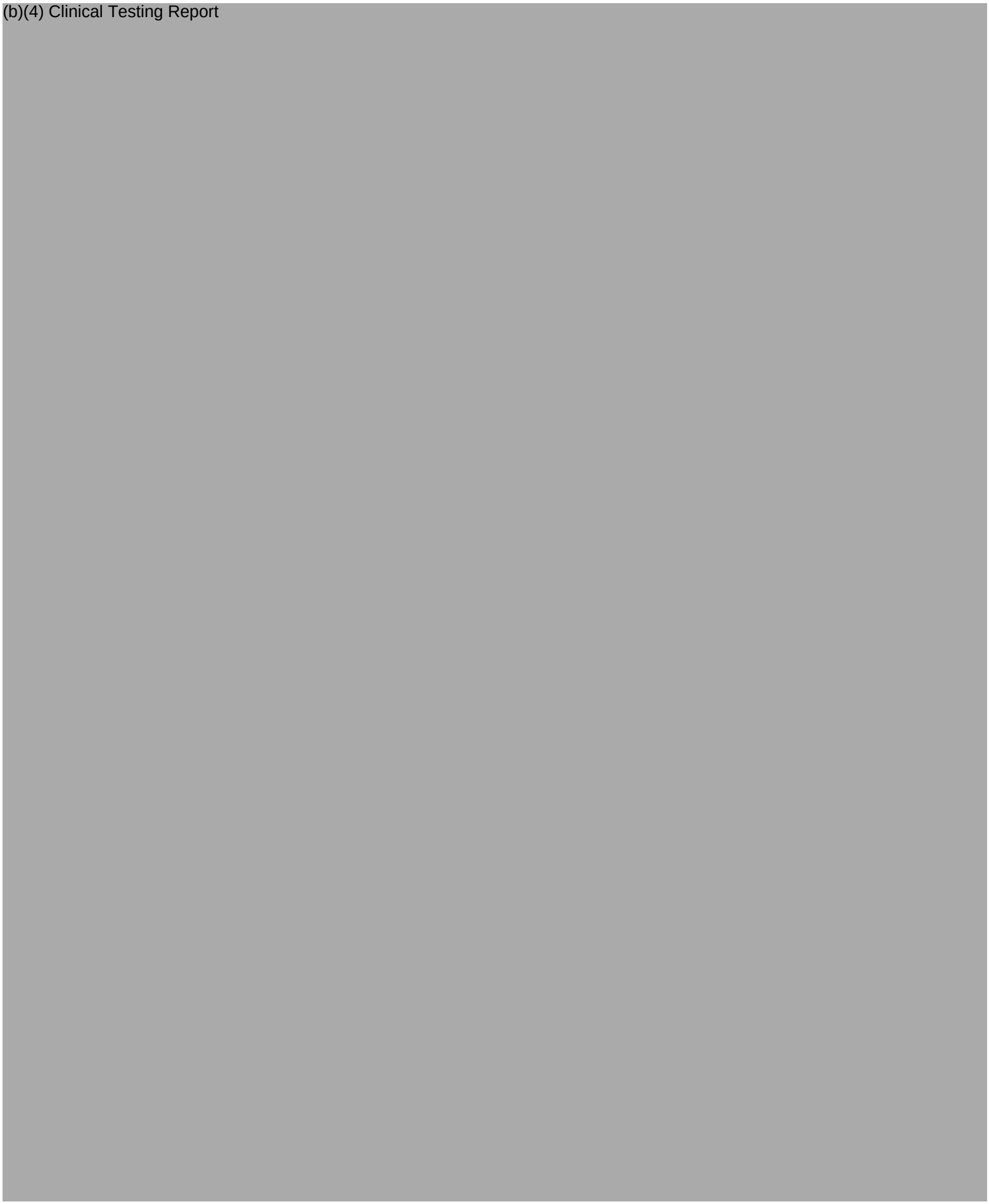

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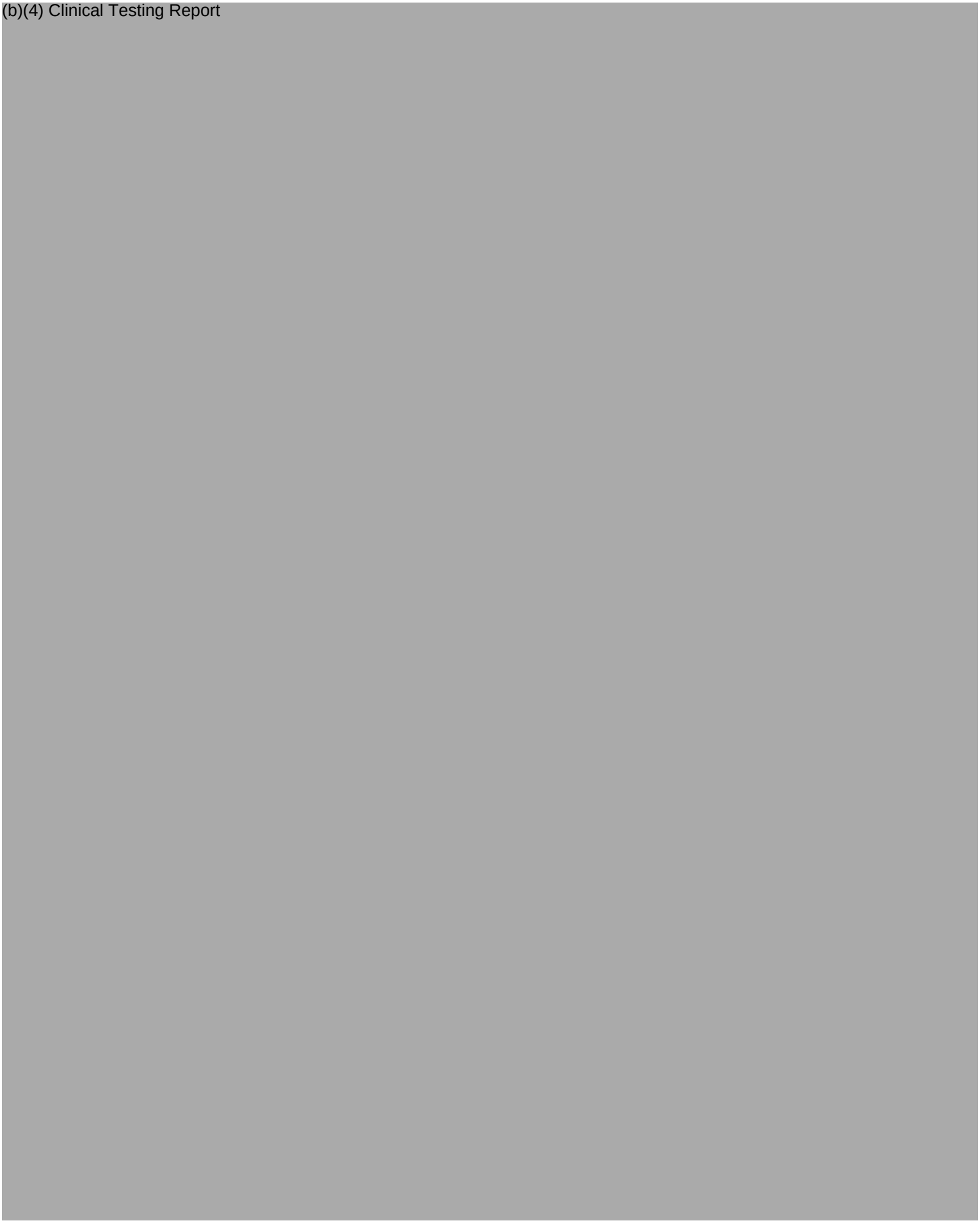

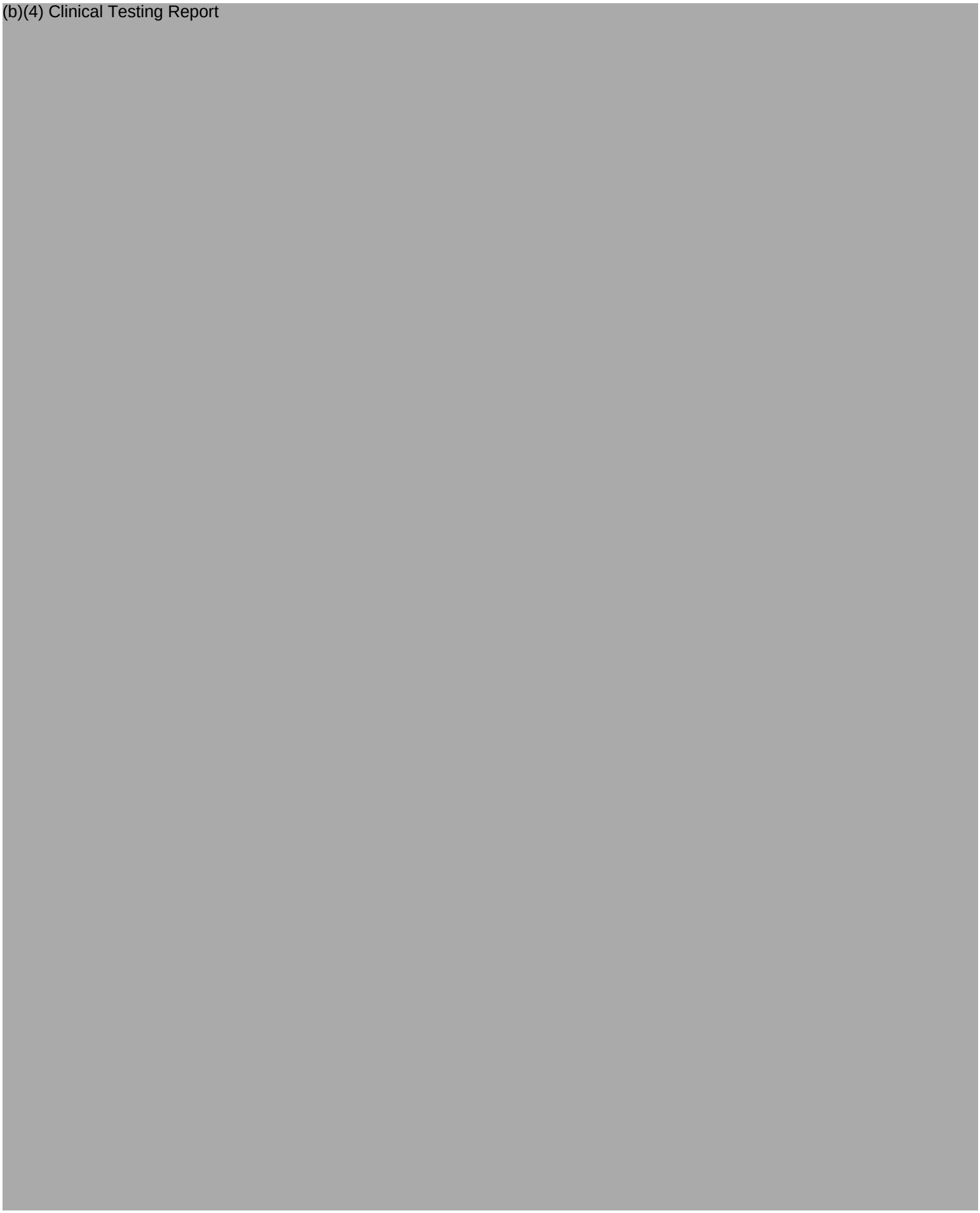

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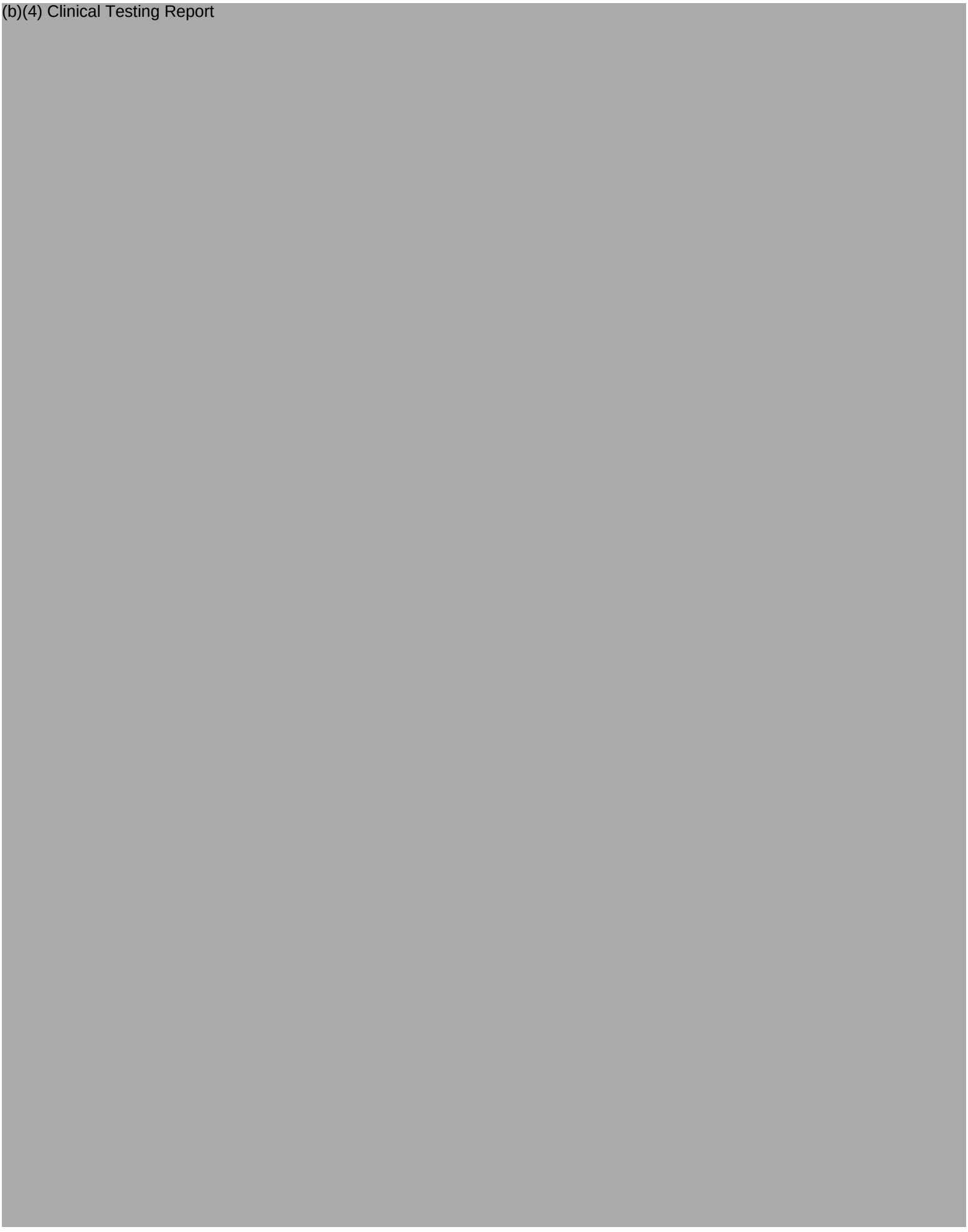

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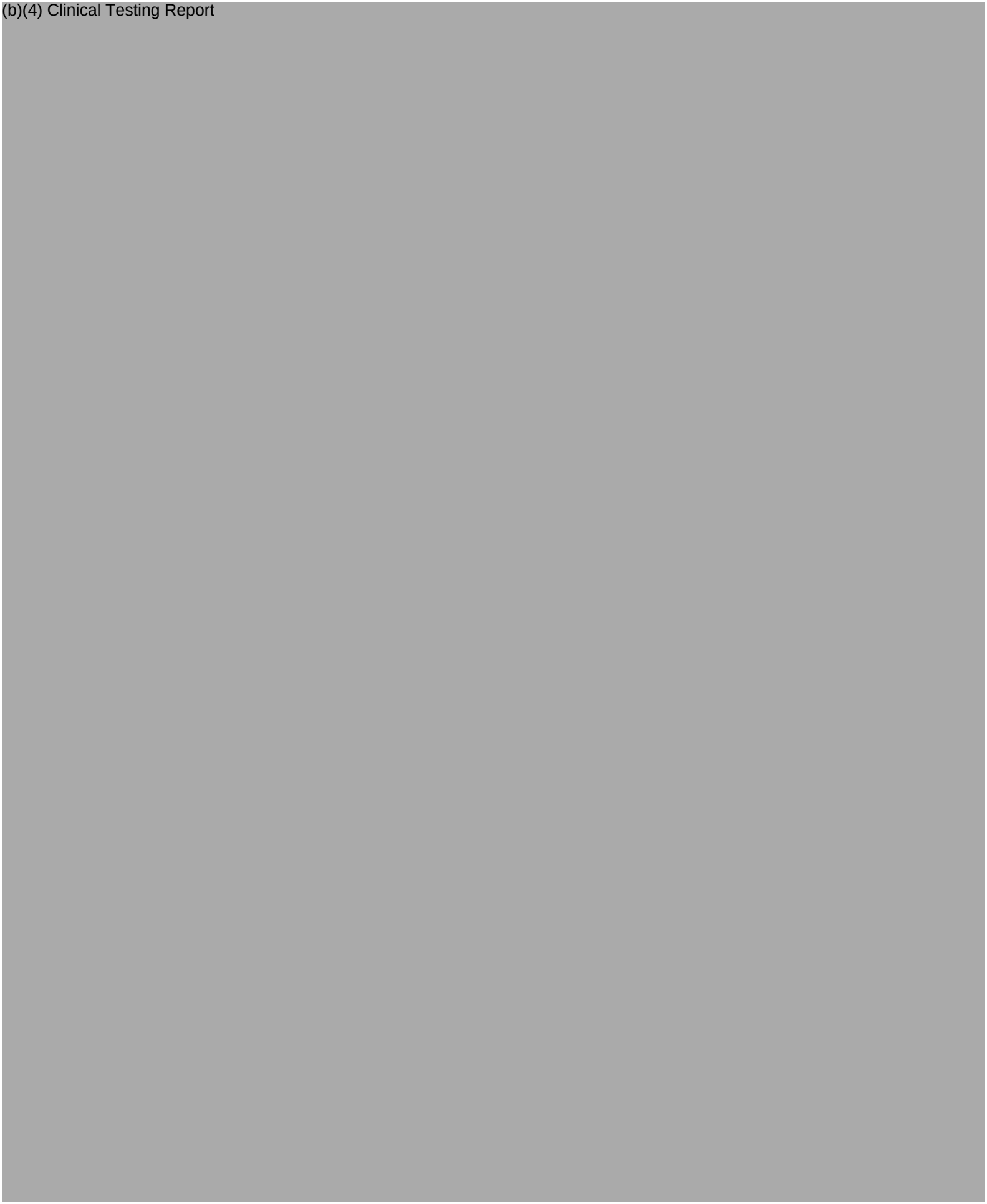

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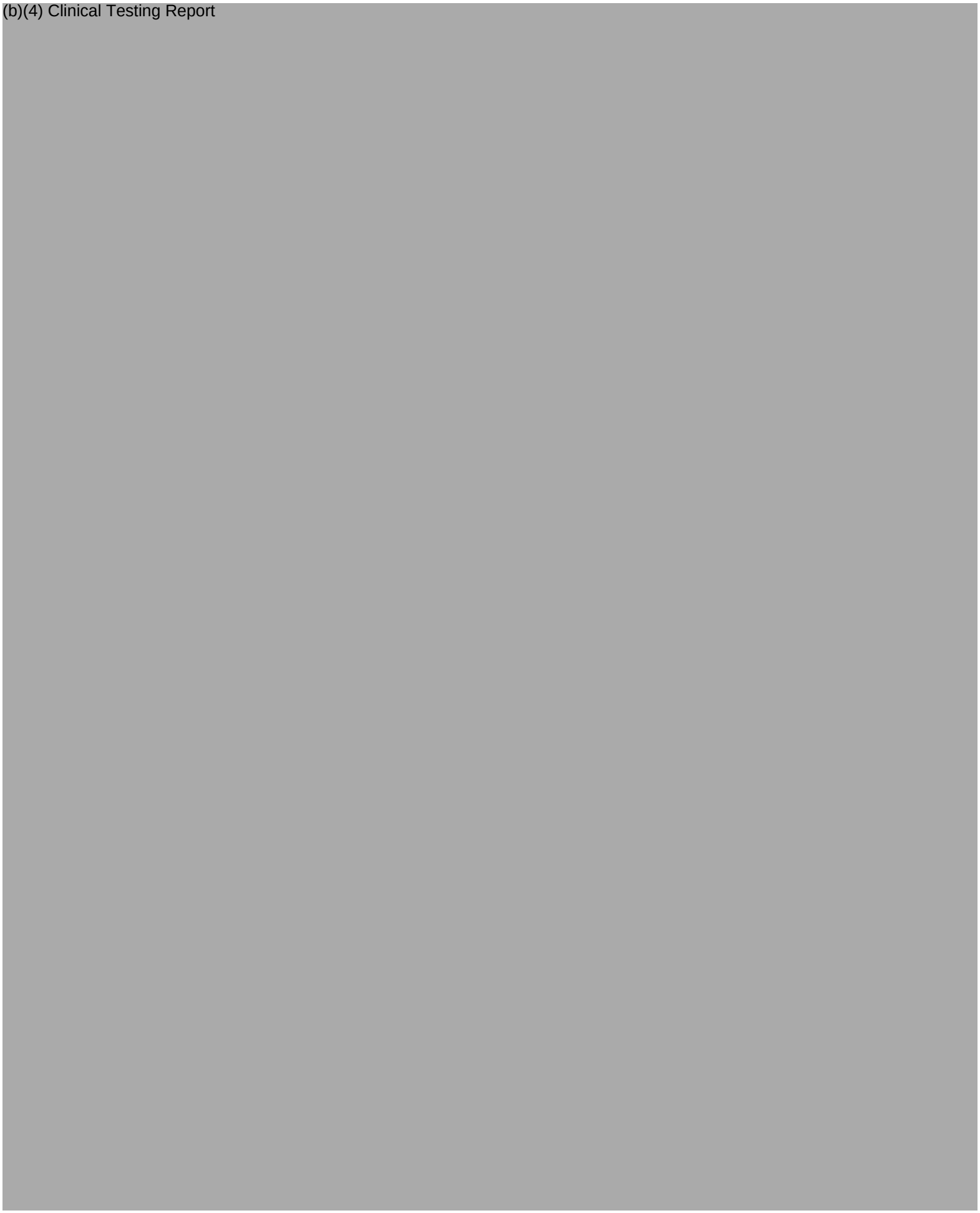

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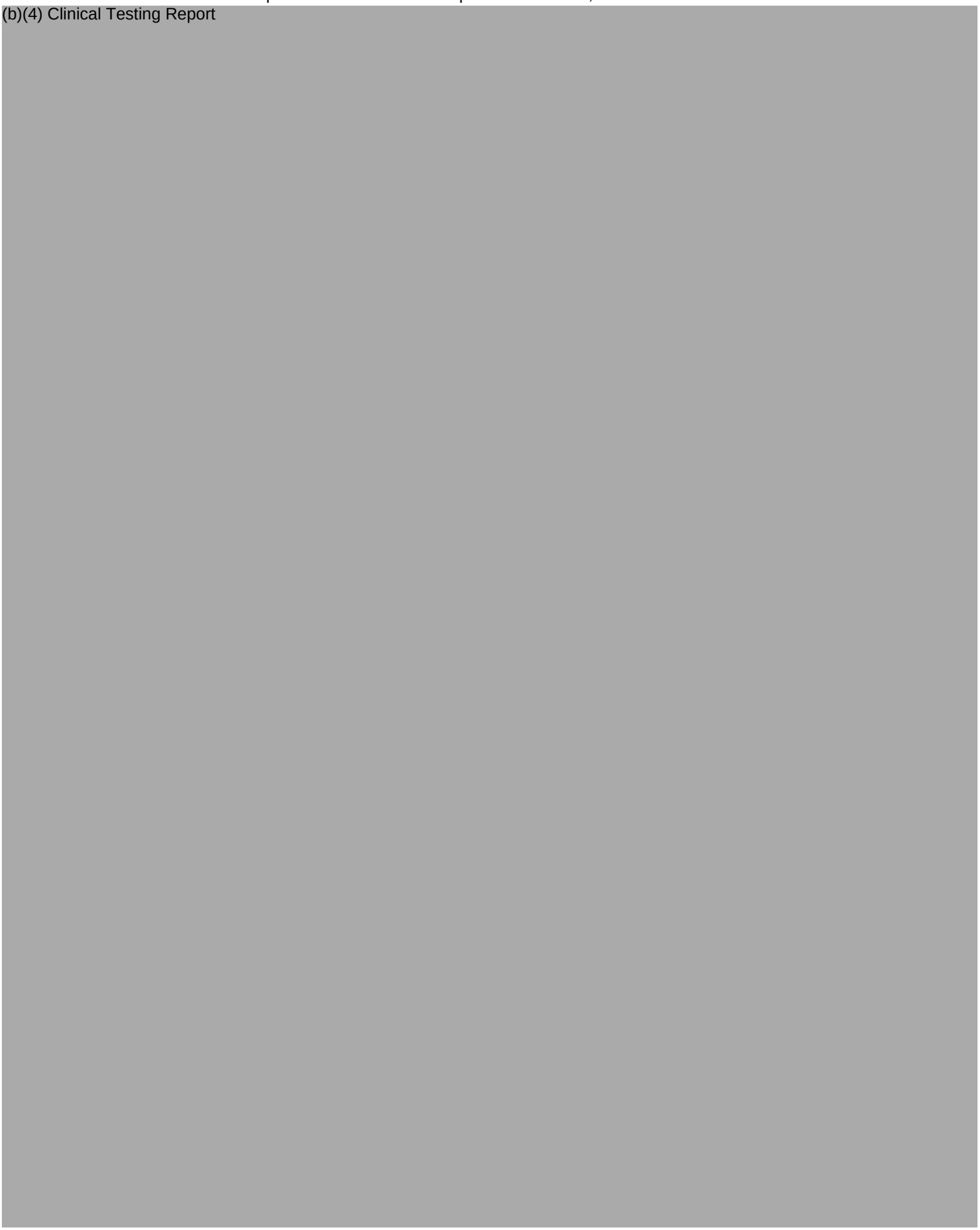

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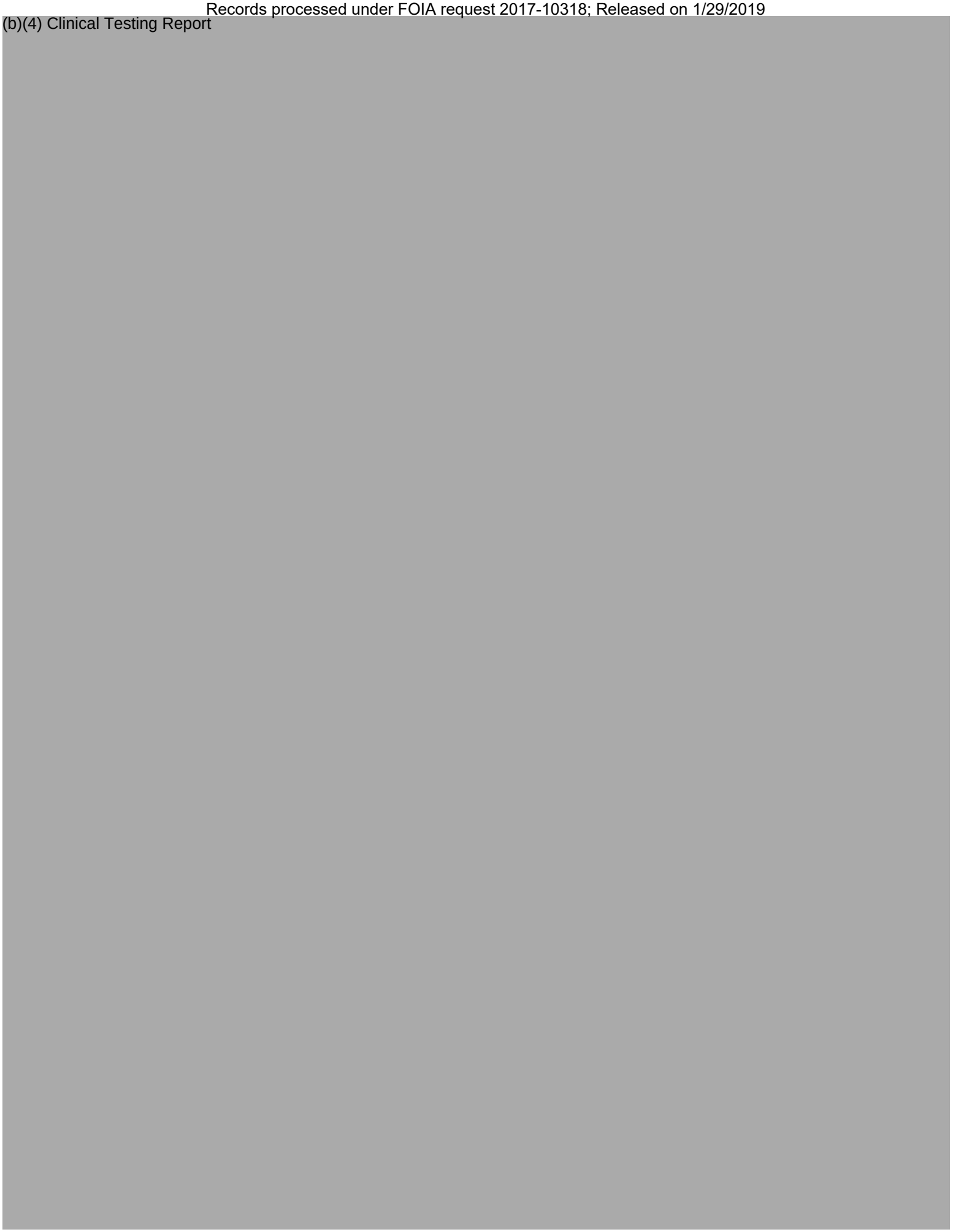

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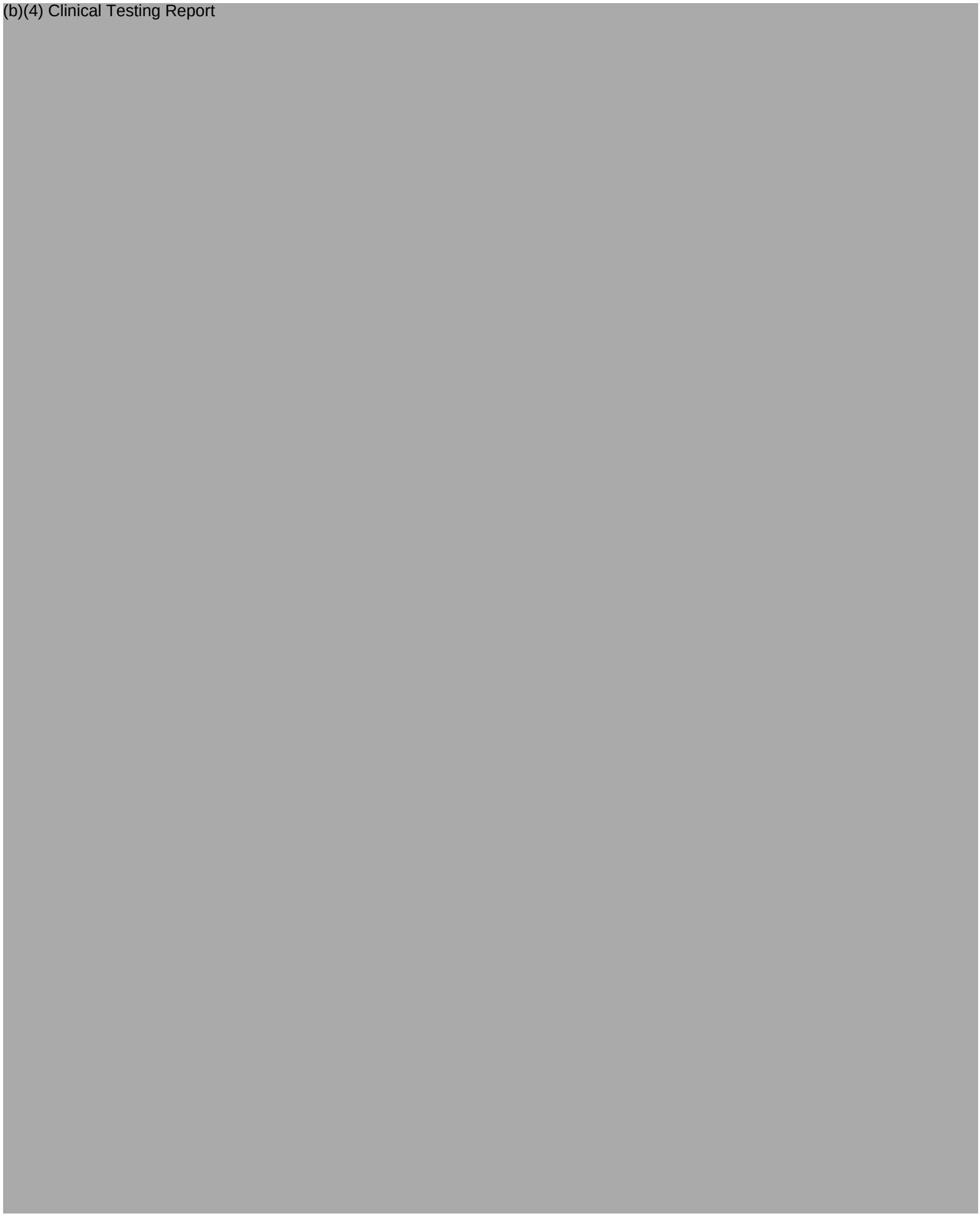

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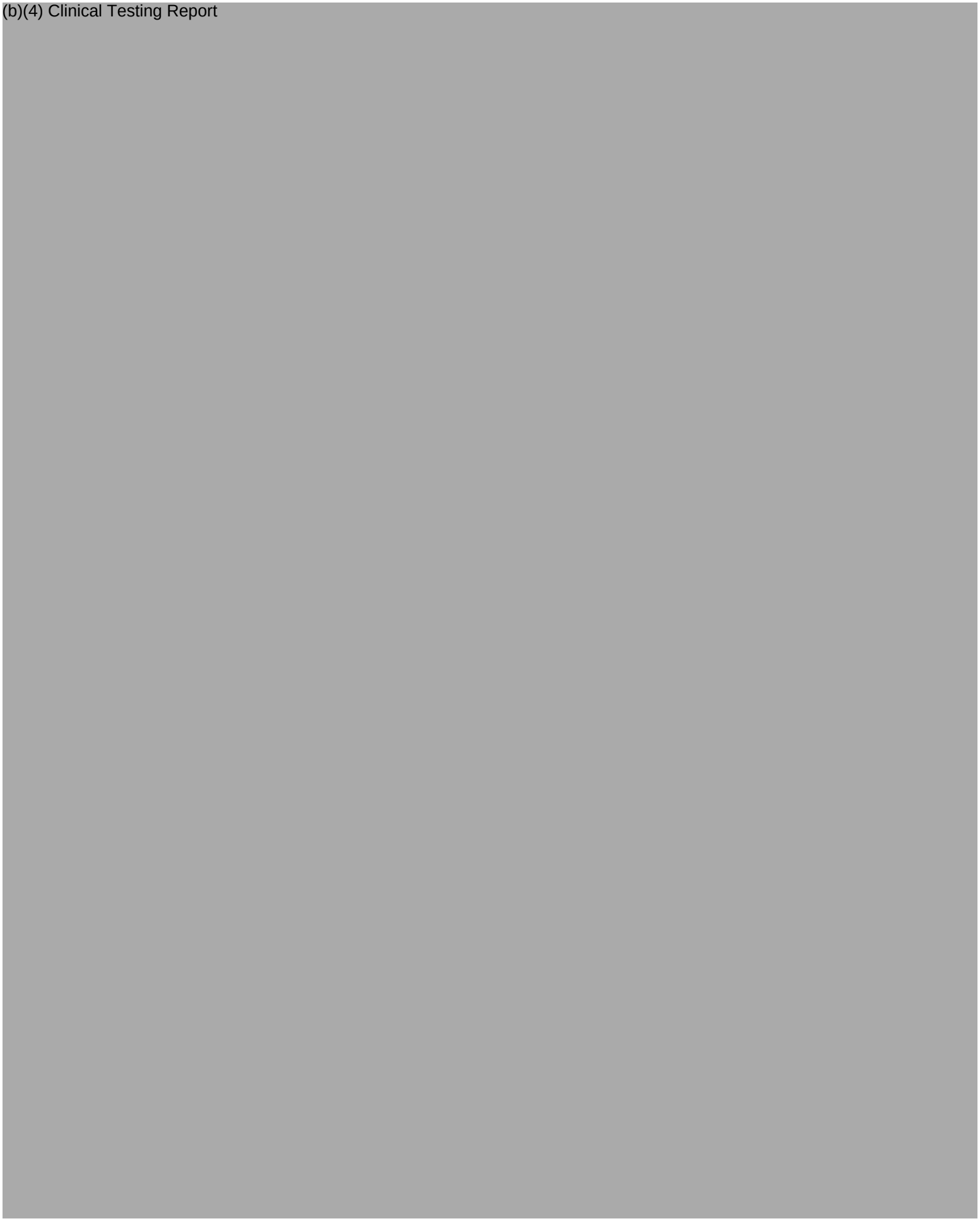

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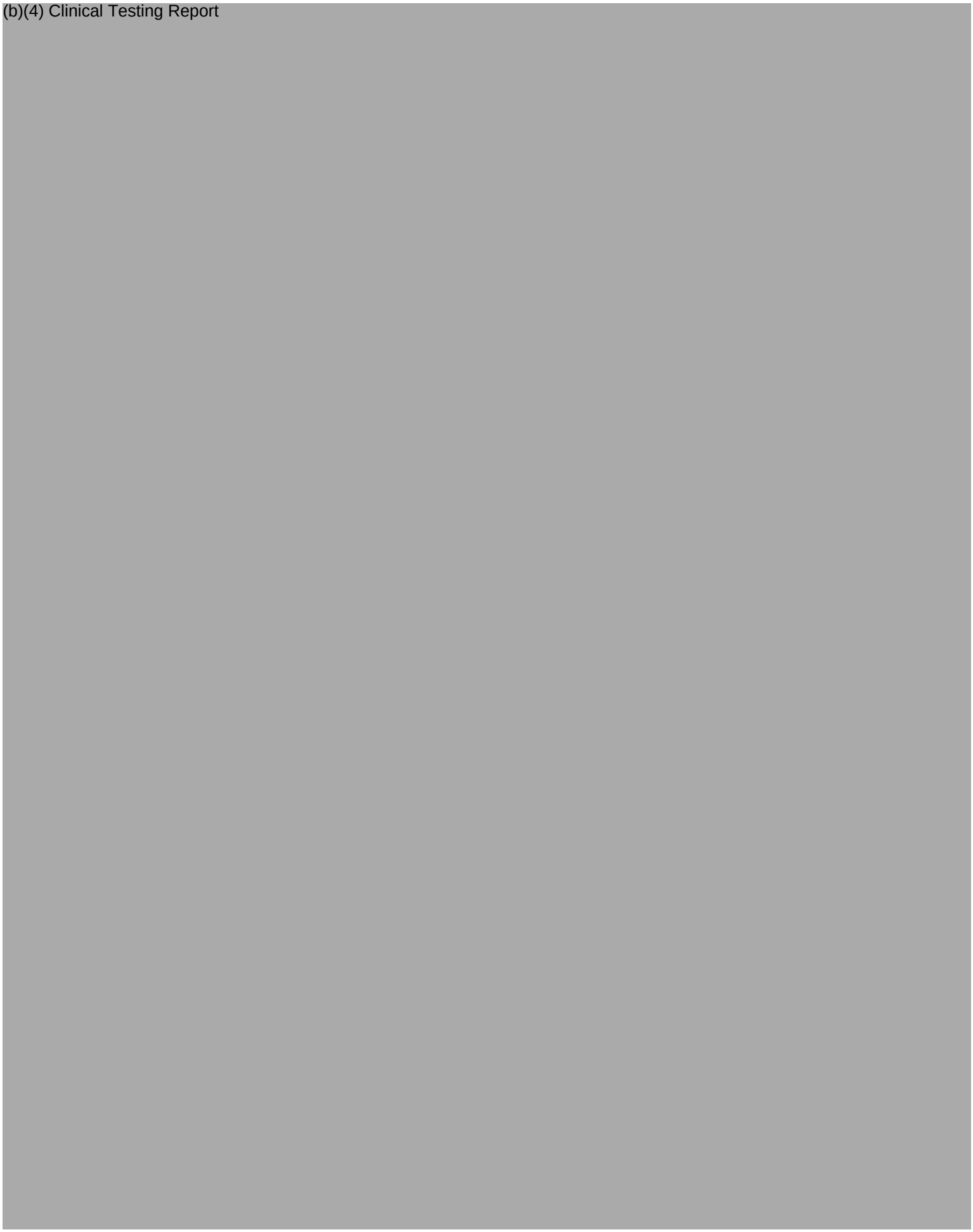

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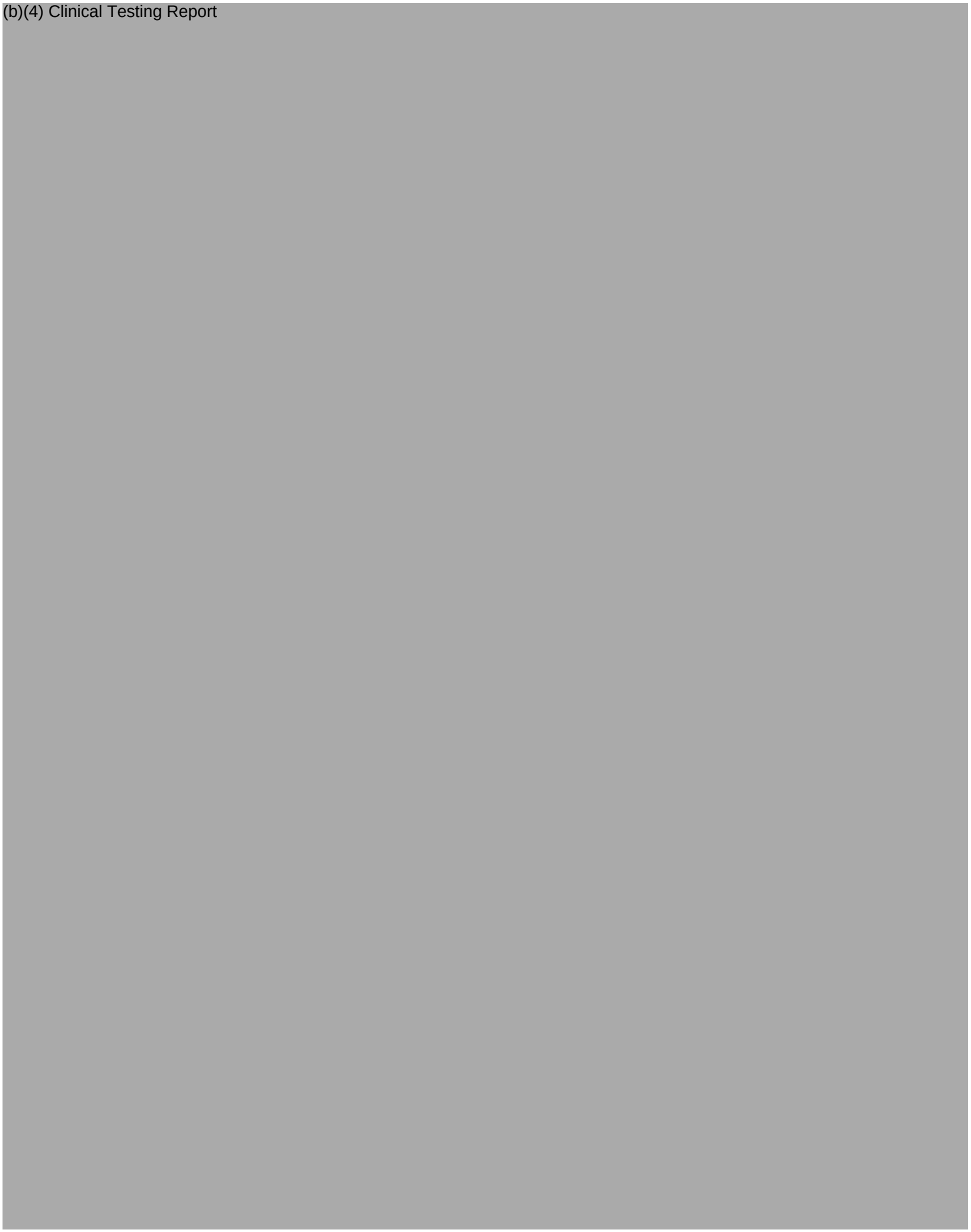

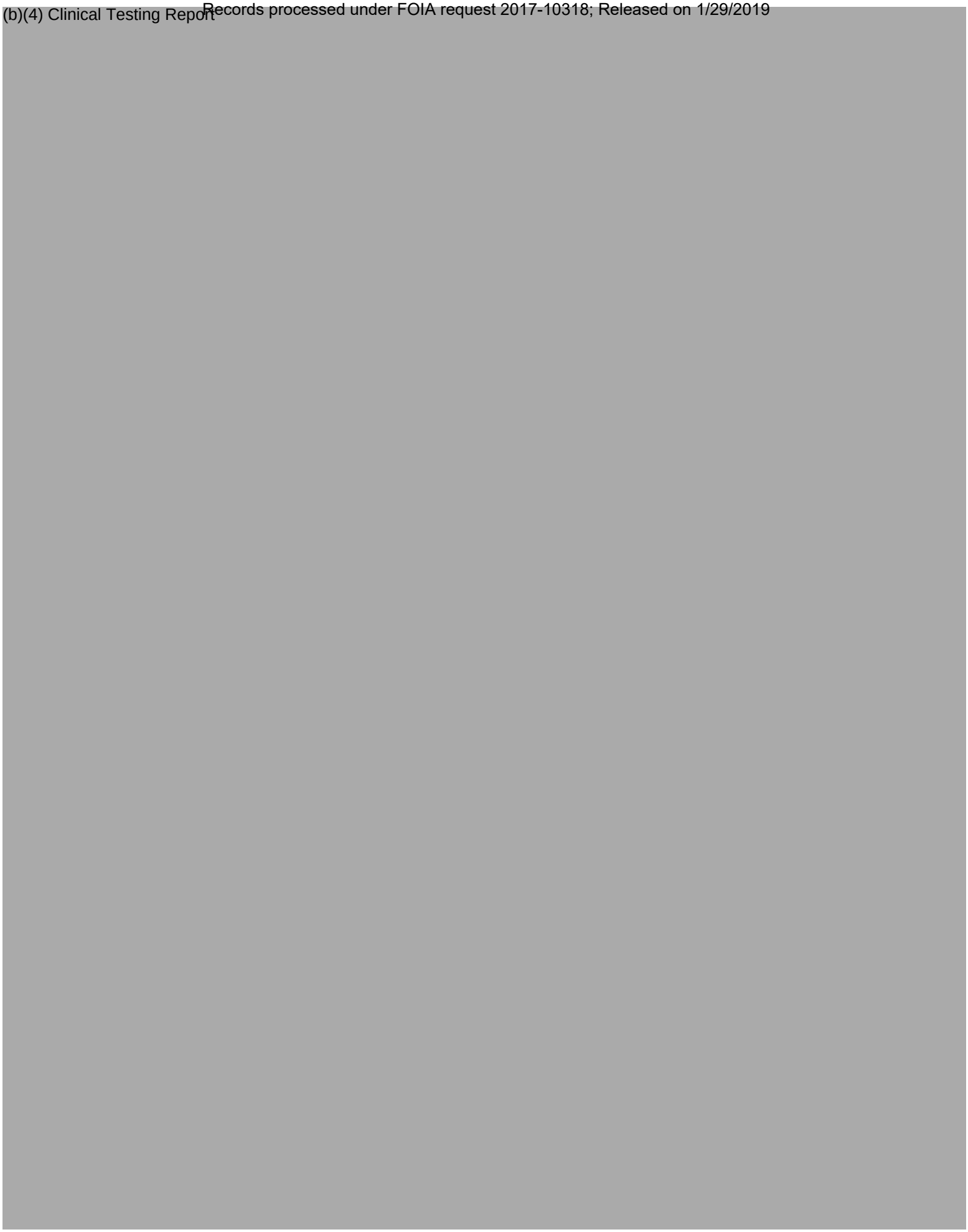

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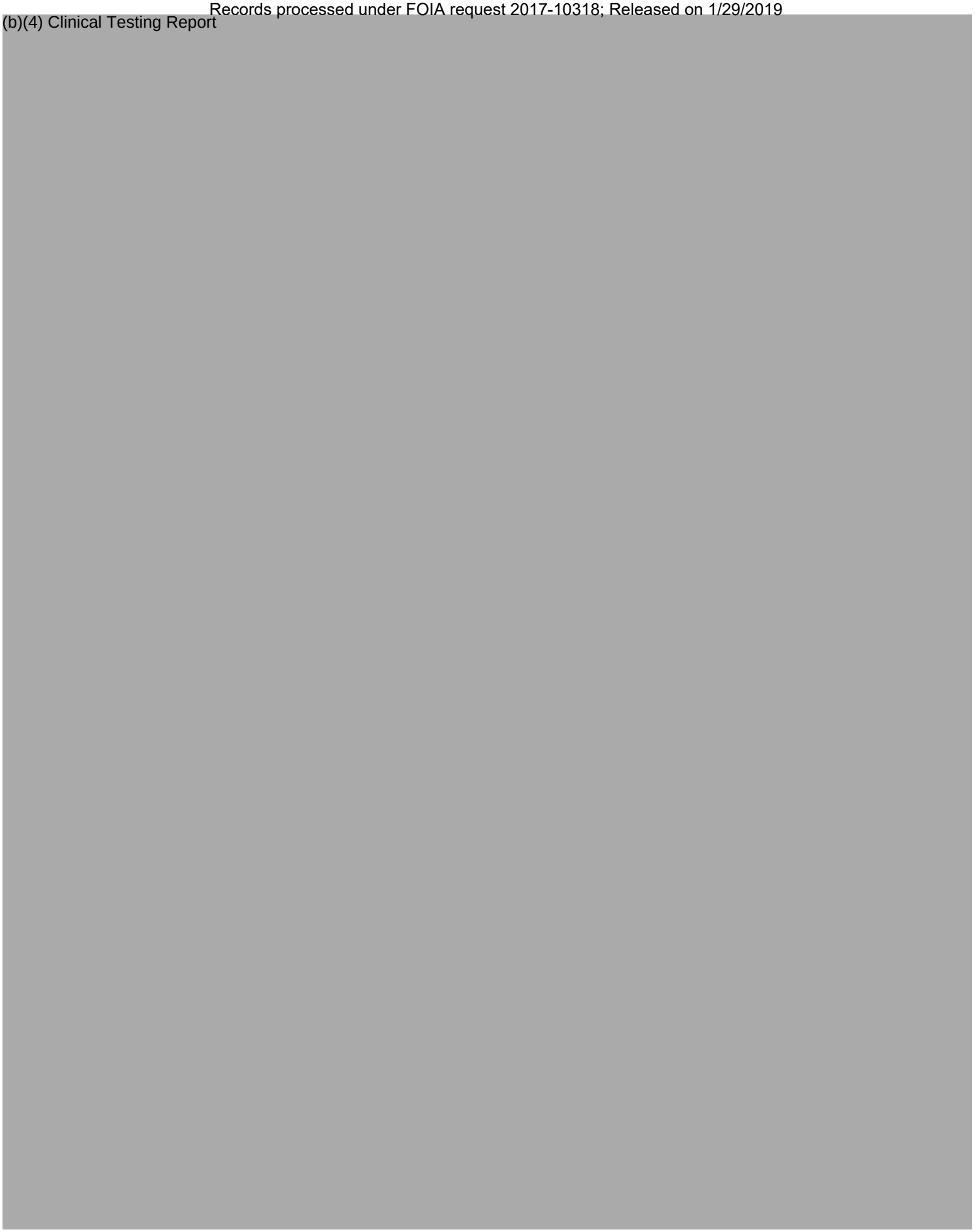

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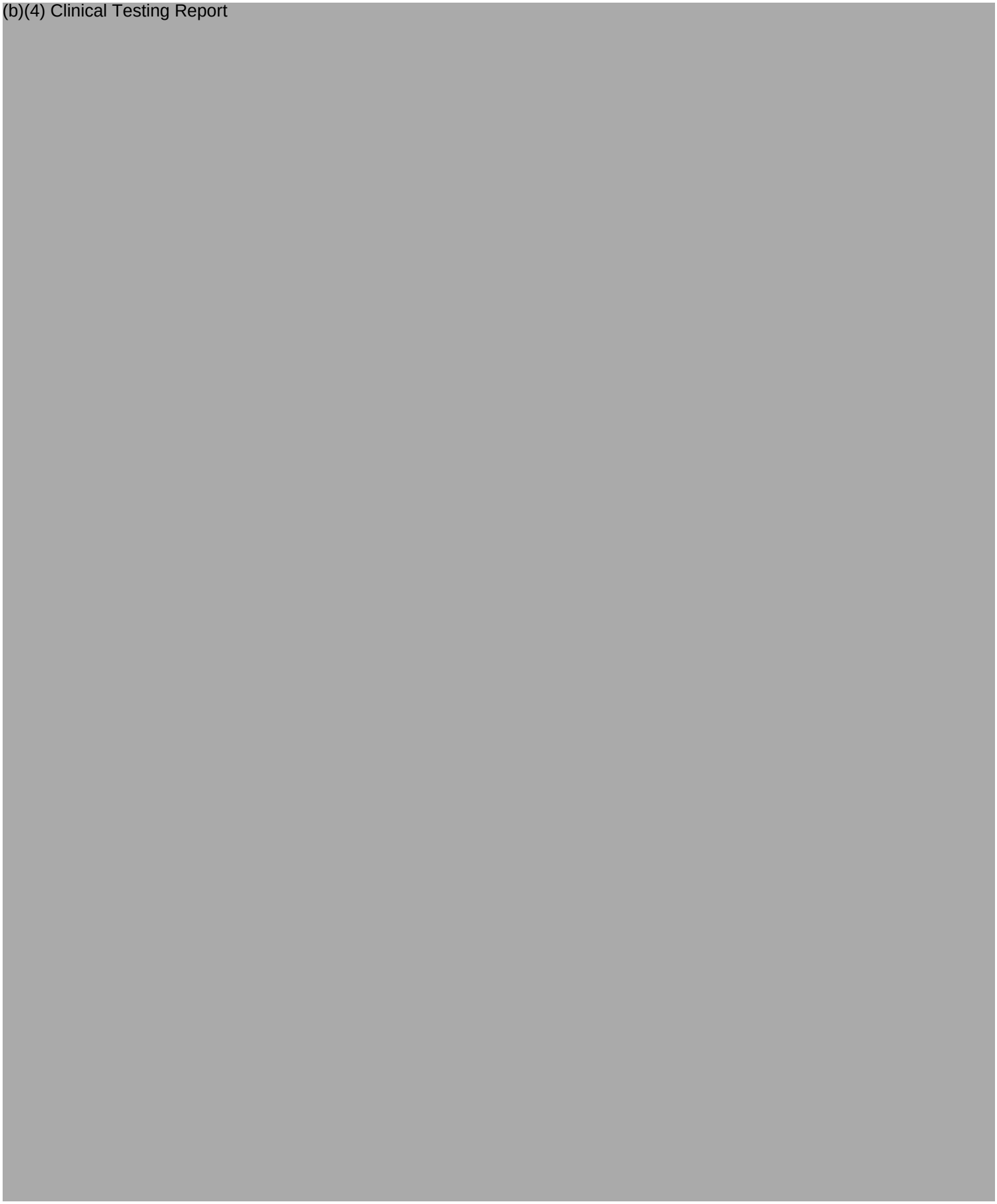

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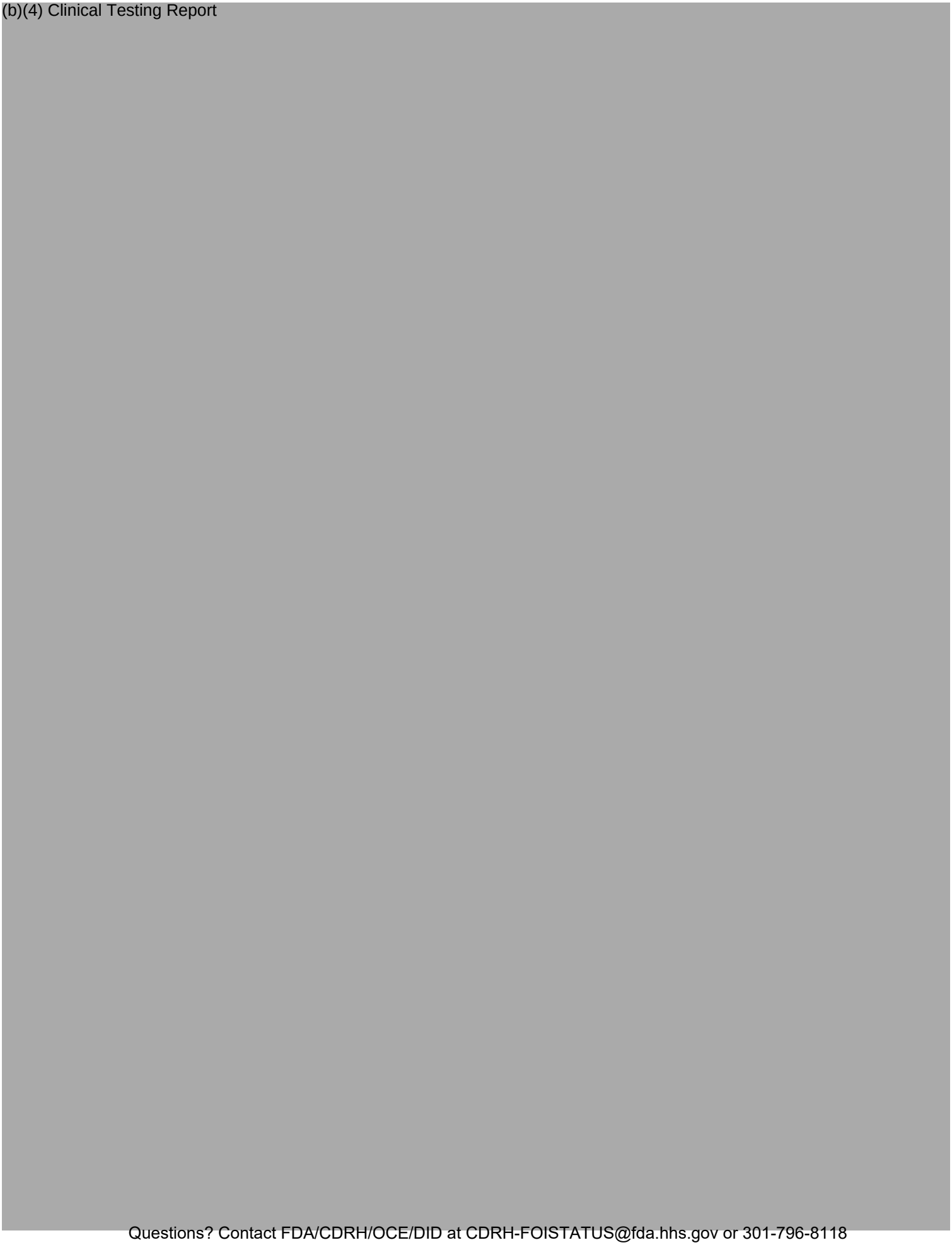

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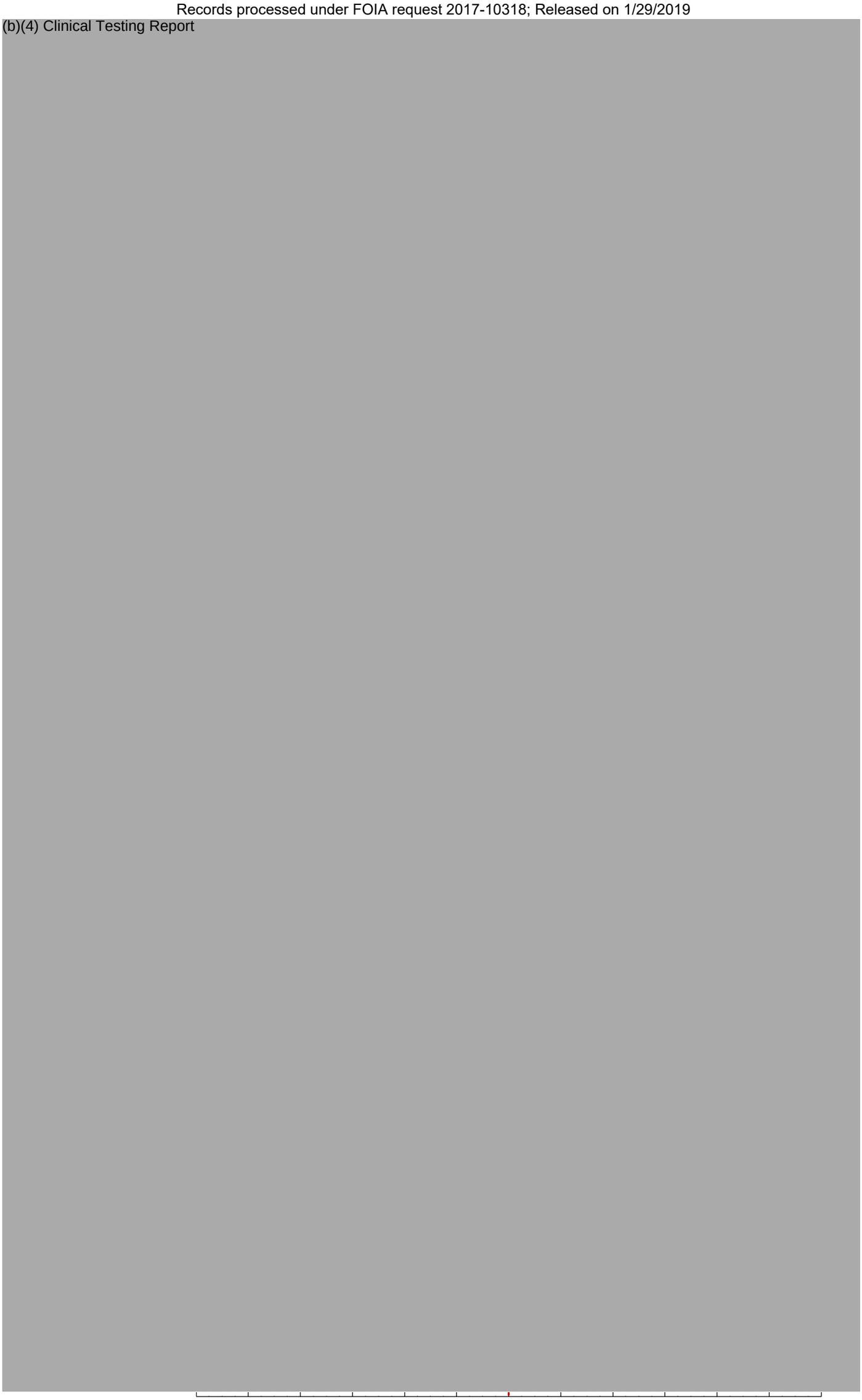

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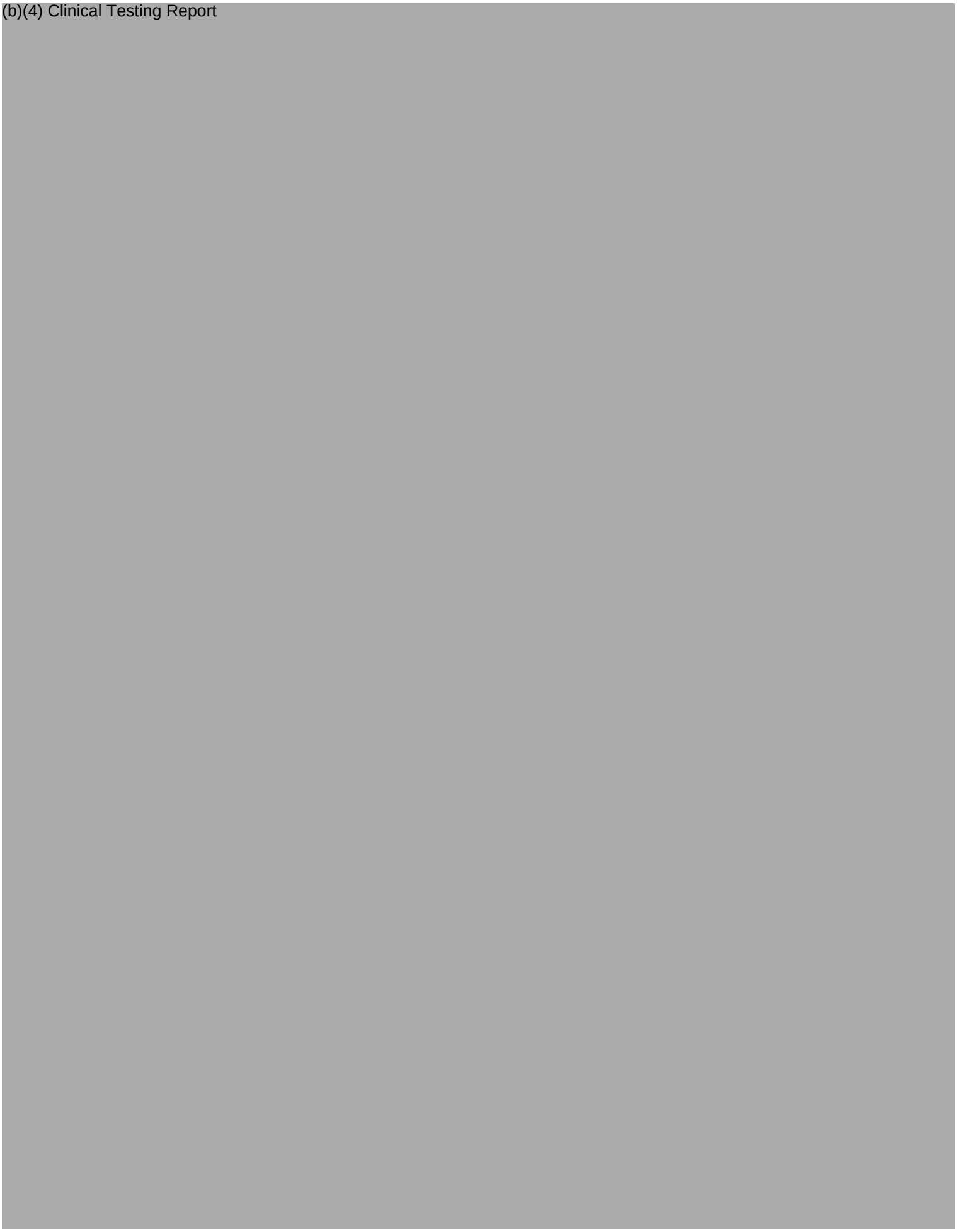

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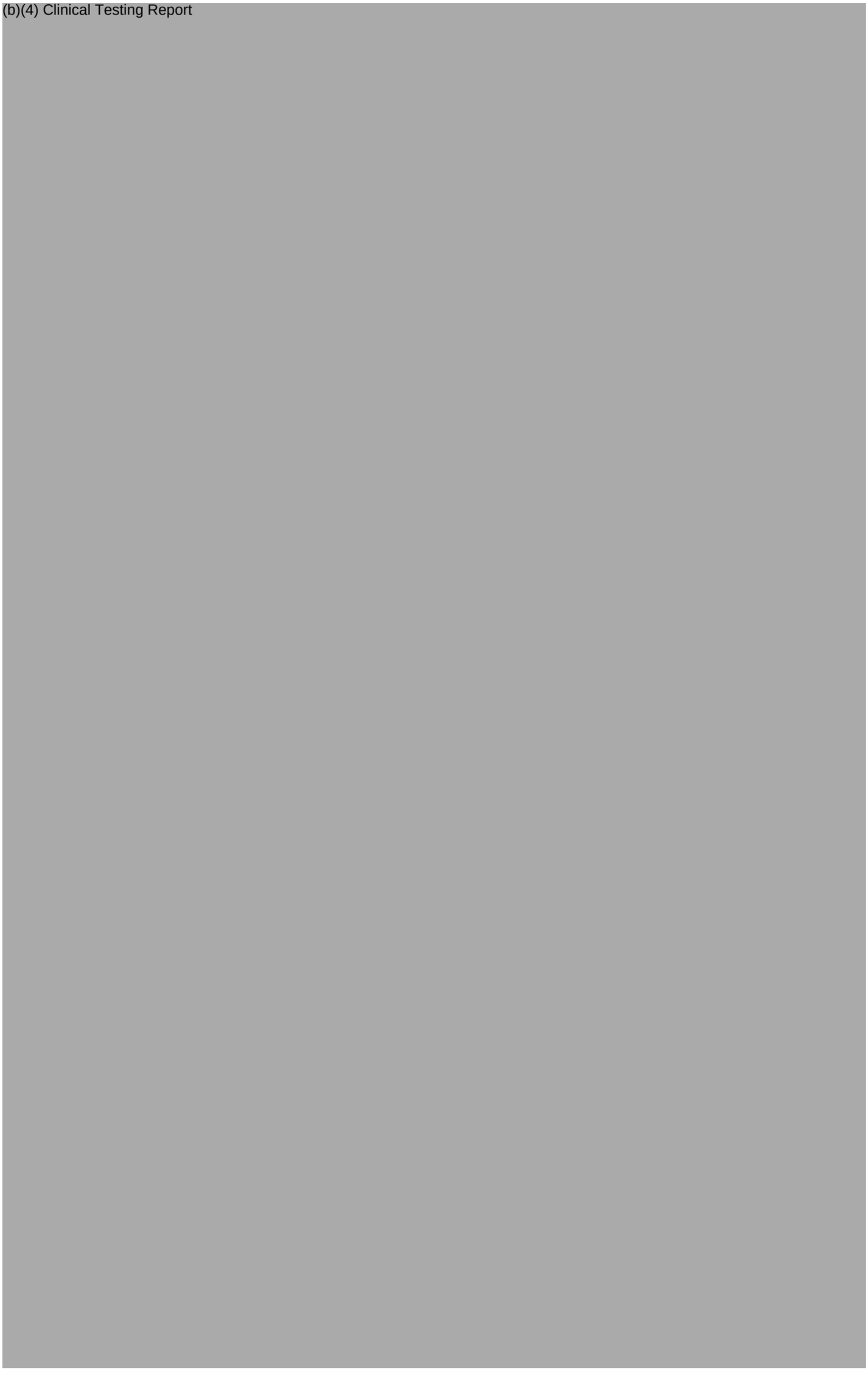

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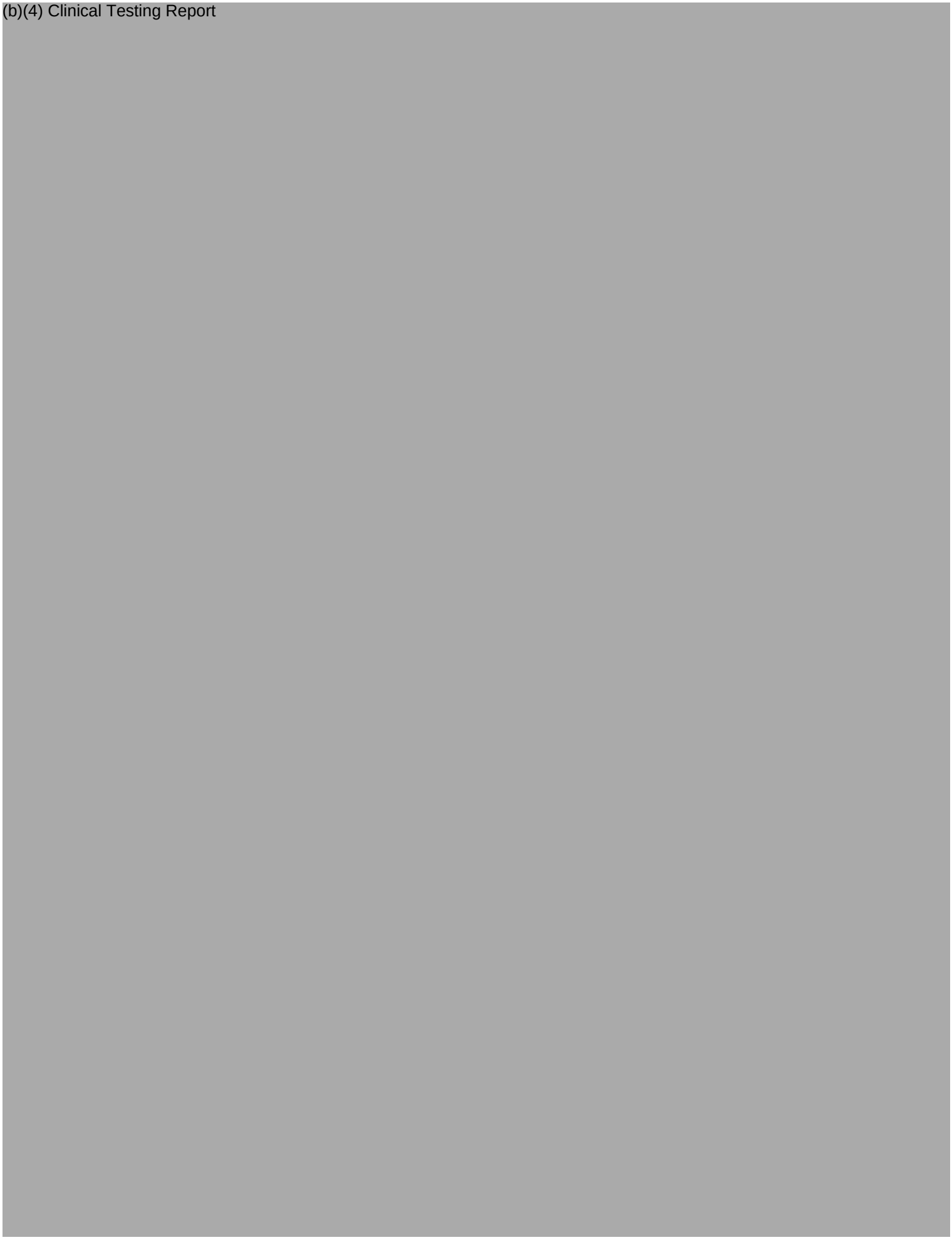

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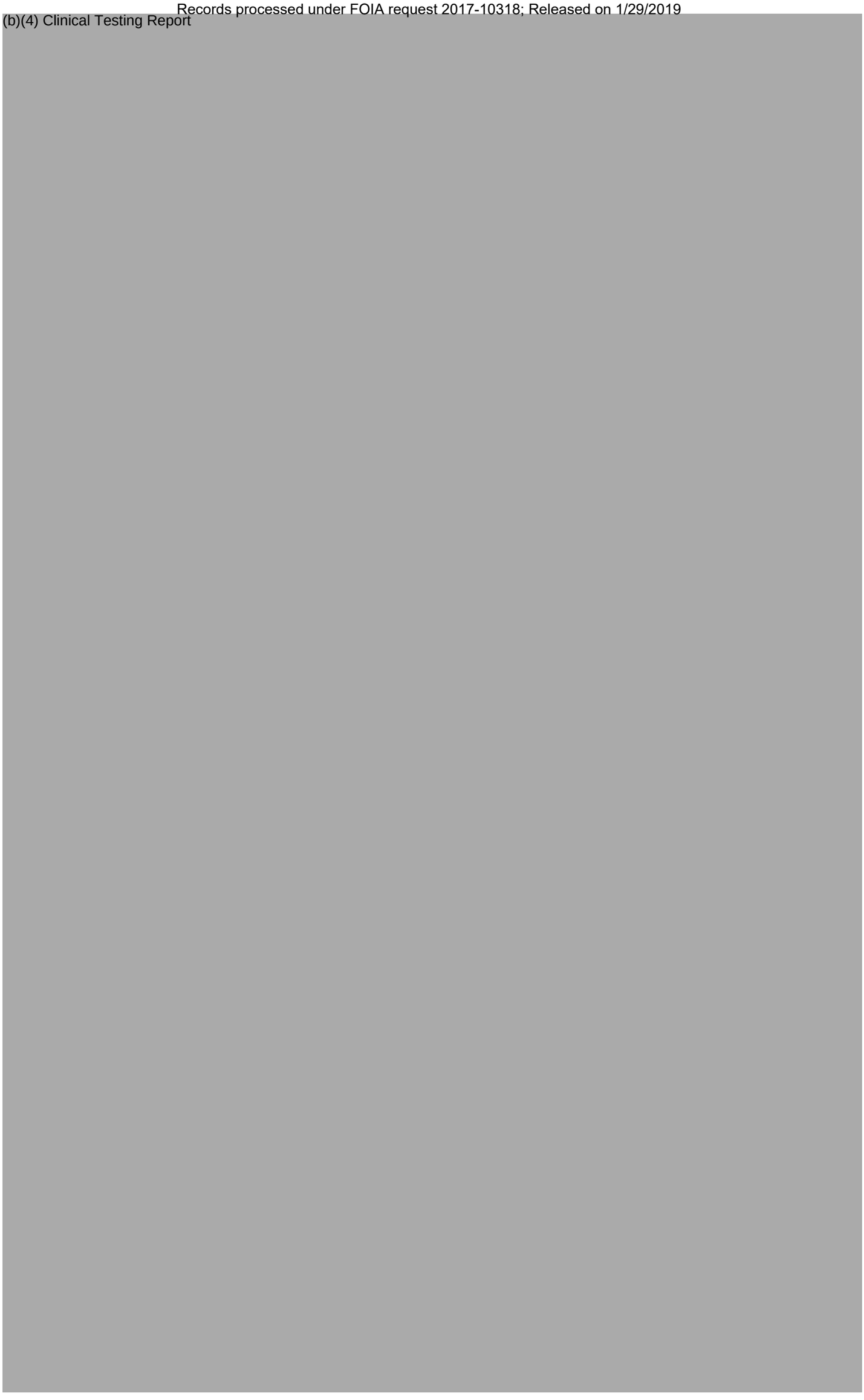

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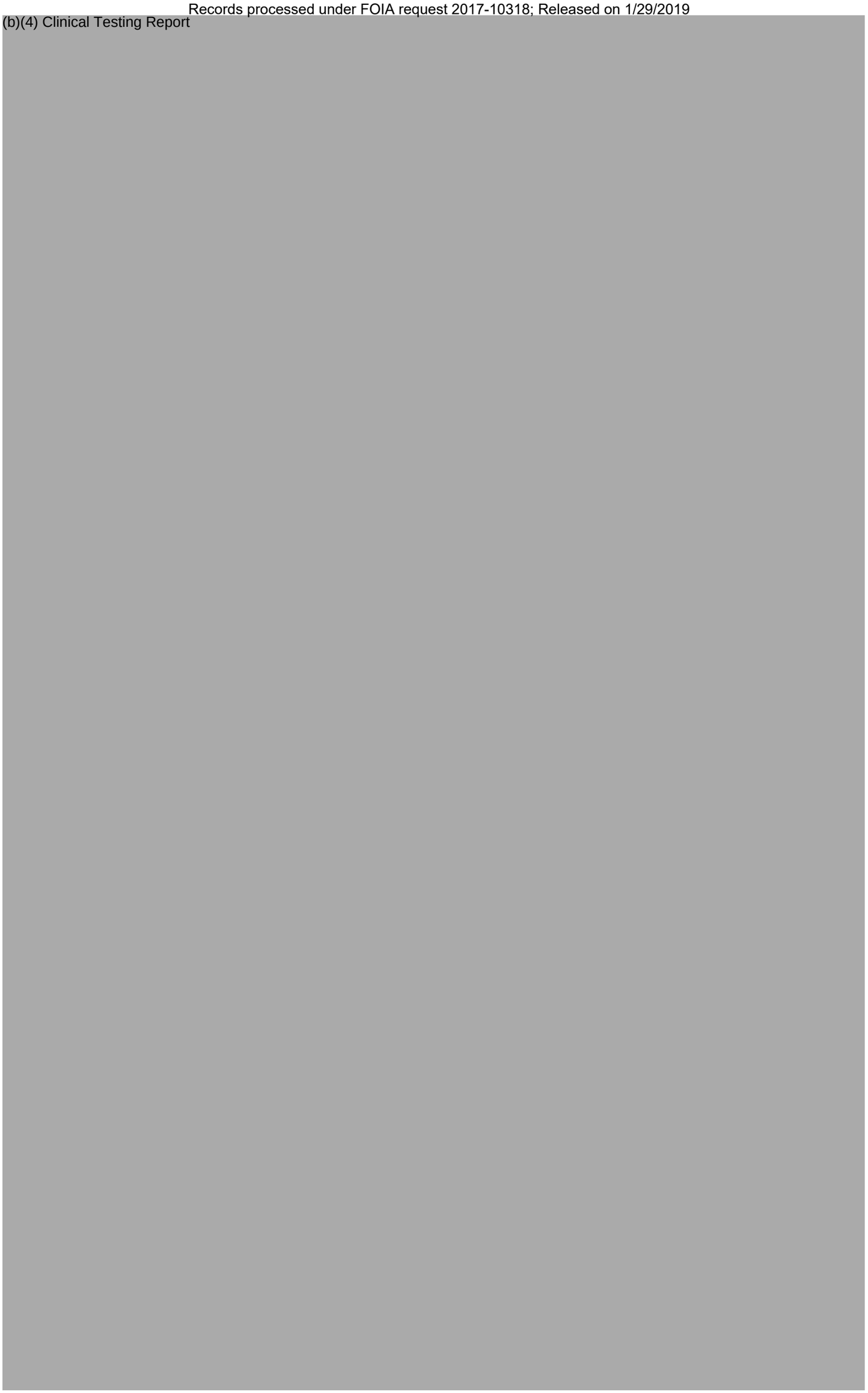

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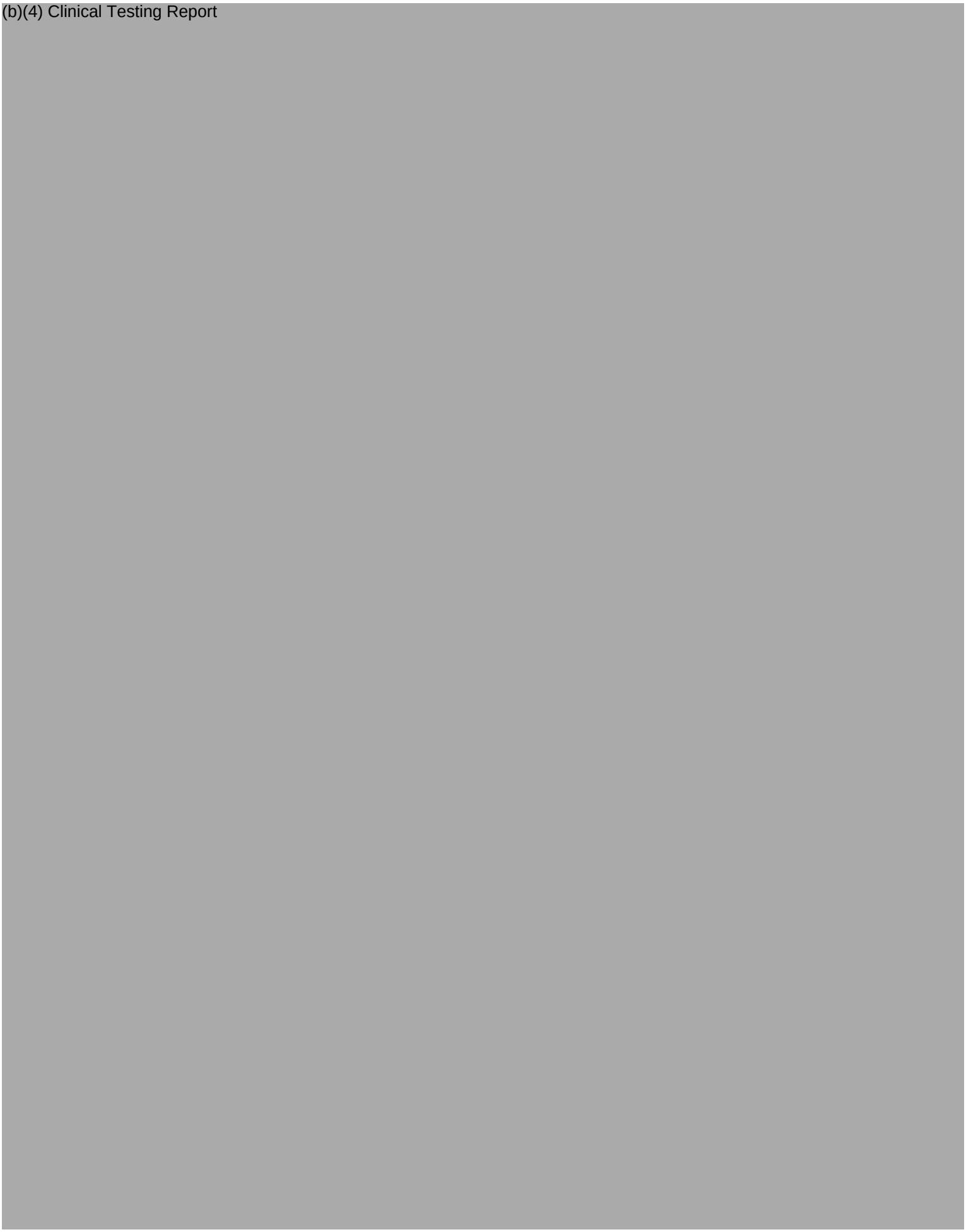

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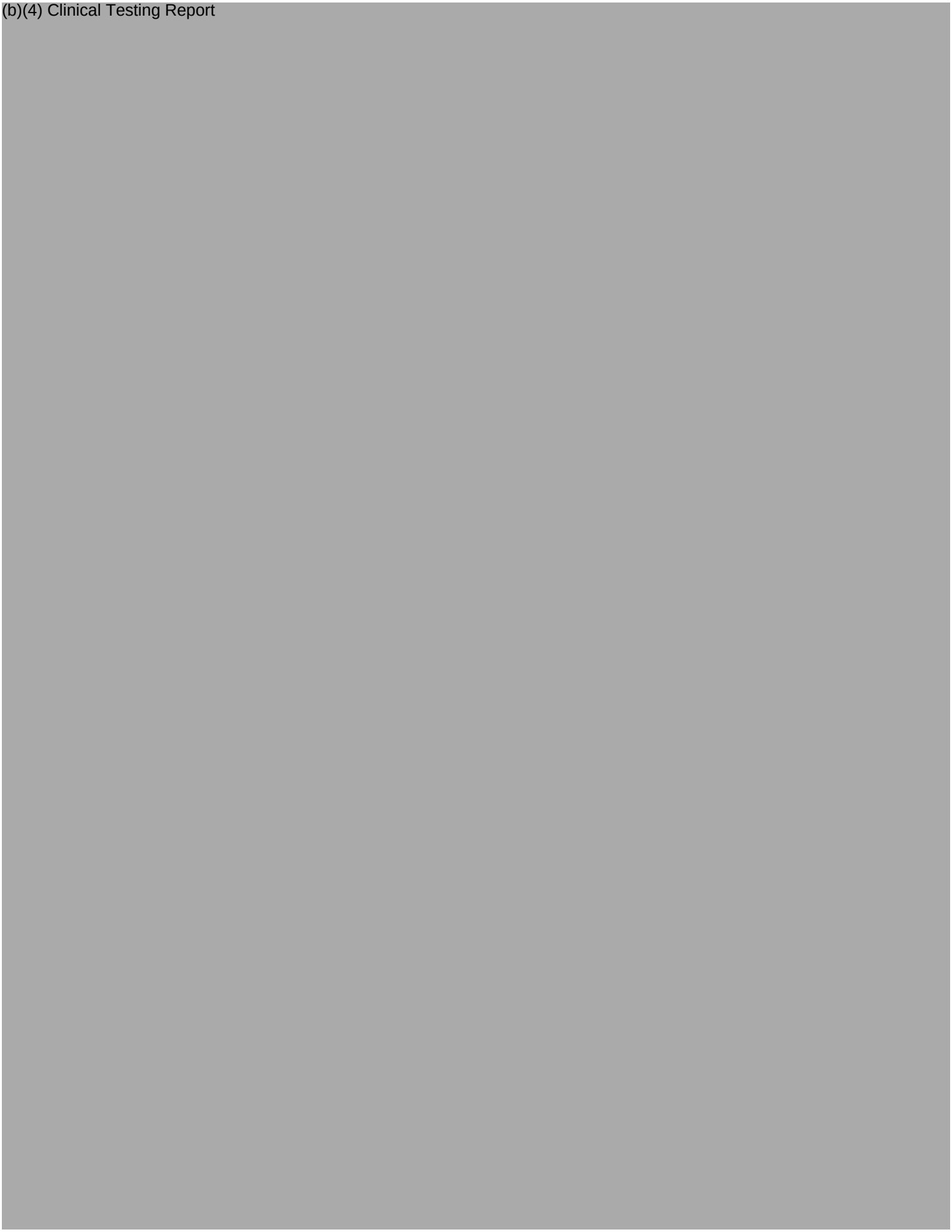

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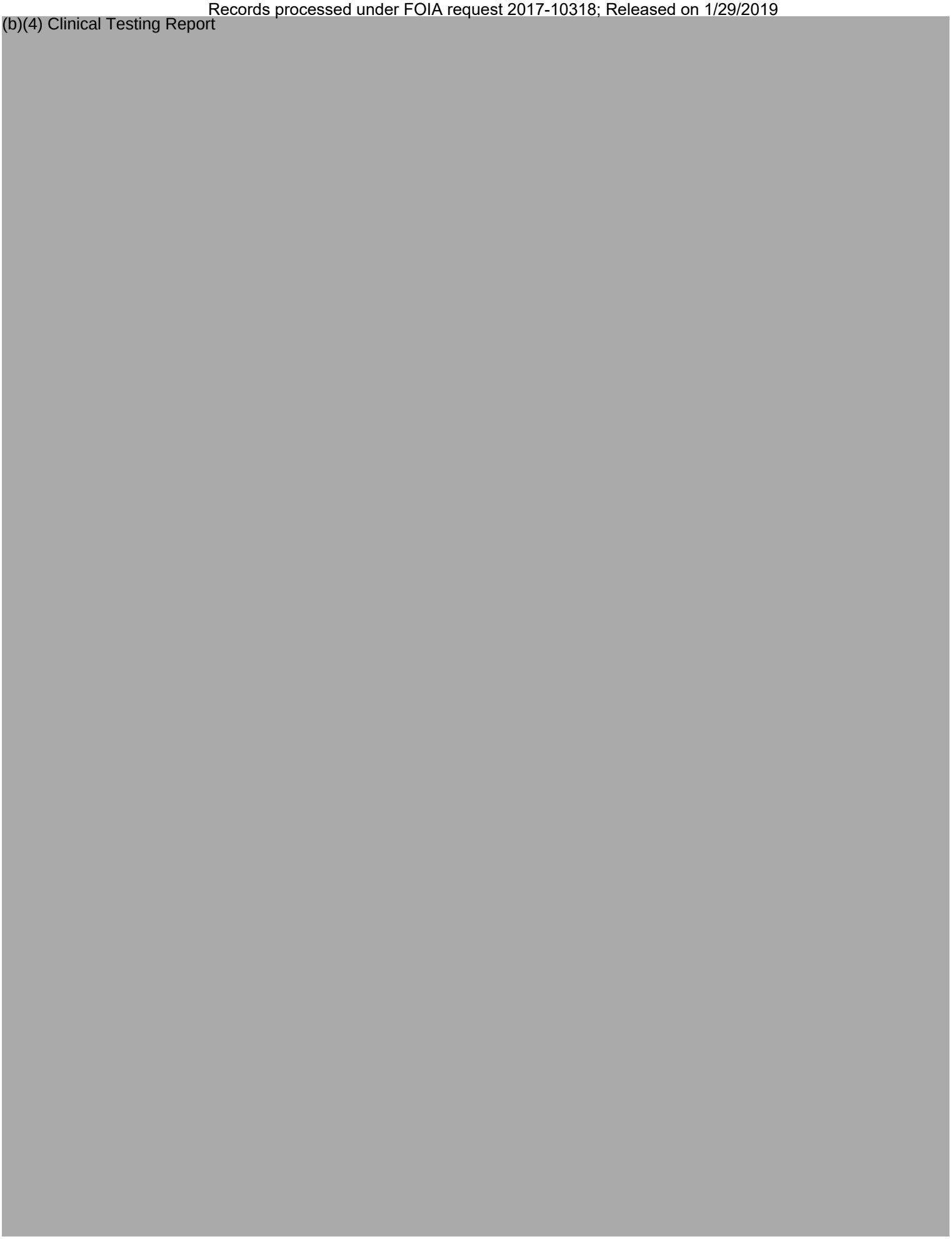

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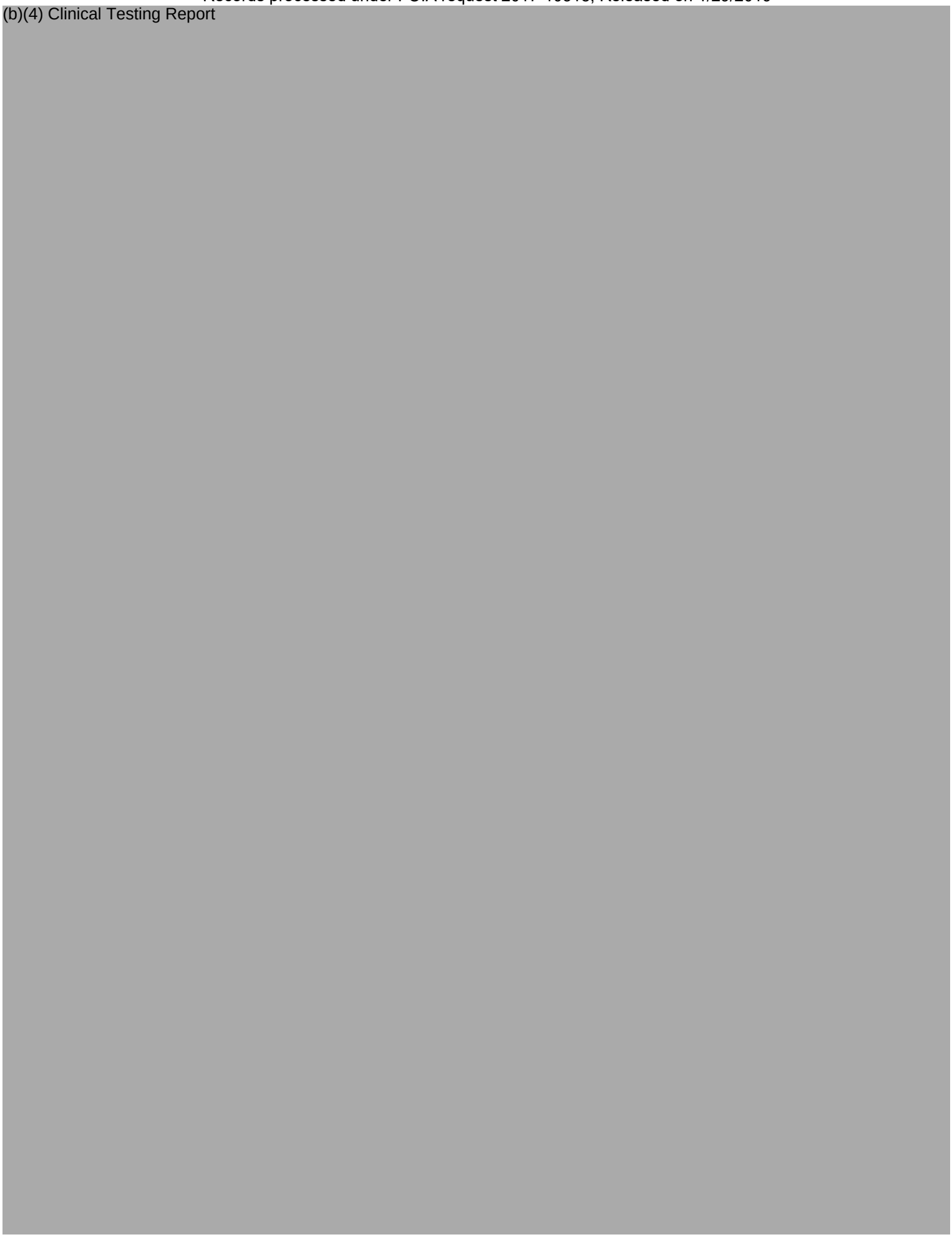

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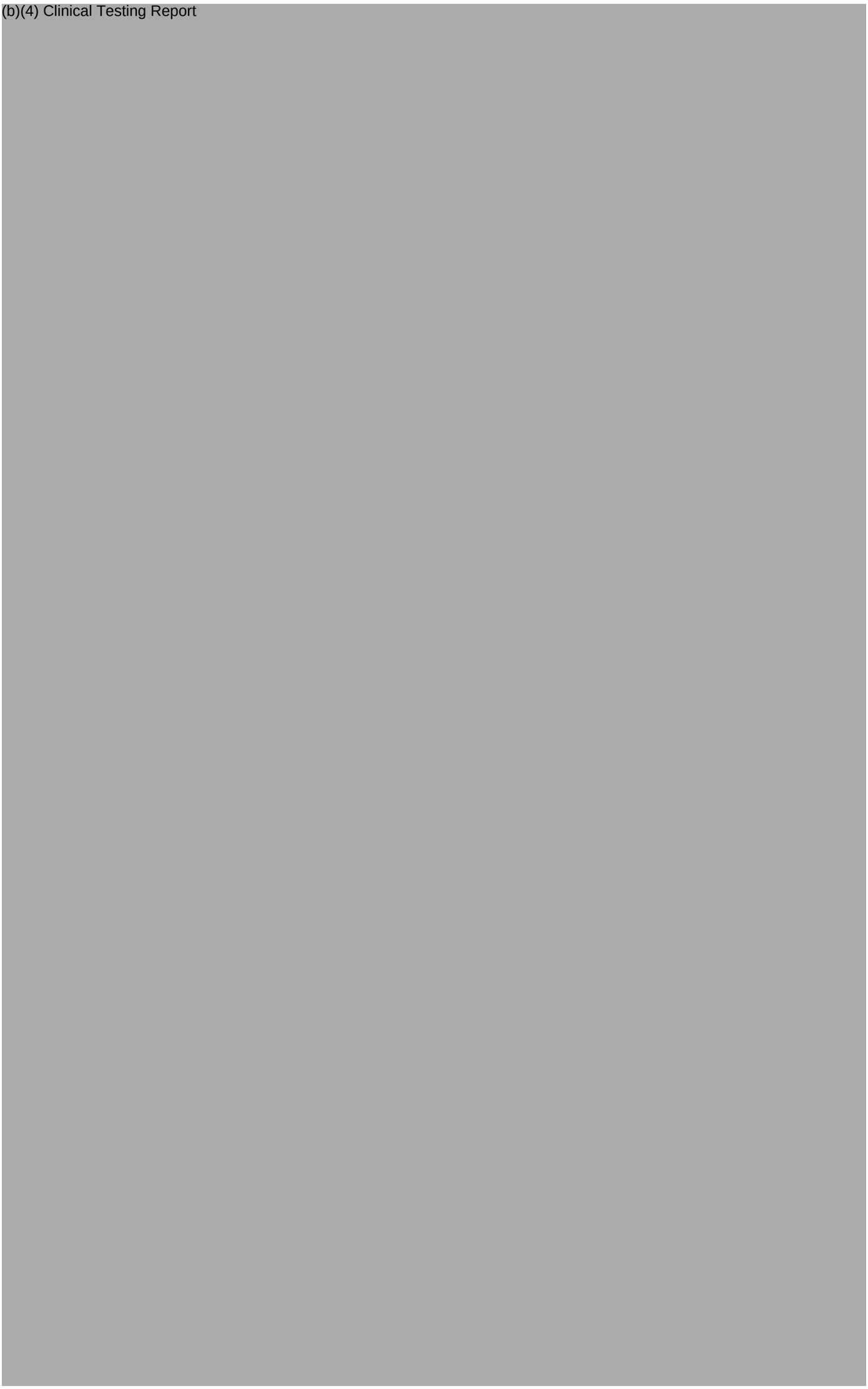

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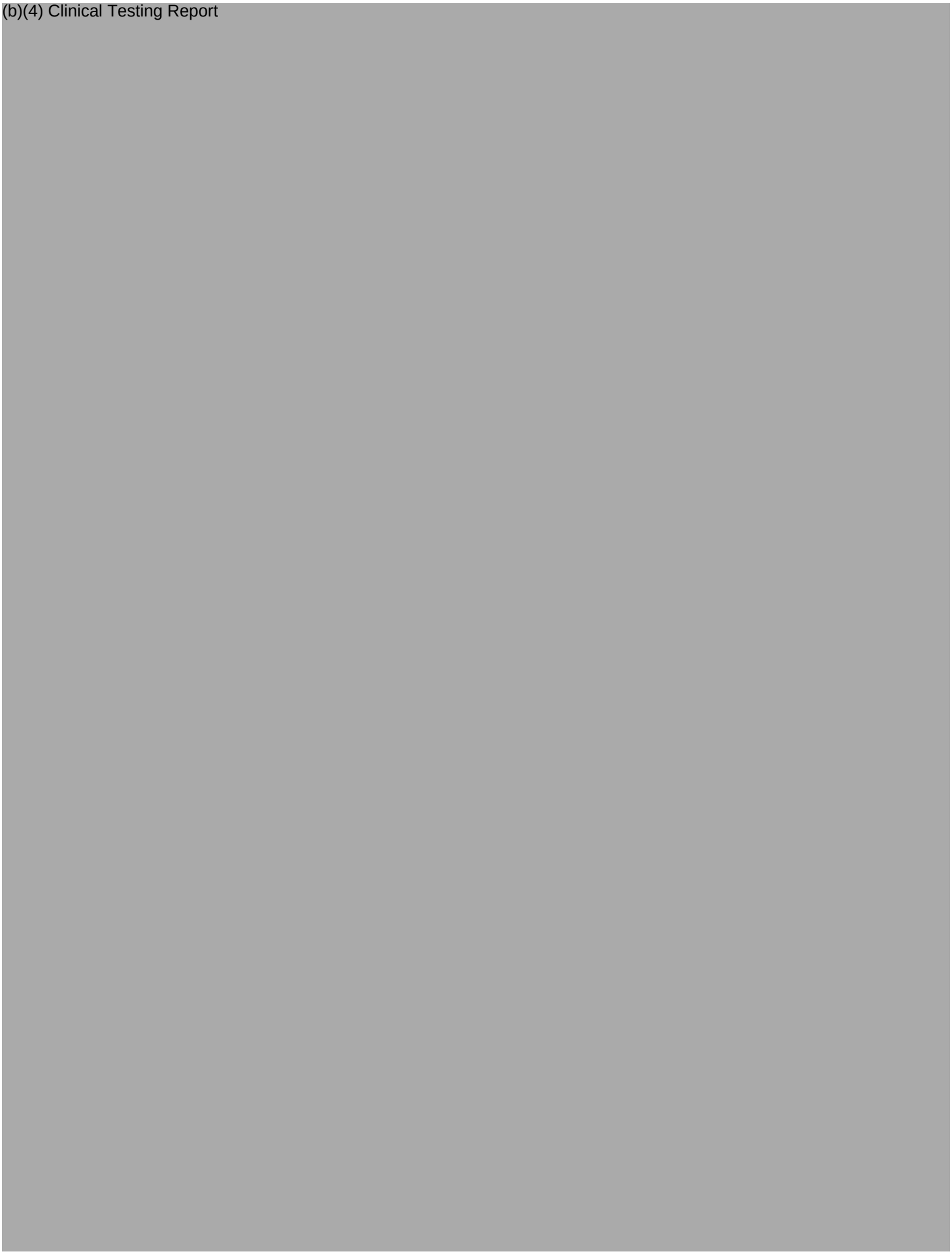

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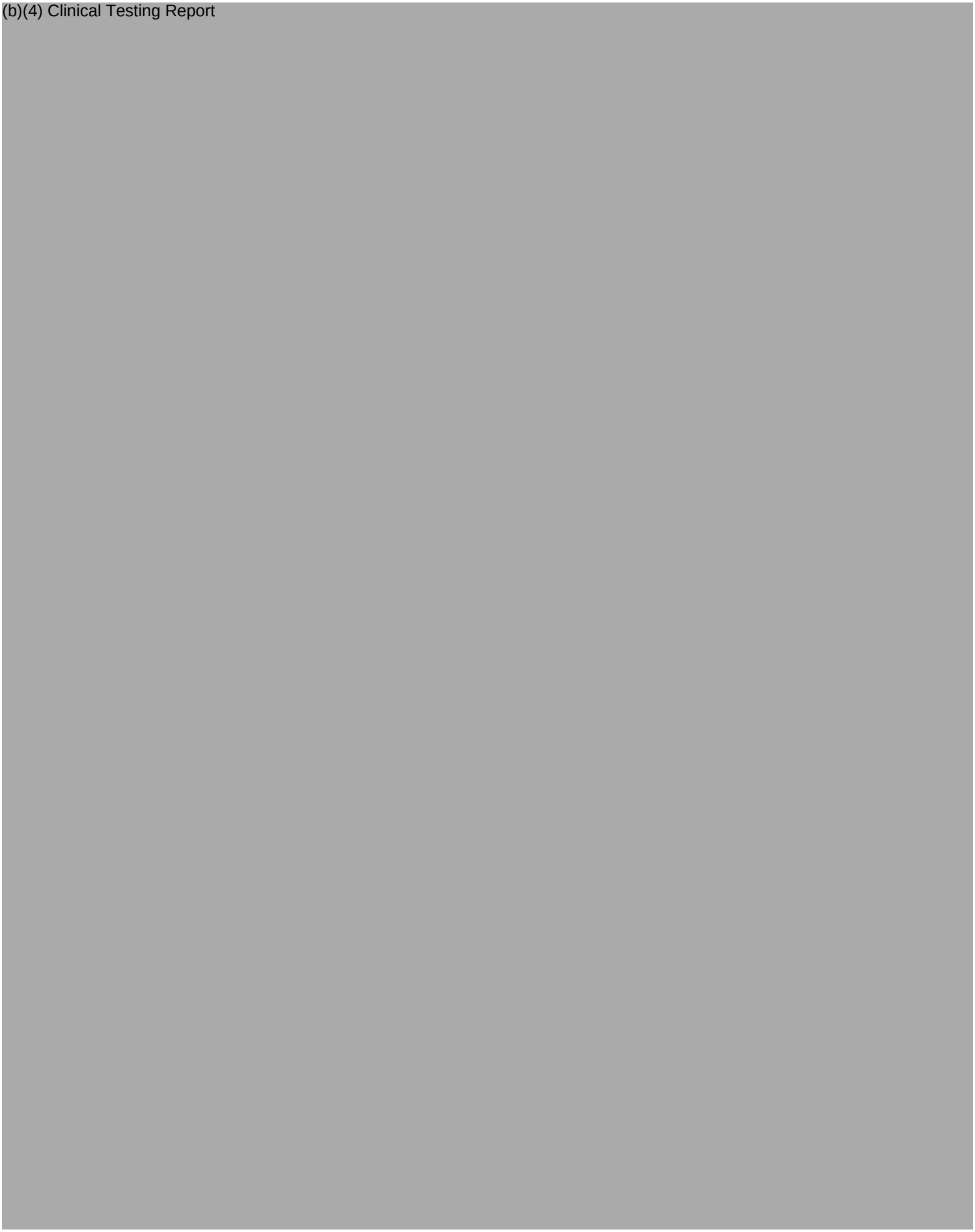

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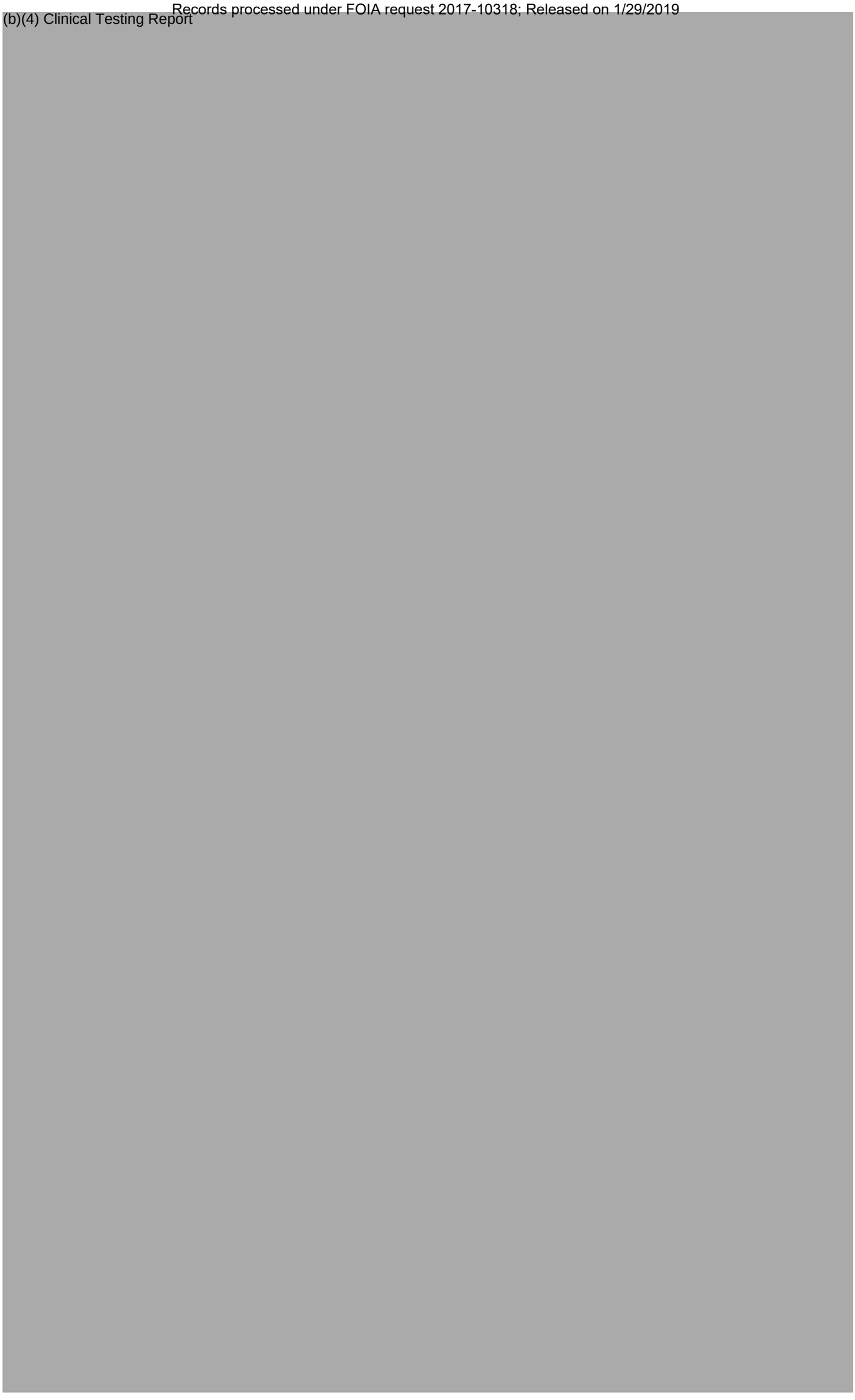

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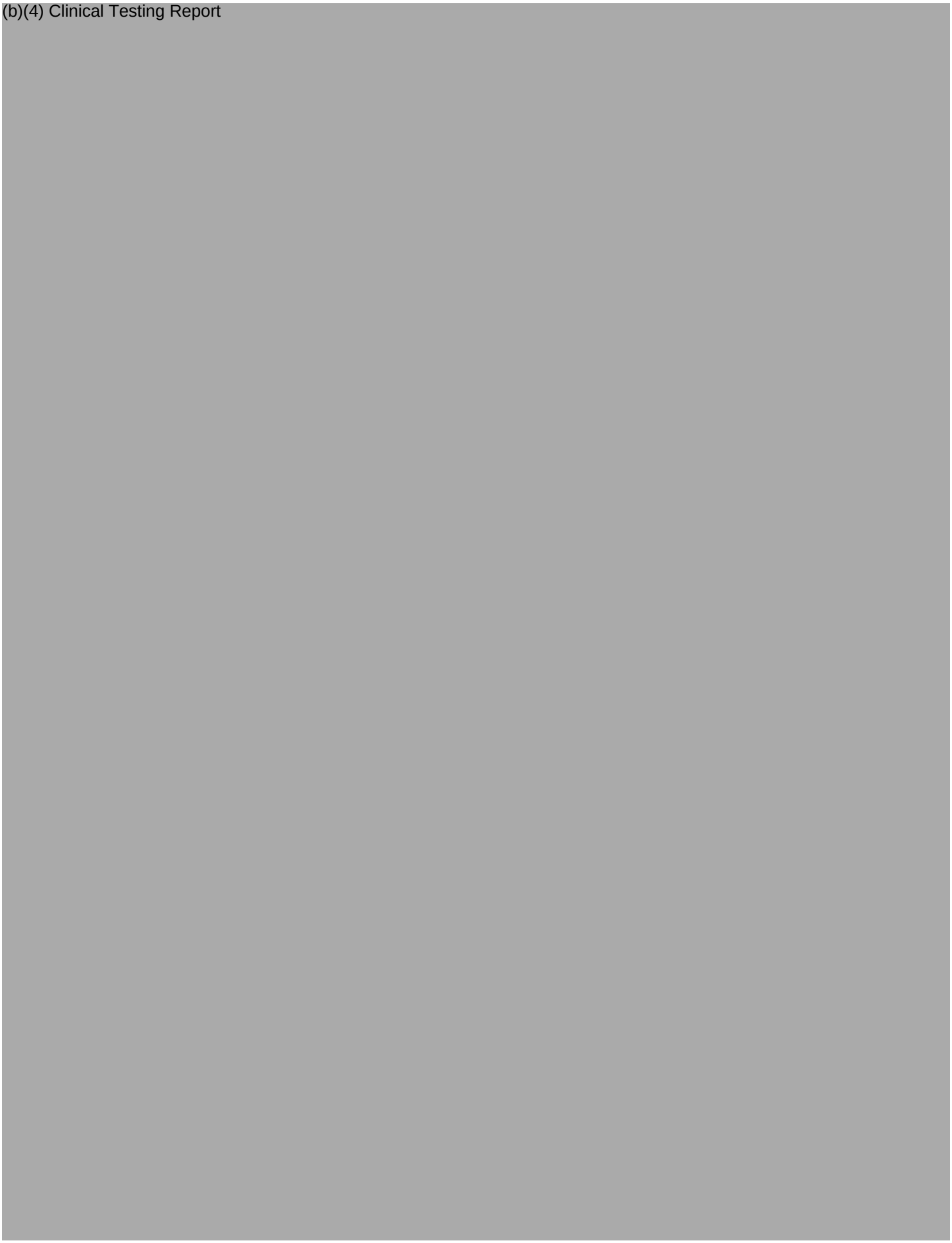

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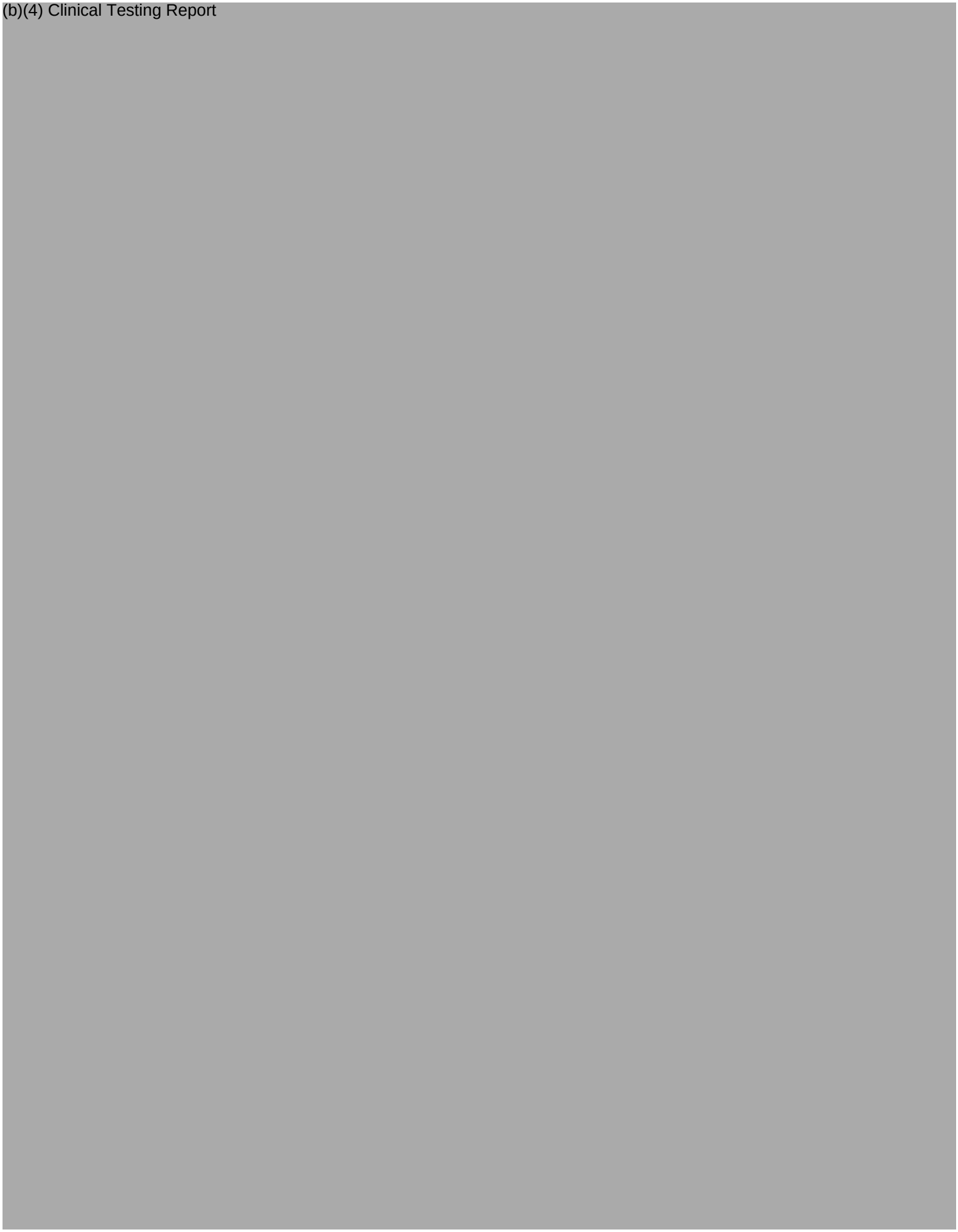

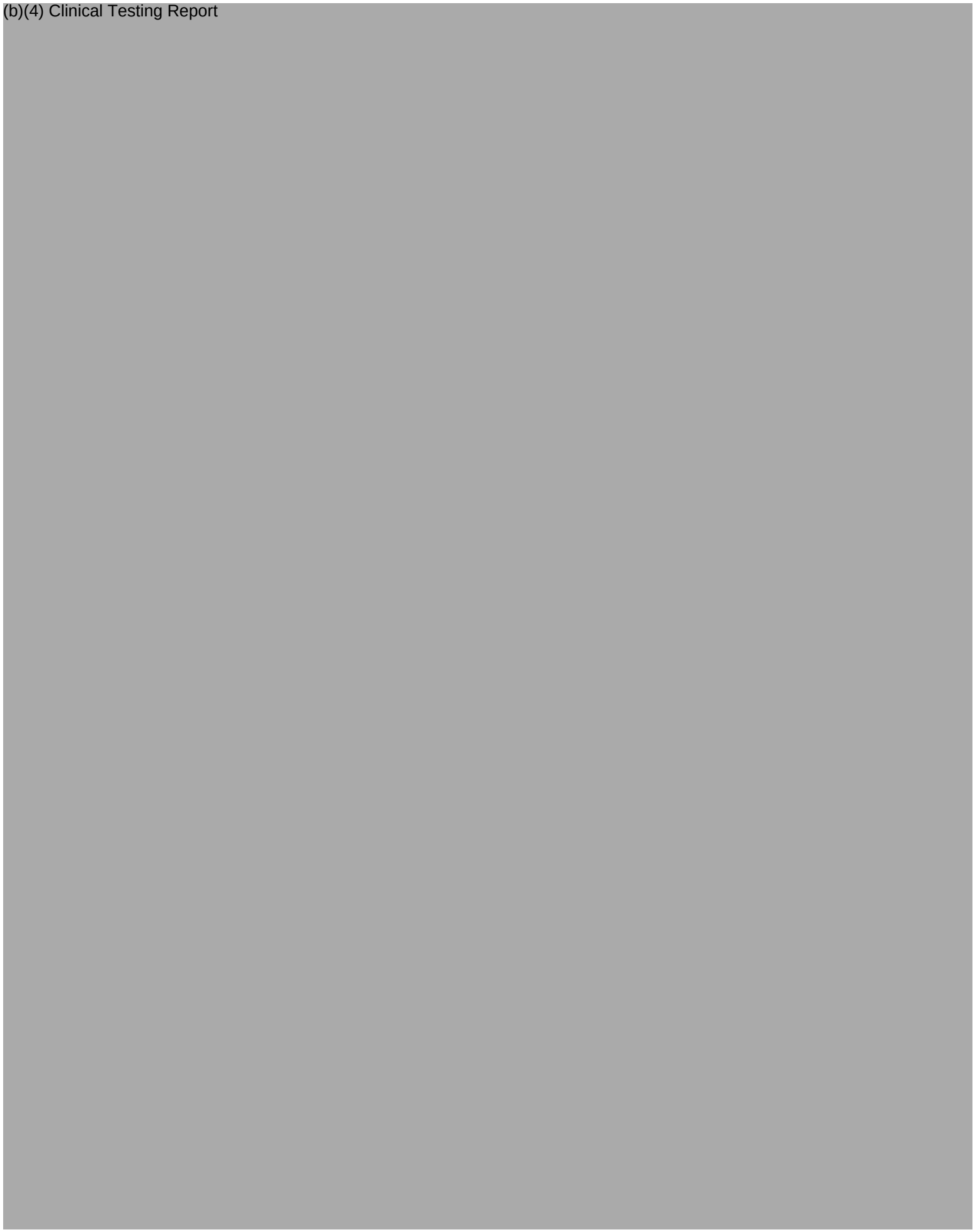

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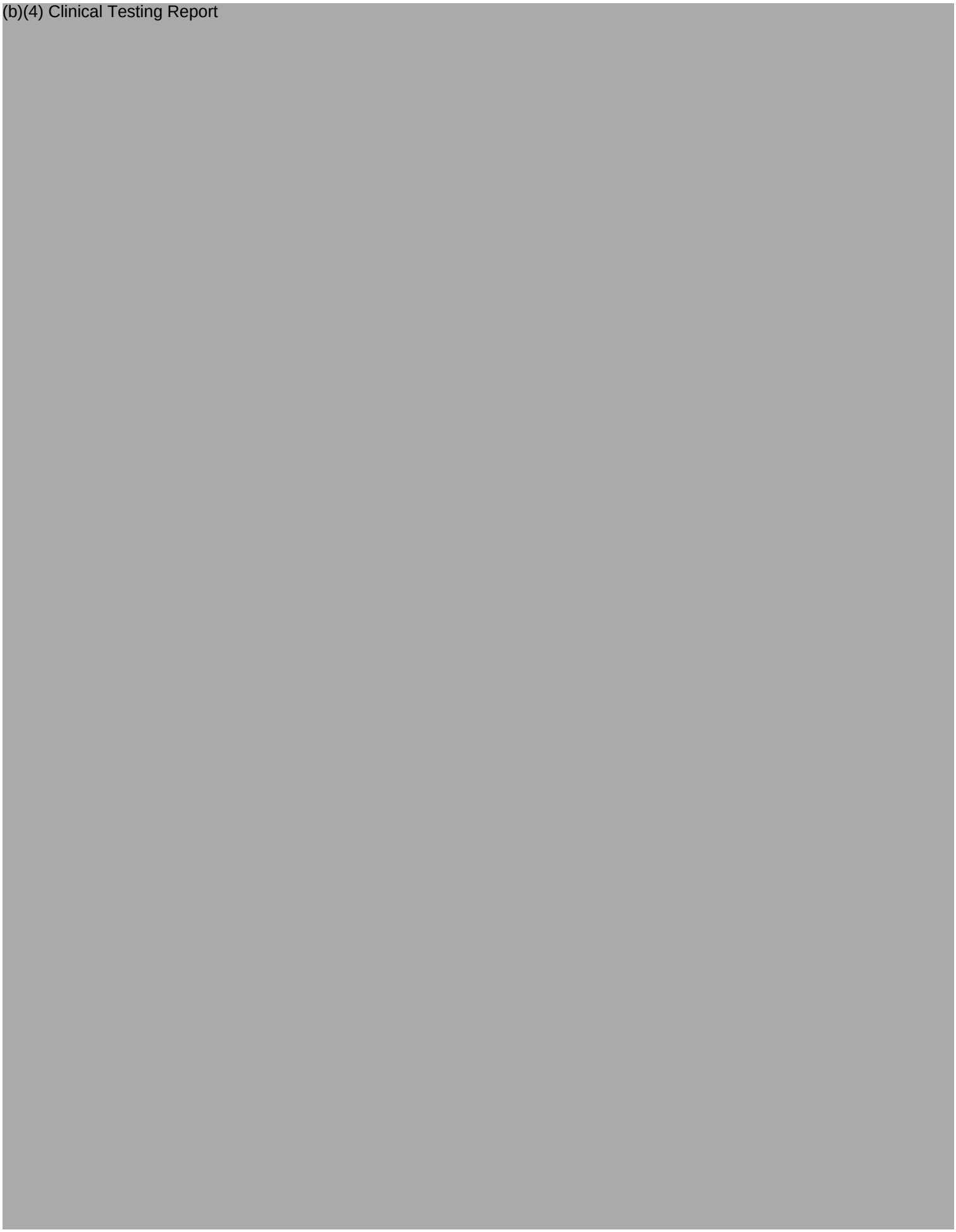

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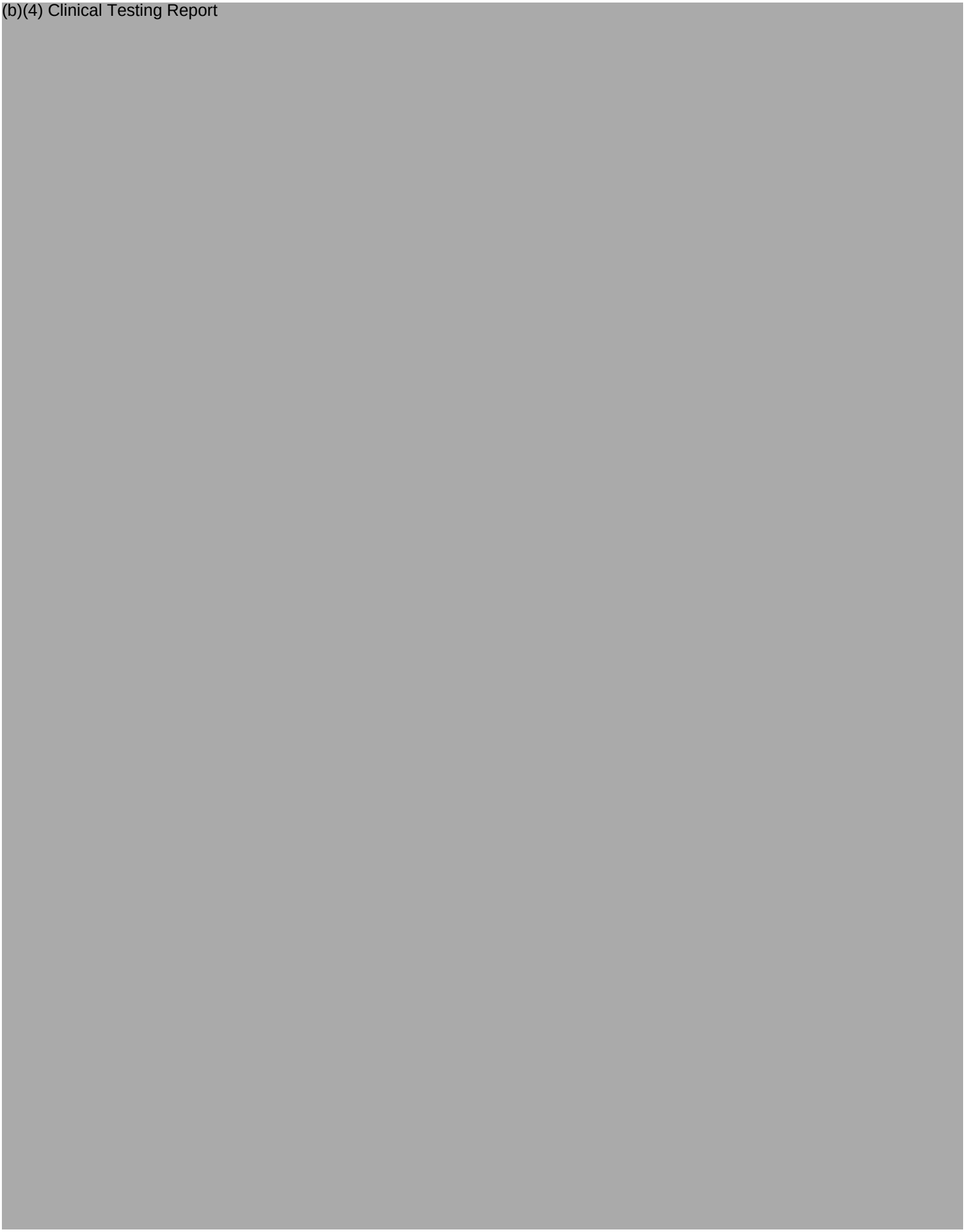

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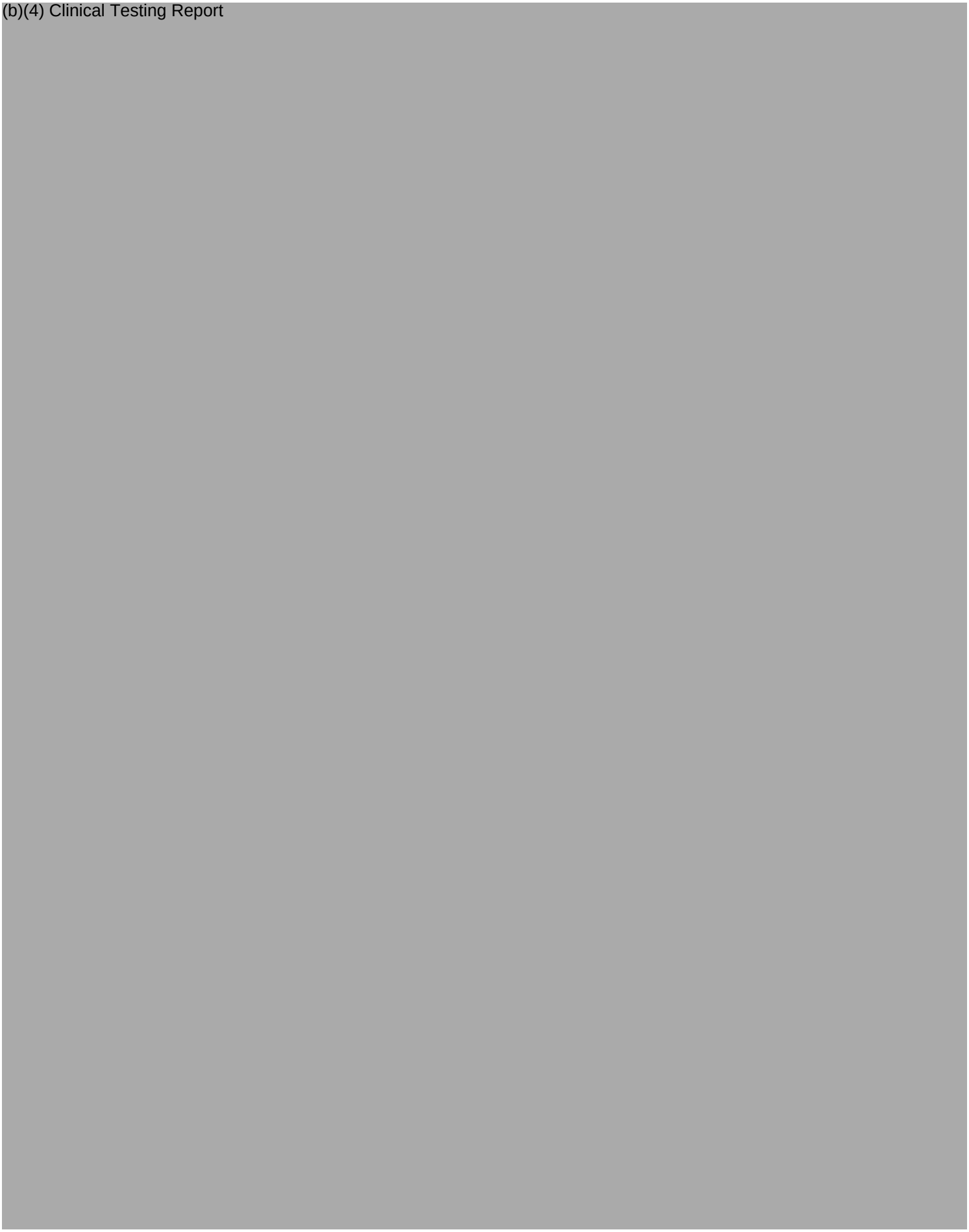

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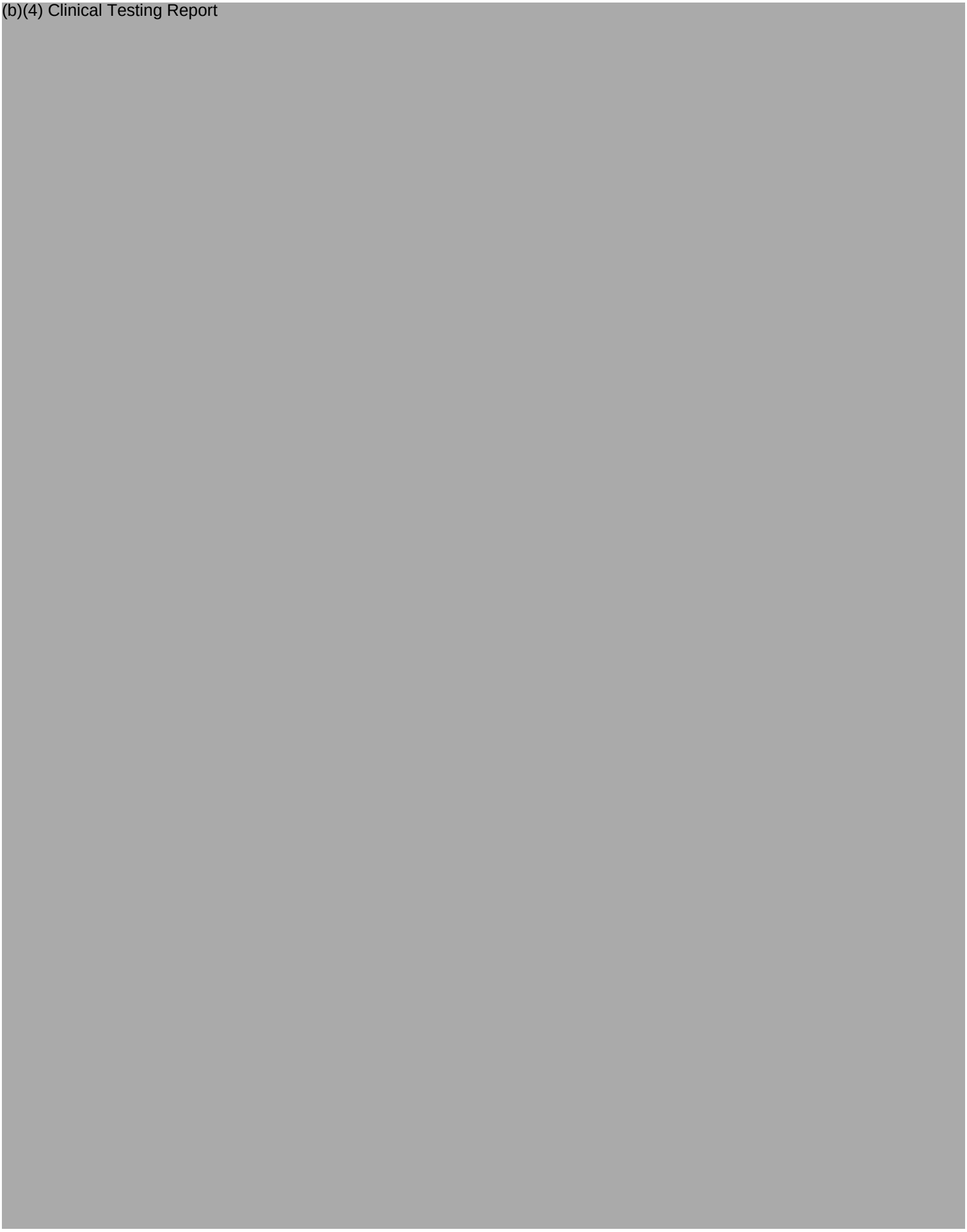

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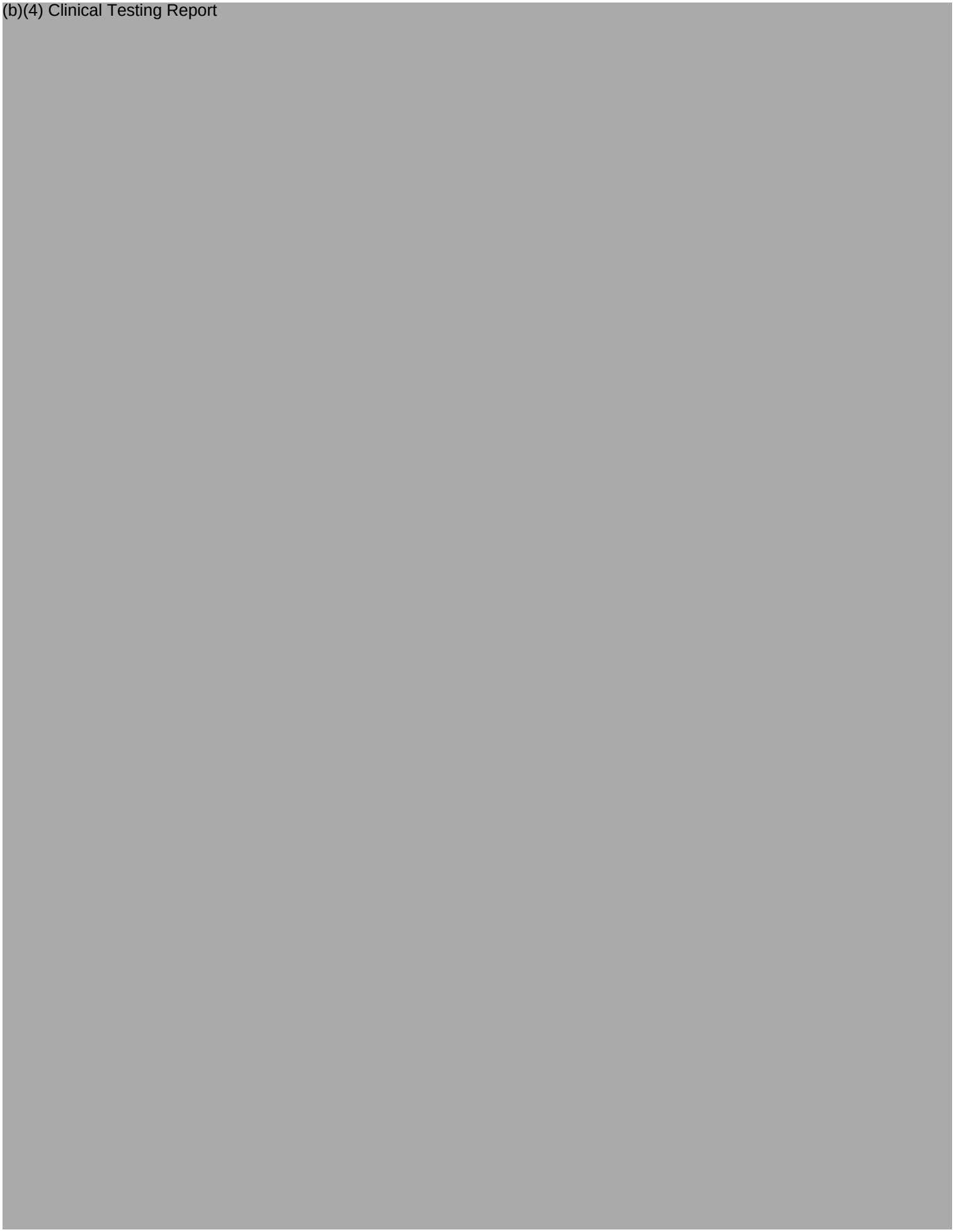

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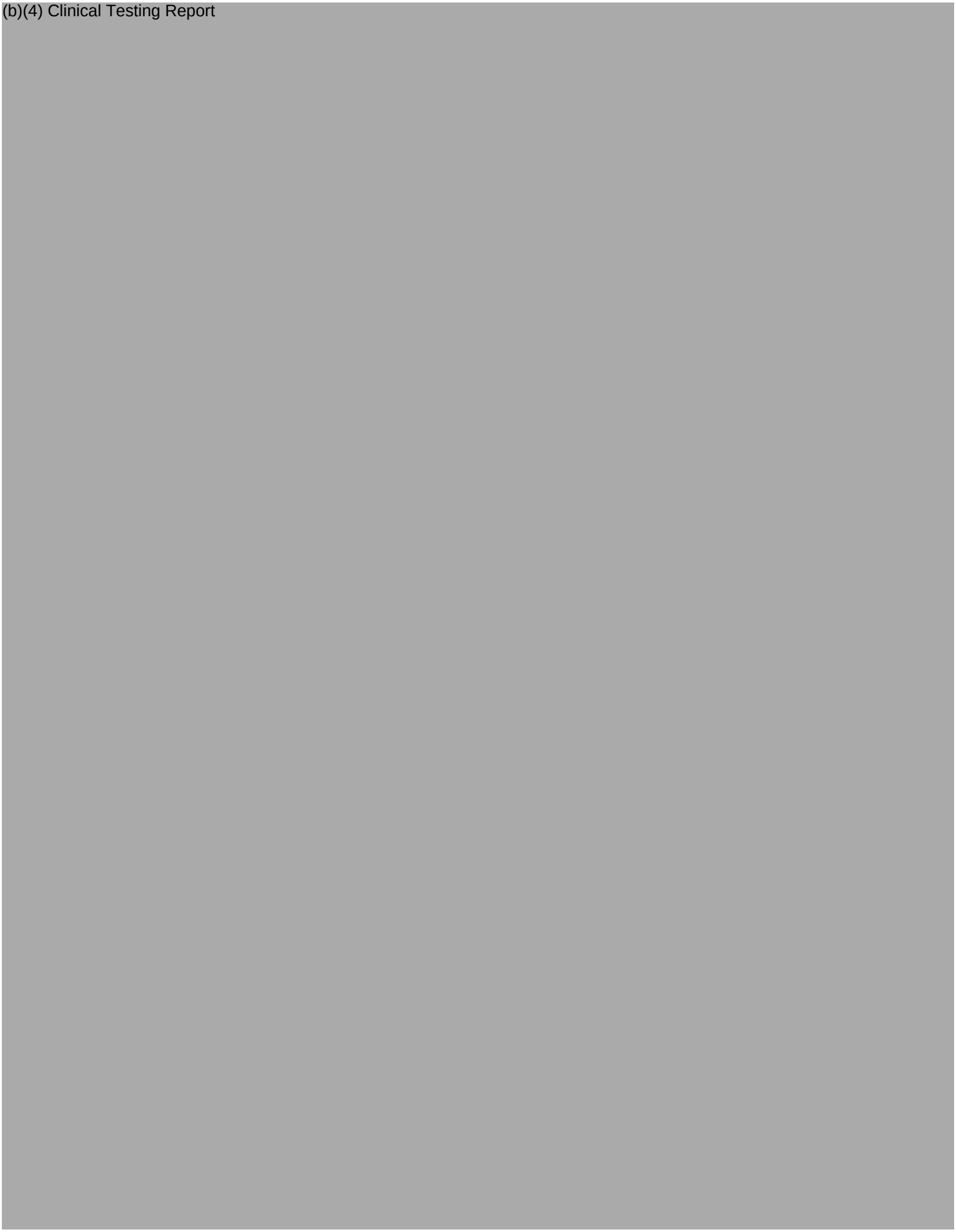

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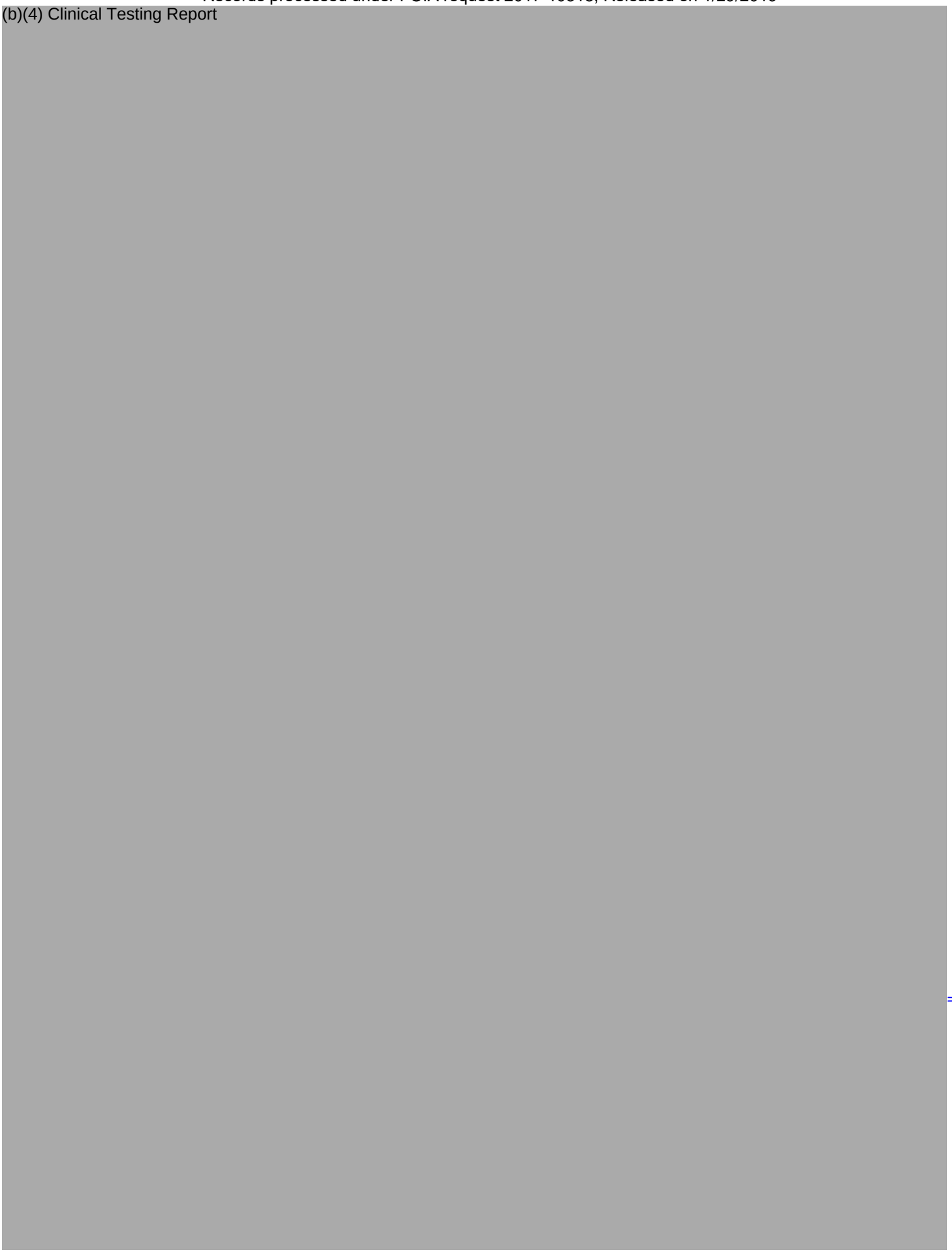

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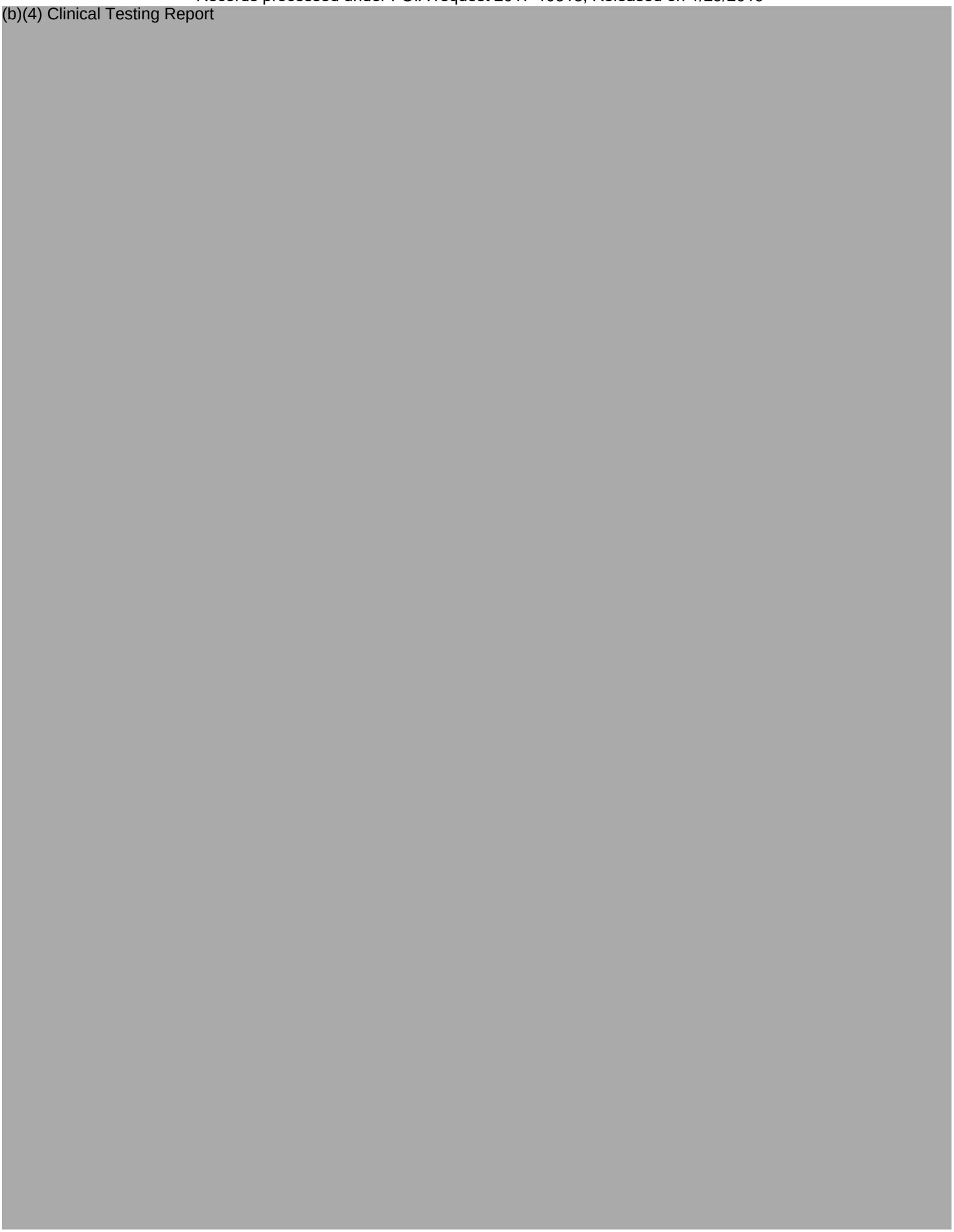

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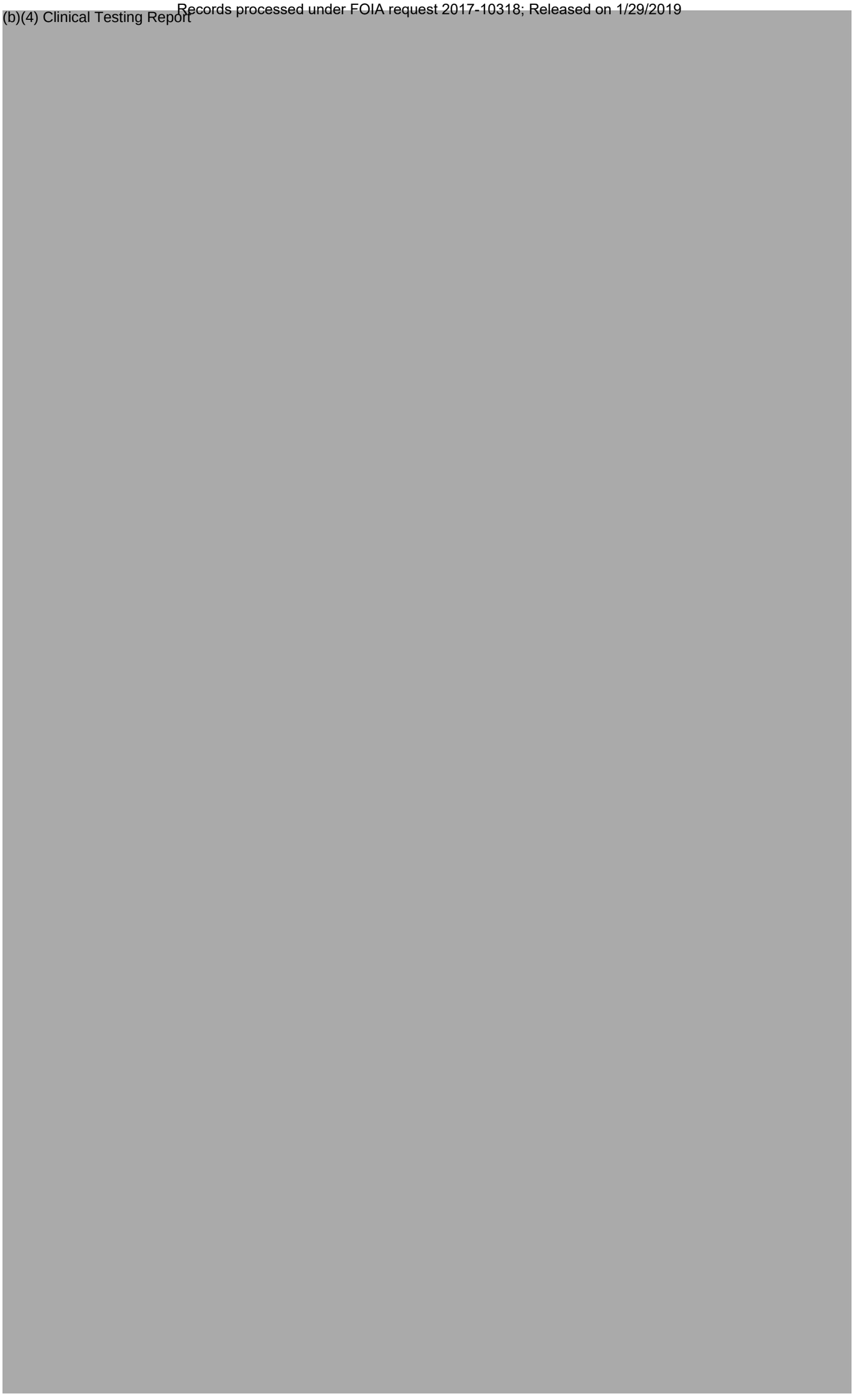

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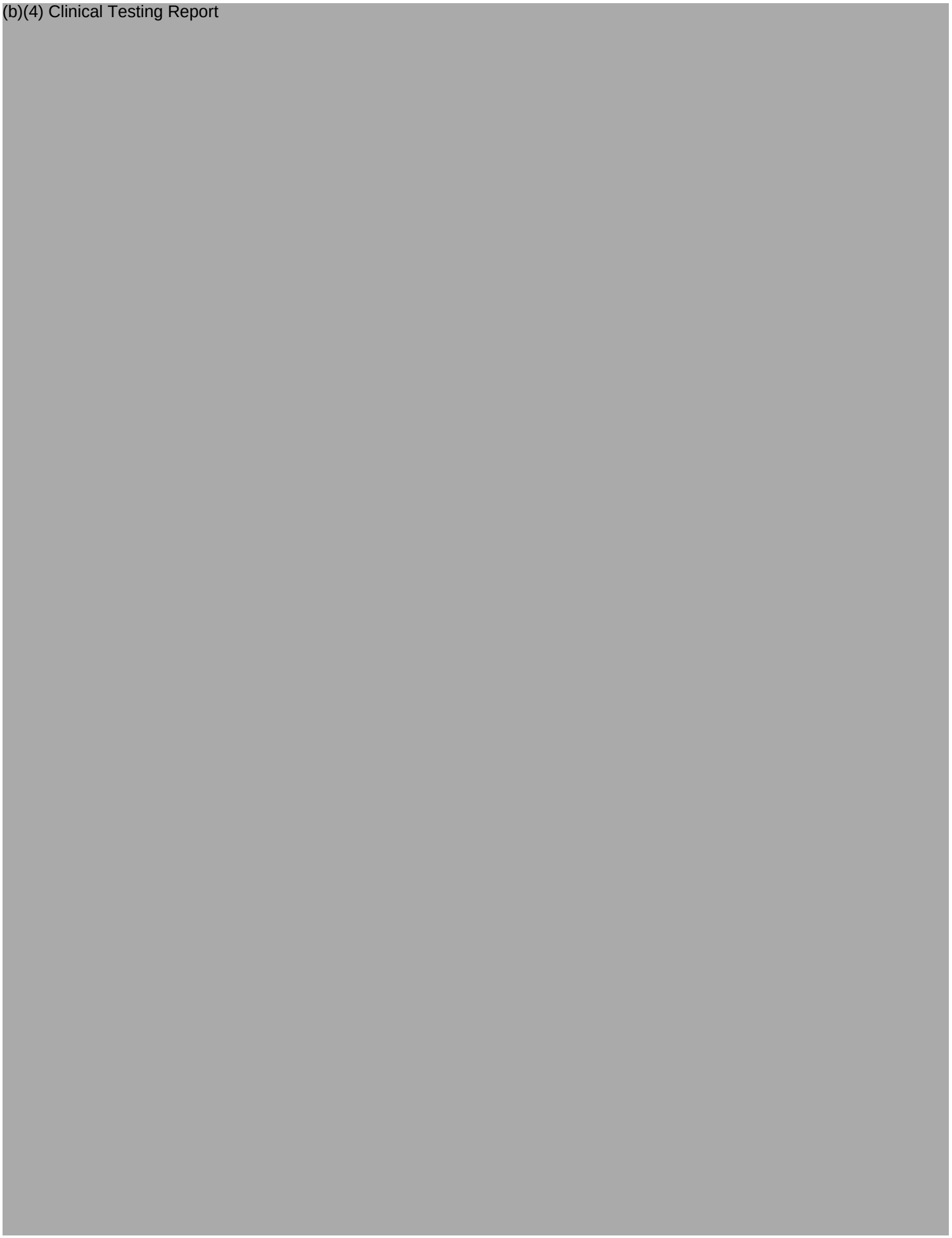

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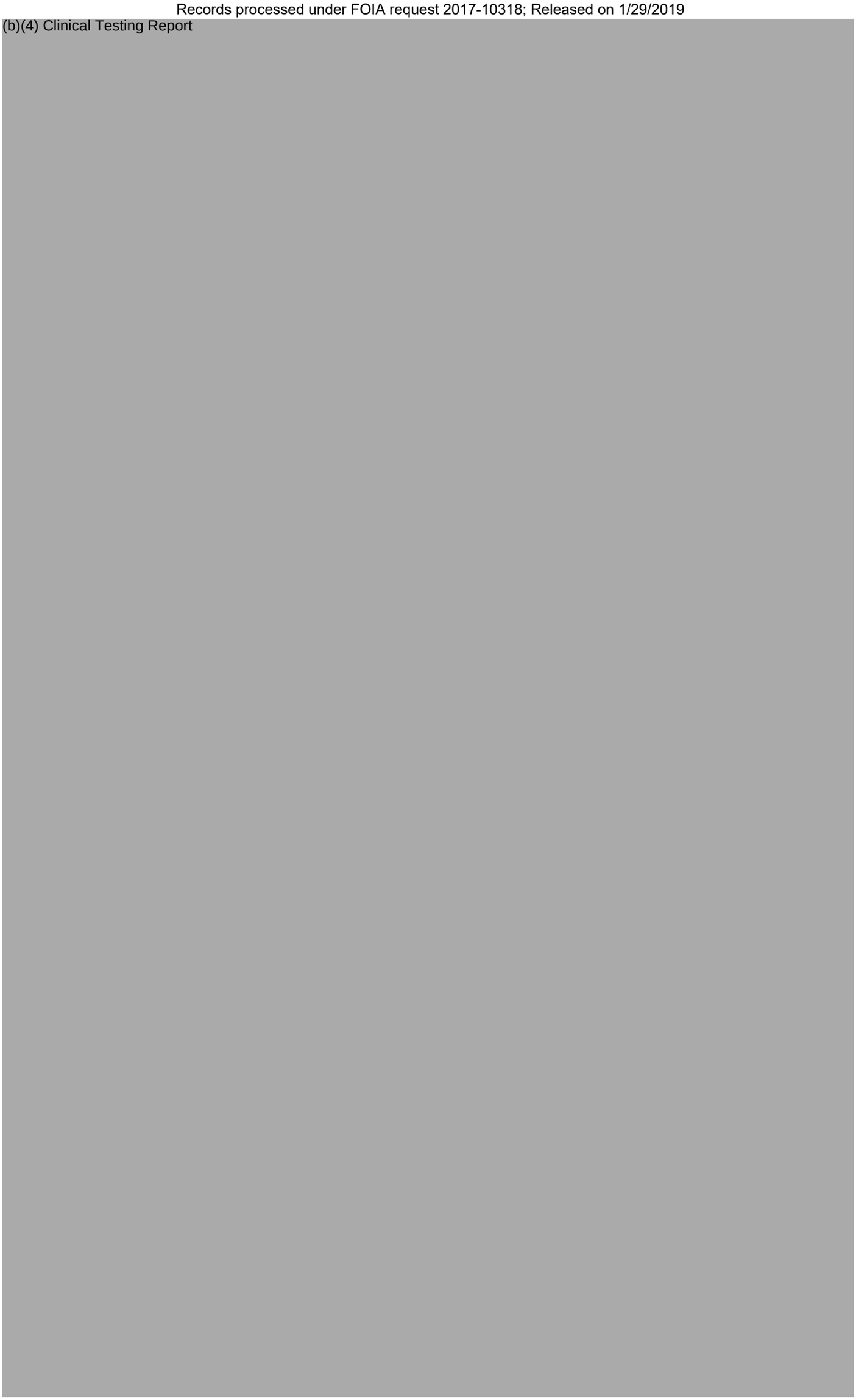

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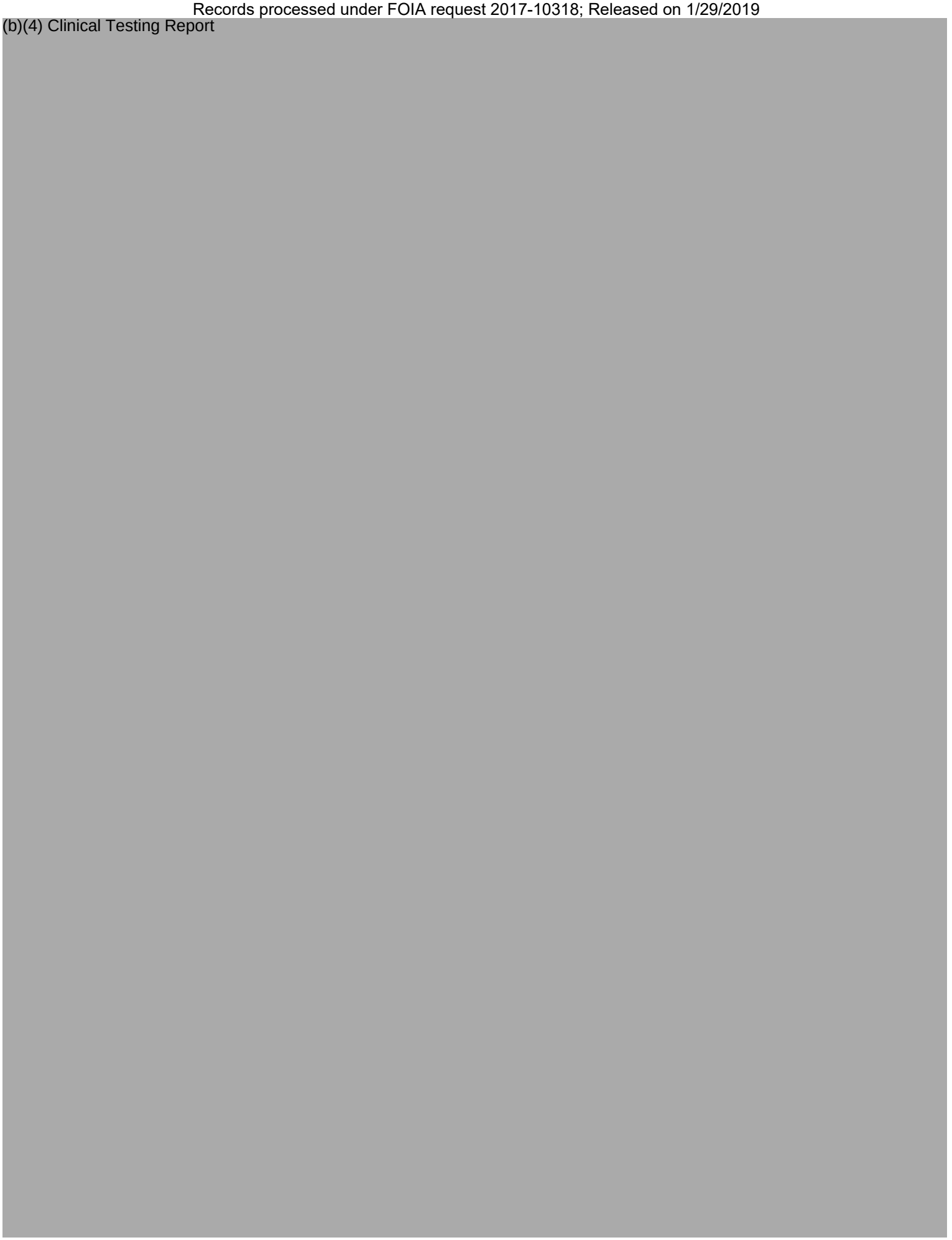

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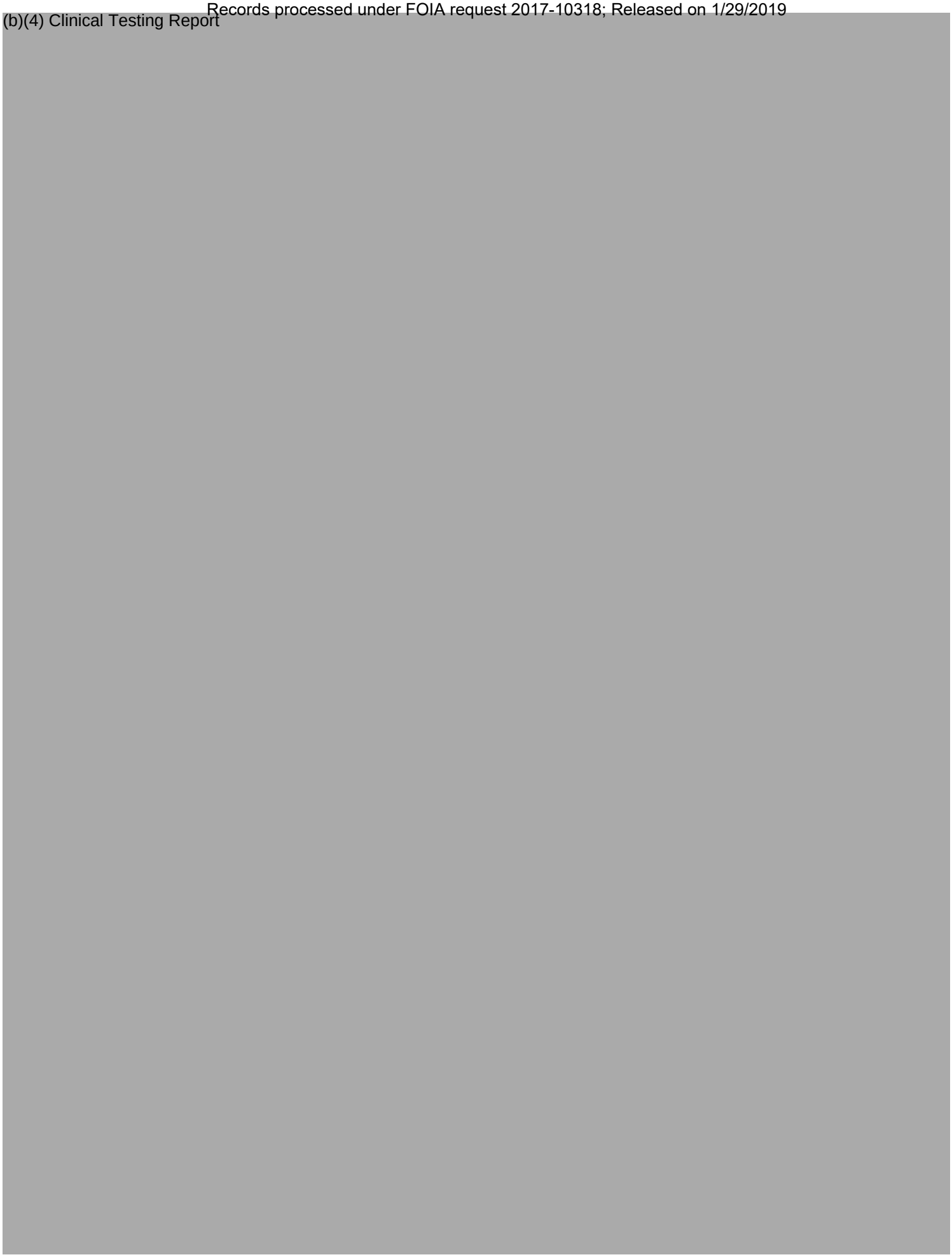
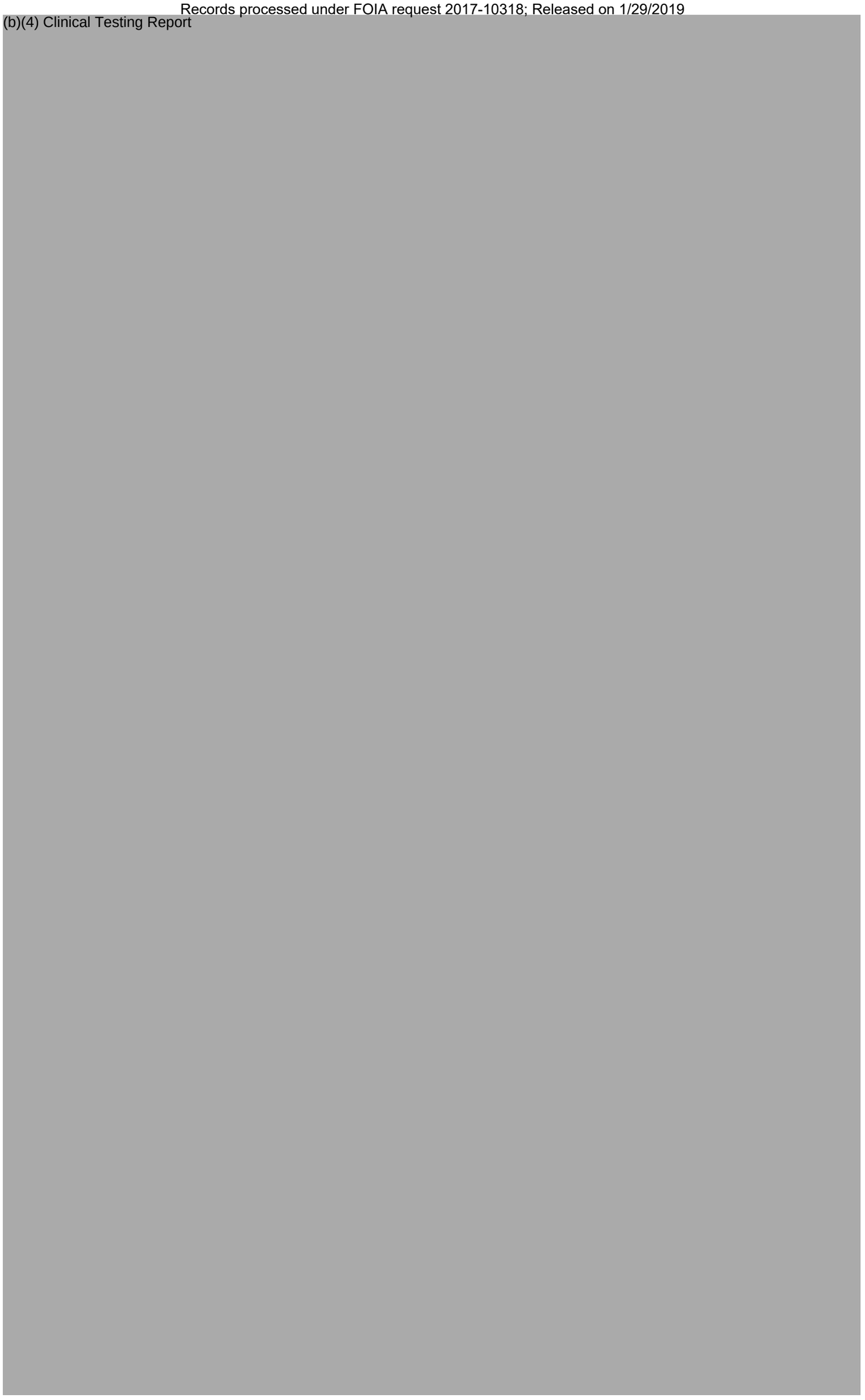
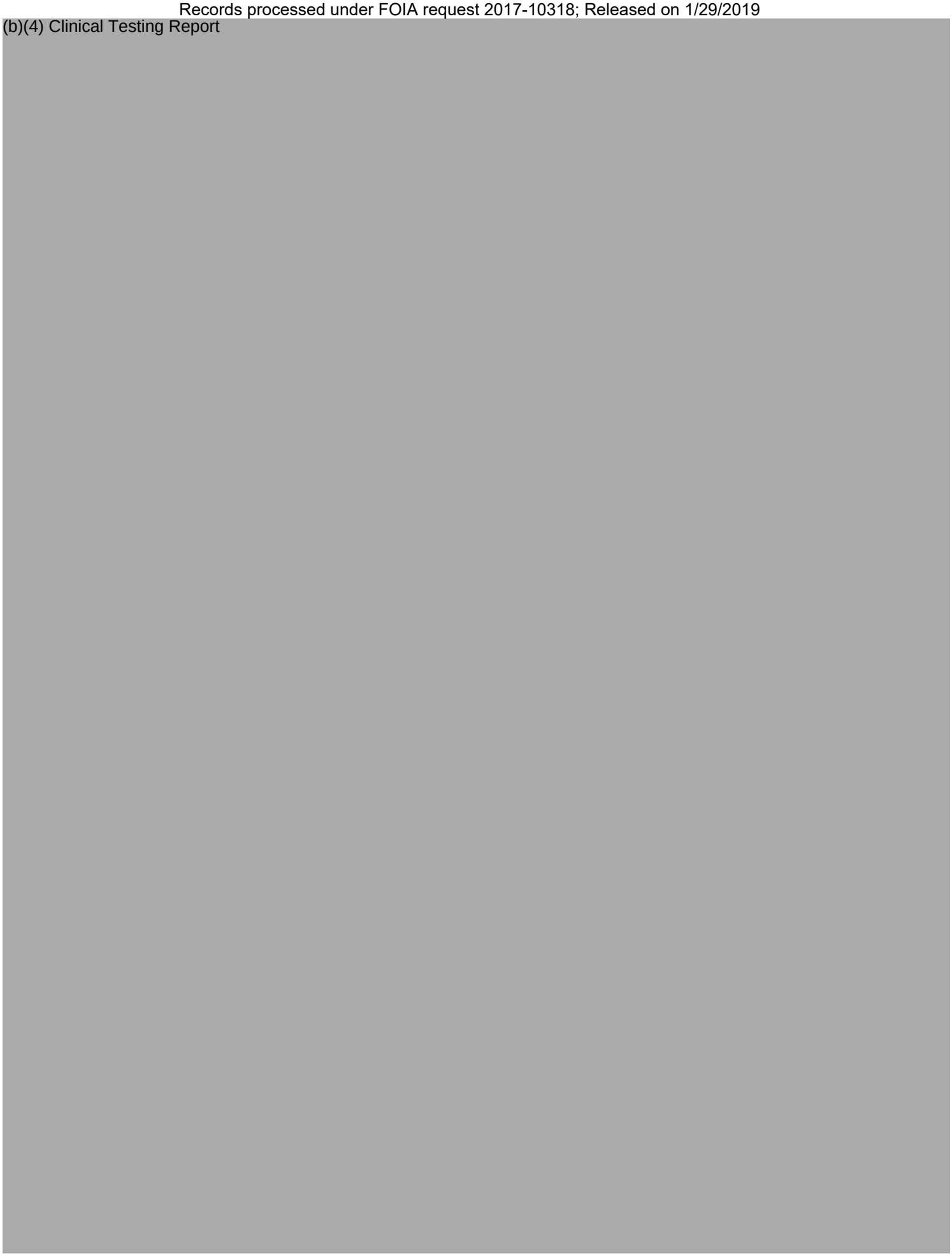


(b)(4) Clinical Testing Report



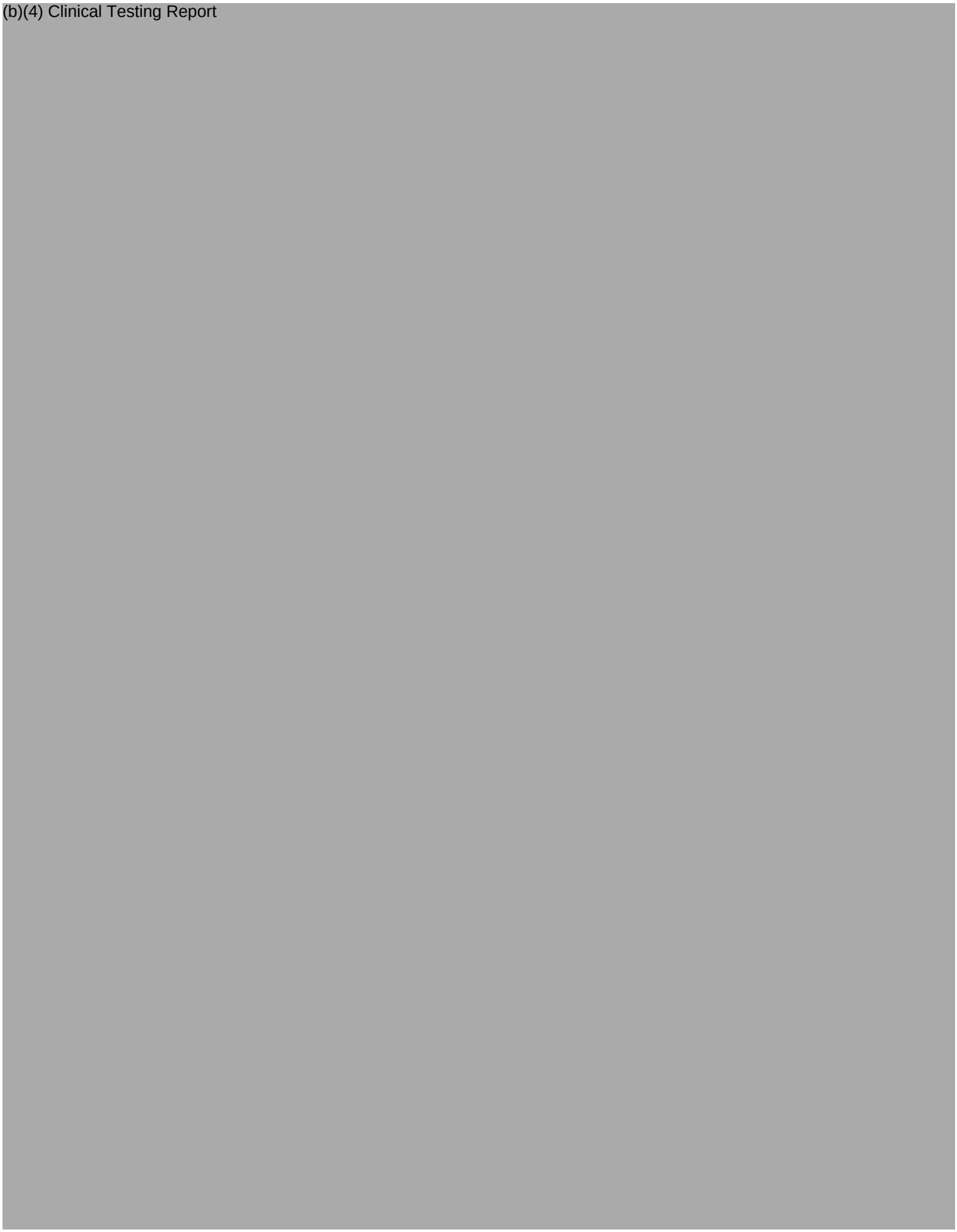
(b)(4) Clinical Testing Report

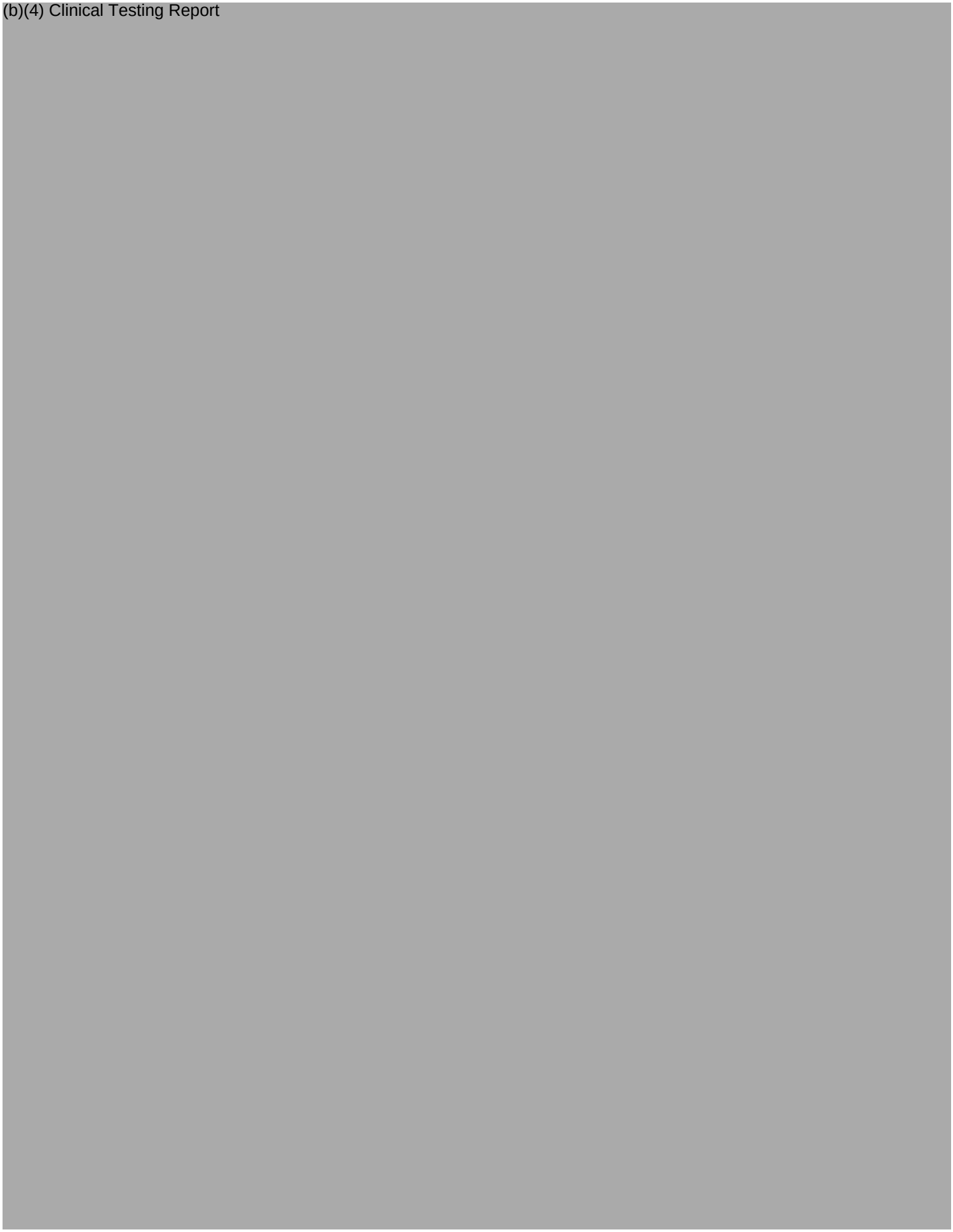


(b)(4) Clinical Testing Report

(b)(4) Clinical Testing Report

(b)(4) Clinical Testing Report





(b)(4) Clinical Testing Report

APPENDIX 11
STANDARDS DATA REPORT FORMS

Provided in this appendix are the Standards Data Report Forms (FDA Form 3654) for the following standards:

- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (2012)
- IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances (2014)
- IEC 60601-2-47, Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems. (Cardiovascular) (2012)
- ISO 10993-1, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process (2009) (CORR:2010)
- ISO 14971, Medical Devices - Applications Of Risk Management To Medical Devices (2012)
- ISO 15223-1, Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements (2012)
- IEC 62304, Medical Device Software - Software Life Cycle Processes (2006)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (2012)

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 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: _____		

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 and 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 for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (2012)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	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

* 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]

IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances (2014)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#19-8	
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: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances (2014)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	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		

* 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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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-47, Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems. (Cardiovascular) (2012)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#3-127	
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: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 and 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 for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-2-47, Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems. (Cardiovascular) (2012)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	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

* 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]

ISO 10993-1, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process (2009) (CORR:2010)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-220	
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: Use Of International Standard ISO 10993-1, Biological Evaluation Of Medical Devices- Part 1: Evaluati...

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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[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 and 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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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-1, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process (2009) (CORR:2010)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	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]

ISO 14971, Medical Devices - Applications Of Risk Management To Medical Devices (2012)

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 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: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971, Medical Devices - Applications Of Risk Management To Medical Devices (2012)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	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

* 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ISO 15223-1, Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements (2012)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-90	
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: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 and 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 for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 15223-1, Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements (2012)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	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

* 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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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]

IEC 62304, Medical Device Software - Software Life Cycle Processes (2006)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-79	
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: Guidance For The Content Of Premarket Submissions For Software Contained In Medical Devices...

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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[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 for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

A11-14

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 62304, Medical Device Software - Software Life Cycle Processes (2006)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	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		

* 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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 K171816/S001

AliveCor®

October 11, 2017

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

RE: Additional Information Request Response - Supplement to Traditional 510(k) Premarket Notification for the Kardia Band System (K171816)

Dear Sir/Madam:

In response to the request for additional information letter dated August 8, 2017, AliveCor, Inc. ("AliveCor") is herein submitting a supplement to the 510(k) Premarket Notification for the Kardia Band System. For the reviewer's convenience, each FDA request for additional information is in Bold Italics followed by AliveCor's response.

AliveCor is also enclosing an electronic copy (eCopy) of this submission on a CD in accordance with FDA's "Guidance for Industry and Food and Drug Administration Staff, eCopy Program for Medical Device Submissions", issued December 3, 2015. The eCopy is an exact duplicate of the paper copy; however, minor formatting changes may have been introduced as a result of the PDF conversions.

Thank you in advance for your review of this supplement. If you have any questions, you may contact me by phone at 408-400-0856 (office), or 408-204-3370 (mobile), or by email at anna@experiengroup.com.

Sincerely,

Anna Libman
Regulatory Consultant to AliveCor, Inc.
Senior Manager, Regulatory Affairs
Experien Group, LLC

Enclosures:
Simon Prakash, VP Product and Design, AliveCor, Inc.

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AliveCor®

October 11, 2017

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

RE: Additional Information Request Response - Supplement to Traditional 510(k) Premarket Notification for the Kardia Band System (K171816)

Dear Sir/Madam:

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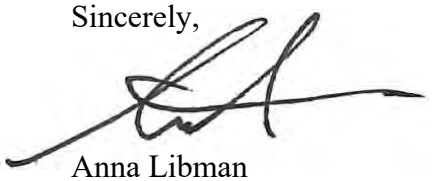
AliveCor is also enclosing an electronic copy (eCopy) of this submission on a CD in accordance with FDA's "Guidance for Industry and Food and Drug Administration Staff, eCopy Program for Medical Device Submissions", issued December 3, 2015. The eCopy is an exact duplicate of the paper copy; however, minor formatting changes may have been introduced as a result of the PDF conversions.

Thank you in advance for your review of this supplement. If you have any questions, you may contact me by phone at 408-400-0856 (office), or 408-204-3370 (mobile), or by email at anna@experiengroup.com.

Sincerely,



Anna Libman
Regulatory Consultant to AliveCor, Inc.
Senior Manager, Regulatory Affairs
Experien Group, LLC

Enclosures:
Simon Prakash, VP Product and Design, AliveCor, Inc.

Table of Contents

Attachments

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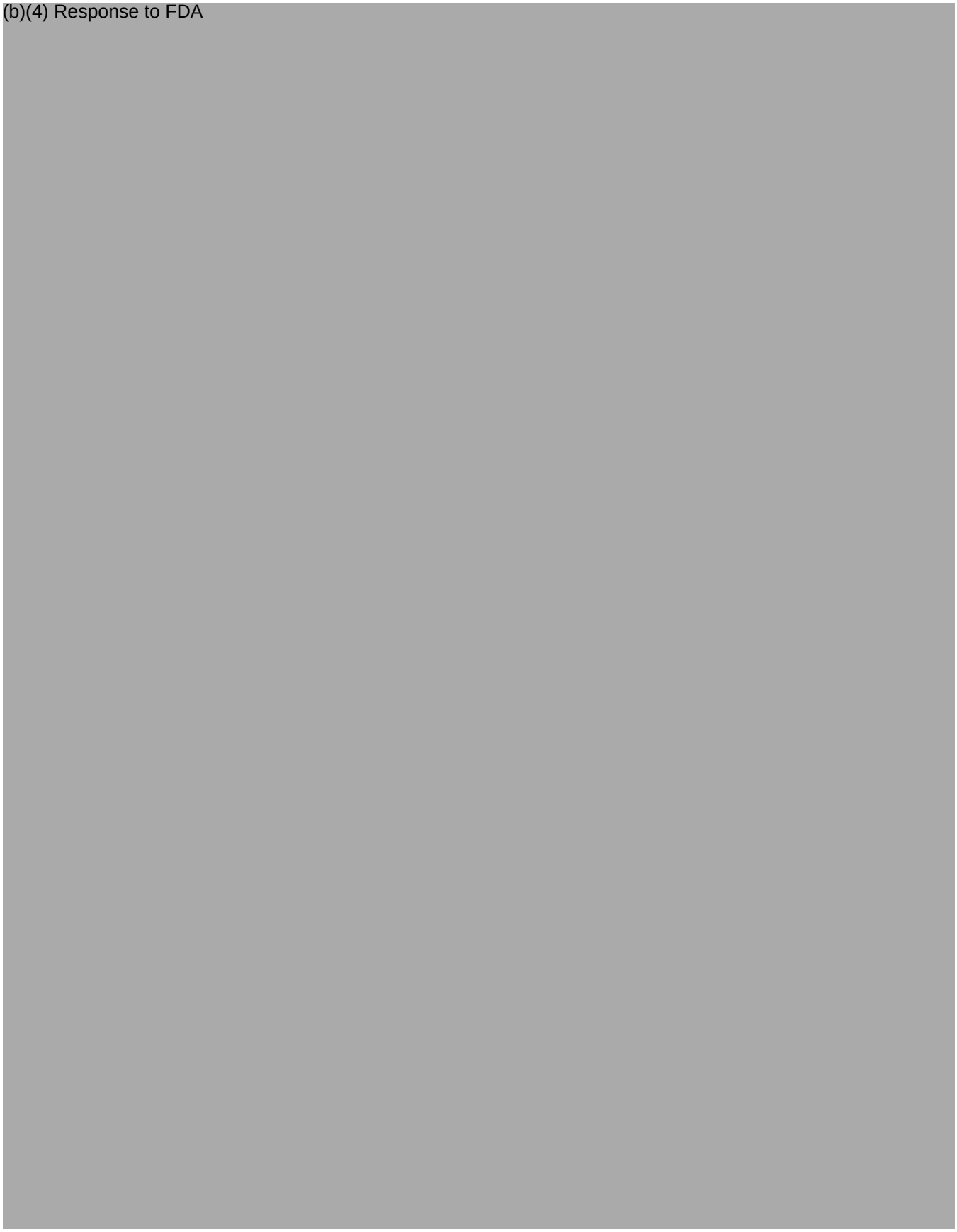
(b)(4) Response to FDA

(b)(4) Response to FDA

(b)(4) Response to FDA

(b)(4) Response to FDA

(b)(4) Response to FDA



(b)(4) Response to FDA

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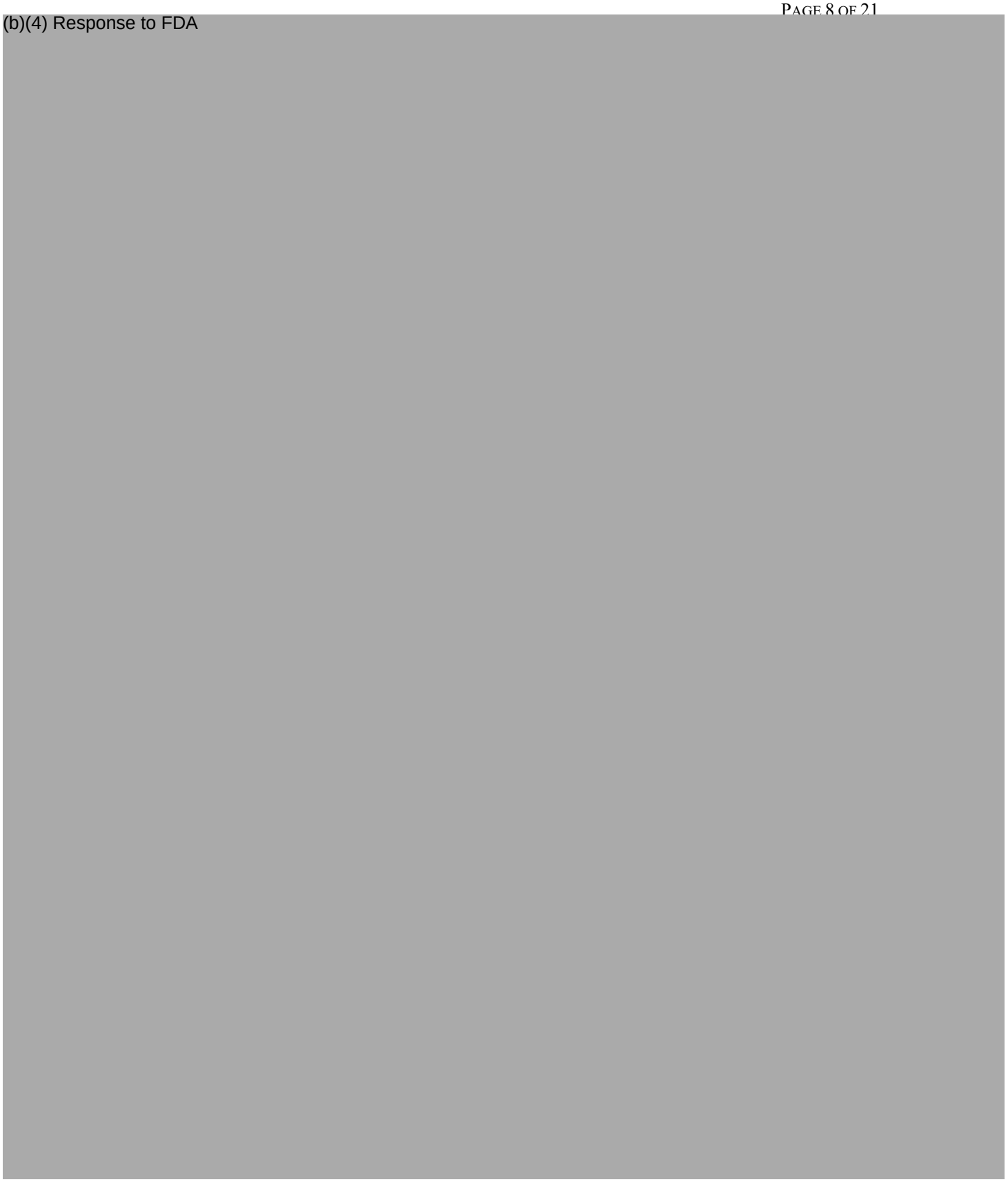

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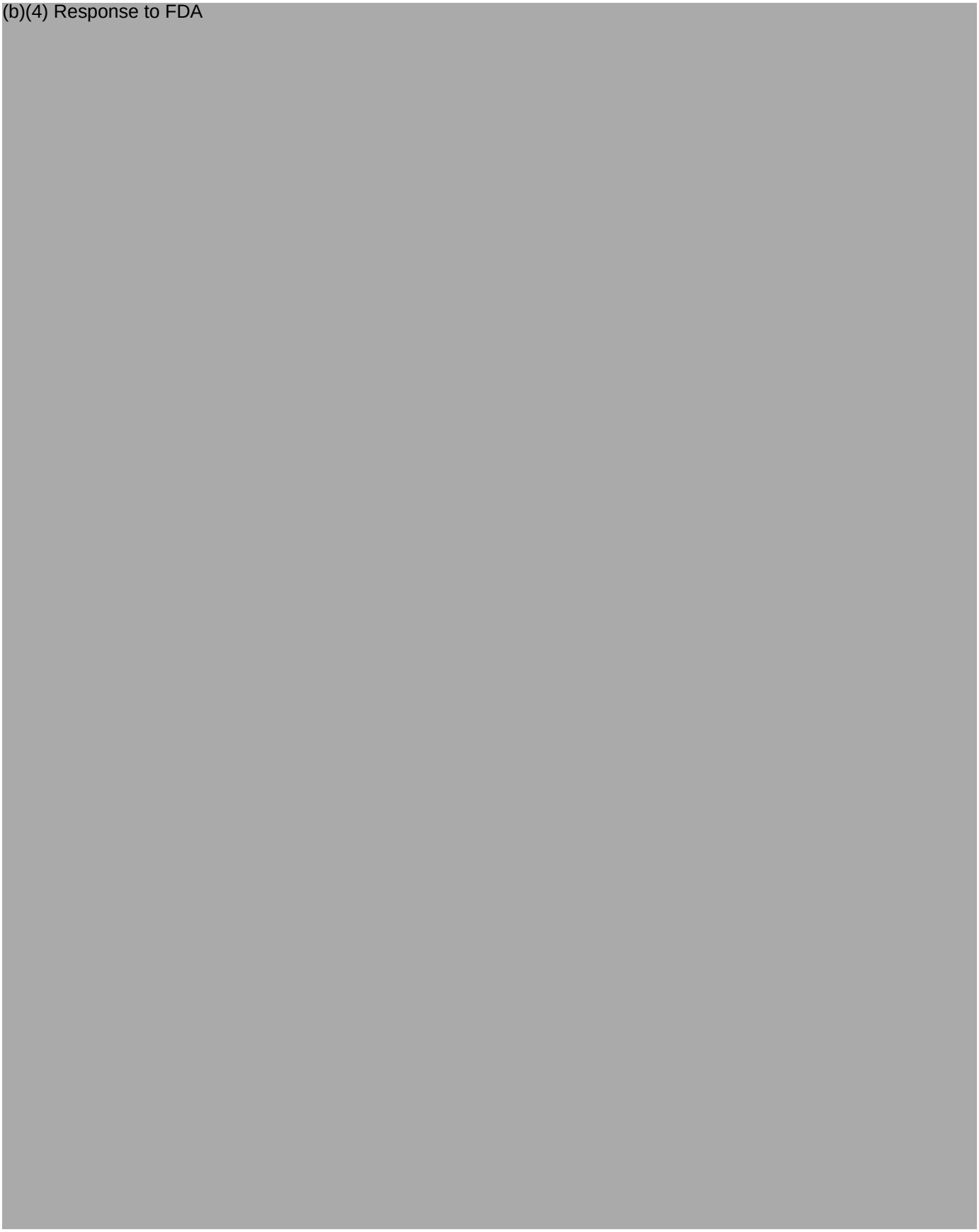

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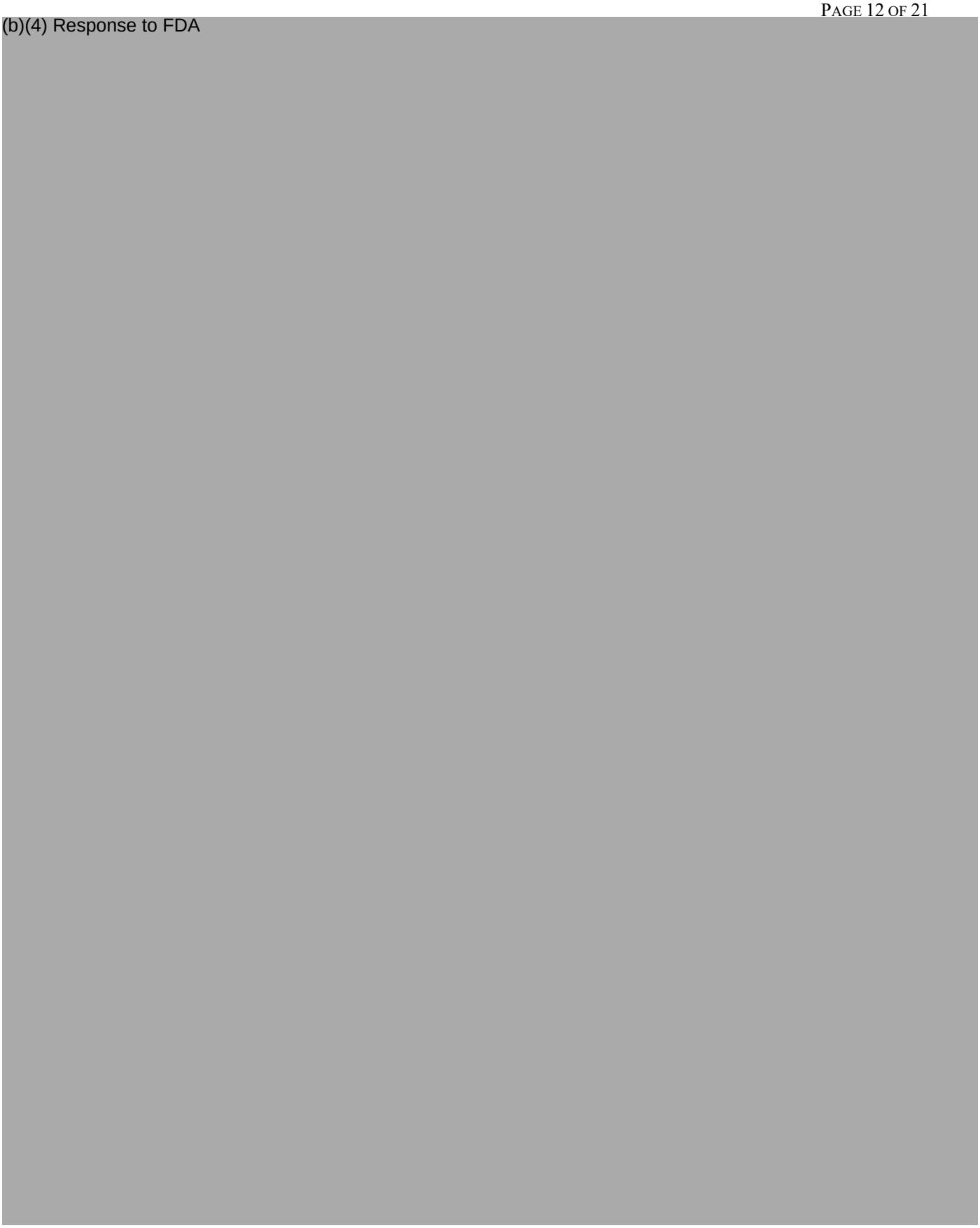

(b)(4) Response to FDA

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(b)(4) Response to FDA

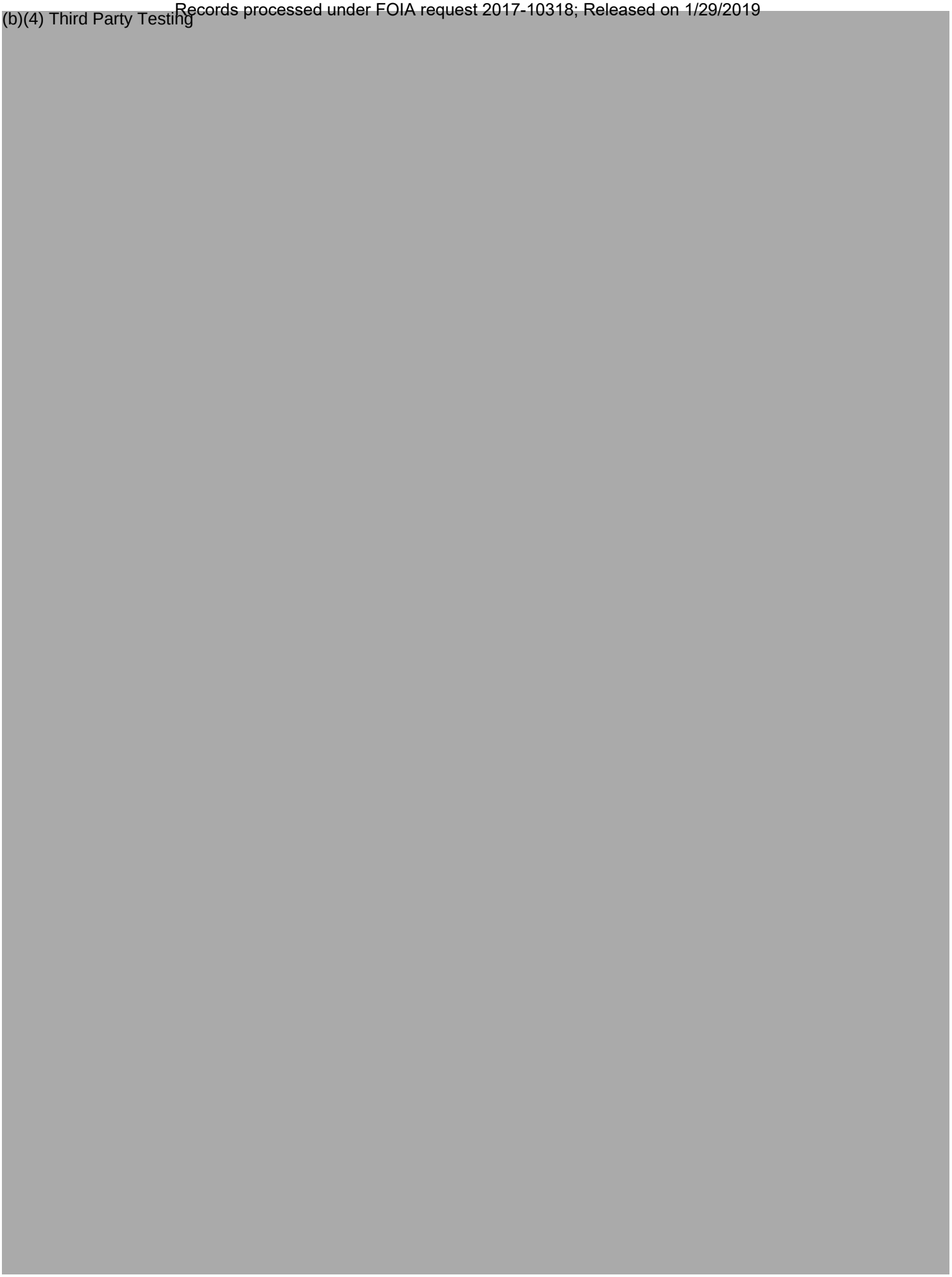
(b)(4) Response to FDA

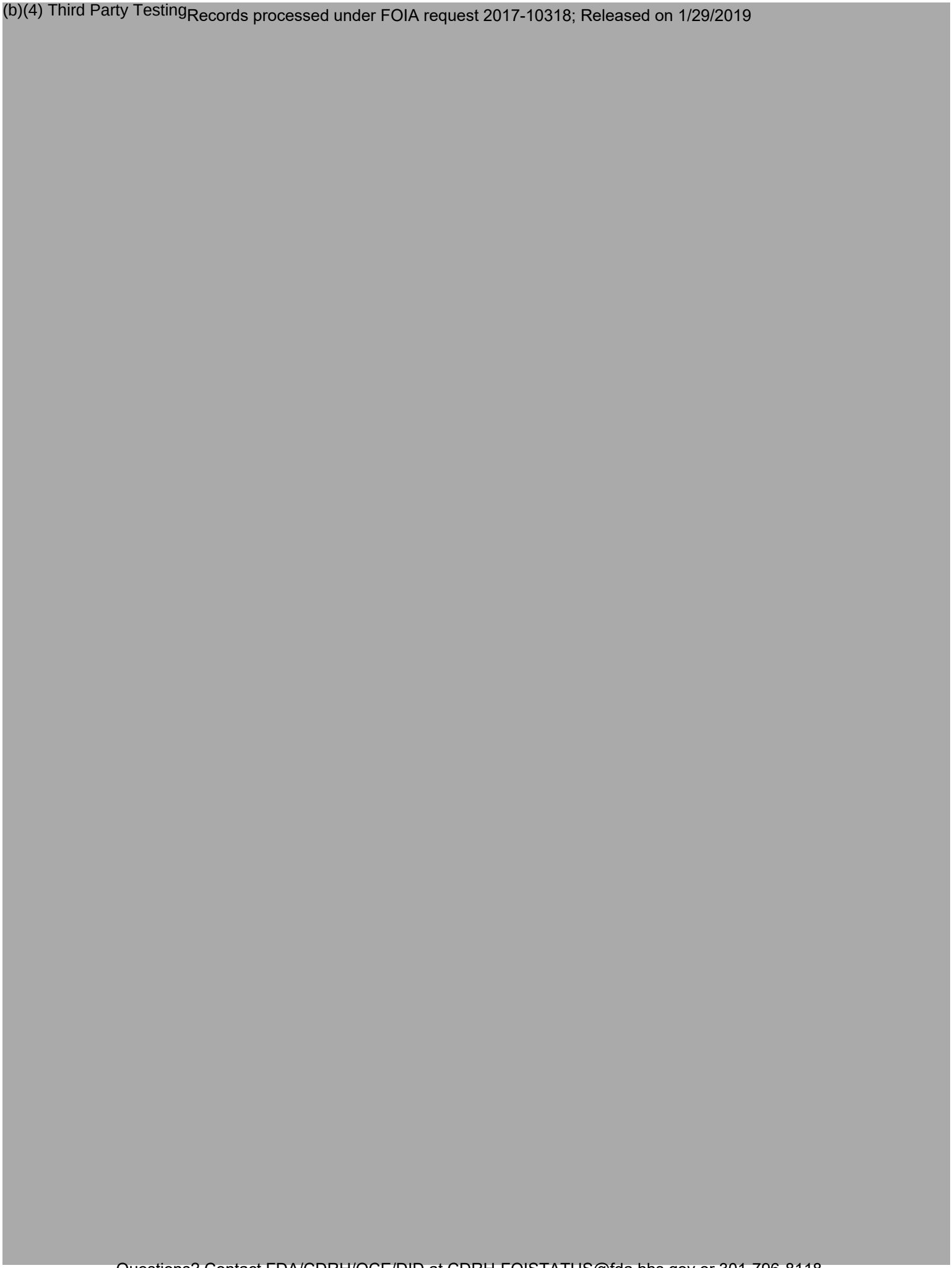
(b)(4) Response to FDA

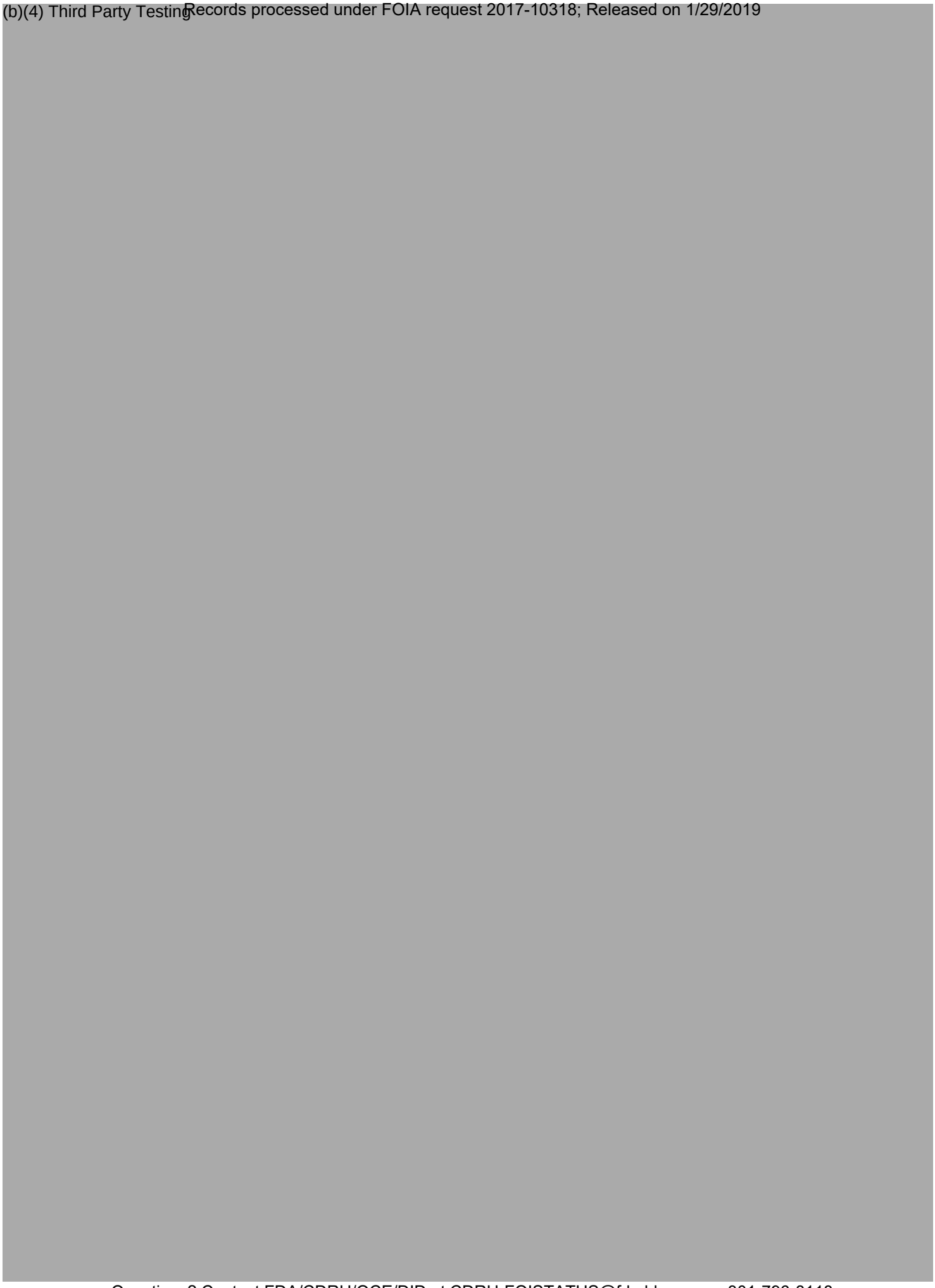
ATTACHMENT 1
REPORT REFERENCE NO. (b) (4)

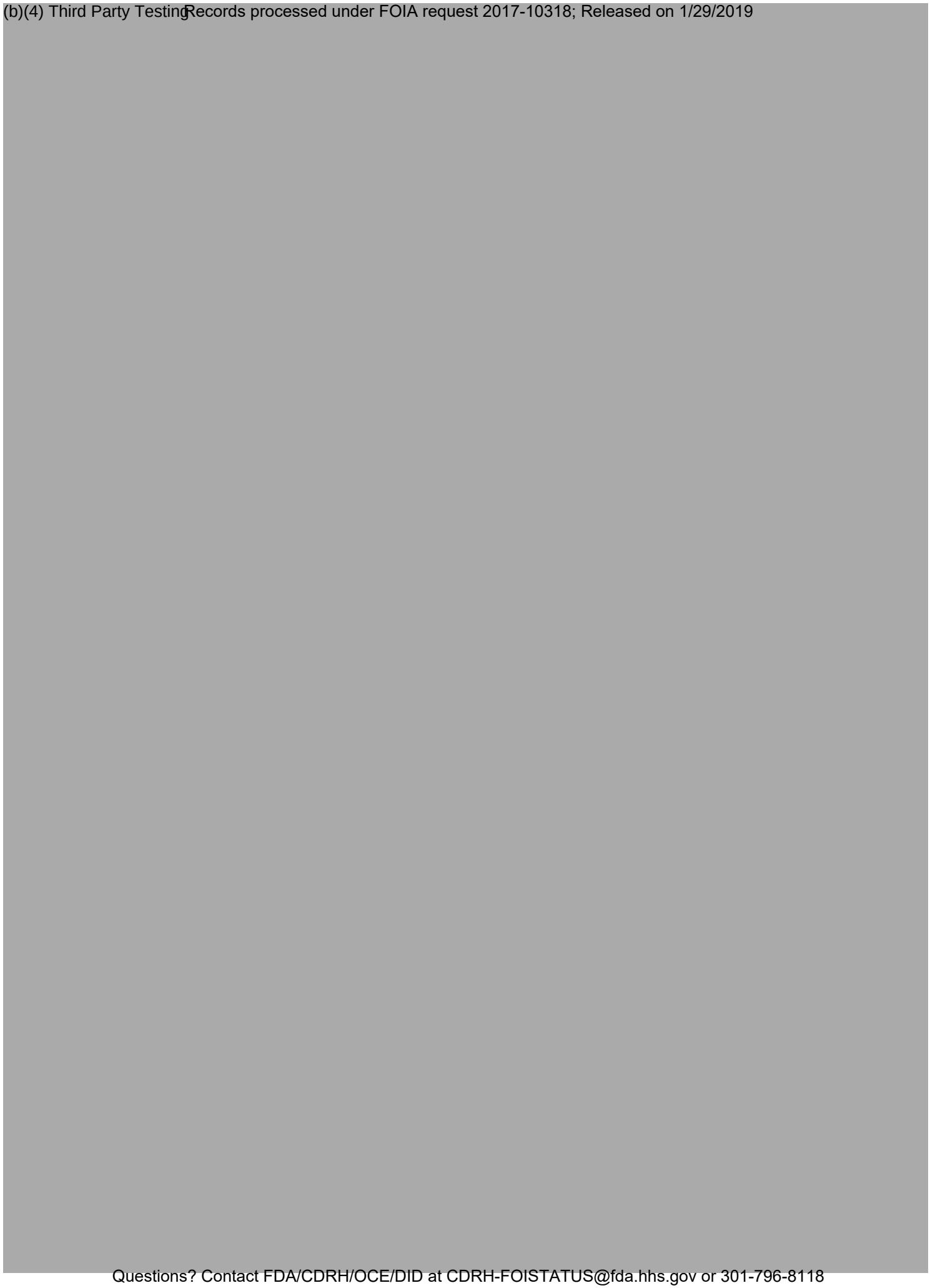
(b)(4) Third Party Testing

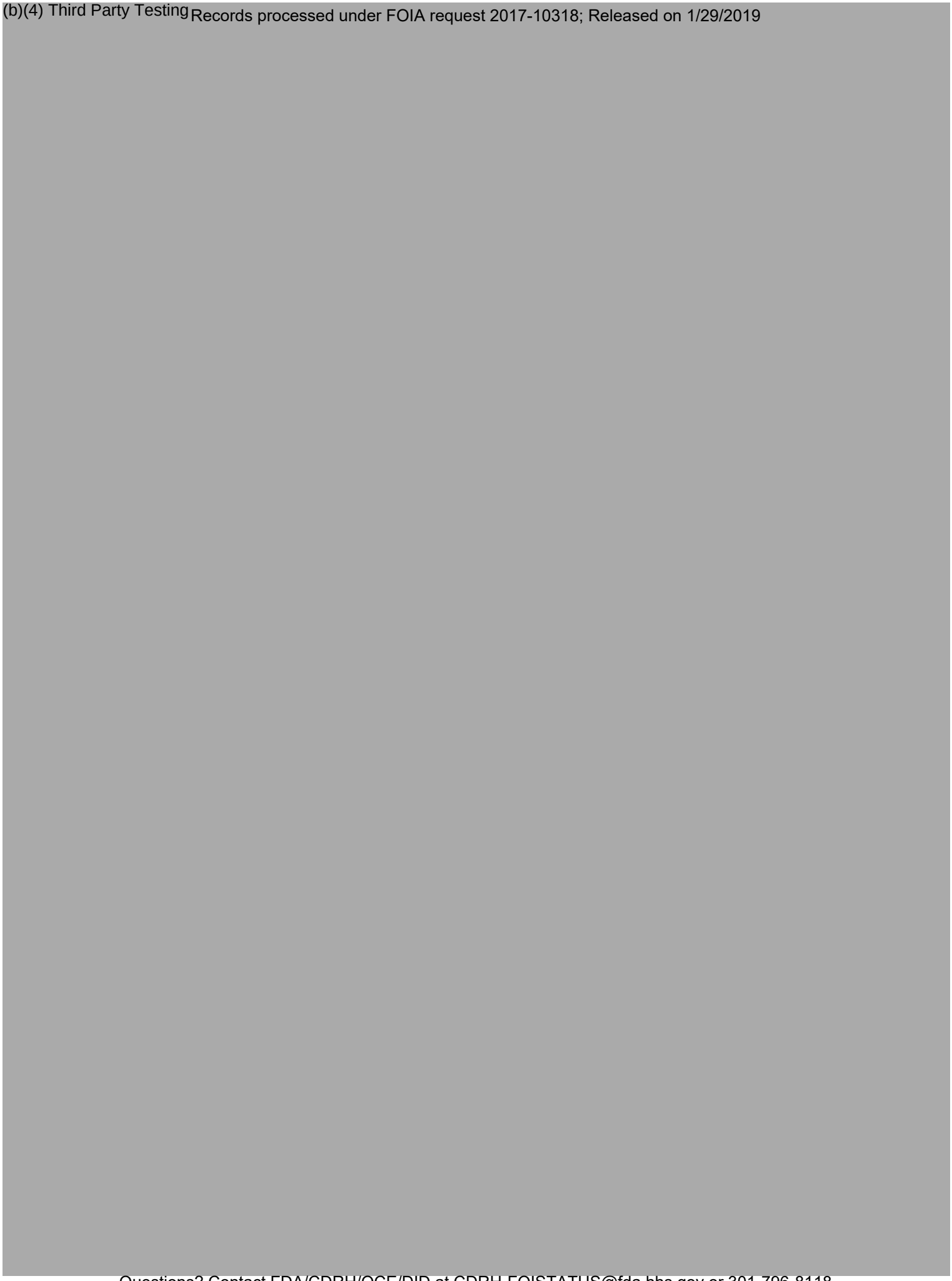
(b)(4) Third Party Testing

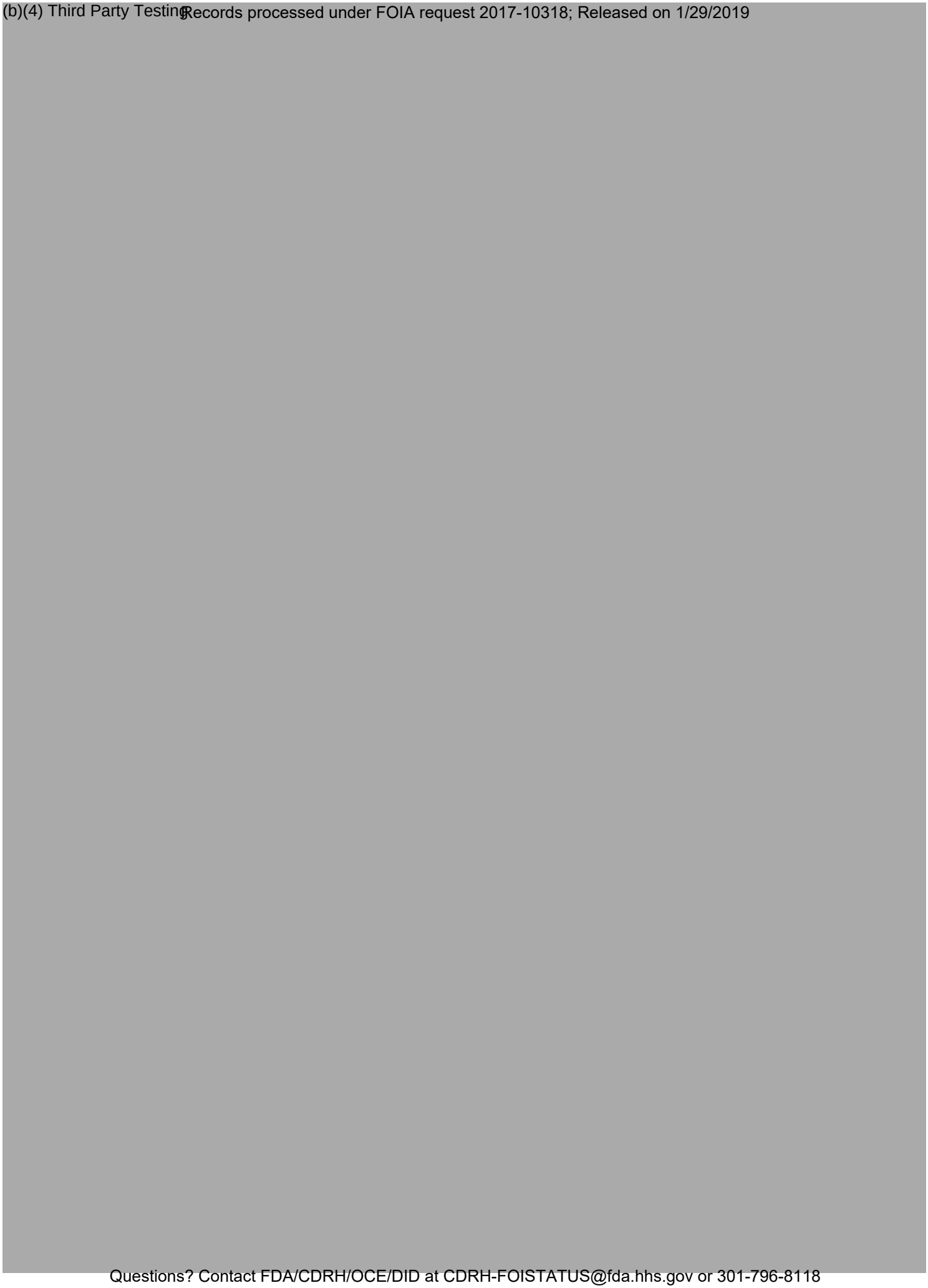


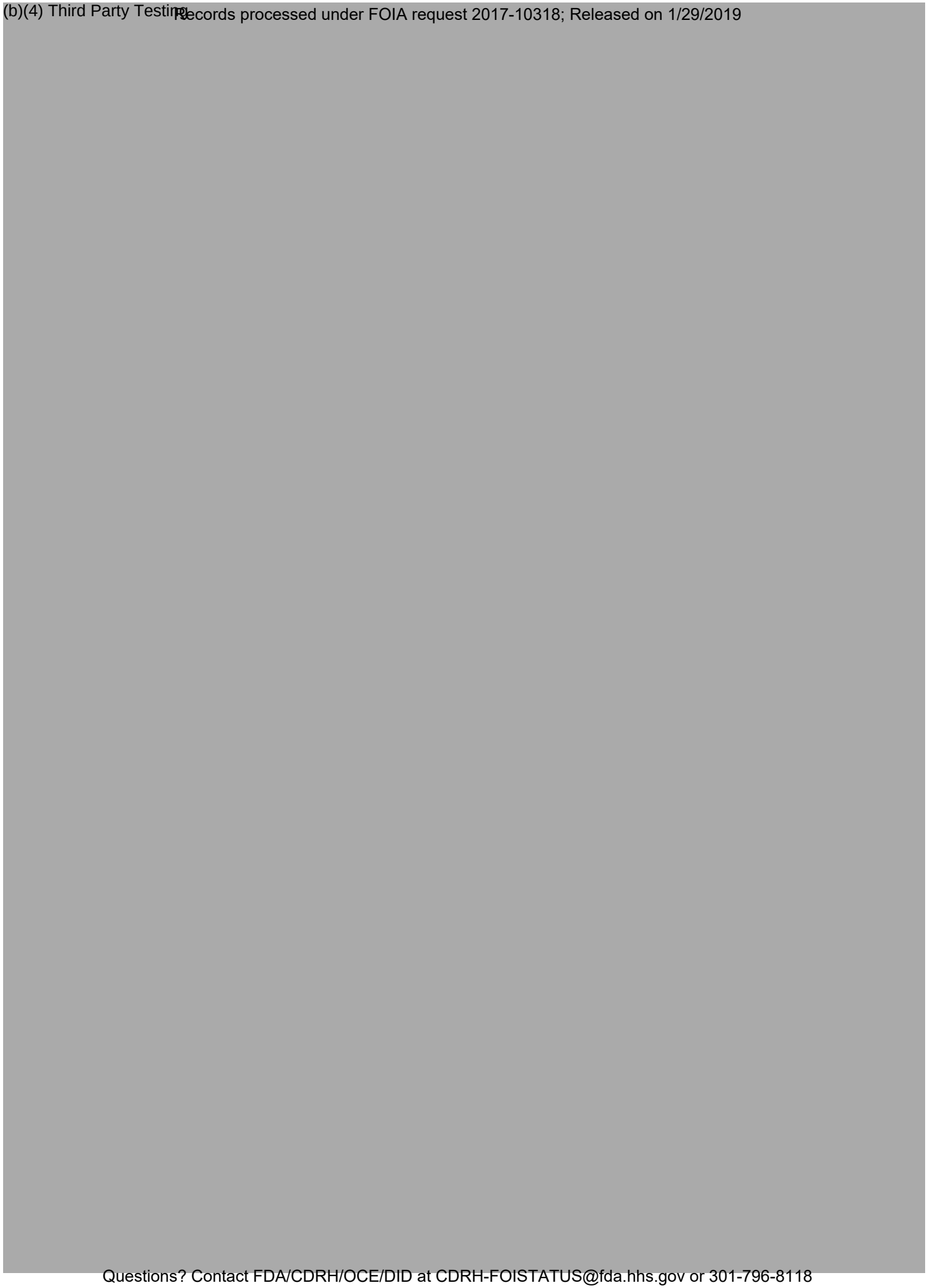


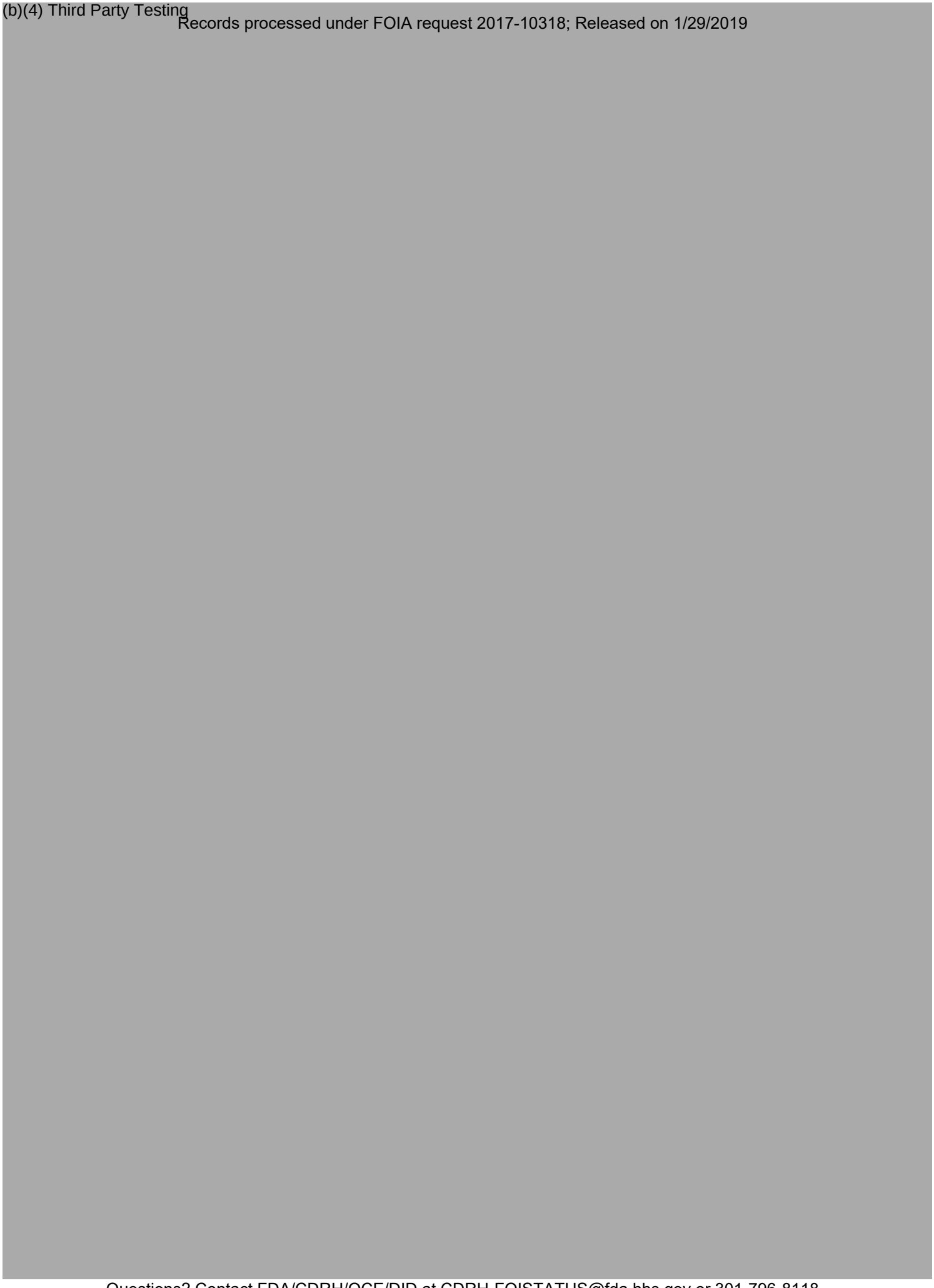


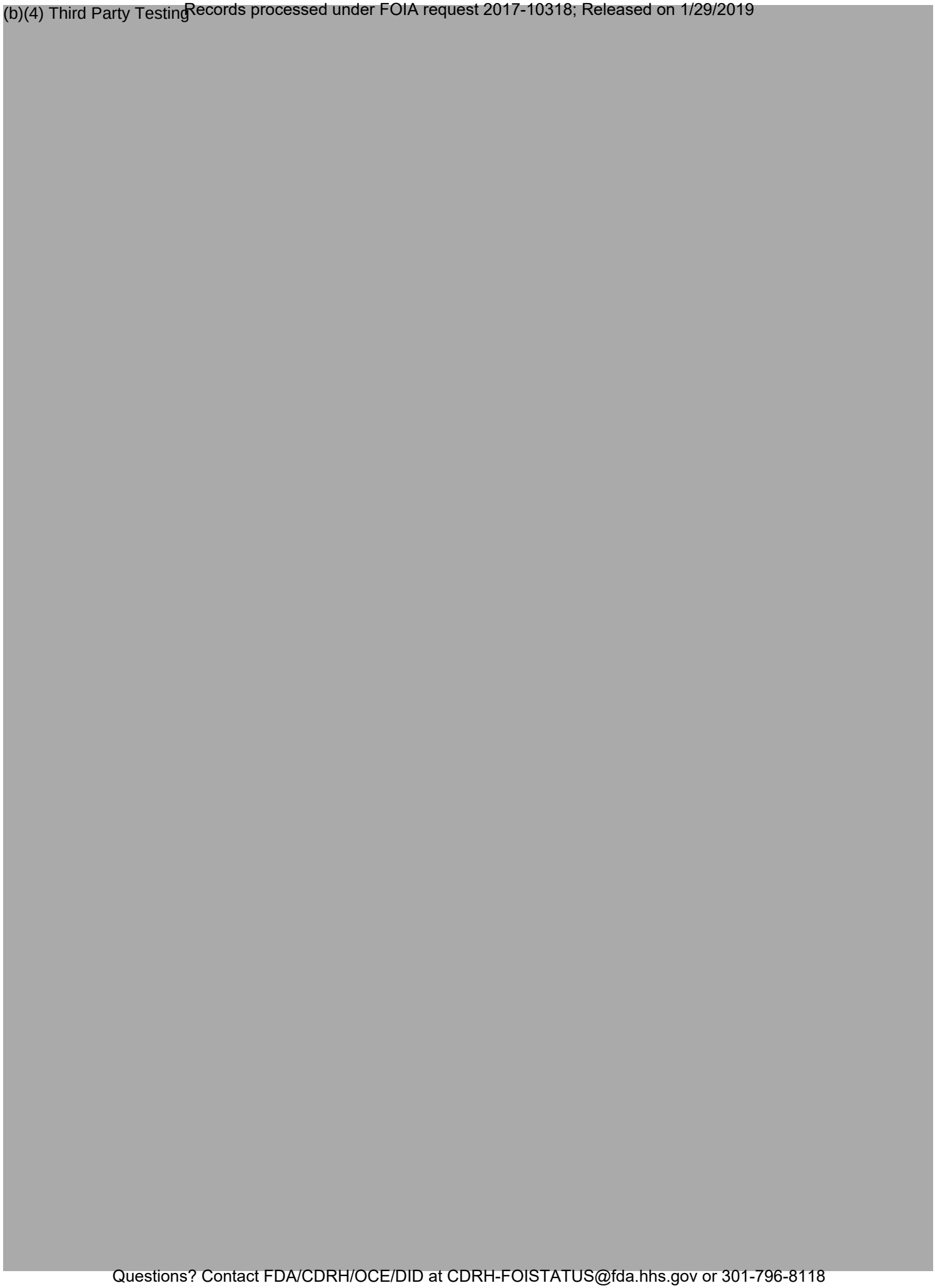


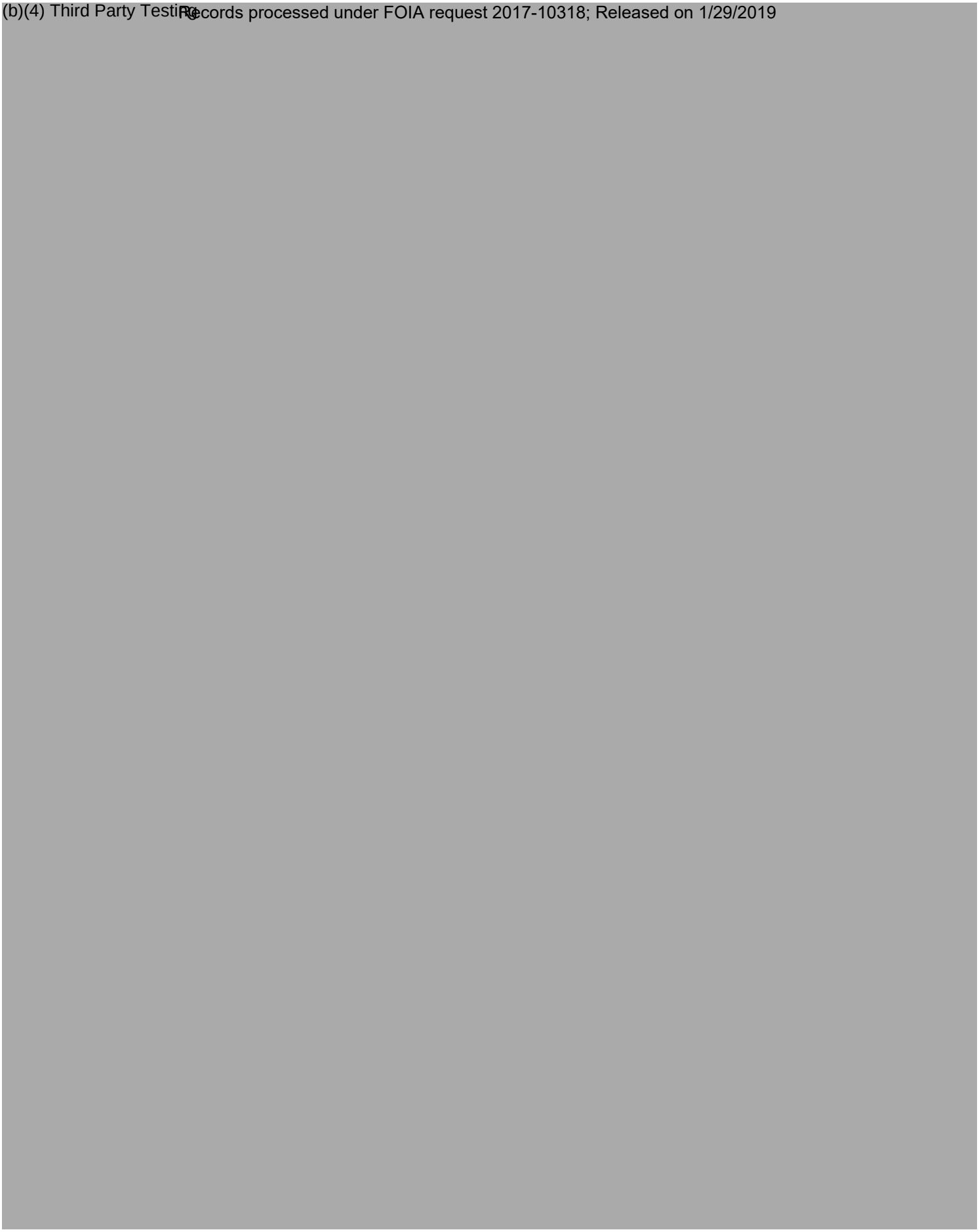


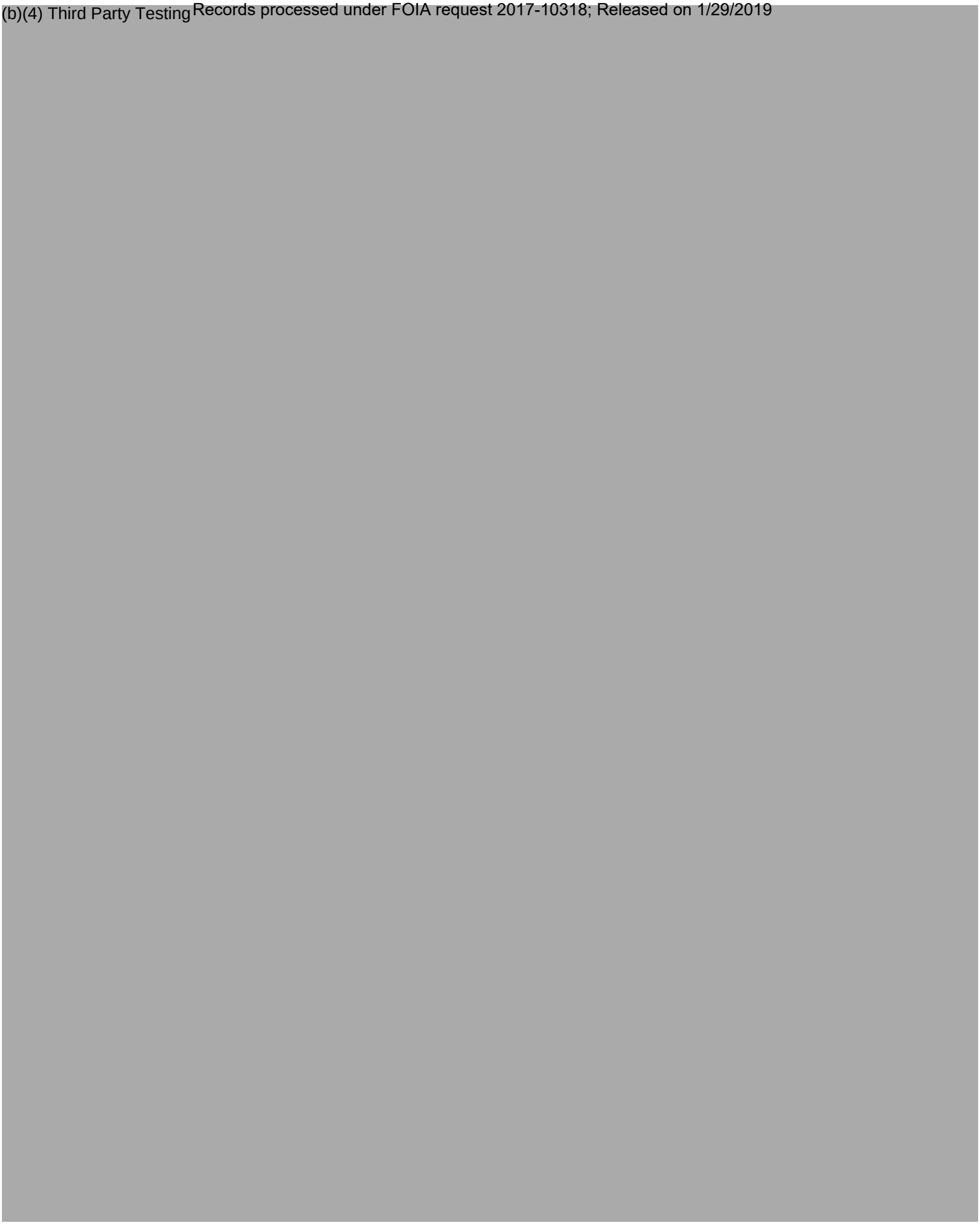






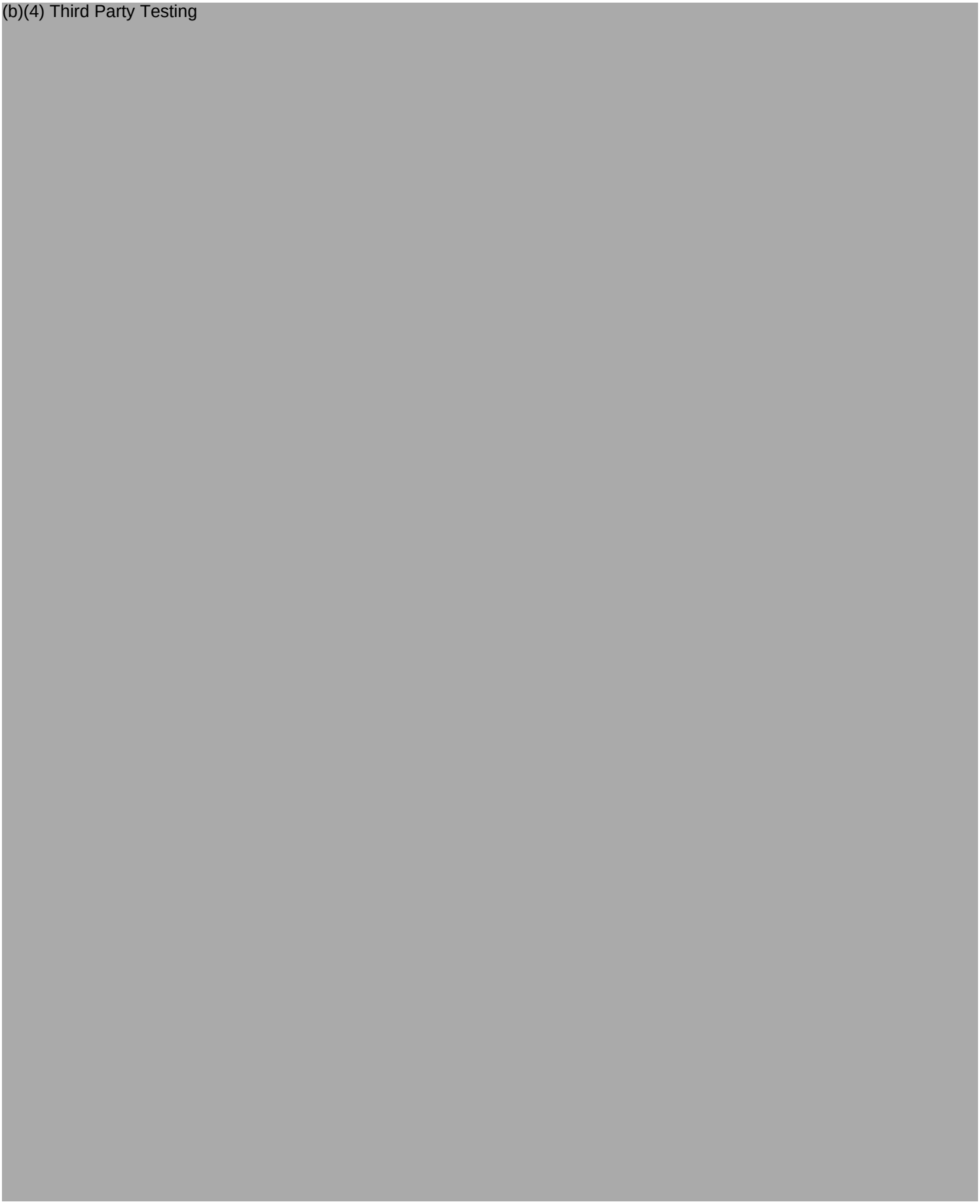






(b)(4) Third Party Testing

(b)(4) Third Party Testing



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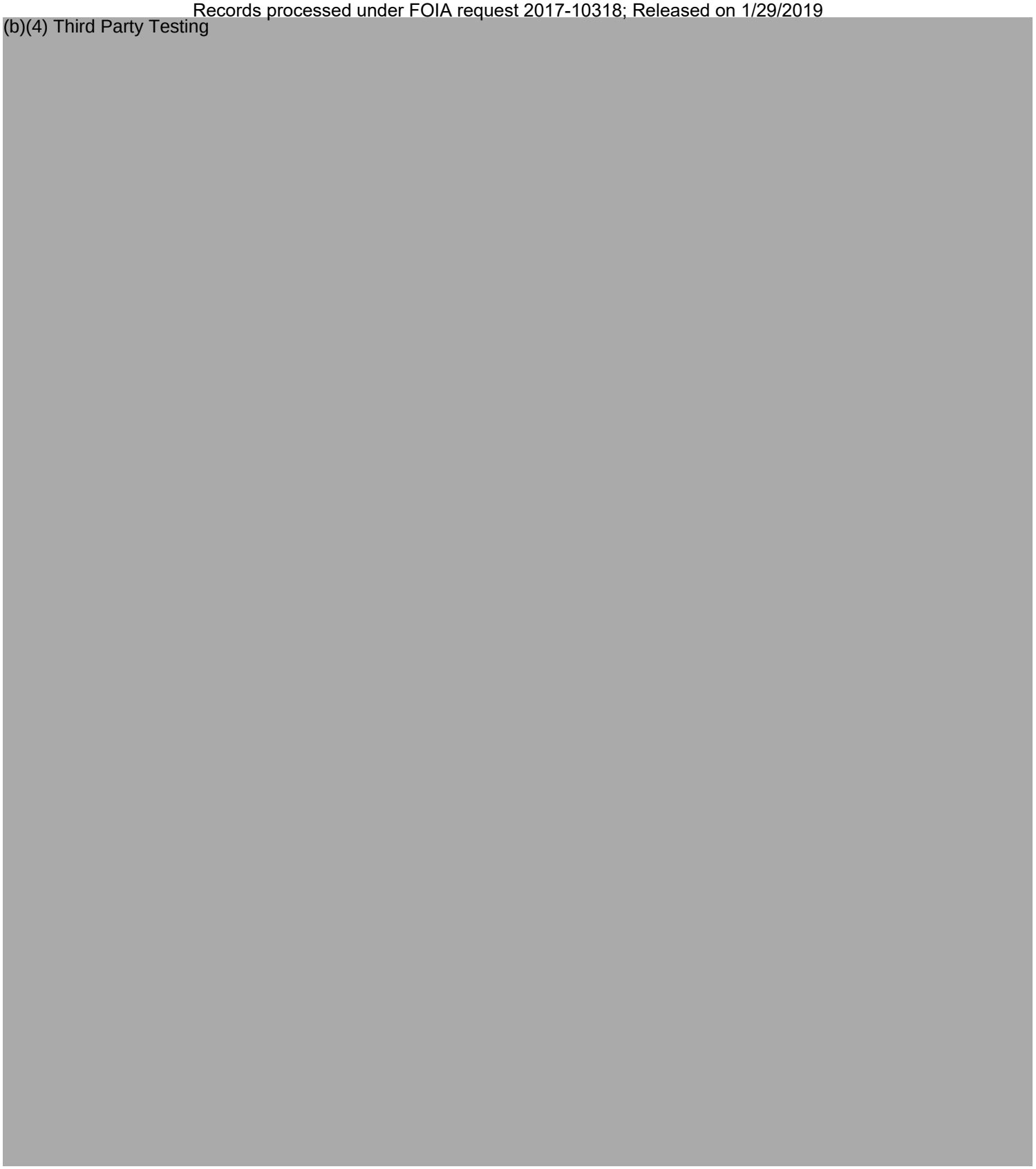

(b)(4) Third Party Testing

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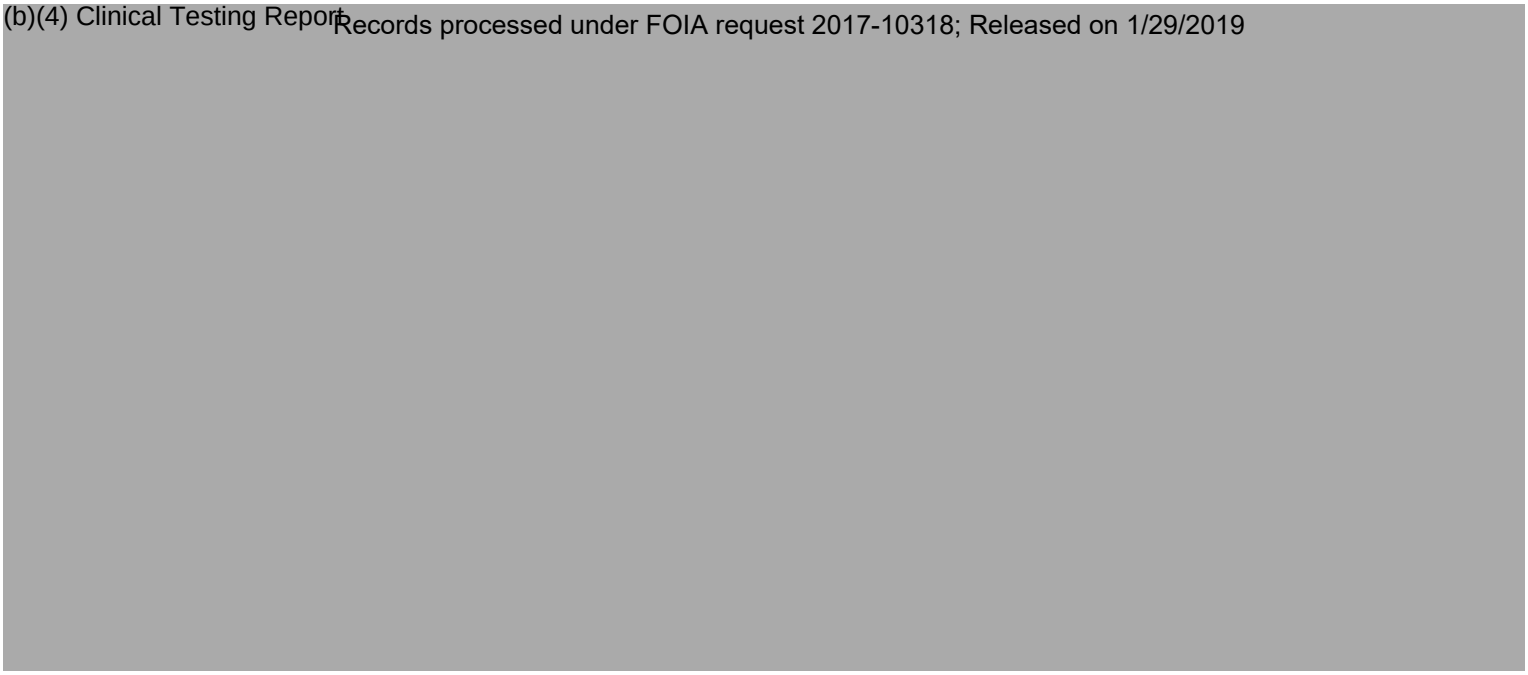
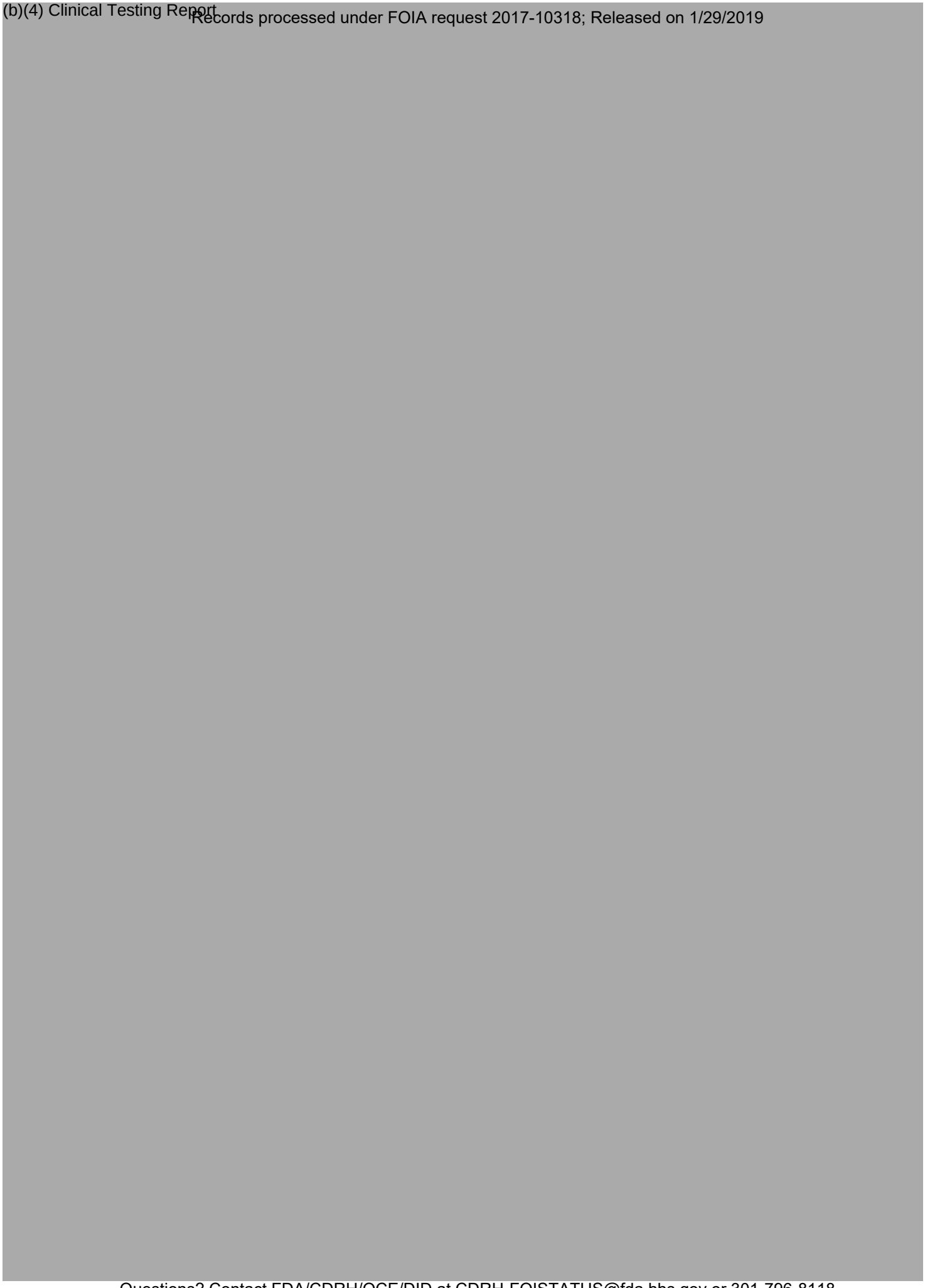
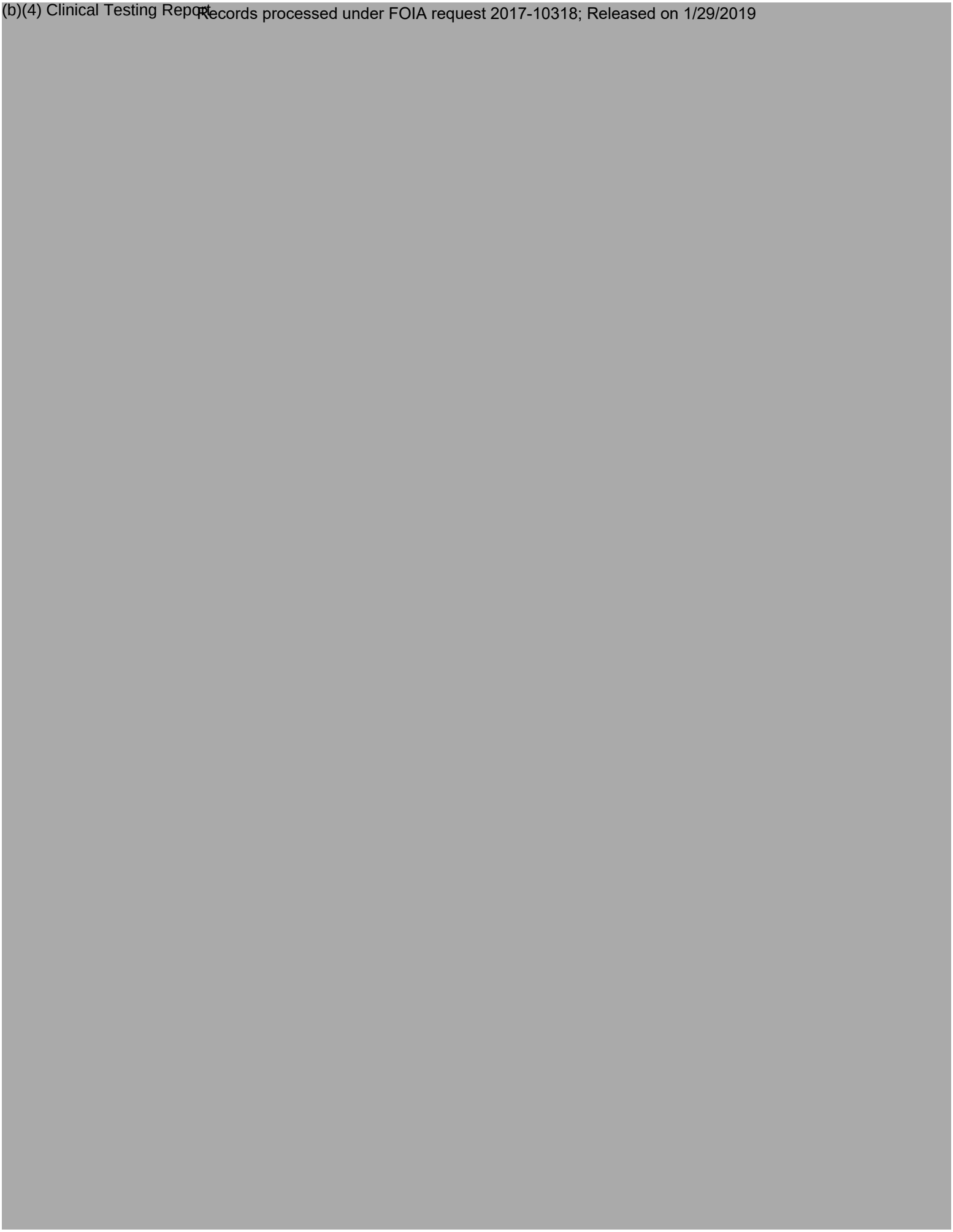
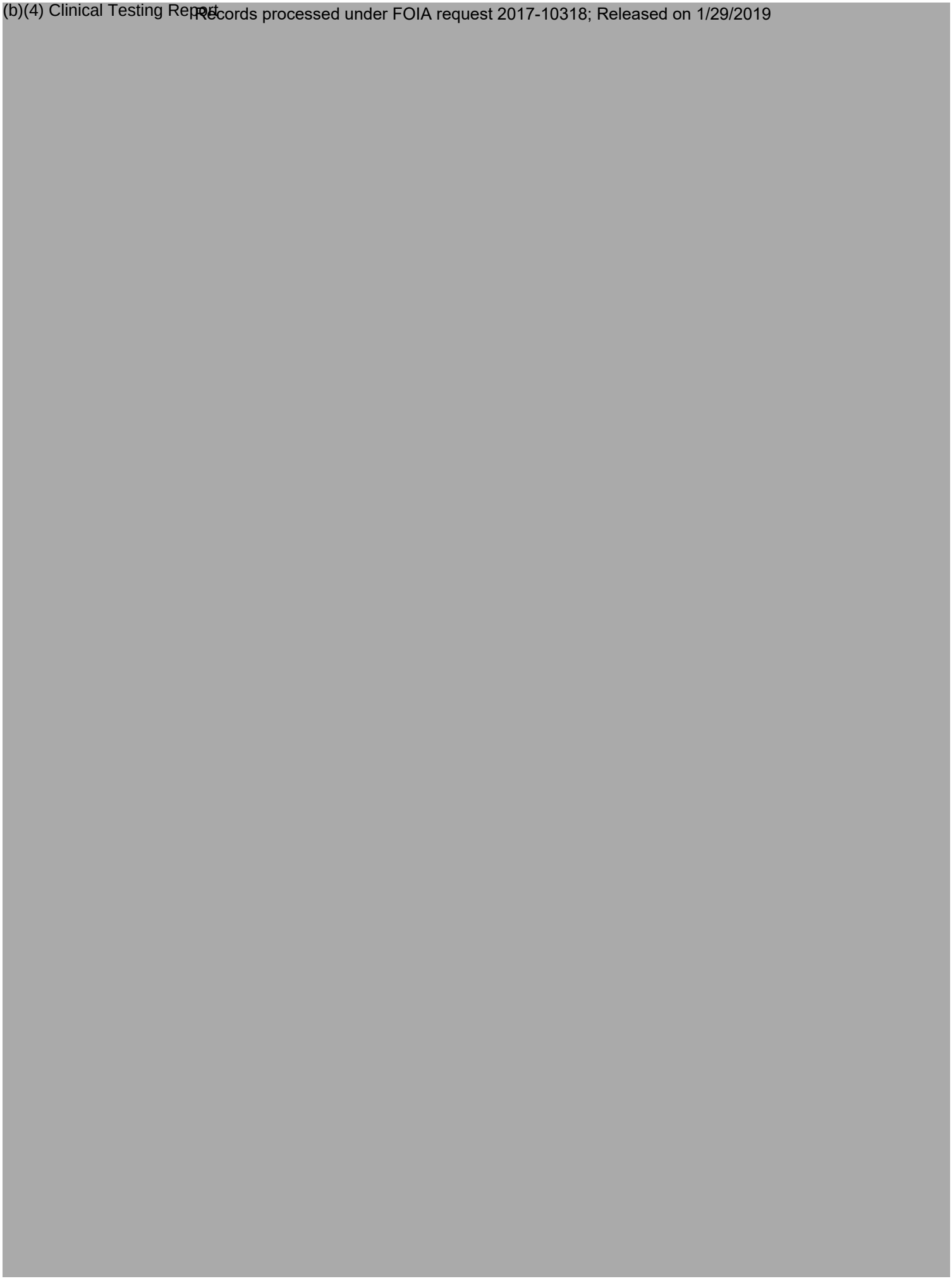
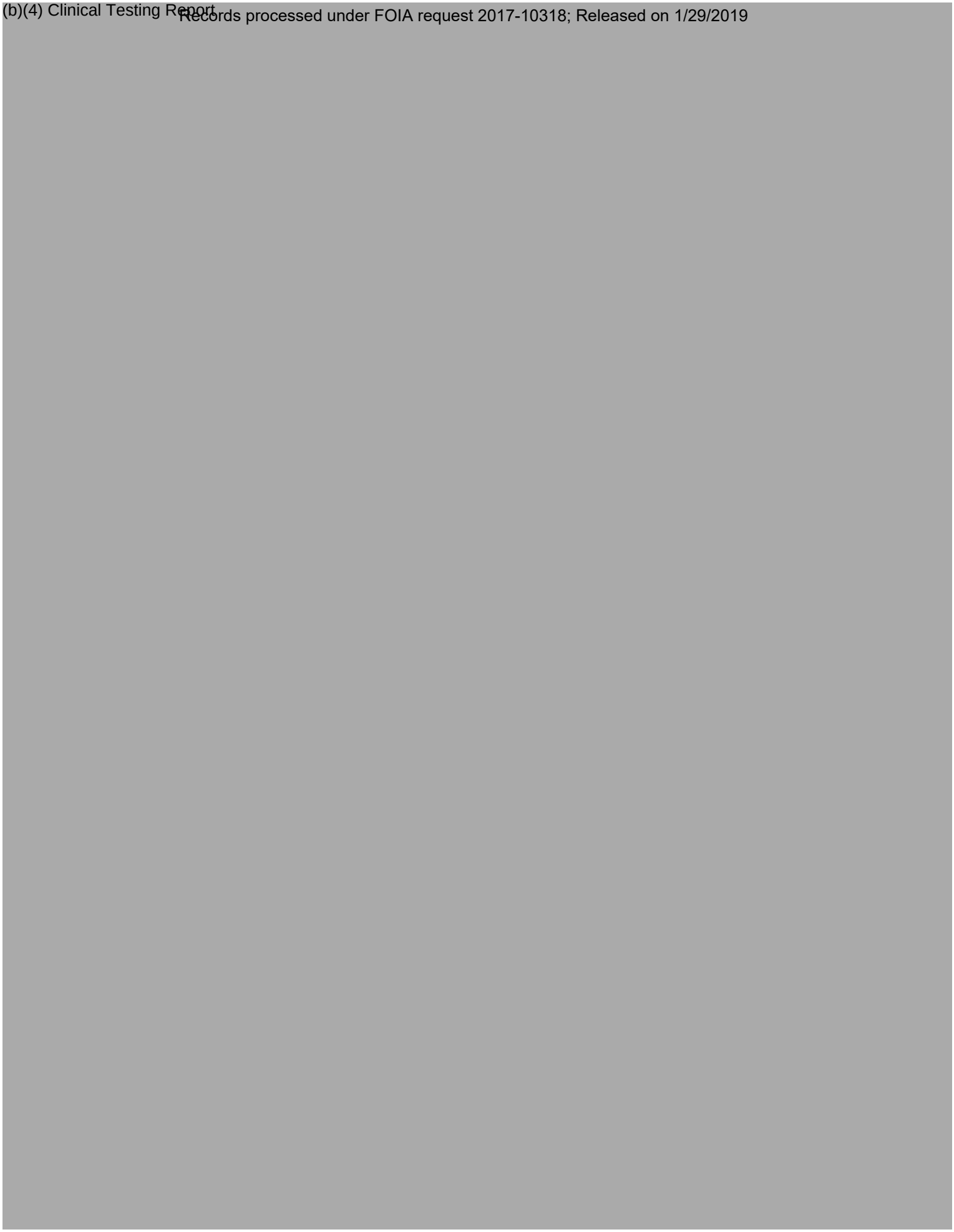
ATTACHMENT 2
(b) (4), CLINICAL TESTING REPORT FOR THE ALIVECOR KARDIA BAND

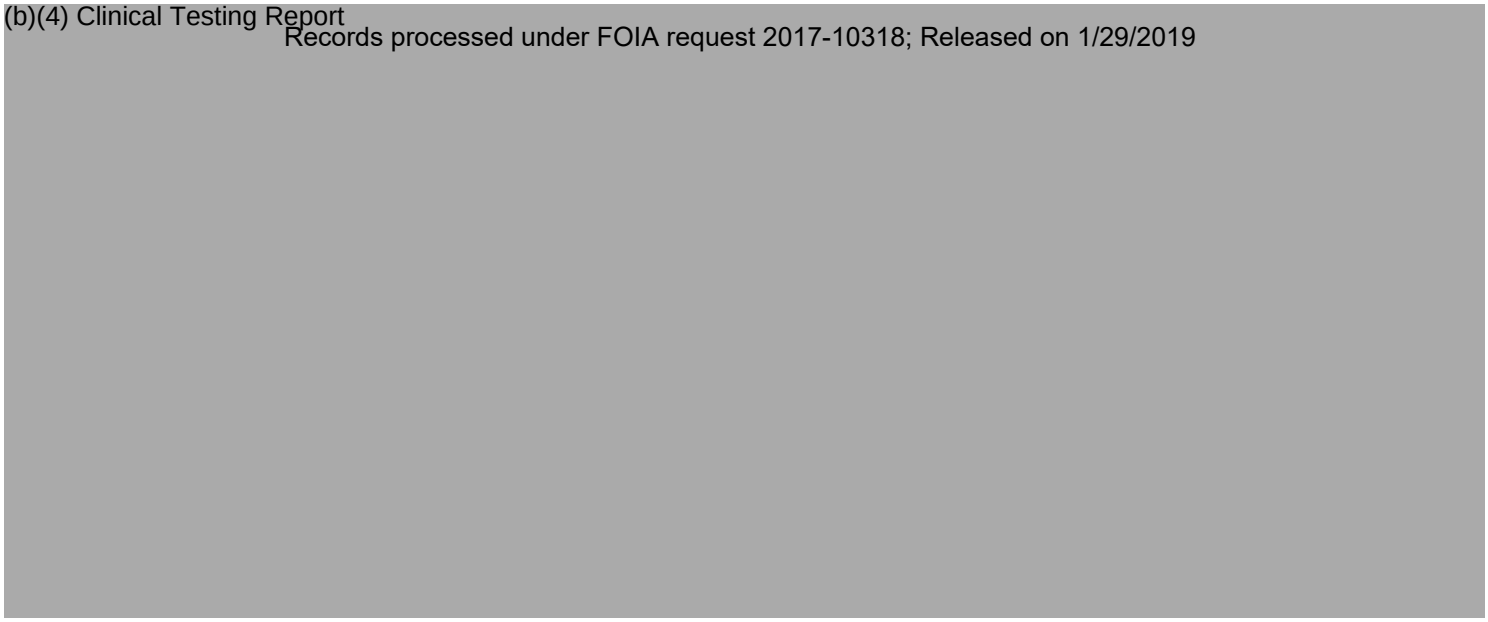


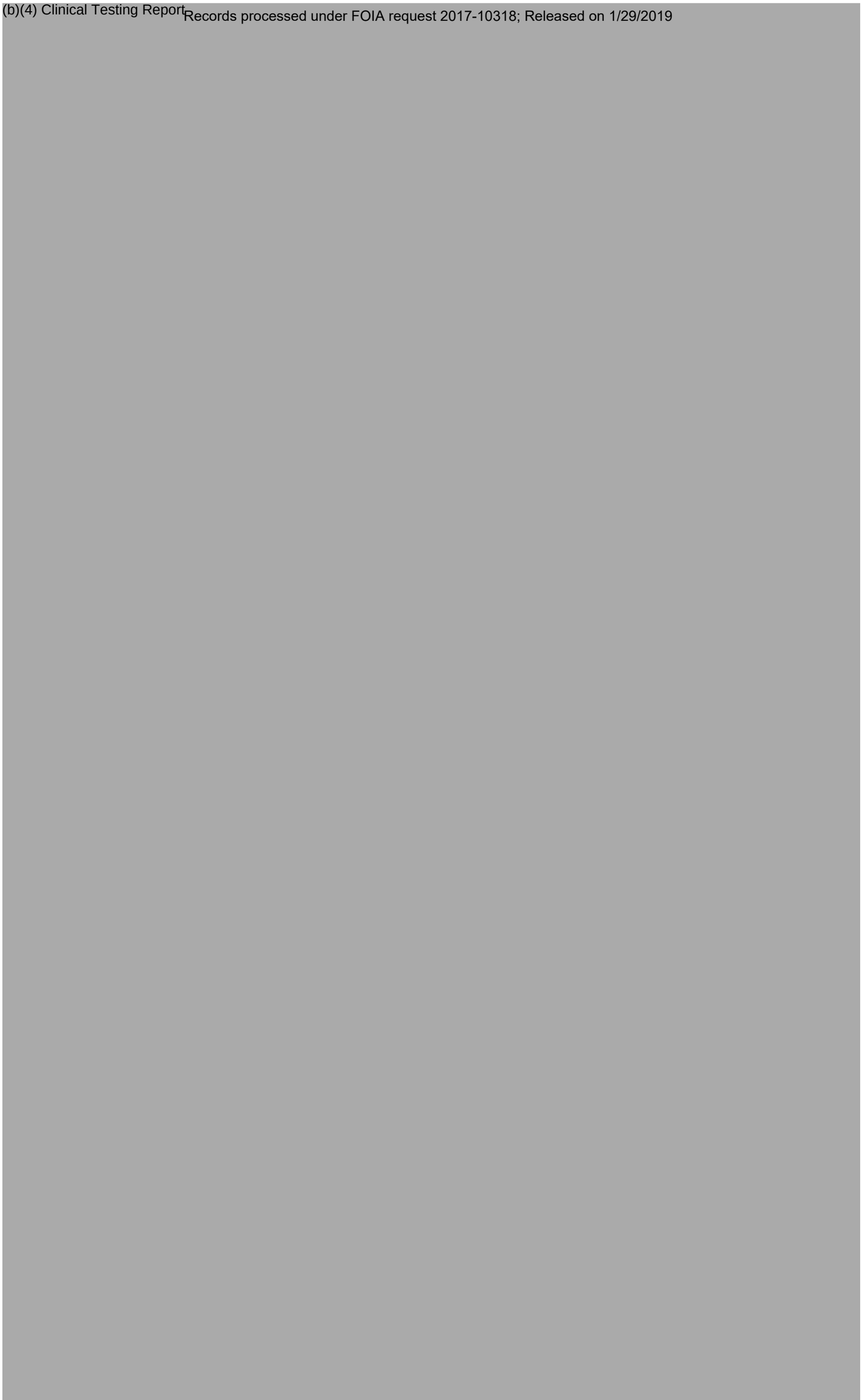


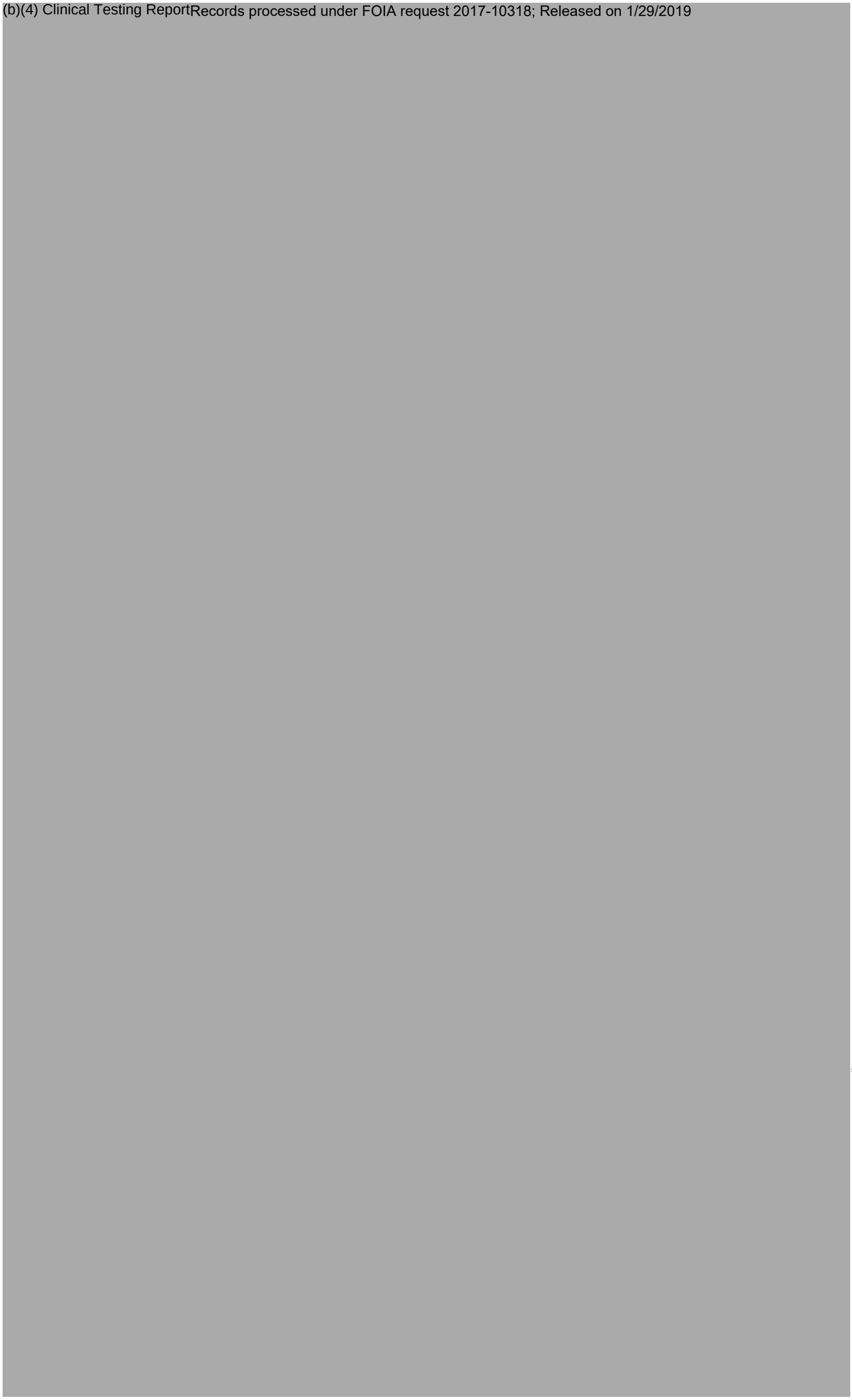


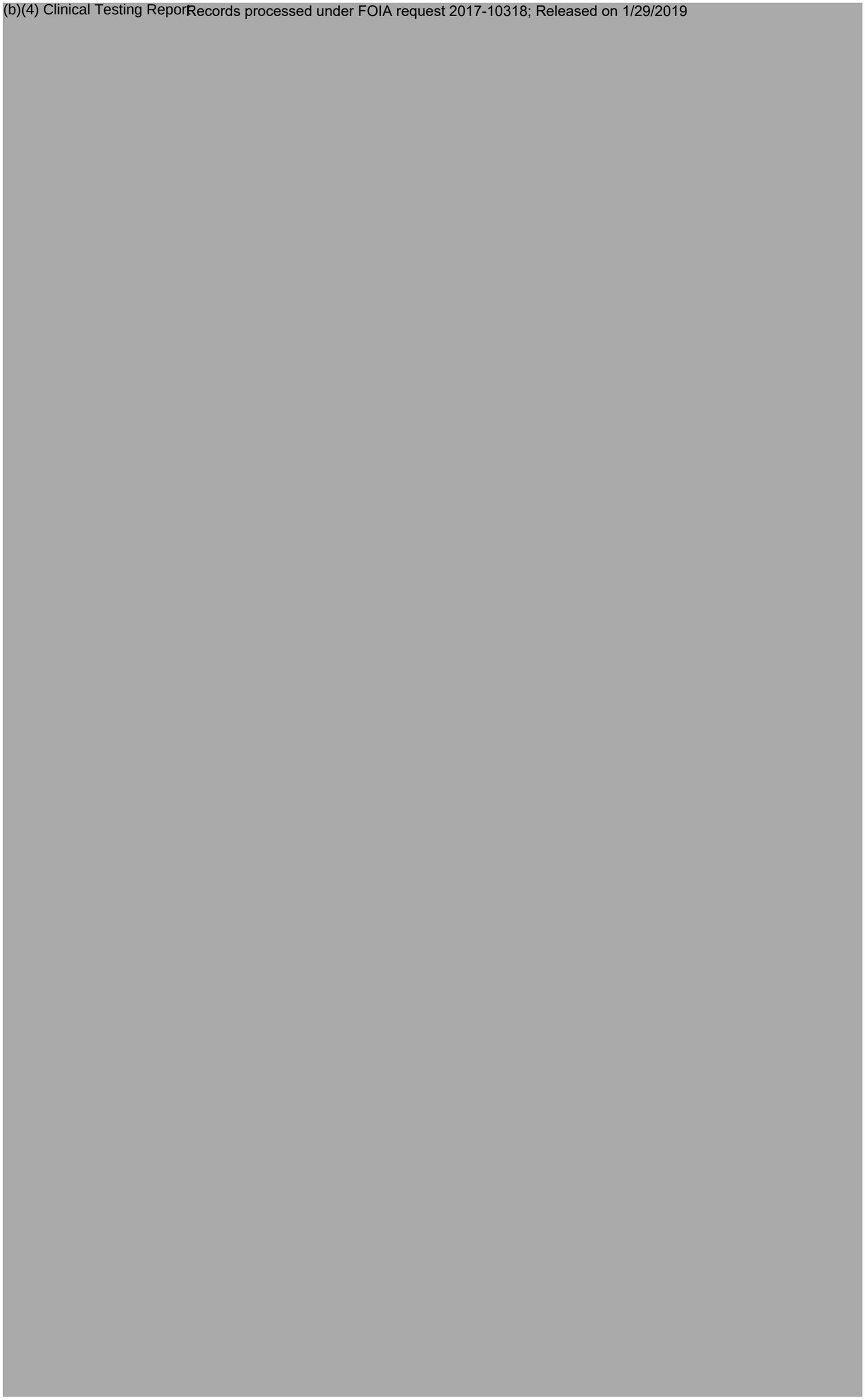


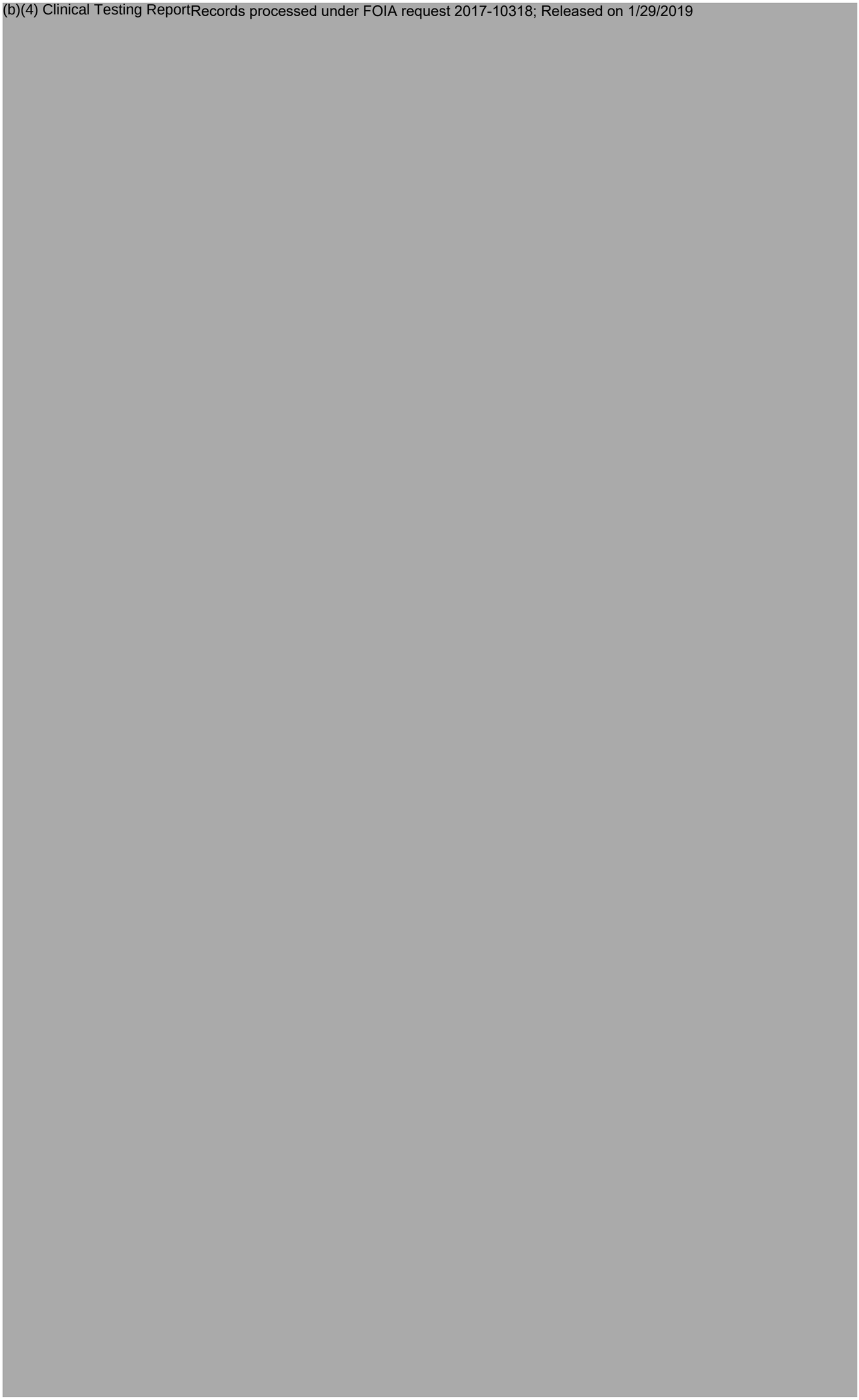


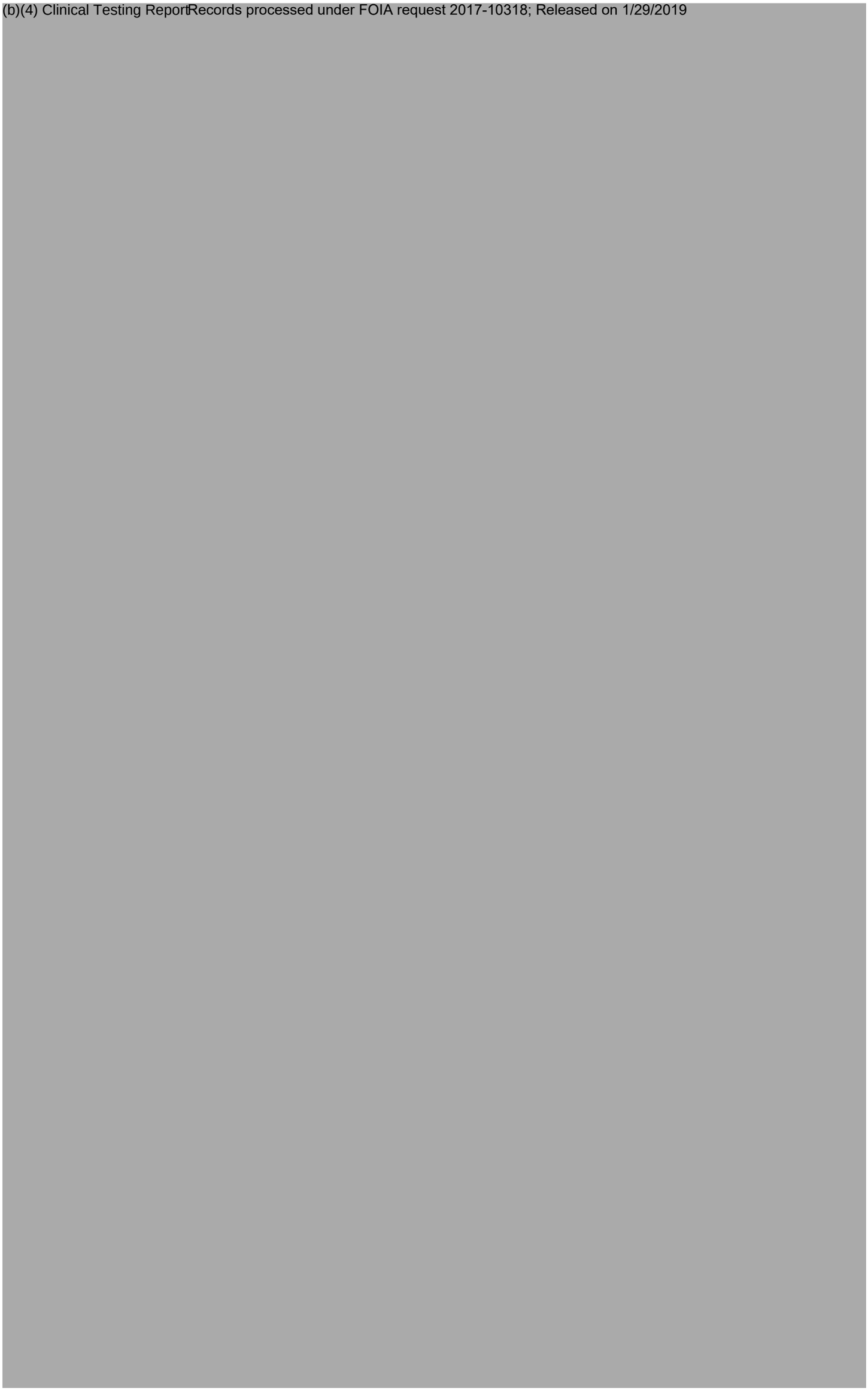




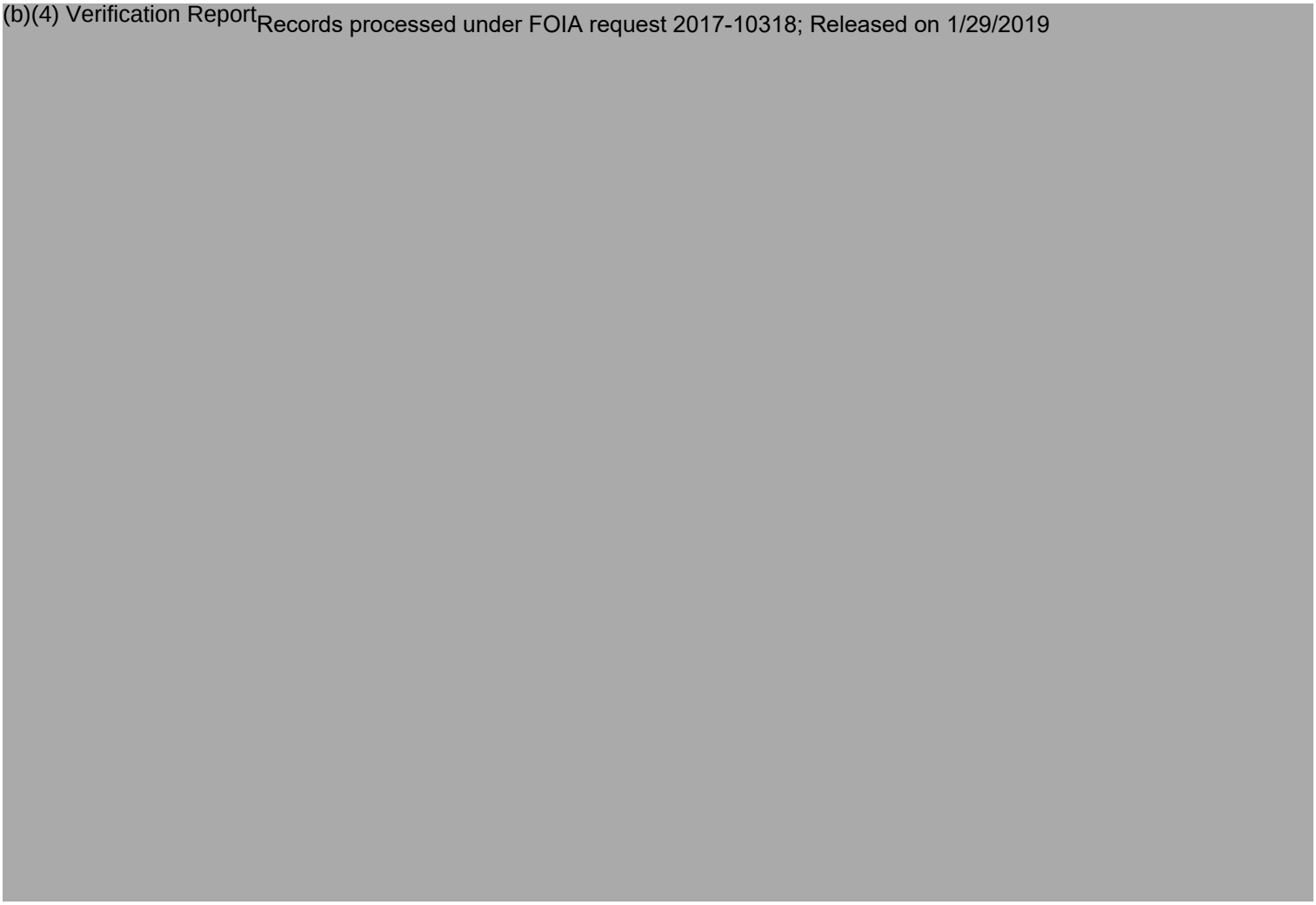


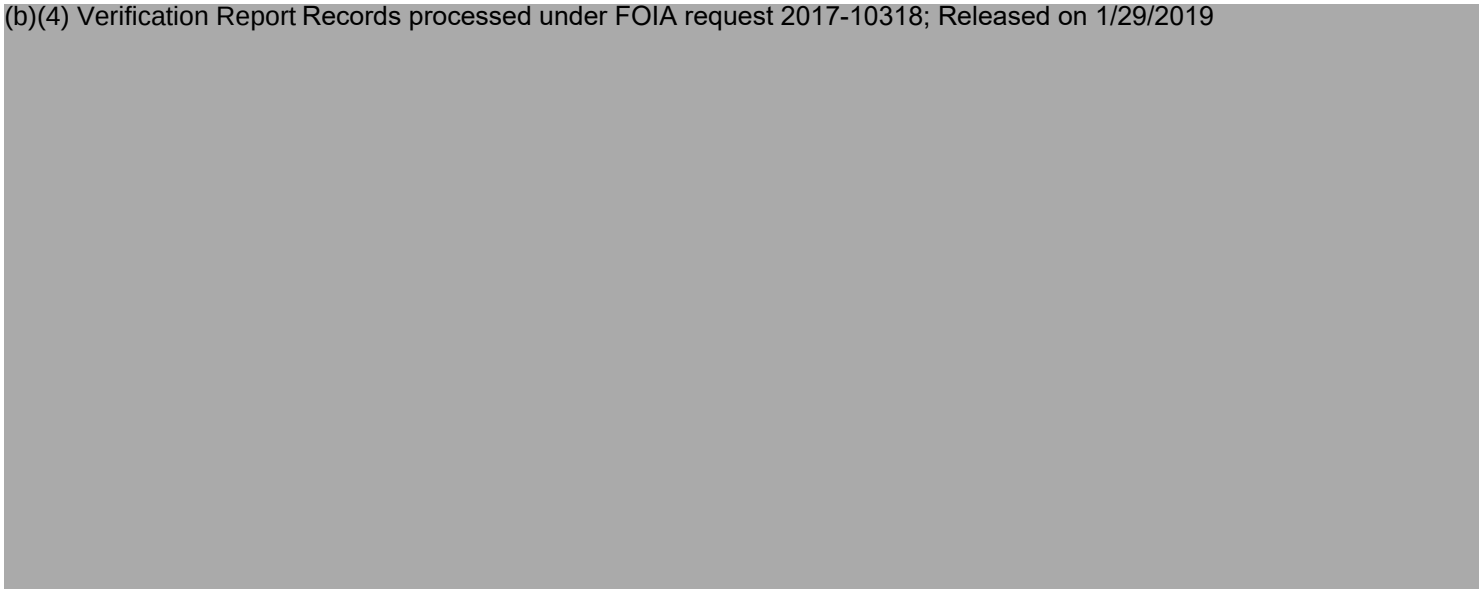


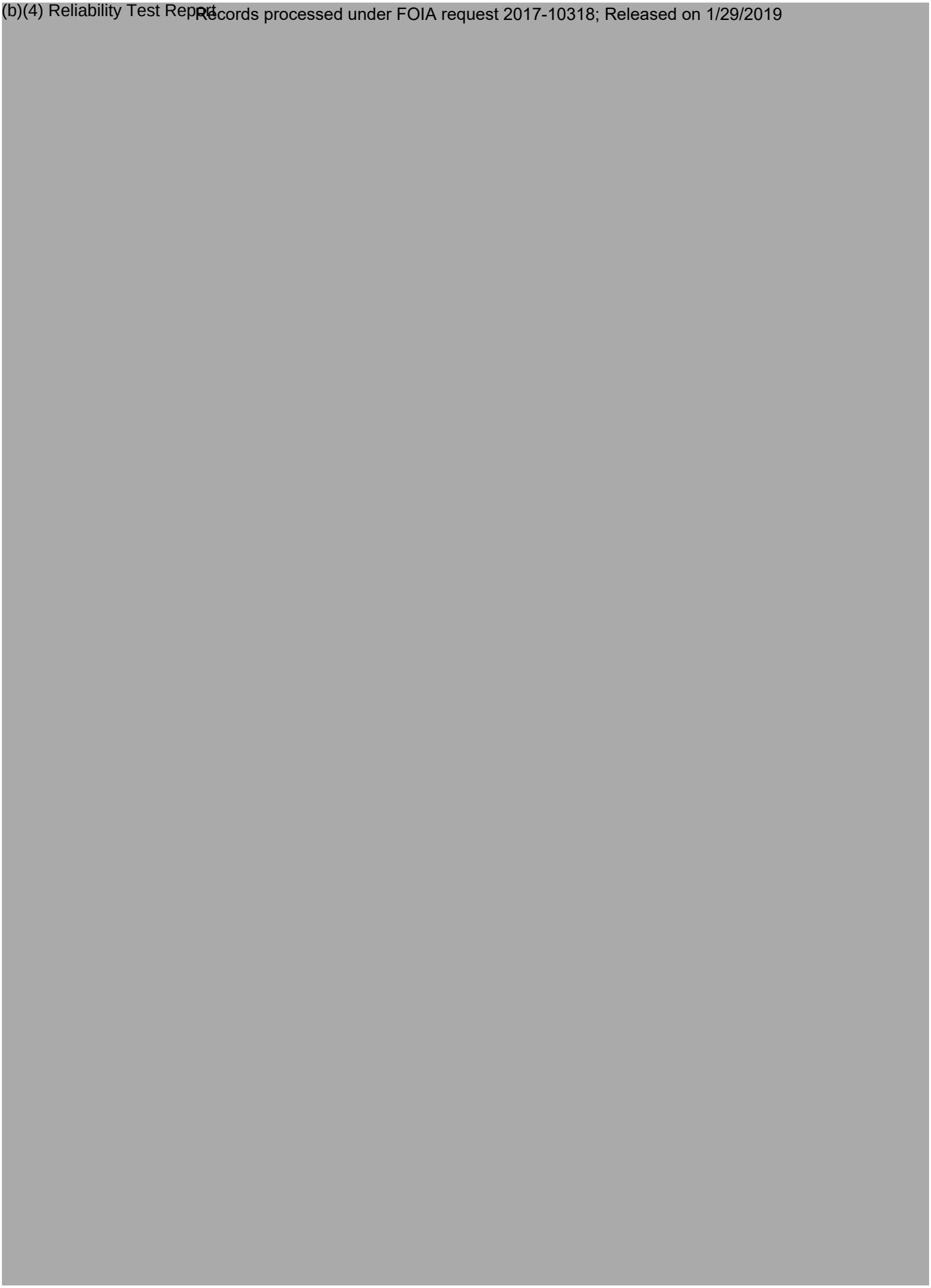


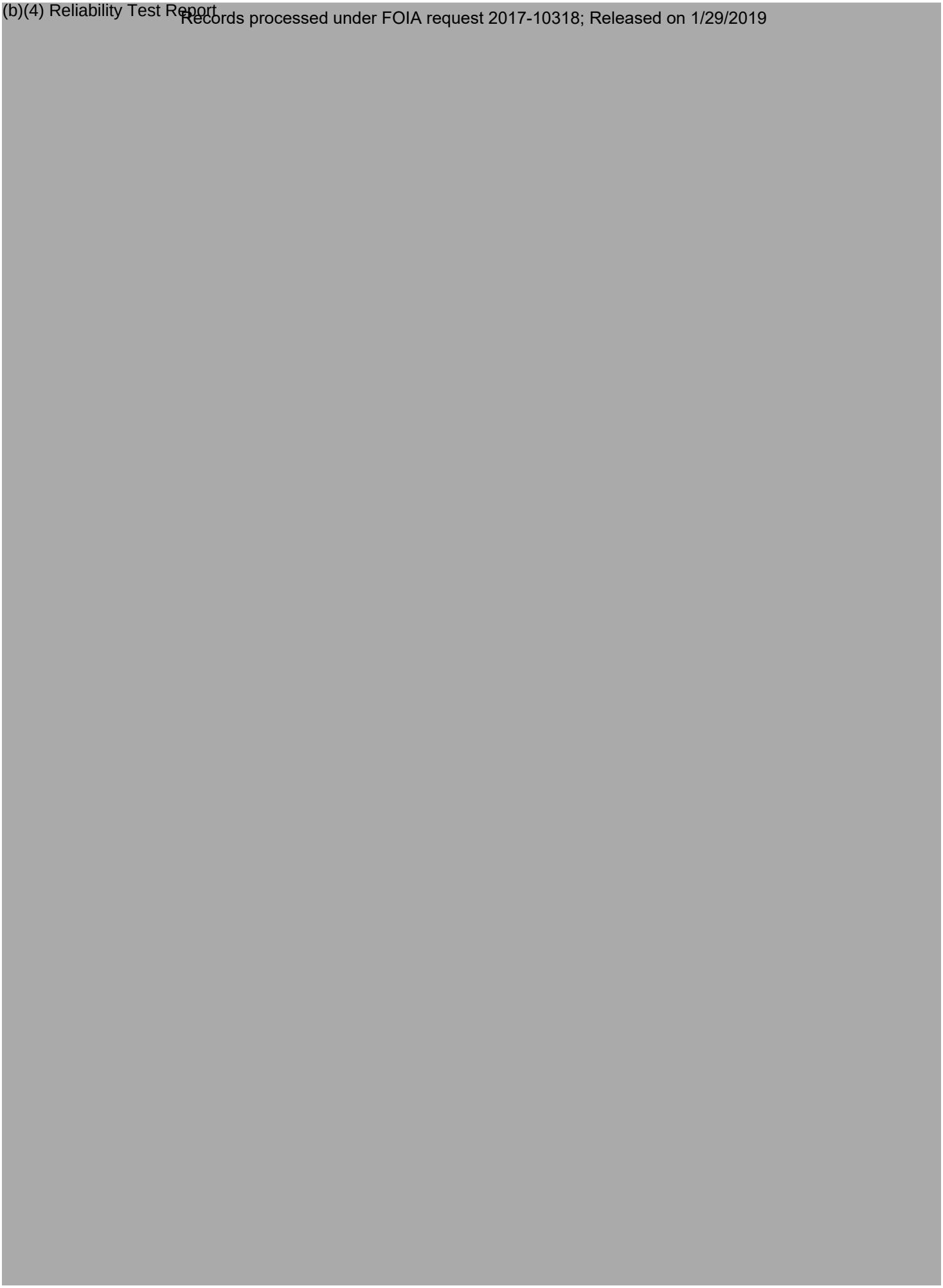


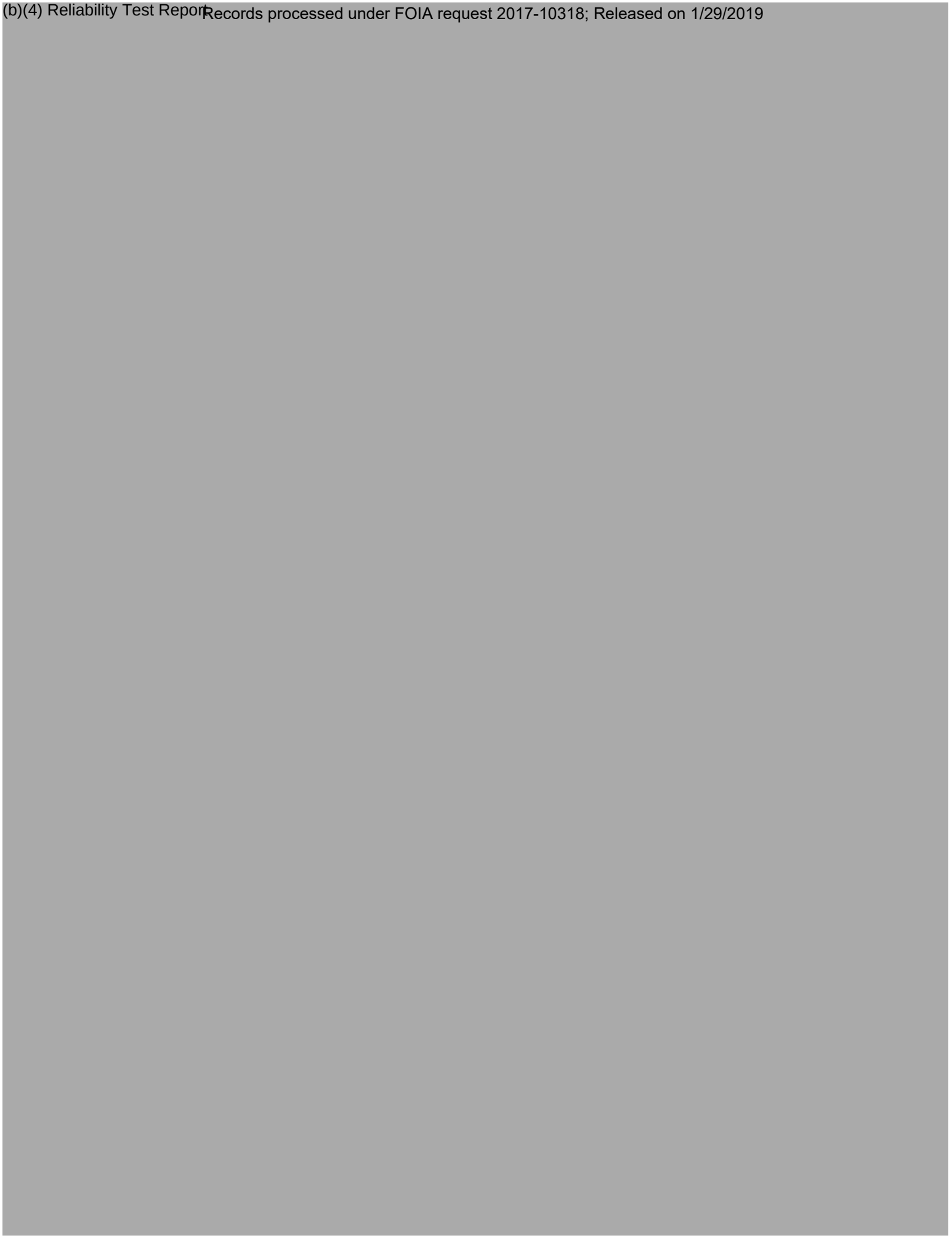
ATTACHMENT 3
14VER4 -01, KARDIA BAND HARDWARE VERIFICATION REPORT

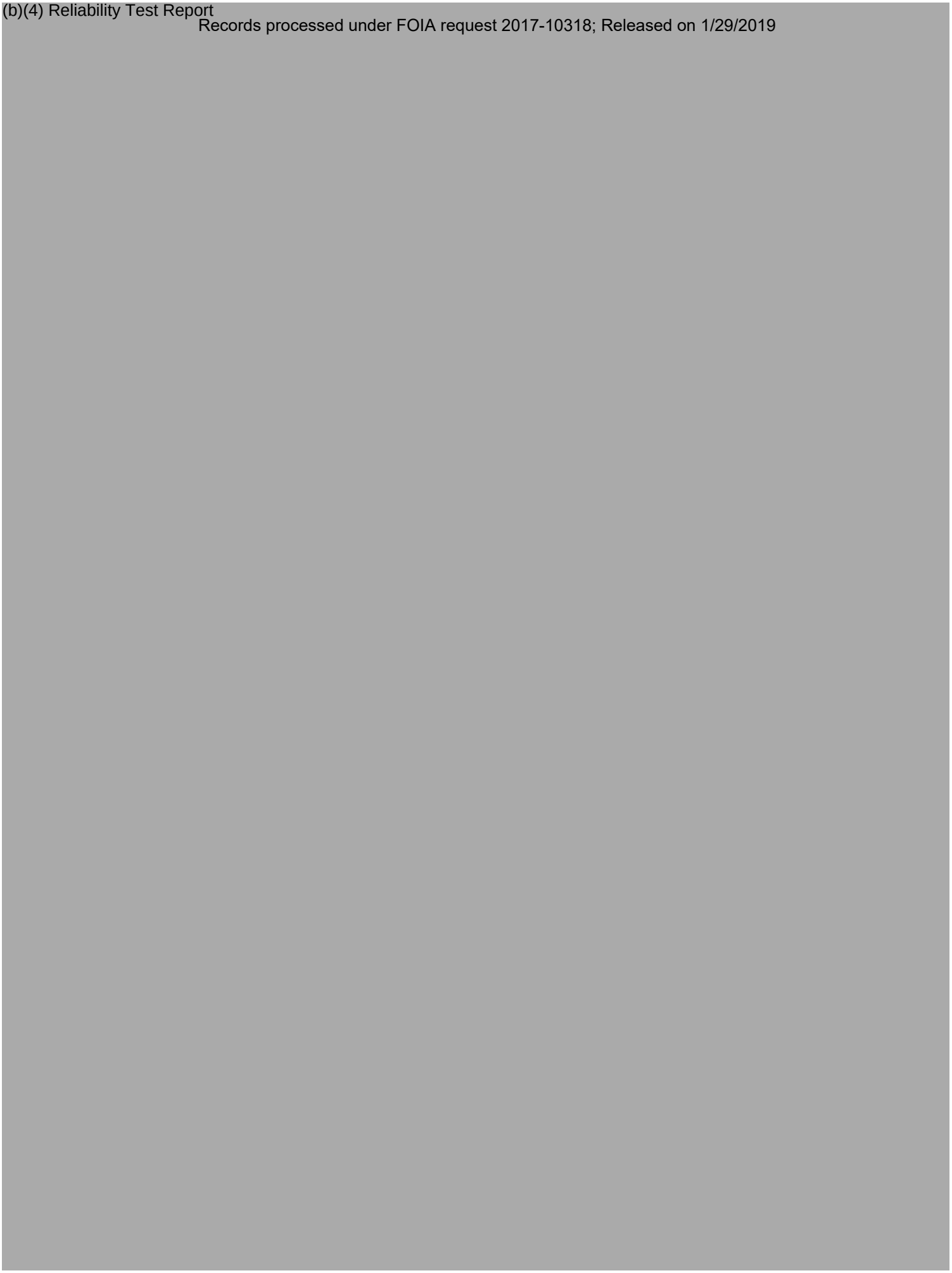


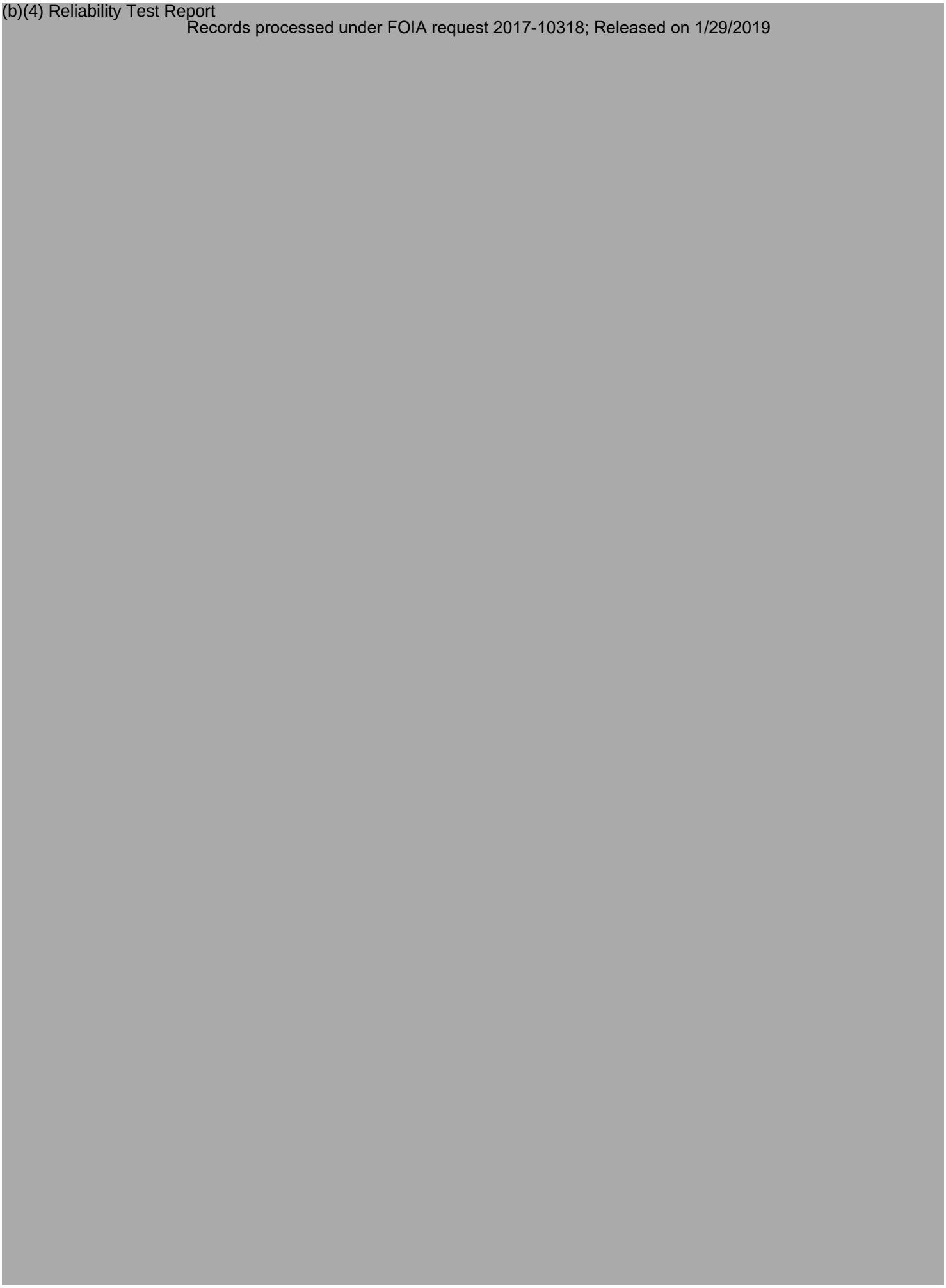


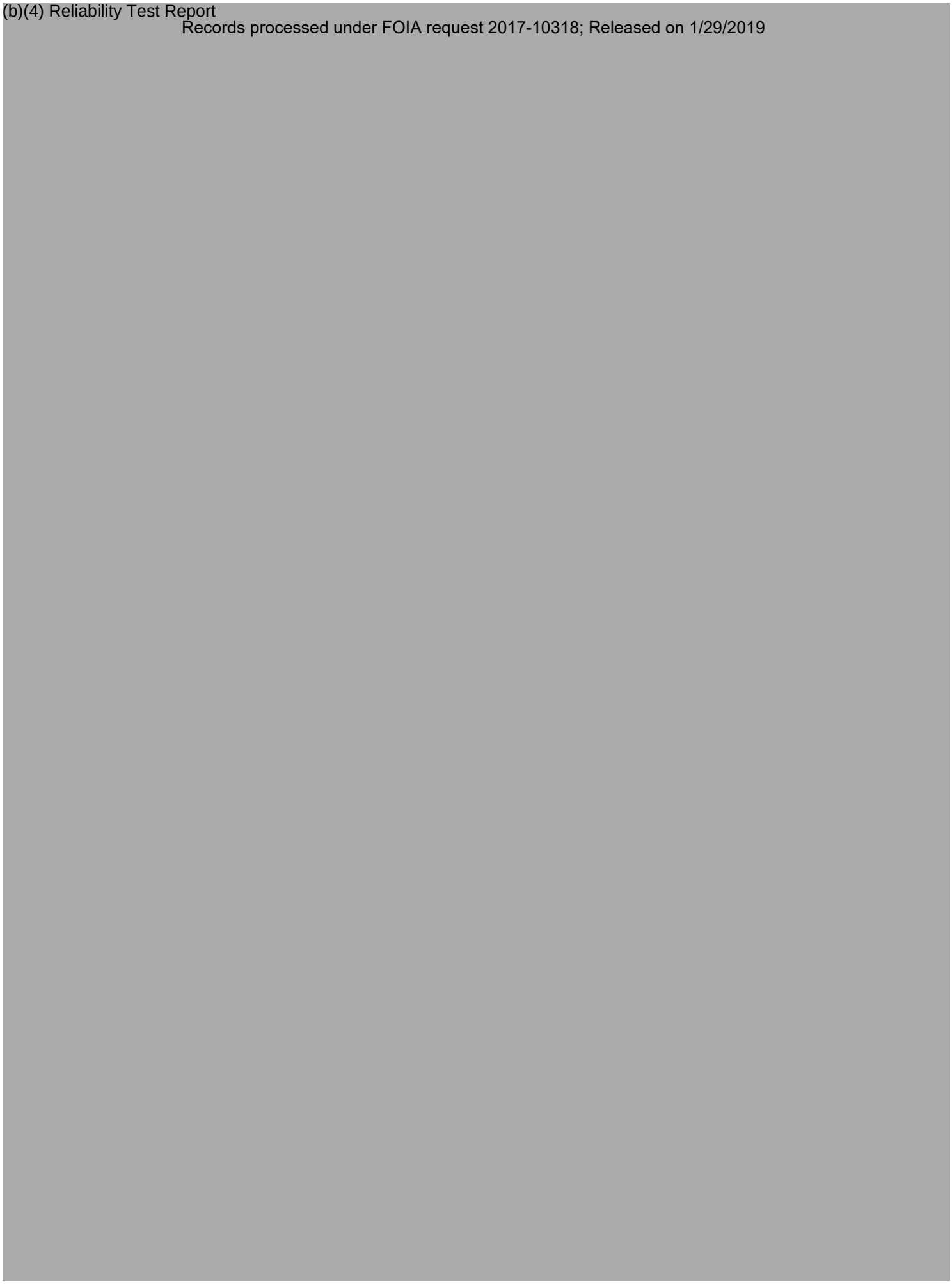


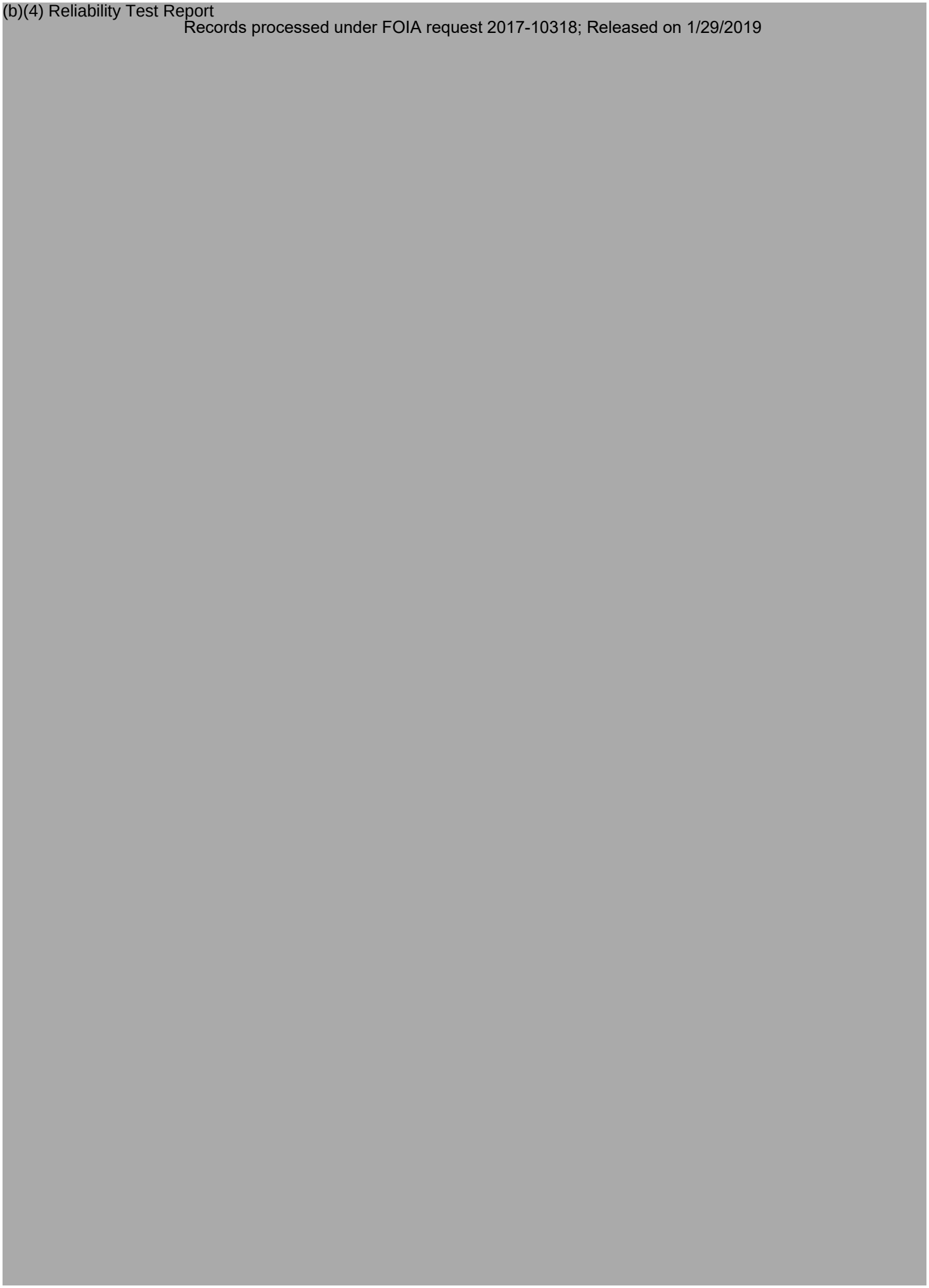












ATTACHMENT 4

(b) DATASET VERIFICATION REPORT