Philips Respironics PE-PUR Recall Remediation Plan (C&R 2021-05-A, 2021-06-A) – US

Sleep & Respiratory Care

Document Number:	ER 2245441
Document Revision:	v05
Document Effective Date:	See Date of Last Approval
Document Security Class:	Confidential

Approvals

	Name	Role	Date & Signature
Approved by:	(b) (6)		

Executive Summary

Plan purpose and scope

Sections 1-3

This document describes Philips Respironics' recall remediation plan in the United States and its territories for the following Class 1 voluntary recall actions:

1) **FDA RES #88071 – VENTS** ..... *Initiated June 2021*
148,729 affected devices; 3 model types.
Recall of certain ventilator devices due to potential health risks from polyester-based polyurethane (PE-PUR) sound abatement foam.

2) **FDA RES #88058 – PAPS** ..... *Initiated June 2021*
10,642,941 affected devices; 15 model types.
Recall of certain bi-level positive airway pressure (BiPAP) and continuous positive airway pressure (CPAP) machines due to potential health risks from polyester-based polyurethane (PE-PUR) sound abatement foam.

3) **FDA RES #91293 – Reworked Trilogy** ..... *Initiated December 2022*
Approx. 13,000 affected devices; 1 model type.
Recall of reworked Trilogy 100/200 ventilator devices due to the potential for silicone foam delamination.

Device owner population. Affected device owners consist of three types: (1) patients using devices in their home (e.g., PAP devices), (2) DMEs and (3) institutions (e.g., hospitals and sleep diagnostic laboratories).

Remediation and financial compensation

Sections 4-5

For each affected device, Respironics is offering: (1) a remediated device (either a new or reworked unit of the same model type, or a new unit of a functionally equivalent model type) with a renewed warranty, and/or (2) financial compensation based on the purchase price of the affected device.

Recall execution

Section 6

General. Respironics deploys a publicly accessible, online recall registration website on which affected device owners are able to register their affected devices with contact information, and through which they can receive information related to the recall.

Device owner and other stakeholder outreach. Respironics has used multiple and extensive methods to publicize the recall to affected device owners, including: direct outreach (b) (4) (b) (4) (b) (4) outreach via DMEs who serve or served affected patients, and indirect outreach through media publications and sleep physicians.

Remediation and financial compensation execution. Respironics employs a mixture of (b) (4) to effect the provision of remediation devices and financial compensation and seek the return of recalled devices.

Recall effectiveness measures. (b) (4)
(b) (4)

Recall completion. RES #88058 and #88071 will be complete when all affected devices registered as of (b) (4)
(b) (4)
process. Remediation of devices affected by RES #91293 will be addressed with RES #88071.

Table of contents

1 Purpose

This document describes the Recall Remediation Plan for the following three Philips Respironics Class I Voluntary Recall Actions:

Recall Enterprise System (RES) reference number assigned by FDA	Subject of Recall	Date Recall Initiated
FDA RES #88071– VENTS	Certain ventilators due to potential health risks from polyester-based polyurethane (PE-PUR) sound abatement foam	June 2021
FDA RES #88058– PAPS	Certain bi-level positive airway pressure (BiPAP) and continuous positive airway pressure (CPAP) machines due to potential health risks from polyester-based polyurethane (PE-PUR) sound abatement foam	June 2021
FDA RES #91293 – Reworked Trilogy 100/200	Reworked Trilogy 100/200 devices	December 2022

This plan specifically describes actions underway or planned for recalled devices distributed within the United States and its territories.

This plan details the approach and methodology deployed in the execution of the recalls including methods used to verify the effectiveness and completion of the recalls.

This plan does not include Health Hazard Evaluations, Corrective and Preventive Action (CAPA) investigations, or related CAPA actions taken or planned to prevent recurrence of issues, that led to the recall decisions. These files are included by reference but are maintained in accordance with the Philips Respironics Quality Management System. The relevant documents are listed below:

- CAPA 7211 (initiated based on a complaint alleging potentially degraded PE-PUR sound abatement foam)

(b) (4)

Recall execution actions outside of the United States and its territories are the subject of separate documents and are outside the scope of this Recall Remediation Plan.

2 Background

This Recall Remediation Plan encompasses RES numbers 88071 [VENTS], RES 88058 [PAP], and RES 91293 [Reworked Trilogy 100/200].

2.1 Sleep therapy device ecosystem and key stakeholders (RES #88058[PAPS])

The sleep therapy device ecosystem in the U.S. includes devices that are prescribed by physicians and typically distributed by DMEs to patients to address sleep apnea. This includes CPAP, BiPAP, and higher acuity devices. Refer to Appendix 1 for more detail on the sleep therapy device ecosystem and key stakeholders.

2.2 Respiratory care device ecosystem and key stakeholders (RES #88071[VENTS])

The respiratory care device ecosystem in the U.S. includes devices that are prescribed by Pulmonologists (Respiratory Physicians) or initiated during a hospital admission to address respiratory failure/insufficiency. Refer to Appendix 1 for more detail on the respiratory care device ecosystem and key stakeholders.

2.3 Recall Decisions

Philips Respironics' decision in June 2021 to initiate the recall of certain CPAP, BiPAP, and ventilator devices due to potential health risks from polyester-based polyurethane (PE-PUR) sound abatement foam is outlined in detail in CAPA 7211 (b) (4) . The subsequent recall of reworked Trilogy 100/200 devices due to the potential for silicone foam delamination is described in (b) (4) .

3 Recall Scope

(b) (4) As a note, this sales data is associated with the Consignee who first received the device, which would include either a DME or institution. Philips Respironics does not have a direct relationship with patients.

Recalled devices in scope of this plan have been identified as devices cleared for sale in the United States and its territories for which the "Ship To Address" was located in the United States and its territories at the time of sale of the original device. (b) (4)

The following devices are included in the scope of the recall in the US and its territories (b) (4) . A comprehensive list of all part numbers subject to the global recall is provided in CAPA 7211.

Category	Device model	Number of devices affected
RES #88058 [PAPS] Sleep therapy devices	DreamStation CPAP	4,149,805
	DreamStation BiPAP	517,270
	DreamStation ASV	67,152
	DreamStation Go	49,120
	System One 50 Series Base	2,183,468
	System One 50 Series BiPAP	338,711
	System One 50 Series ASV4 (Auto SV4)	32,024
	System One 60 Series Base	2,632,119
	System One 60 Series BiPAP	373,441
	System One 60 Series ASV4 (Auto SV4)	67,700
	DreamStation ST, AVAPS	56,823
	C-series S/T, AVAPS (C-series and C-series HT)	139,301
	E30	19,514
	OmniLab Advanced Plus	16,478
	Dorma 400/500, REMStar SE Auto	15
RES #88071 [VENTS] Respiratory care devices	Trilogy 100/200, Garbin Plus, Aeris, LiveVent[1]	141,896
	A-Series	350
	V30 auto	6,483
	Total	**10,791,670**

[1] ~13,000 affected Trilogy 100/200 devices in U.S. were reworked, then subsequently recalled (FDA RES #91293 – Reworked Trilogy 100/200) due to the potential for silicone foam delamination.

4 Overall recall execution approach

Manufacturing of products subject to this recall for sale/commercialization has been paused. PE-PUR sound abatement foam is no longer used for CPAPs, BiPAPs, or ventilators. Refurbished devices and the new updated device models (DreamStation 2) now use a silicone sound abatement foam, (b) (4)

As required by the Order under section 518(a) of the FD&C Act, Philips Respironics has published a summary of available, third-party confirmed data and results from additional PE-PUR foam testing through Philips Respironics' Recall Website (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/news/update-on-the-test-and-research-program). Philips Respironics periodically updates this testing summary as new data and results become available.

Additional testing is being carried out to further assess and understand risks associated with the PE-PUR foam. Details of the testing processes for PE-PUR can be found in the Philips Respironics PE-PUR Test Plan Summary for PE-PUR test as submitted to FDA on April 26, 2022.

5 Recall Remediation options

5.1 Remediation options available by device type

Philips Respironics works with customers and patients to identify affected devices, which include those that remain in the field (owned by patients, DMEs or institutions) and those that remain in the inventory of DMEs and non-patient consignees. Philips Respironics' primary objective when defining remediation options is to enable patients to continue therapy as quickly as possible, with minimal disruption.

This Recall Remediation Plan (***"Updated Plan"***) document contains some updates to the remediation pathways outlined in the draft recall remediation plan that the company submitted to FDA on June 1, 2022 (the **"*June Draft Plan*"**). These updates are due to evolved remediation options as (b) (4)

Further detail can be made available upon request.

Types of remediation options

Under the Plan, the following remediation pathways are available (specific available options vary by device type):

1. **Reworked Device:** Rework the Recalled Device and return the reworked device to the same patient or customer that had been using that Recalled Device. A Reworked Device will carry a 2-year warranty on the materials and workmanship for the rework performed on that device pursuant to the Recall.

2. **Reworked "U" Device:** Replace Recalled Device with a "U" part – a previously used device (b) (4) (b) (4) A reworked "U" Device will include a 2-year warranty.

3. **"F" Device:** A replacement device containing corrected foam (b) (4) (b) (4) . The F Device will include a 2-year warranty. (b) (4)

4. **"F" Device with Accessories:** A replacement device containing corrected foam (b) (4) (b) (4) (b) (4) A "F" Device with Accessories will (b) (4) a 2-year warranty.

5. **Alternative Device:** A new or reworked device of a different product type, but that performs the equivalent function as the Recalled Device. A 2-year warranty and all accessories are included with the alternative device. It may include a humidifier.

6. **Financial compensation:** Financial compensation made available to patients, DMEs, and institutions (b) (4)

In all reworked "U" devices or reworked devices, the PE-PUR foam is replaced. Information on engineering changes and respective regulatory alignment is provided in Section 5.1.2 of this document.

Any rework, F-device or alternative remediation option delivers equivalent therapy, and the selection a given replacement or reworked device is based solely on criteria of most expeditious remediation of the registered device.

Availability of Remediation Options by Recalled Device Type

As of August 2023, the following remediation options are available by device group for FDA RES #88058 - PAPS. (b) (4)
(b) (4)

REMEDIATION OPTIONS: RES #88058 - PAPS						
Device Type	**Reworked Device**	**Reworked "U" Device**	**"F" Device**	**"F" Device with Accessories**	**Alternative Device**	**Financial Compensation (Section 5.1.1)**
System One 50 Series – CPAP, BiPAP, ASV	(b) (4)					
System One 60 Series – CPAP, BiPAP, ASV						
DreamStation CPAP						
DreamStation BiPAP						
DreamStation ASV						
DreamStation Go						
OmniLab Advanced Plus						
E30						

REMEDIATION OPTIONS: RES #88058 - PAPS						
Device Type	**Reworked Device**	**Reworked "U" Device**	**"F" Device**	**"F" Device with Accessories**	**Alternative Device**	**Financial Compensation (Section 5.1.1)**
C-series ST, AVAPs	(b) (4)					
DreamStation ST, AVAPS						

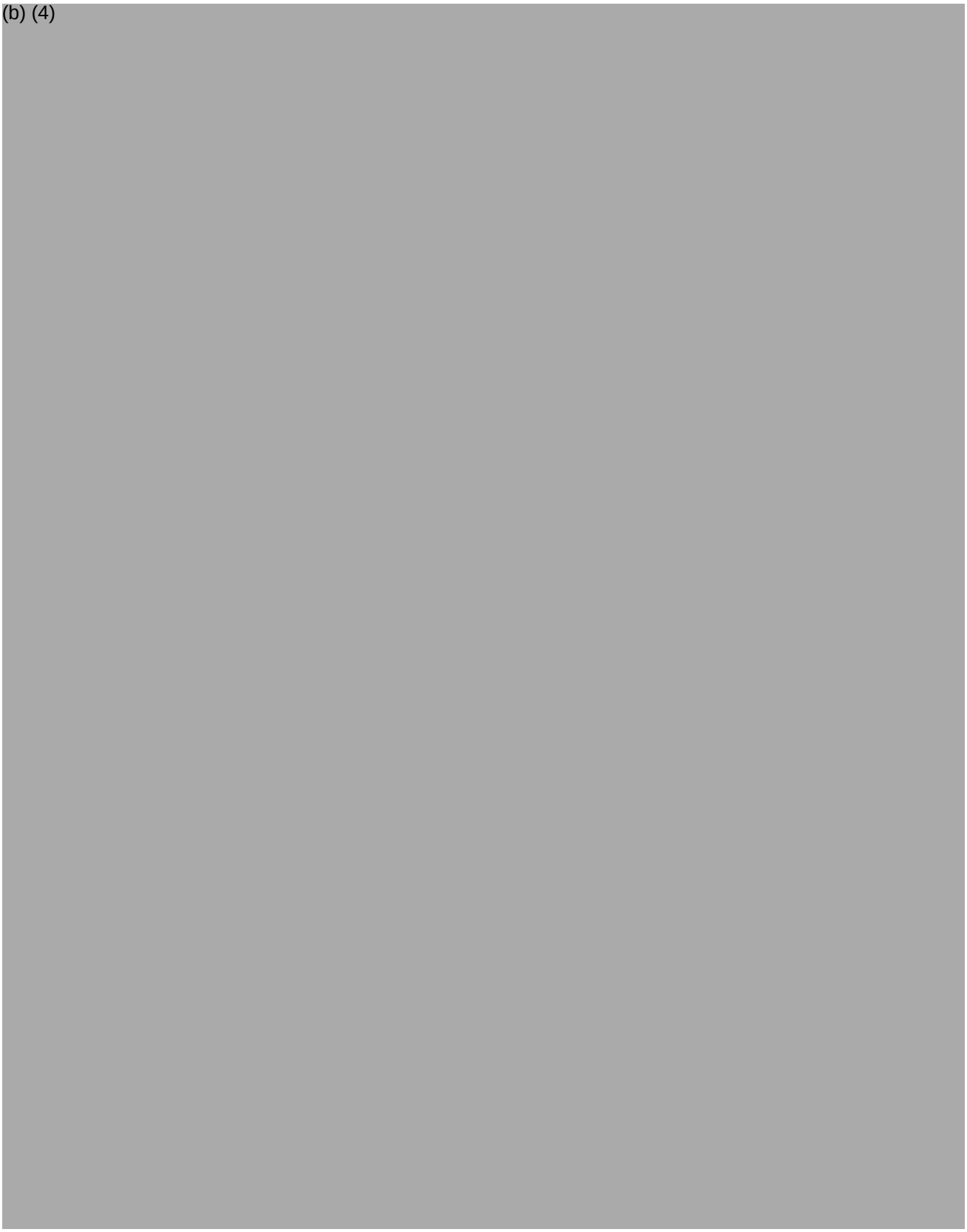
(b) (4)

The following remediation options are available by device group for **FDA RES #88071 – VENTS:**

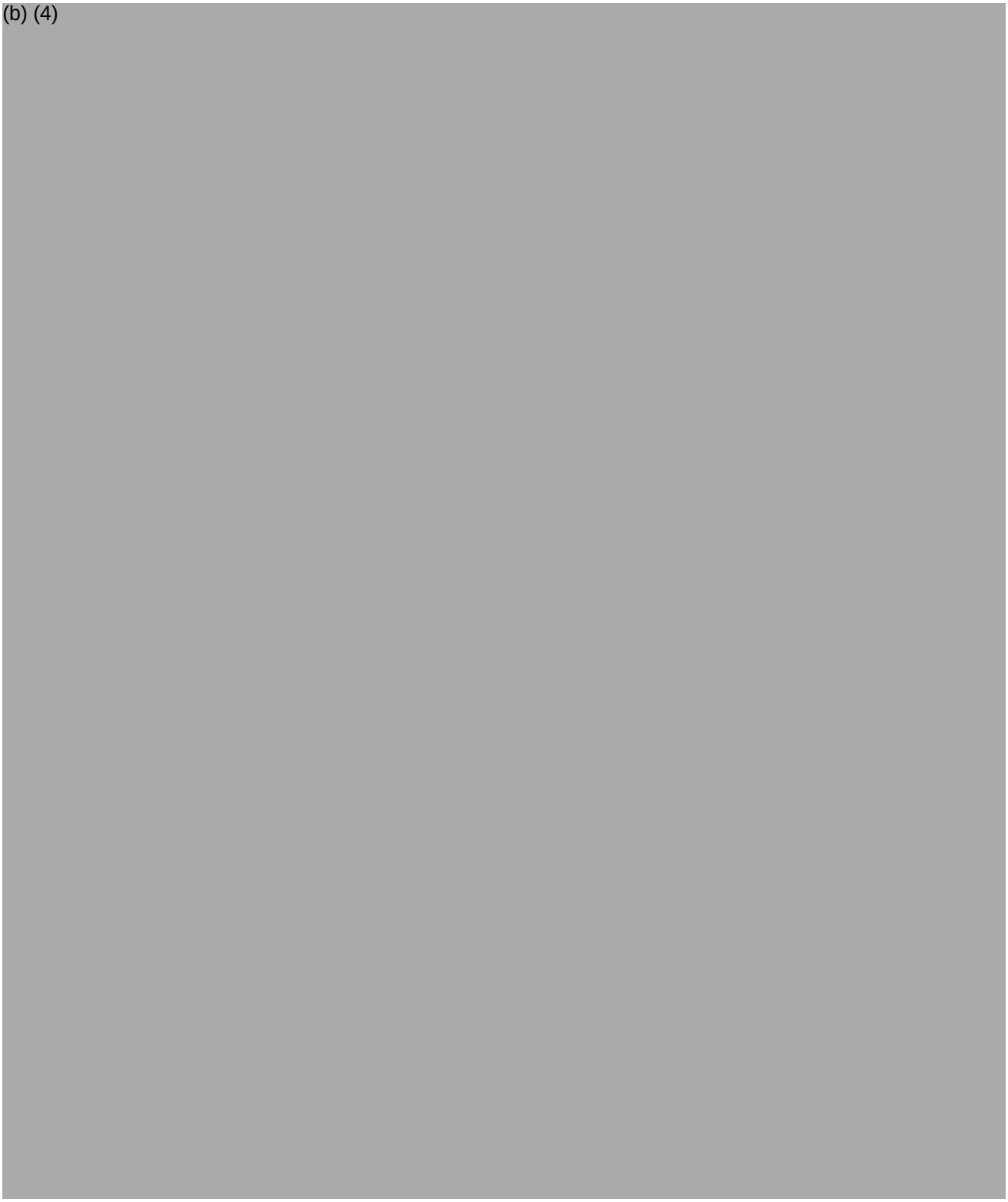
REMEDIATION OPTIONS: RES #88071 – VENTS							
Device type	**Reworked Device**	**Reworked U Device**	**"F" Device**	**"F" Device with Accessories**	**Alternative Device**	**Provide Loaner Device (temporary measure only)[2]**	**Remediation Financial Compensation (Section 5.1.1)**
Trilogy 100/200 *Also includes RES # 91293*	(b) (4)						
V30 Auto							

(b) (4)

(b) (4)

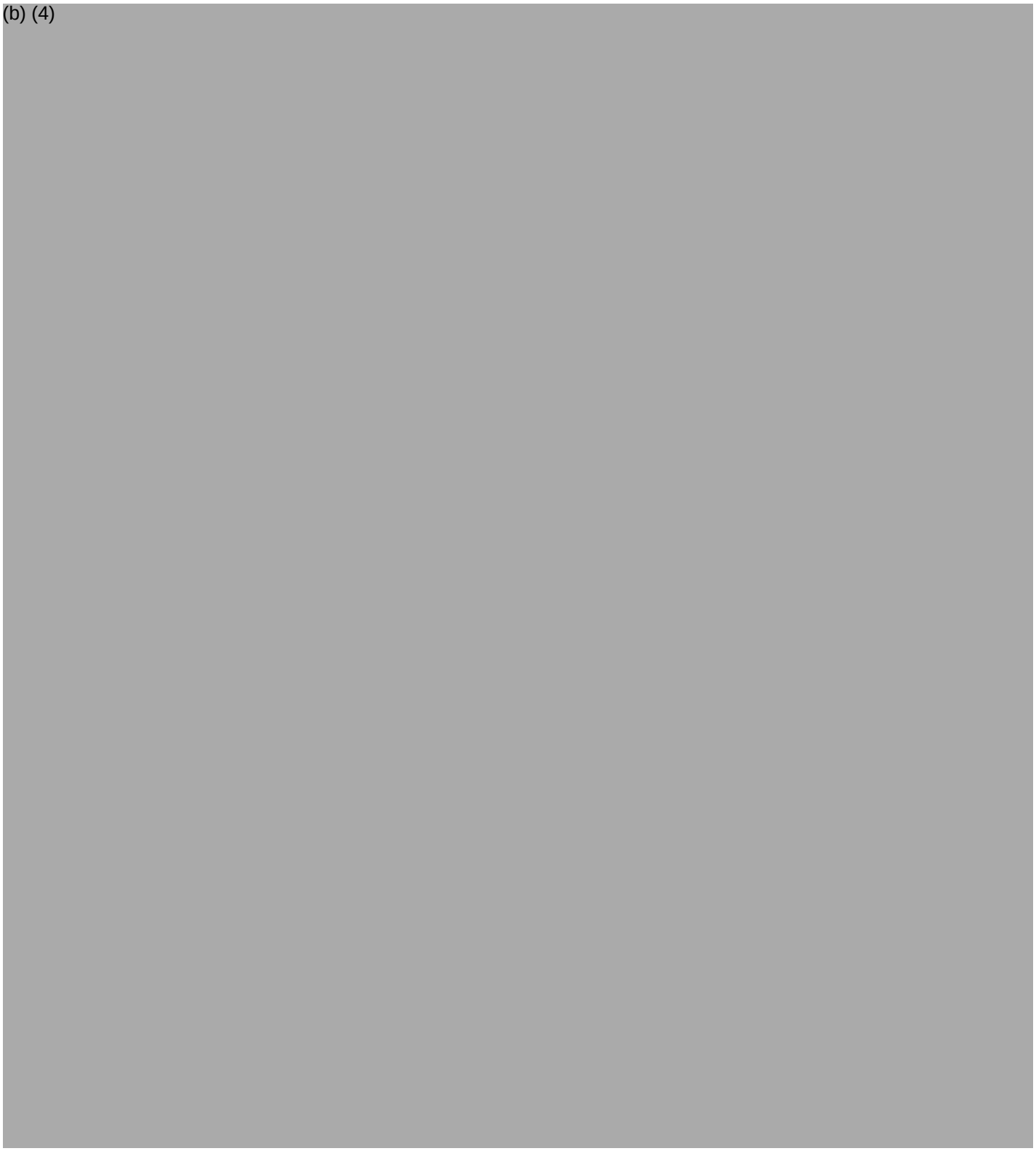


(b) (4)

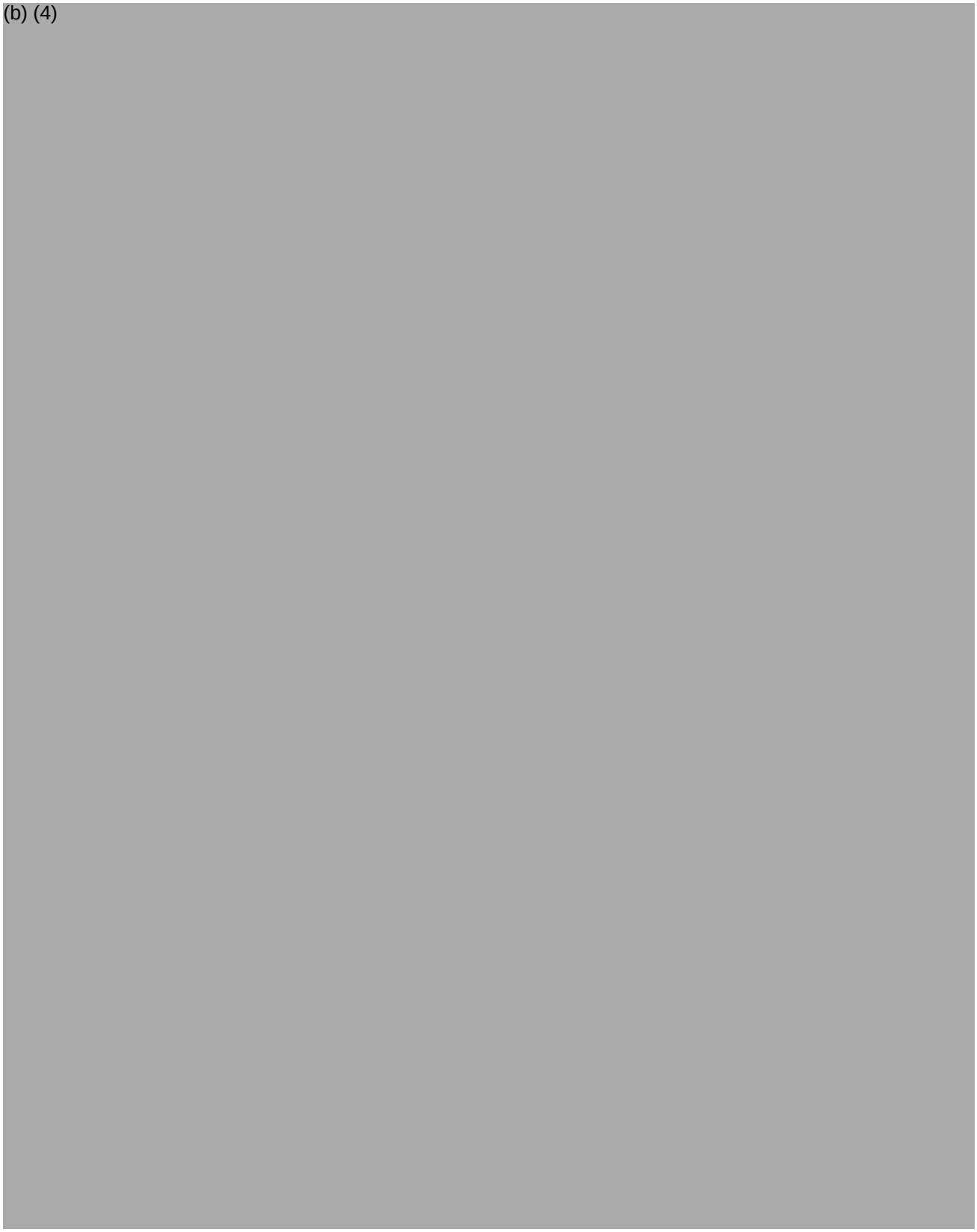


5.1.1 Financial compensation pathways

(b) (4)



(b) (4)

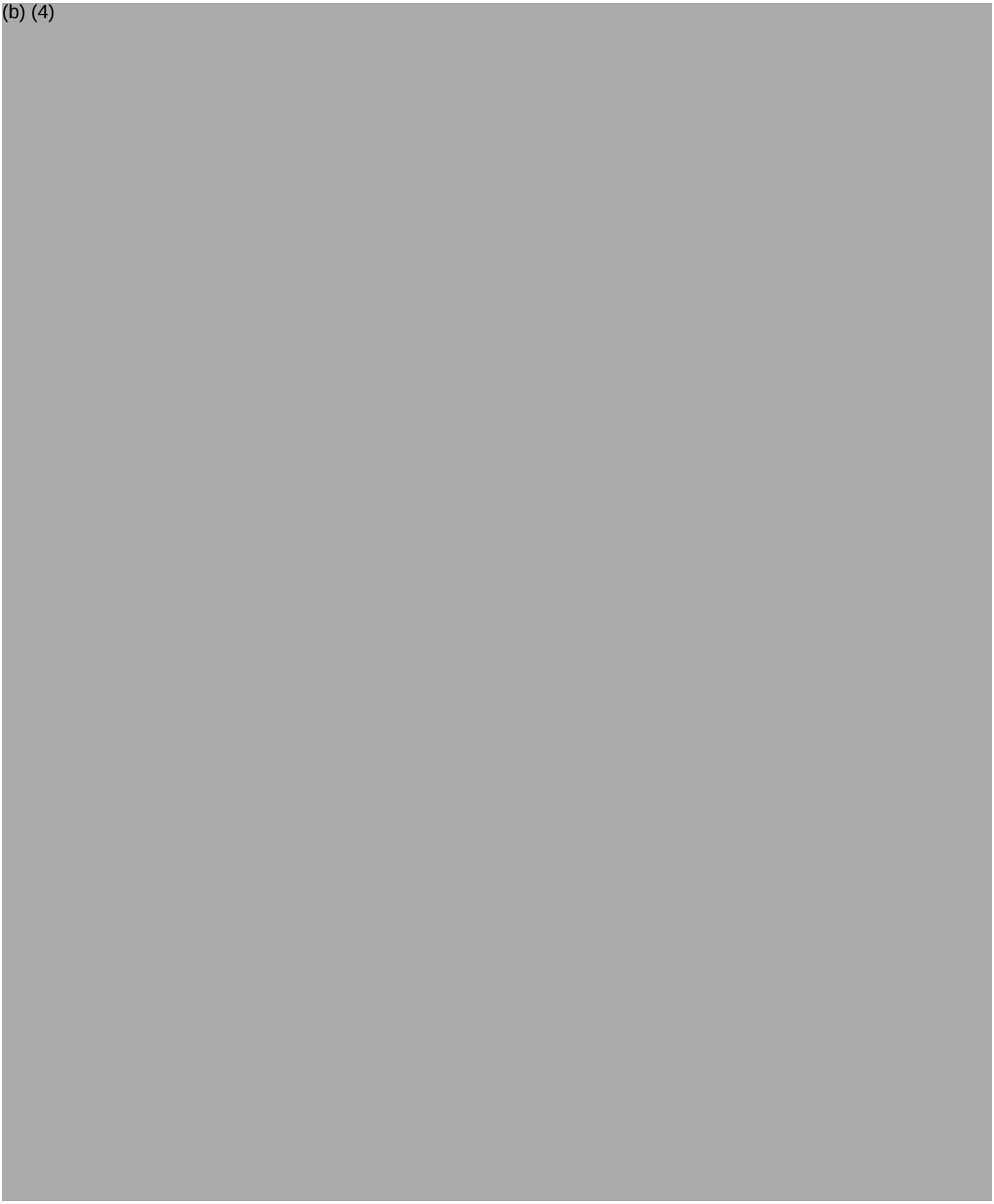


(b) (4)

5.1.2 Engineering changes to enable remanufacturing and rework

(b) (4)

(b) (4)

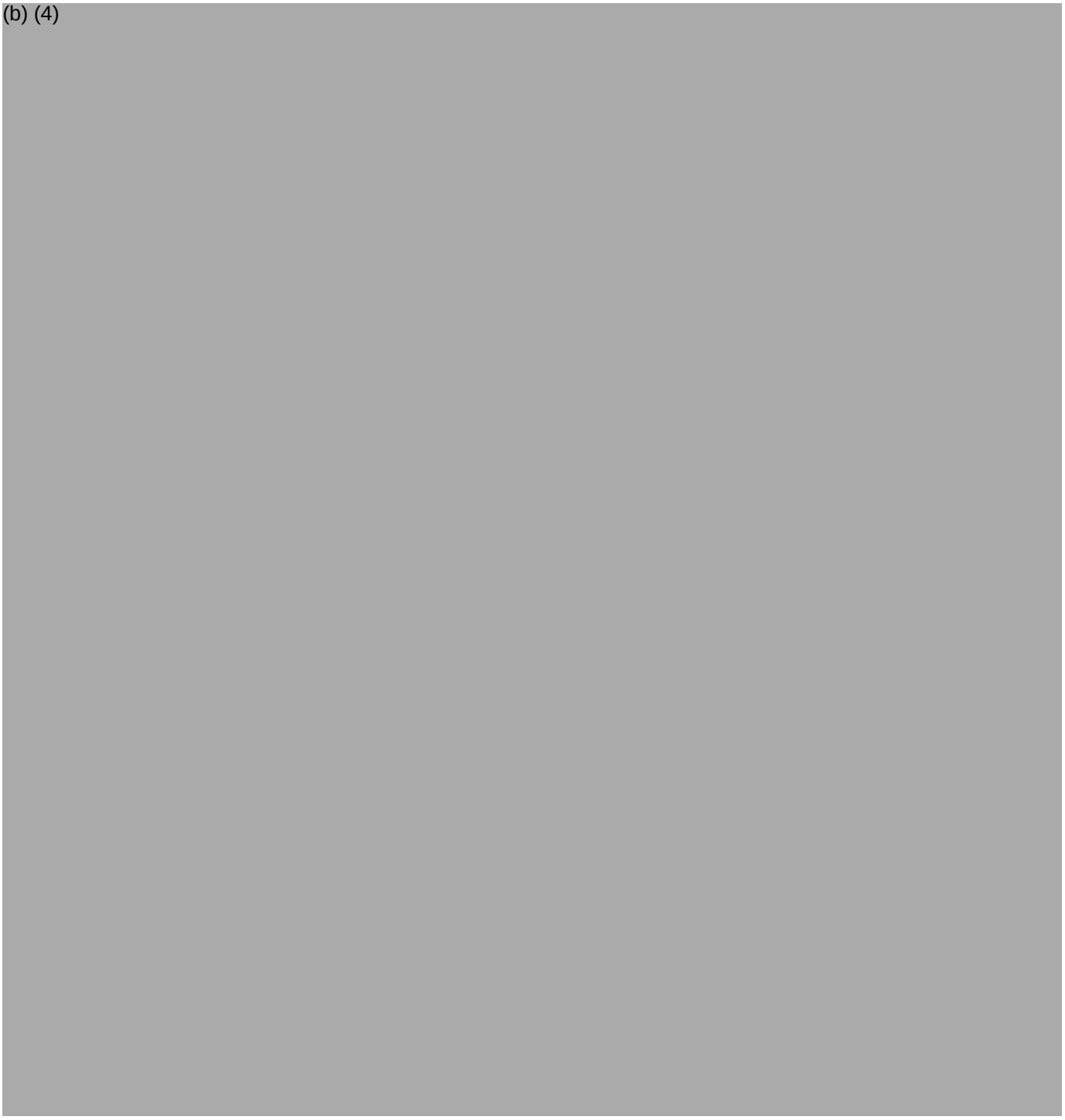


(b) (4)

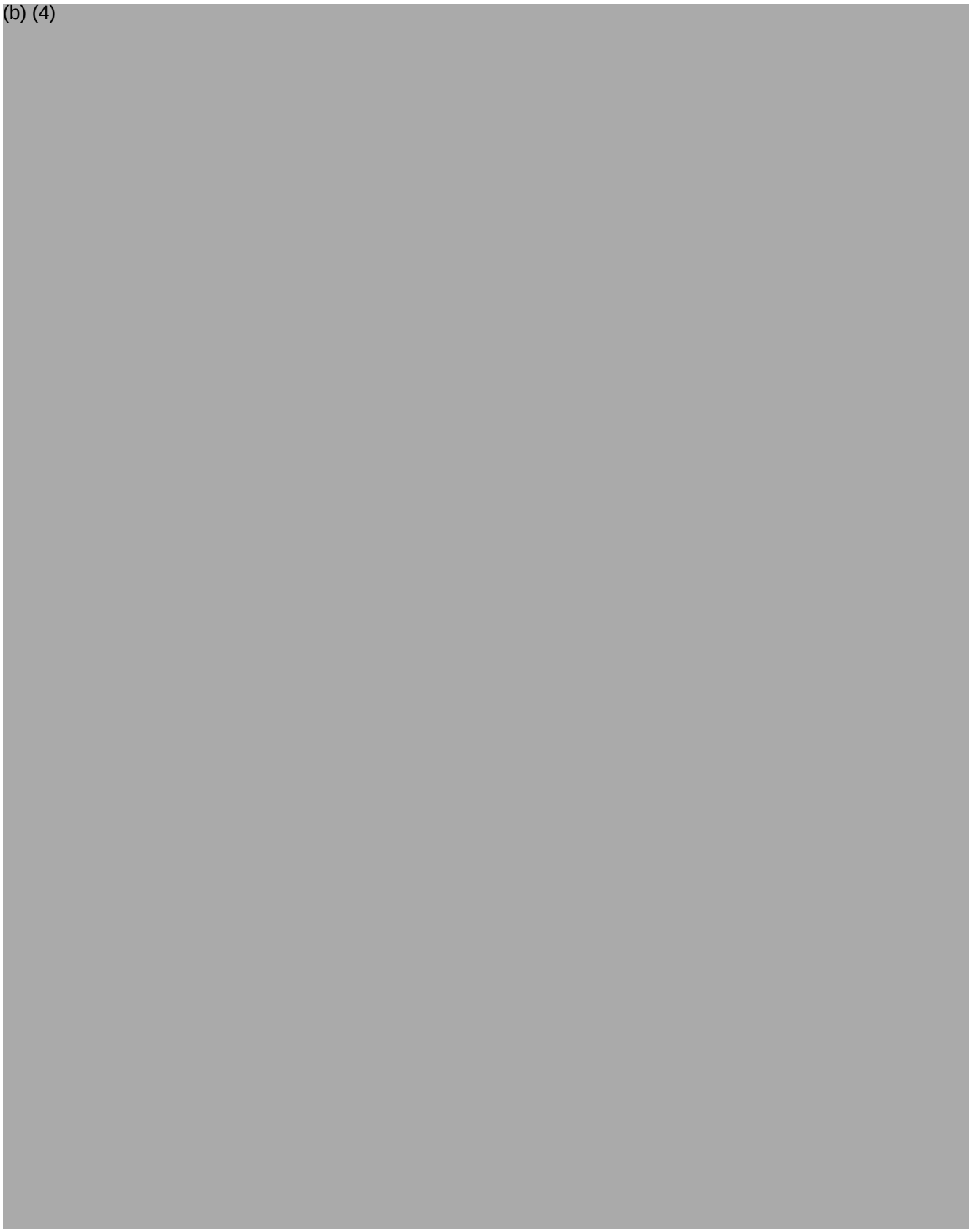
6 Recall Execution

6.1 Stakeholder outreach, registration, stakeholder engagement, and device replacement

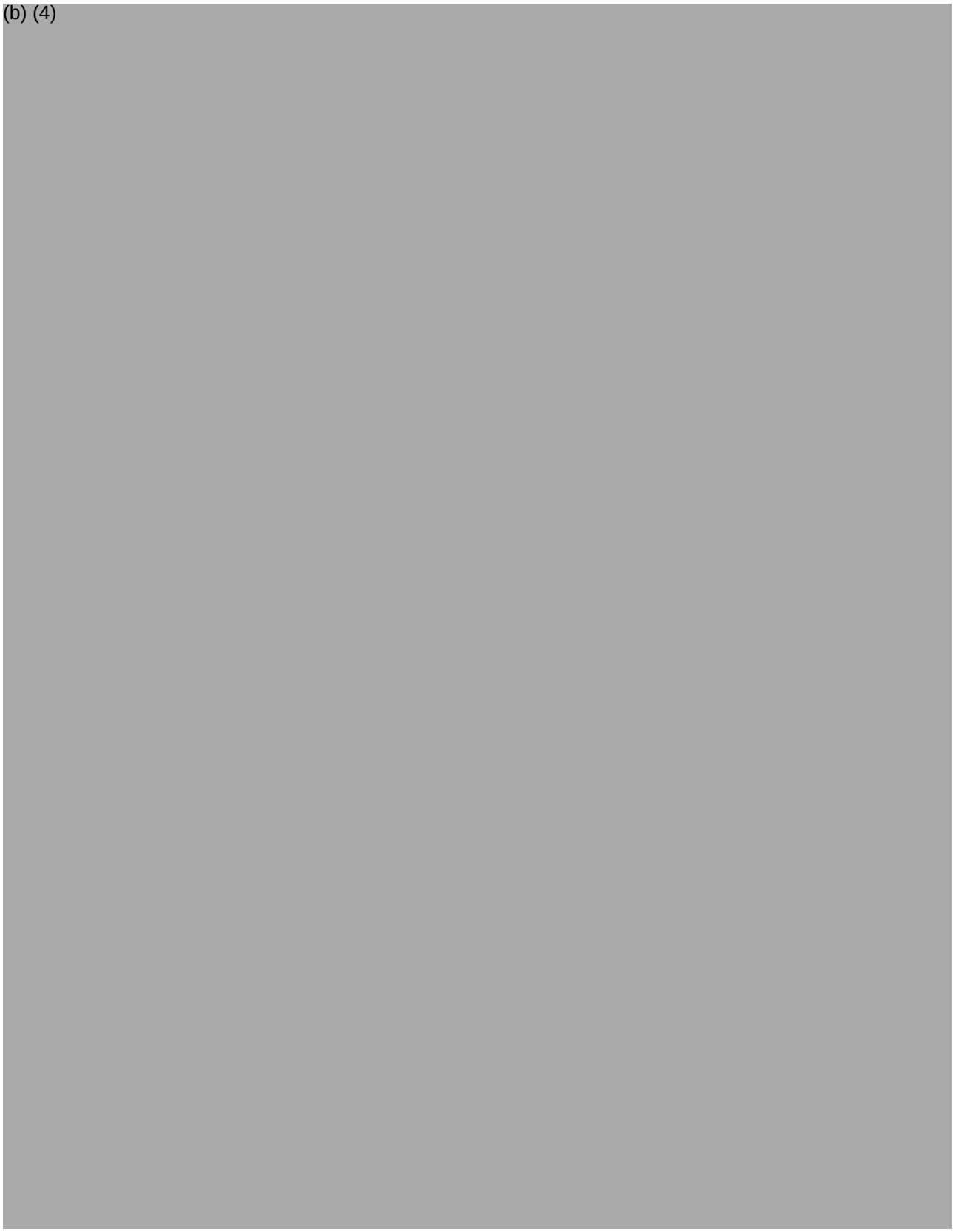
(b) (4)



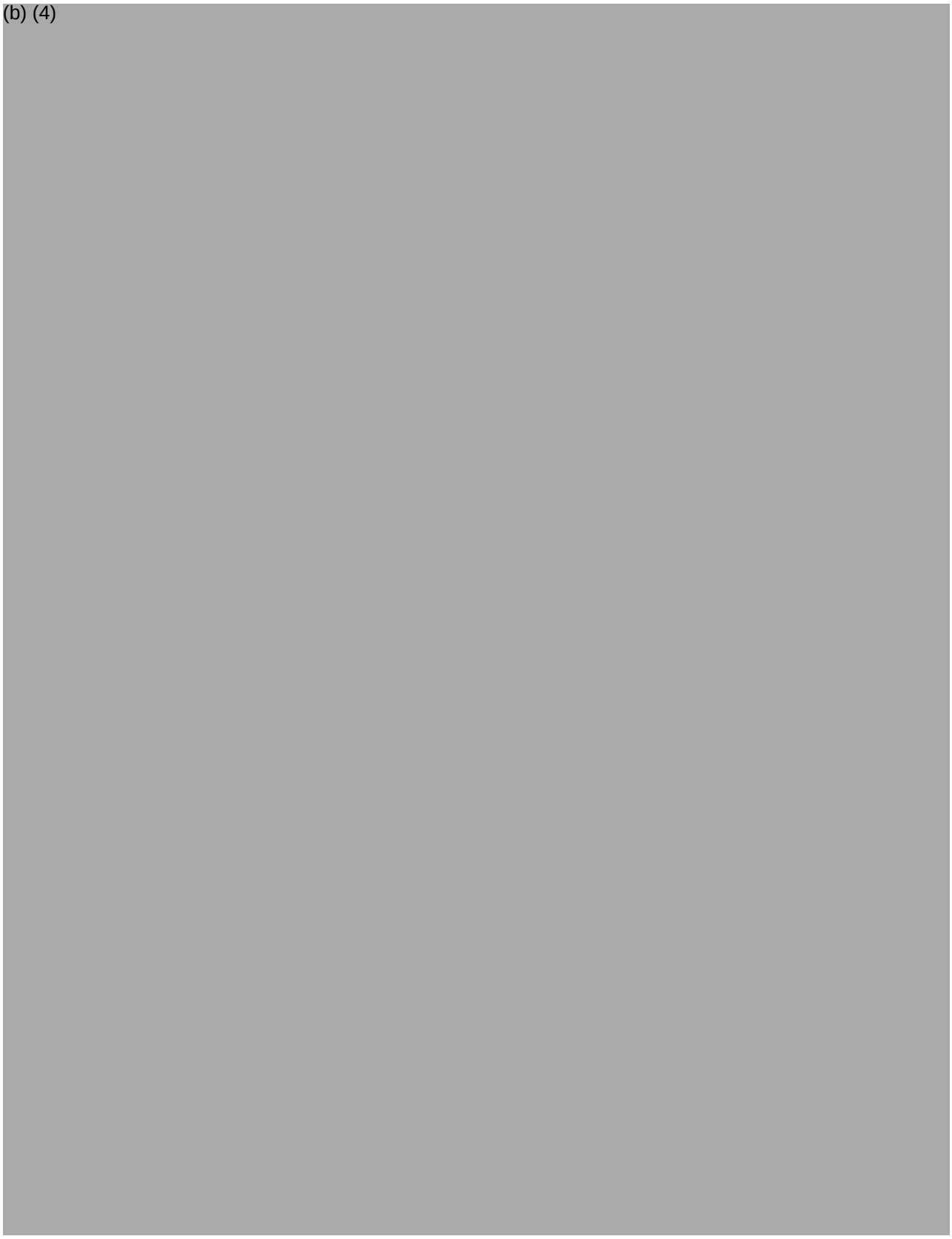
(b) (4)



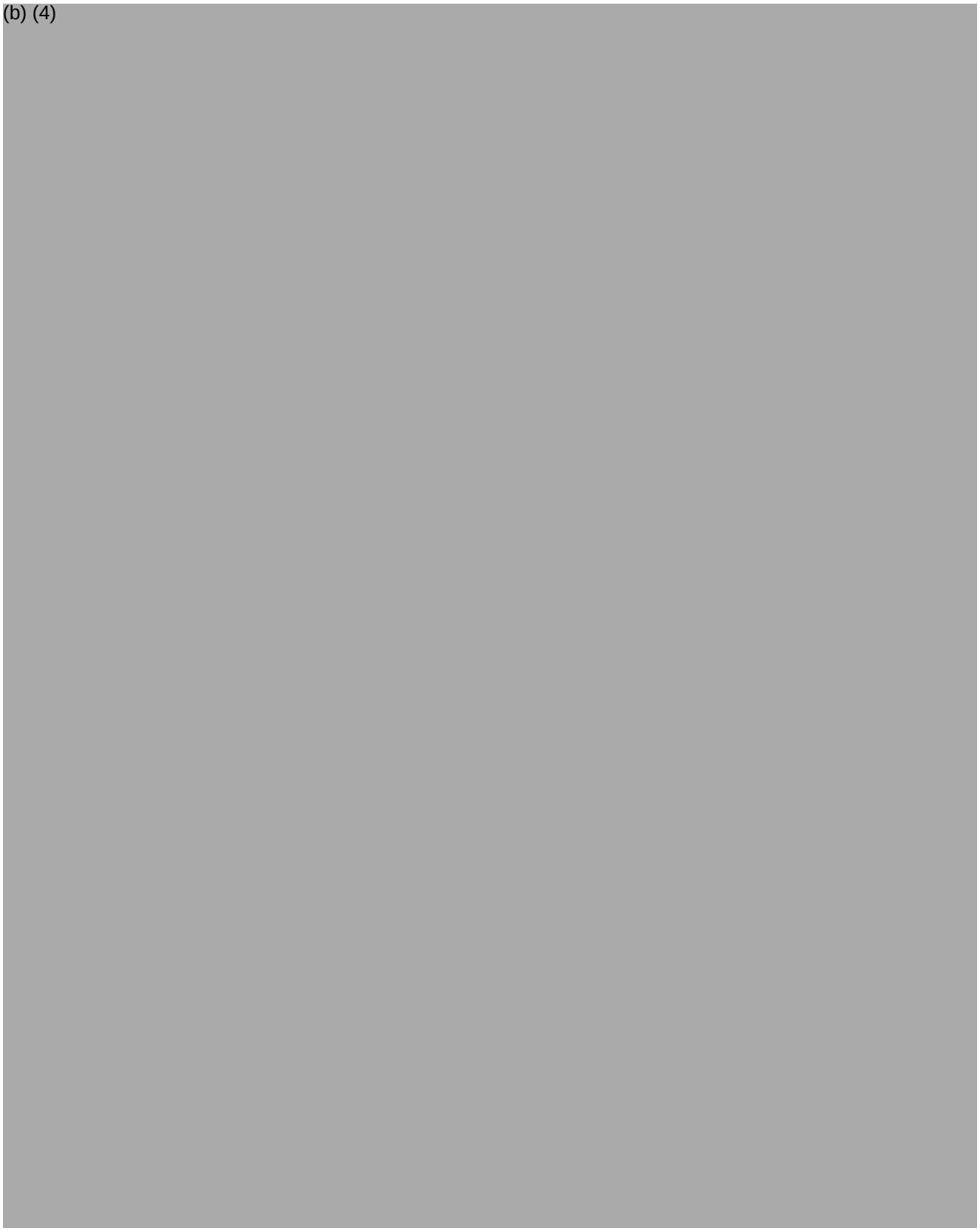
(b) (4)



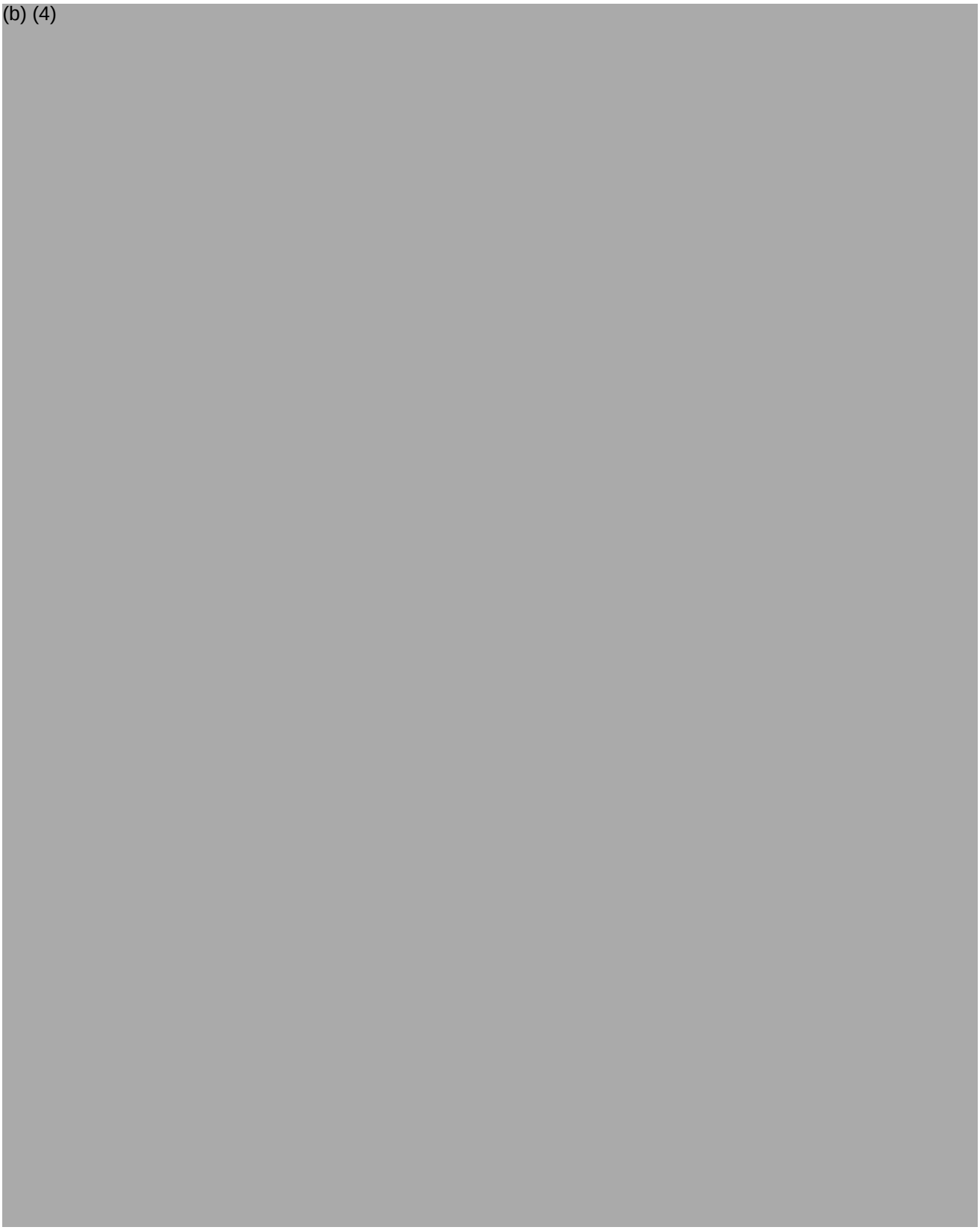
(b) (4)



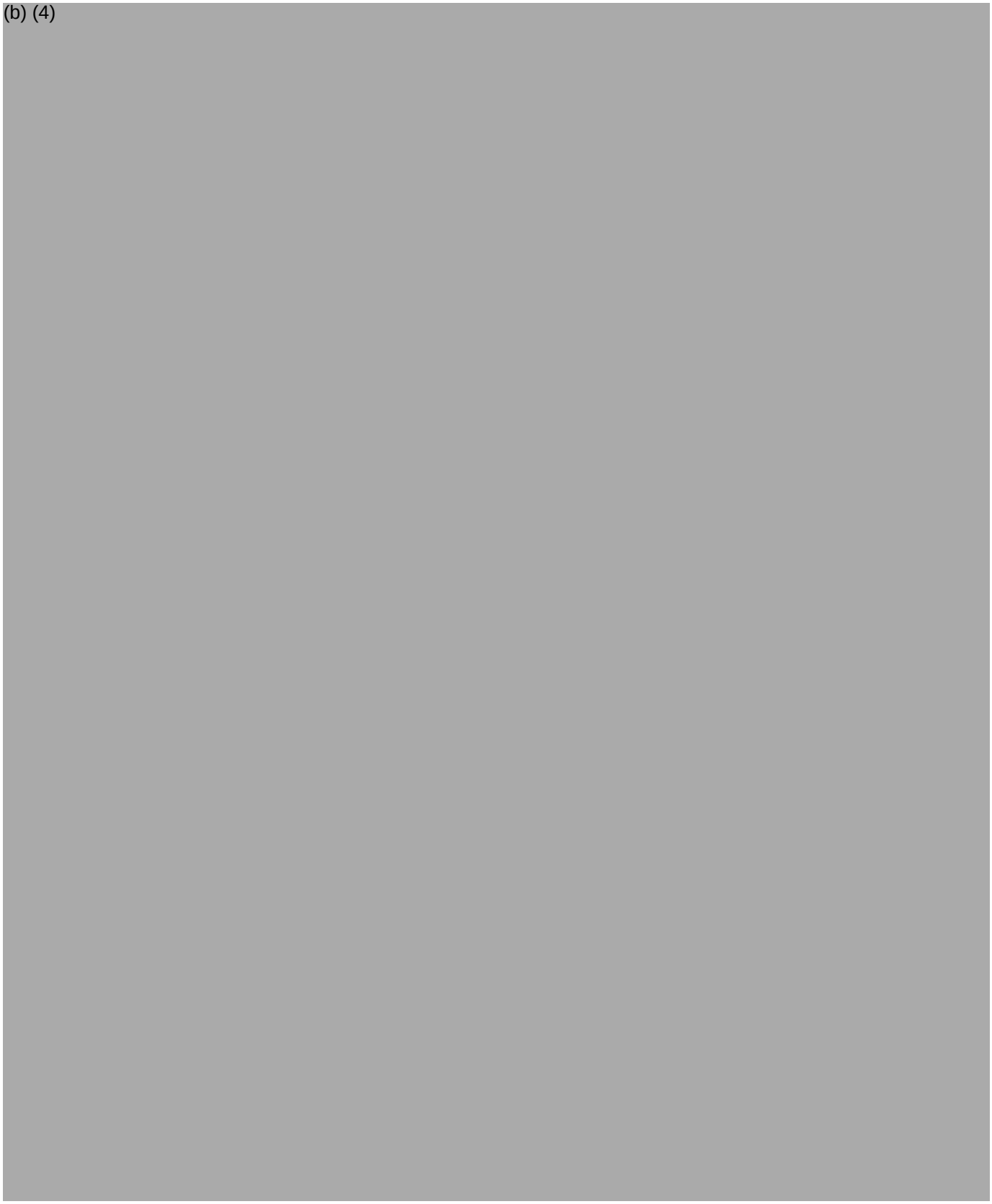
(b) (4)



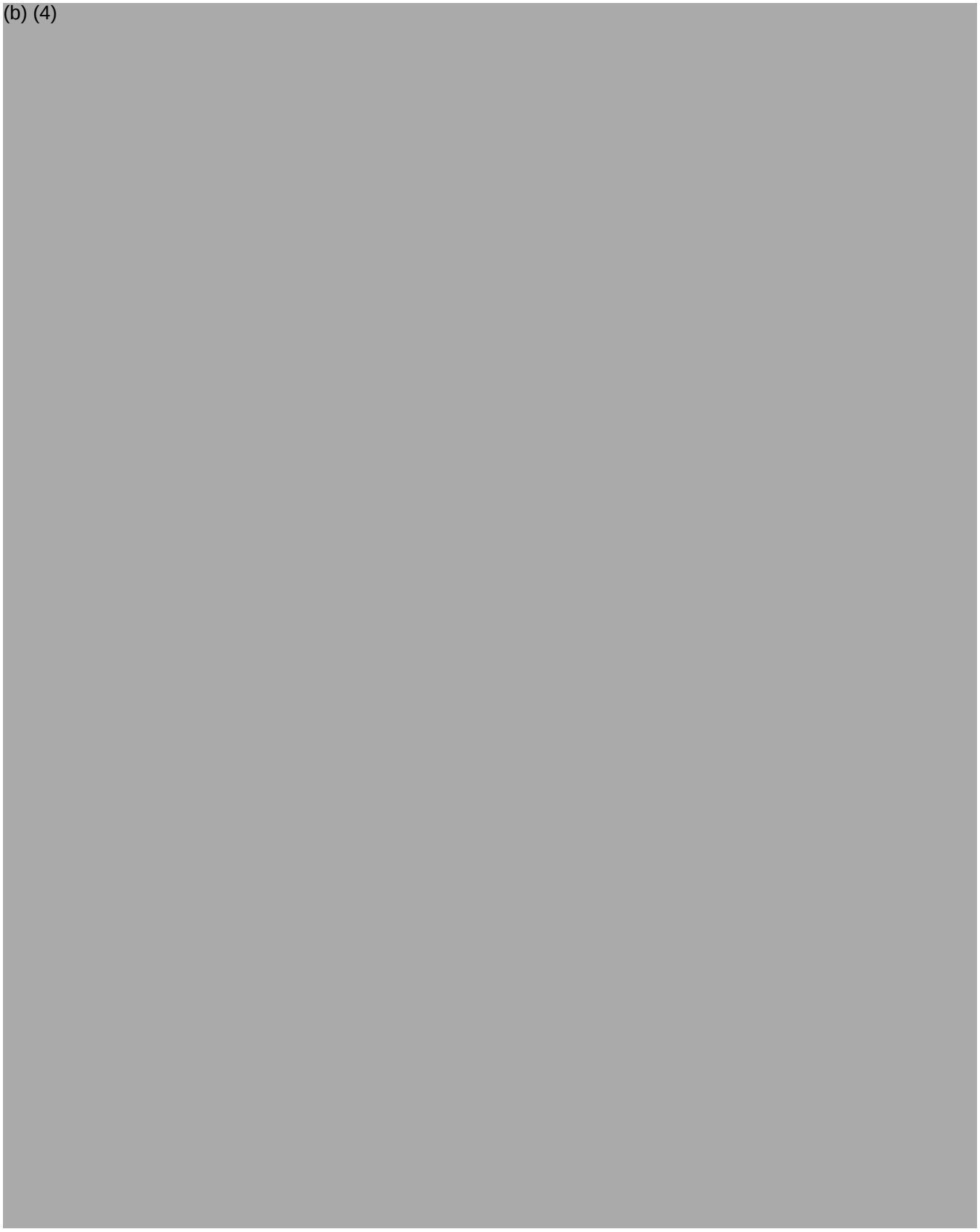
(b) (4)



(b) (4)

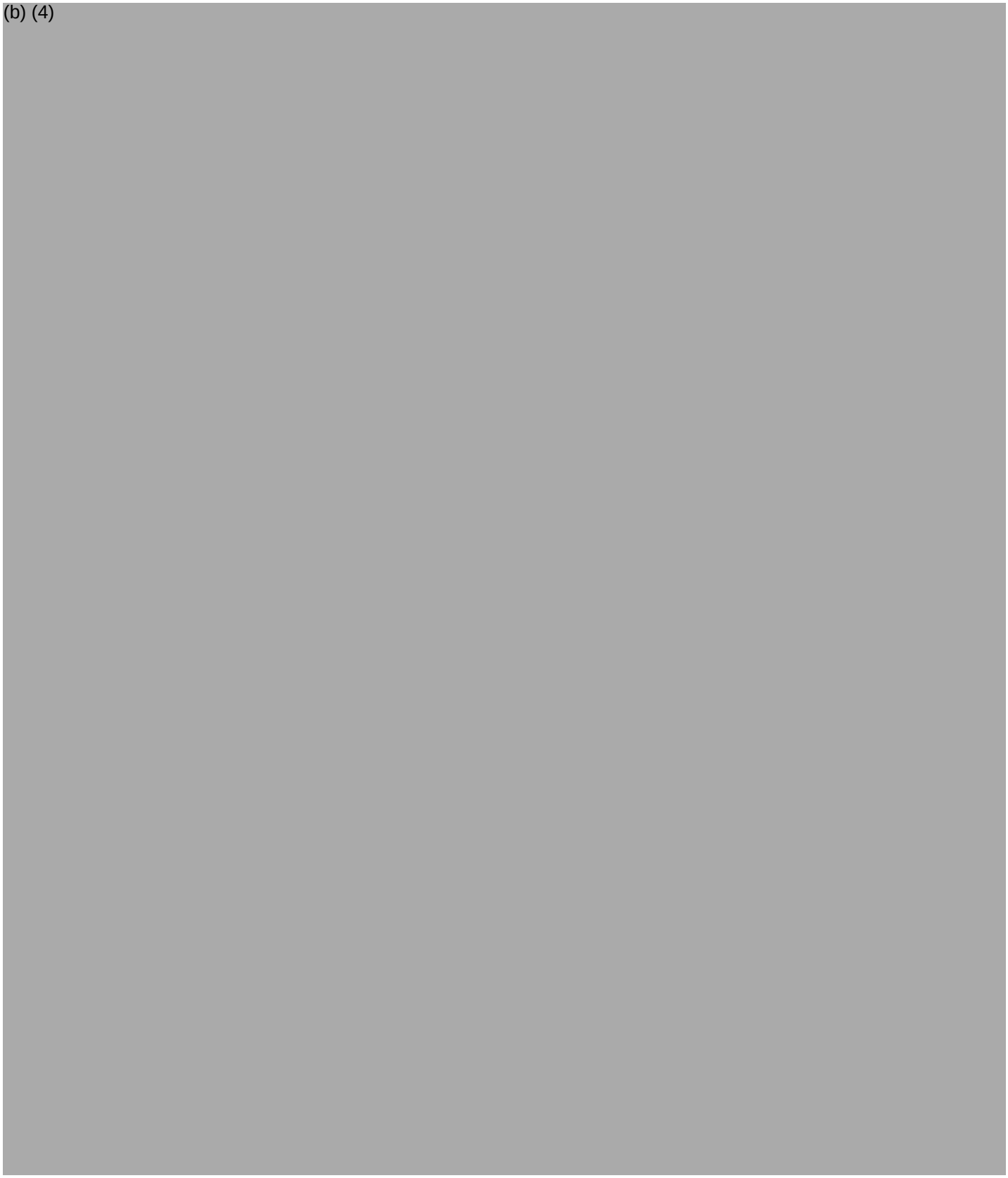


(b) (4)



(b) (4)

(b) (4)

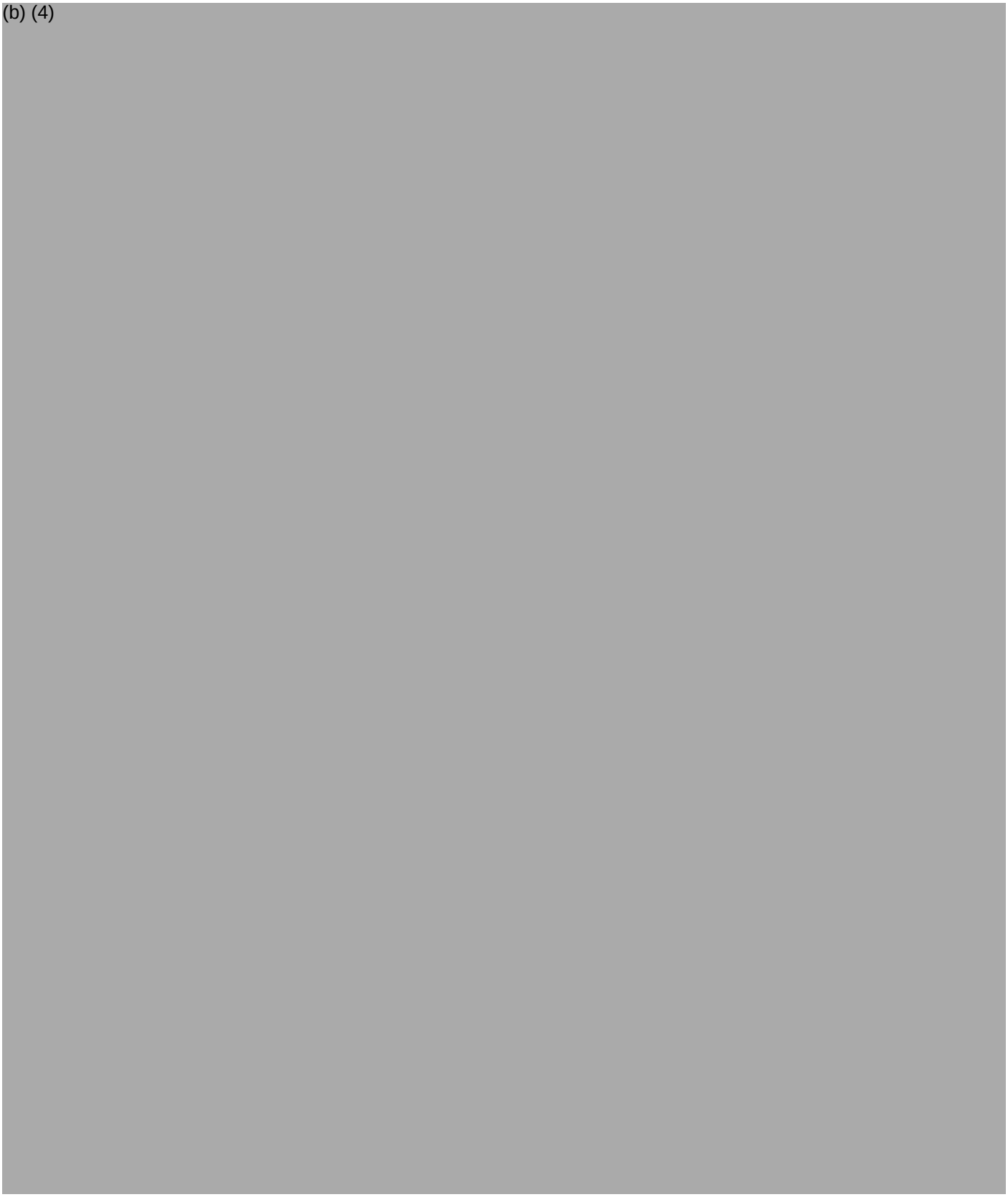


(b) (4)

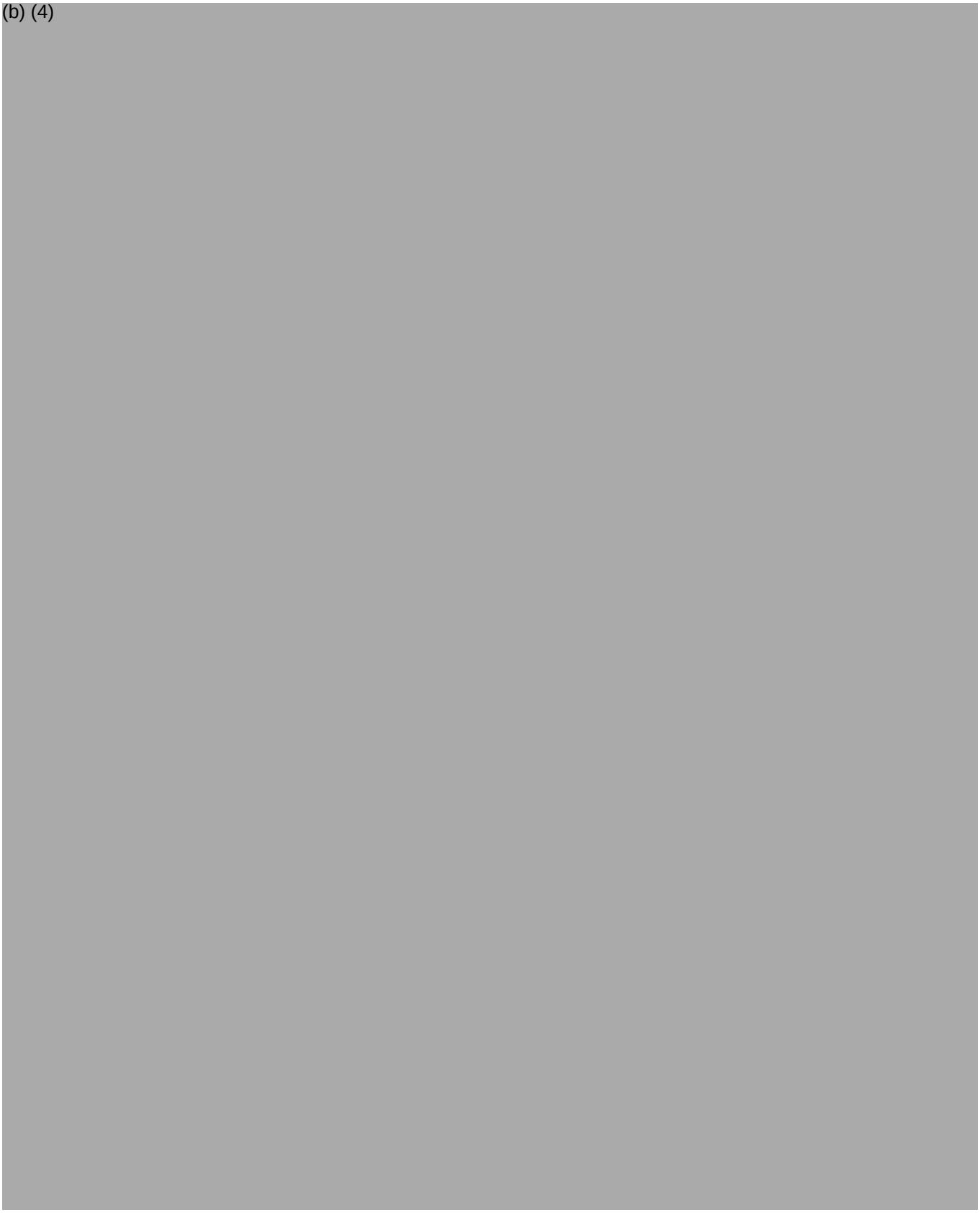
6.1.1 Stakeholder outreach – Communications

(b) (4)

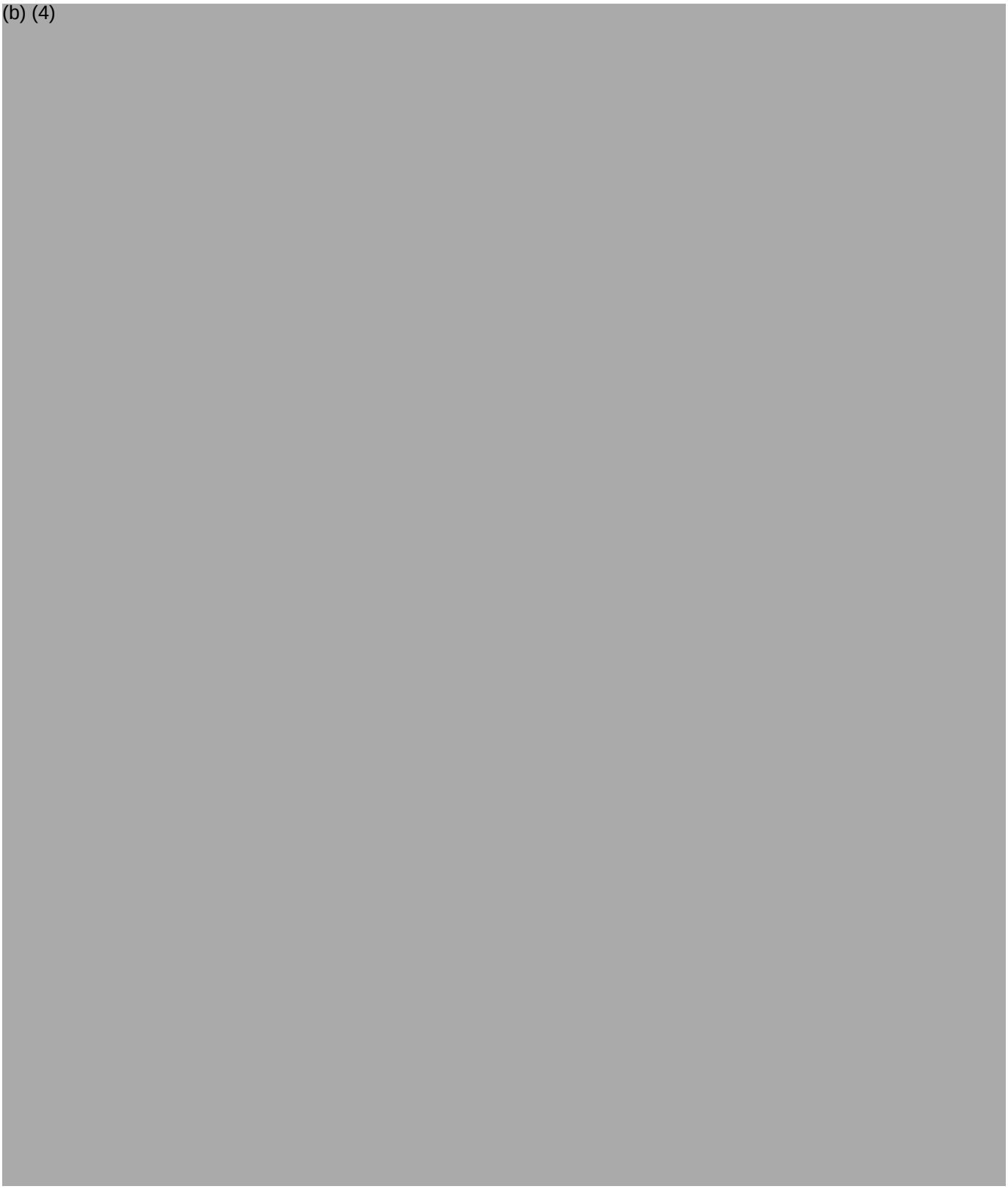
(b) (4)



(b) (4)



(b) (4)

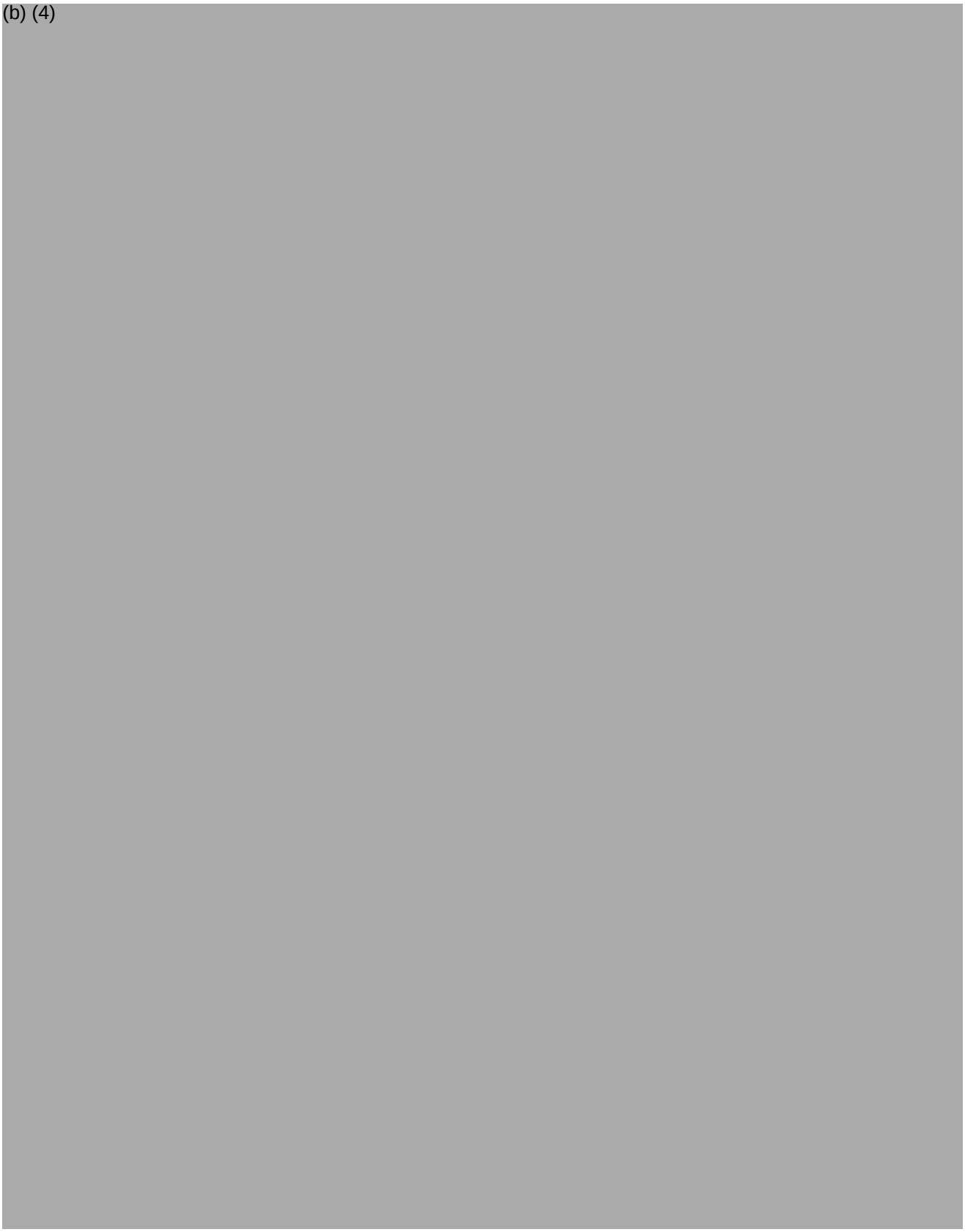


(b) (4)

6.1.2 Stakeholder registration – DME/Consignee engagement

(b) (4)

(b) (4)

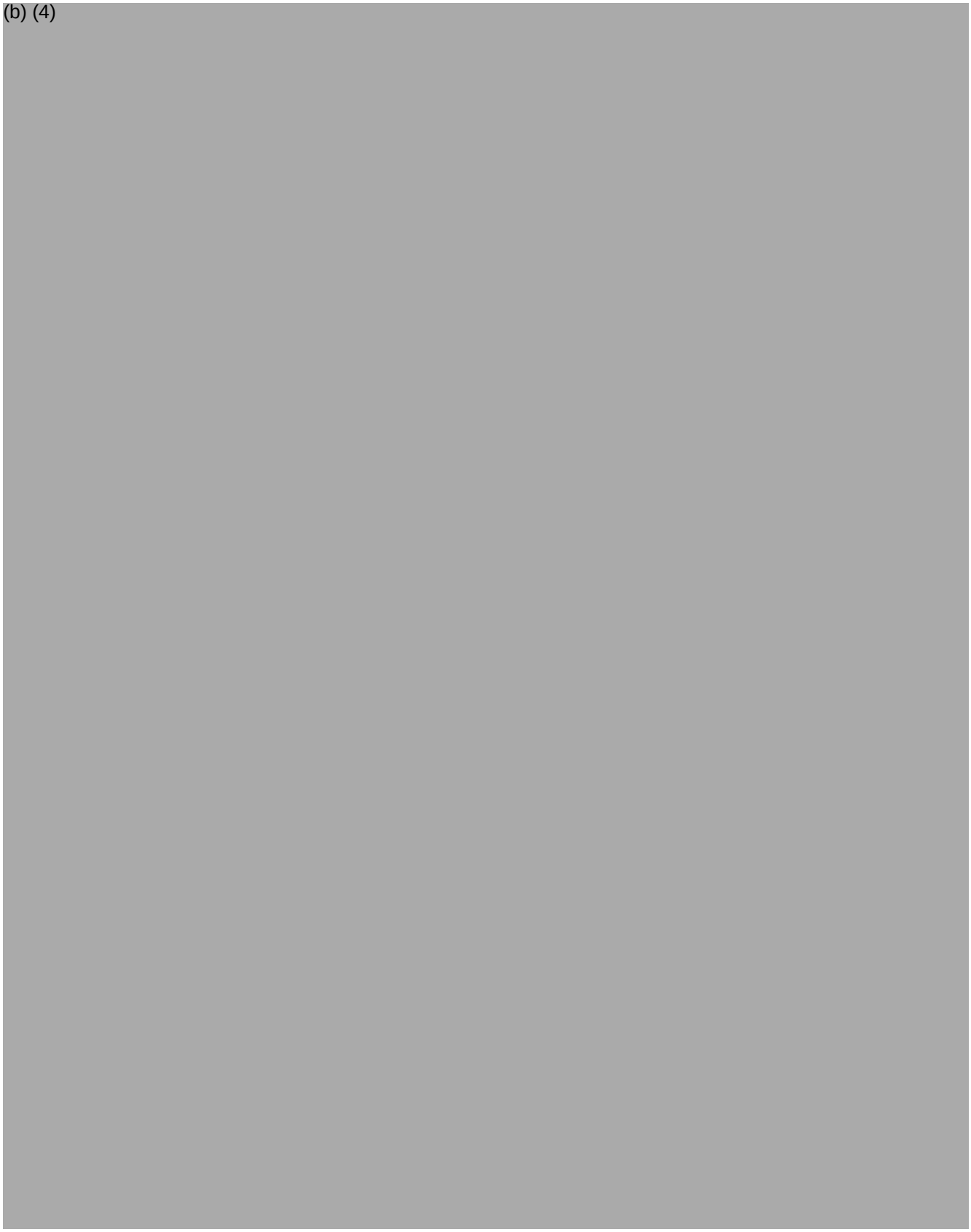


(b) (4)

6.1.3 Stakeholder registration – Patient registration and eligibility verification, patient communication following registration, patient onboarding with new device, and return of the recalled device

(b) (4)

(b) (4)



(b) (4)

6.1.4 Stakeholder registration – Risk-based prioritization

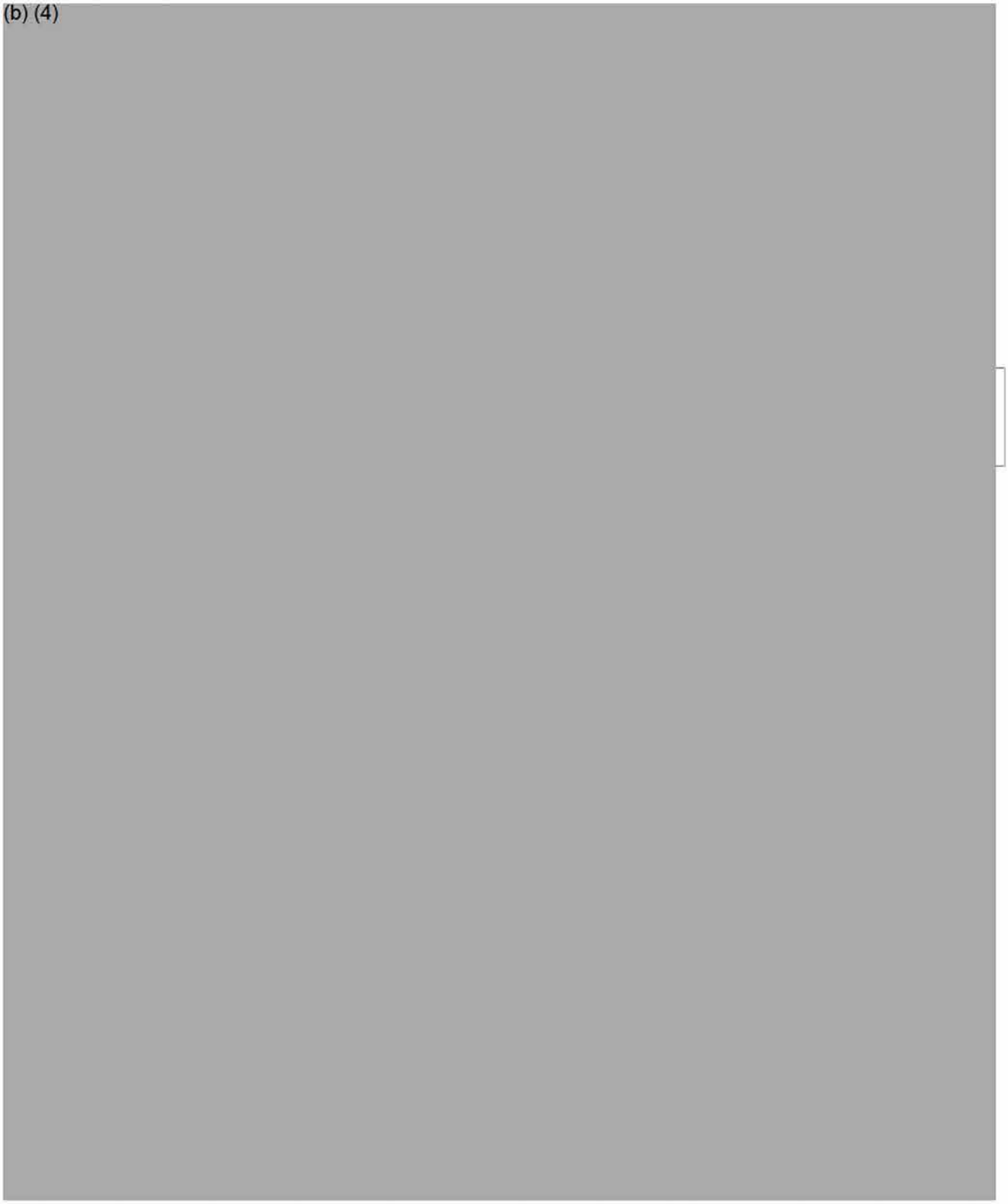
(b) (4)

6.2 Product fulfillment (rework & manufacturing of new devices), recalled device return and disposition

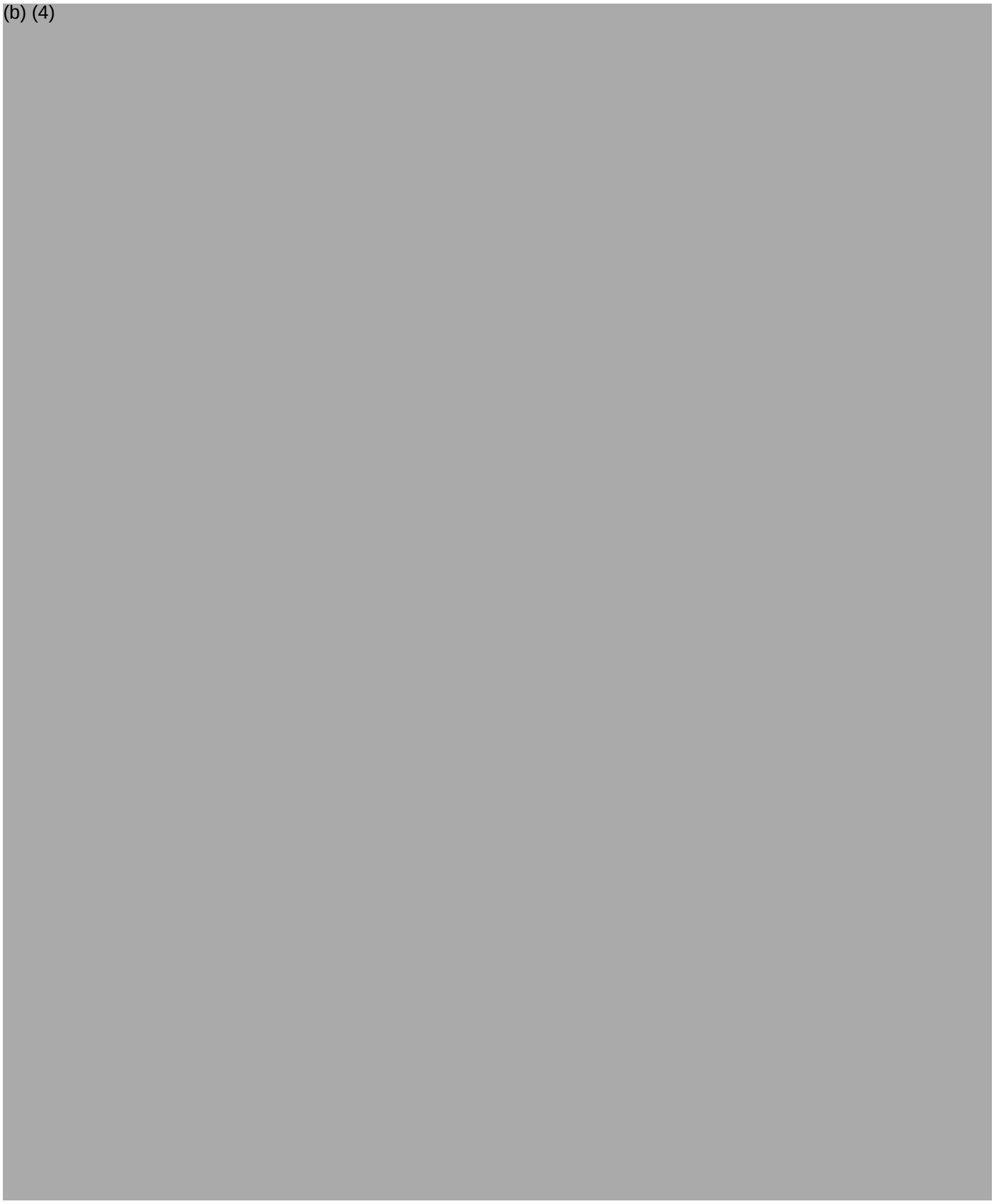
(b) (4)

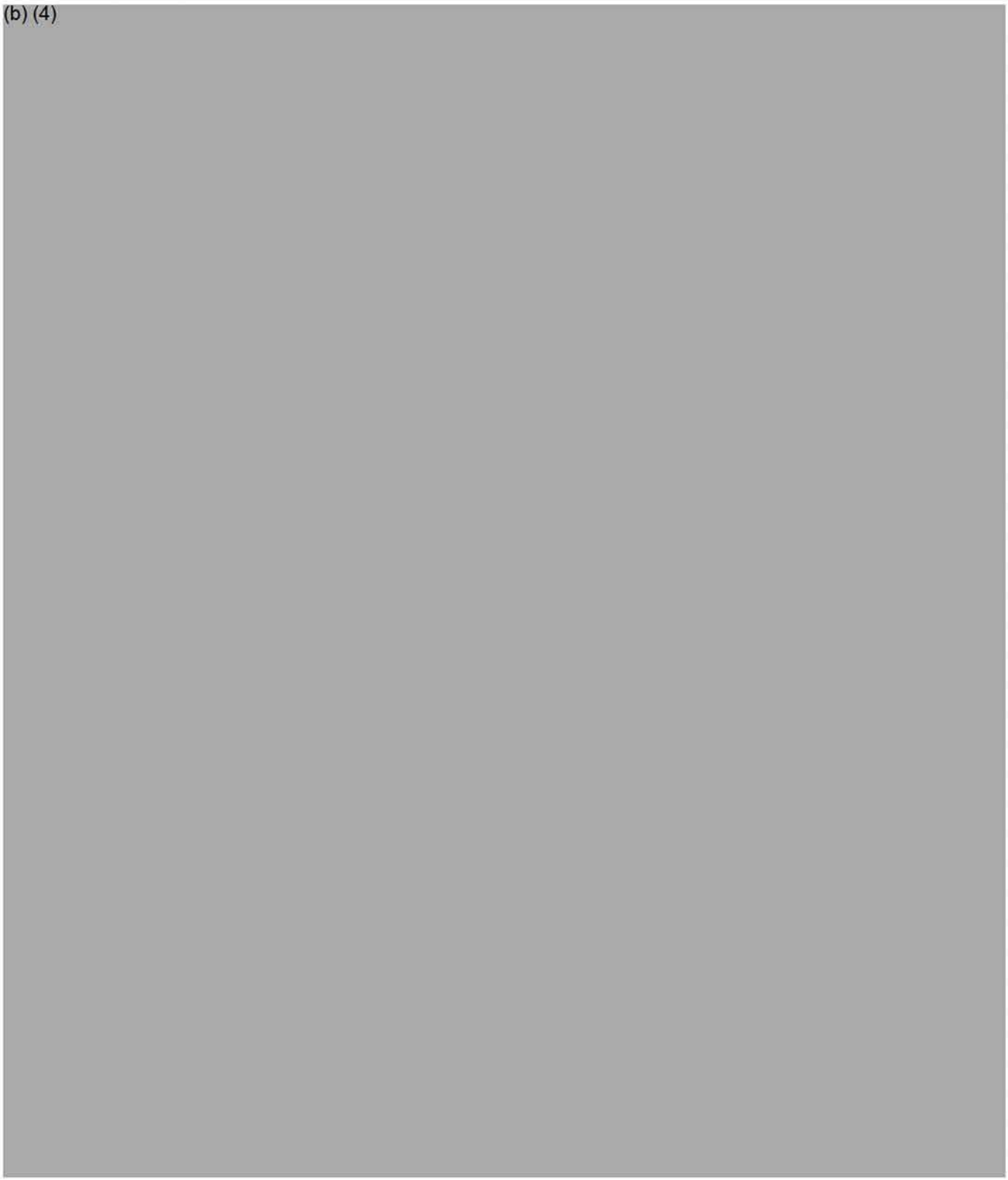
6.2.1 Remanufacturing, manufacturing, rework, return device strategy

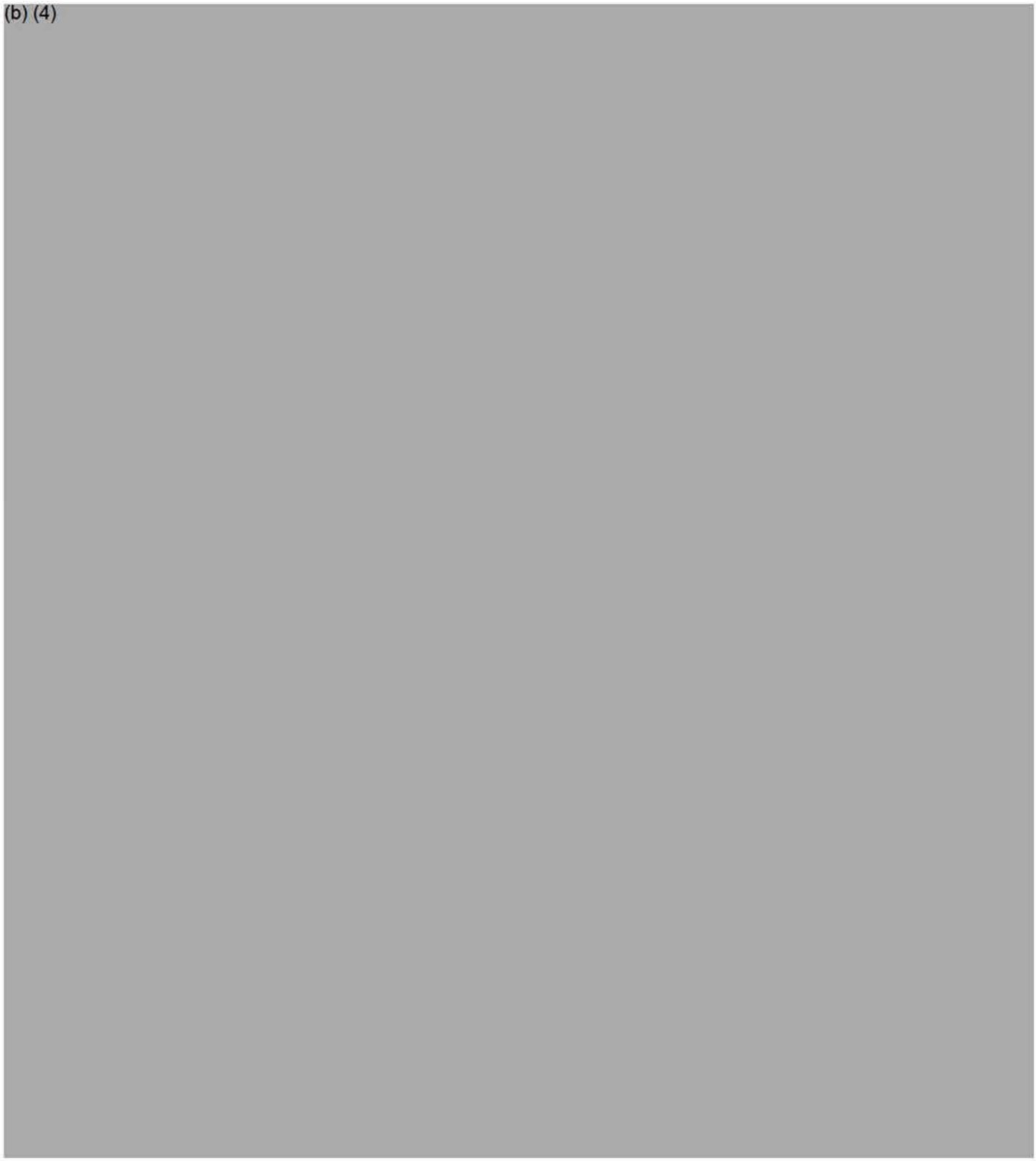
(b) (4)


(b) (4)

(b) (4)



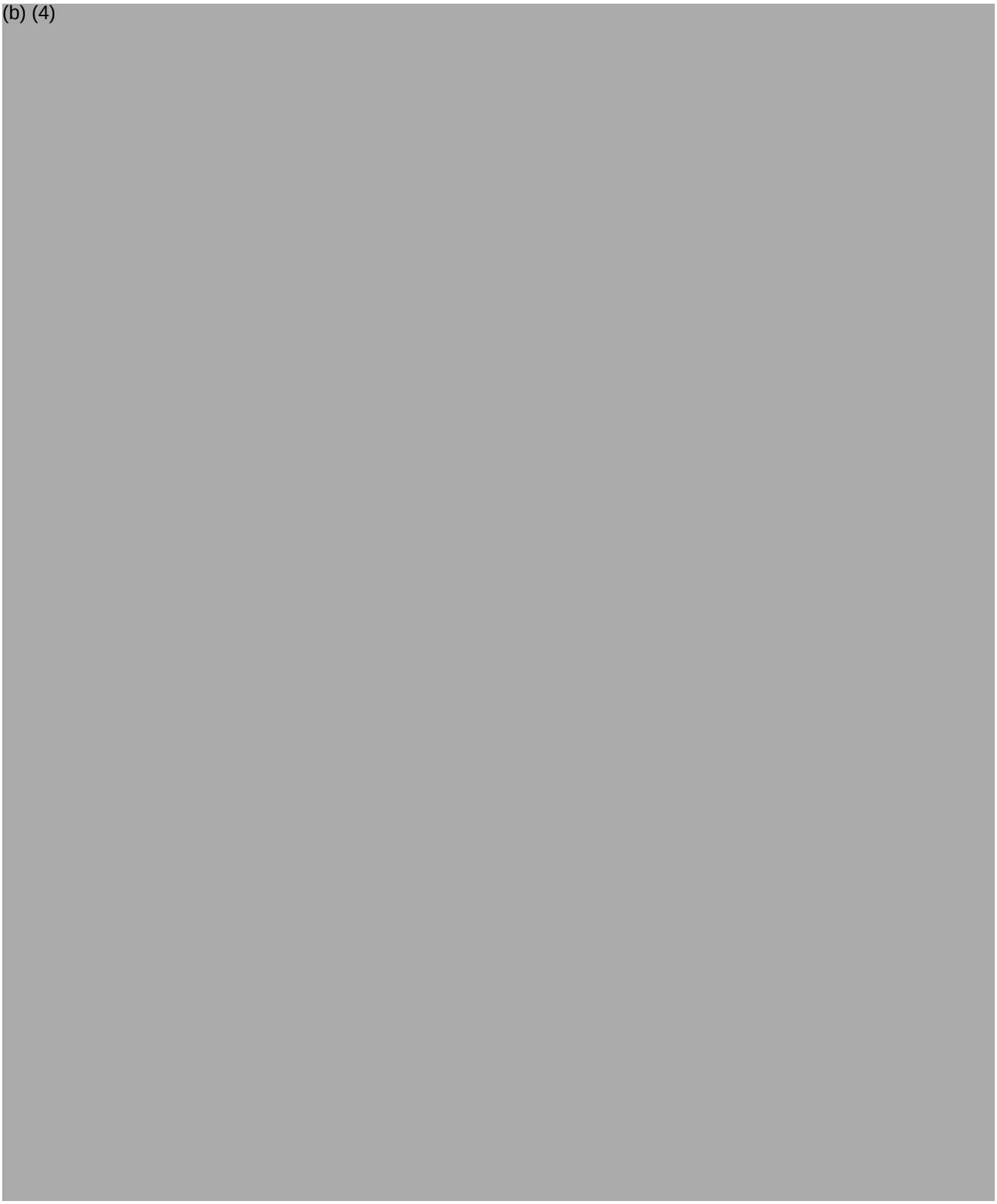

(b) (4)


(b) (4)

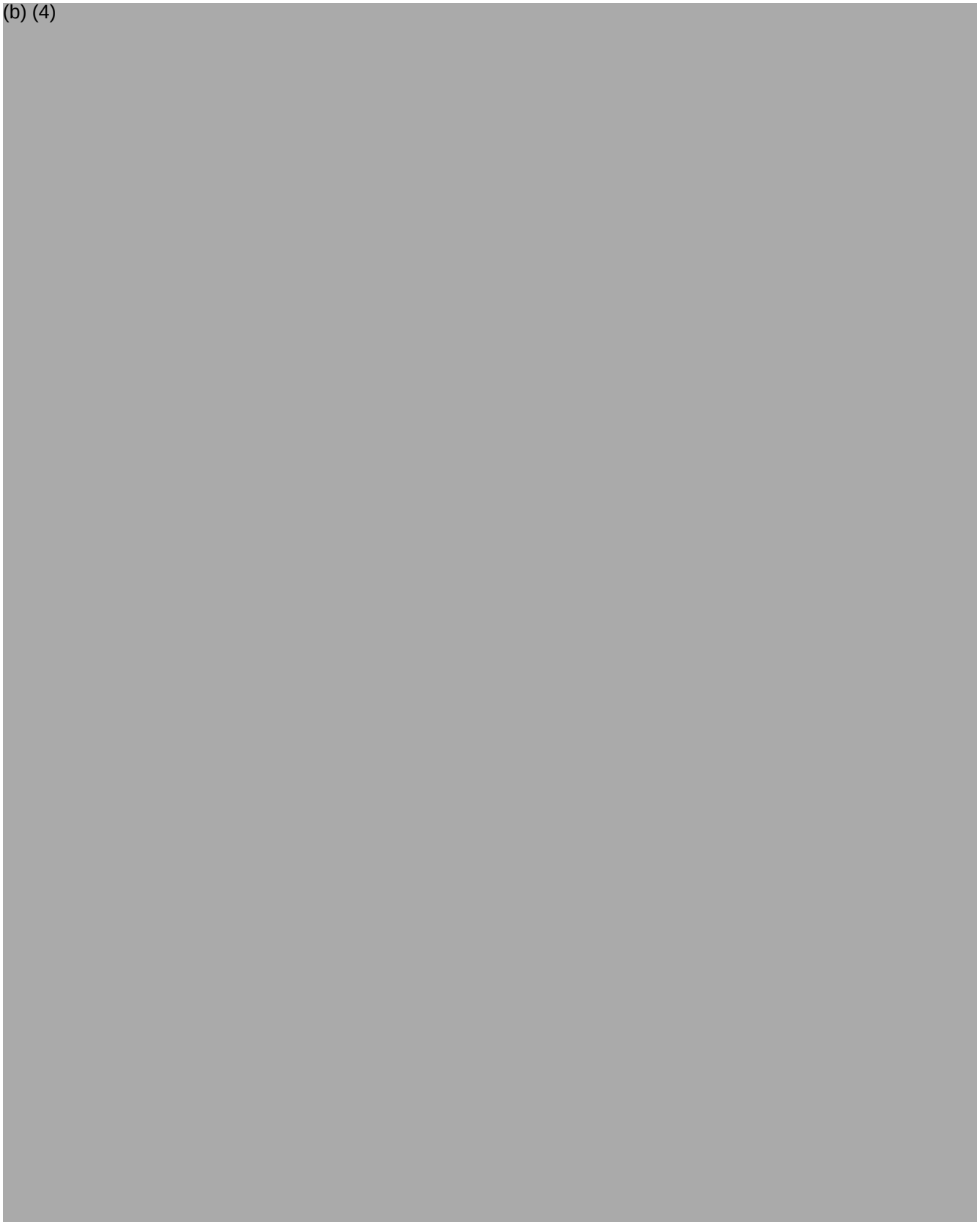
Series name	(b) (4)
DreamStation ASV	
DreamStation ST, AVAPS	
OmniLab Advanced Plus	
DreamStation (CPAP, BiPAP)	
DreamStation Go	
Trilogy 100/200	
V30	

(b) (4)

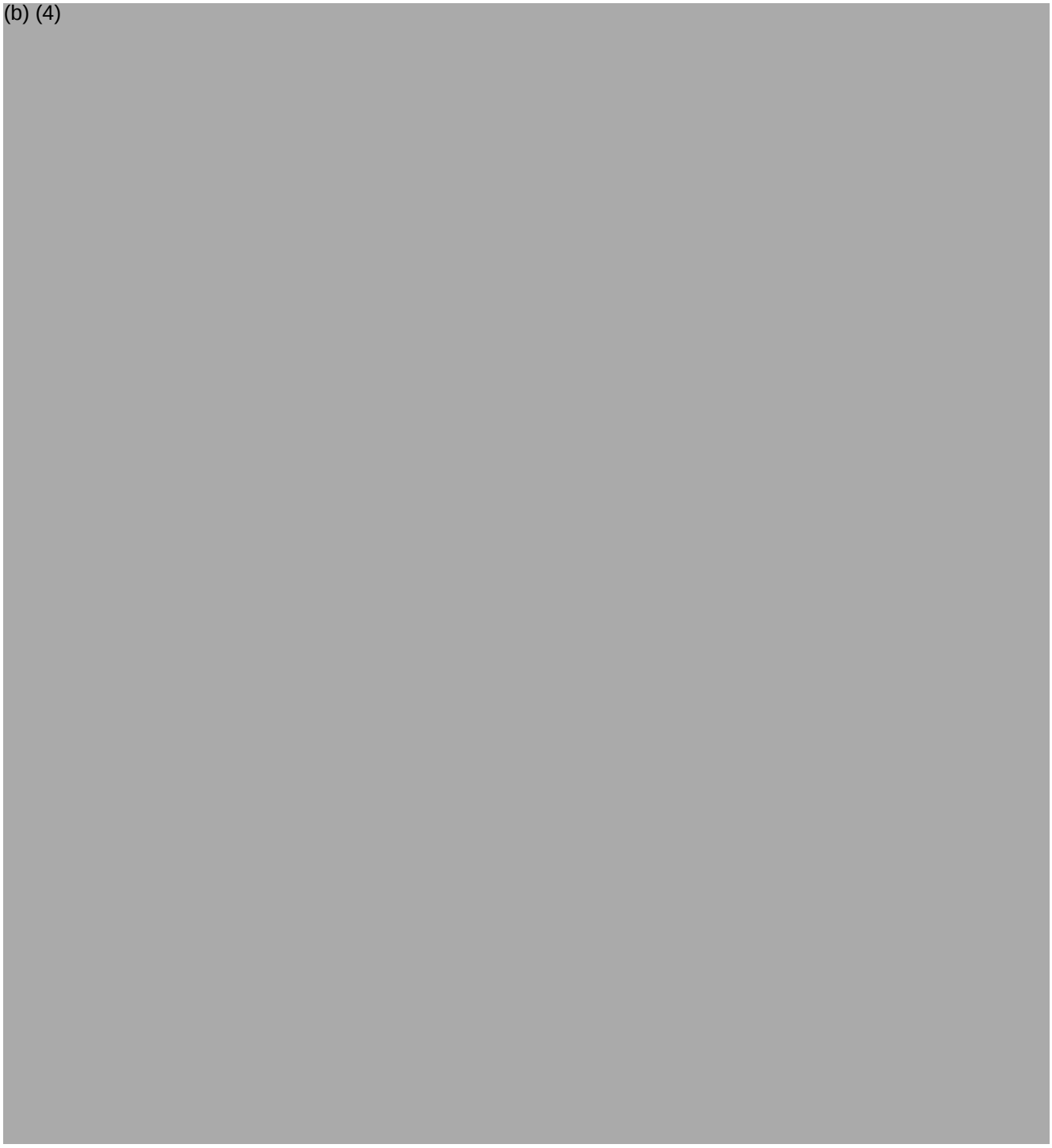
(b) (4)



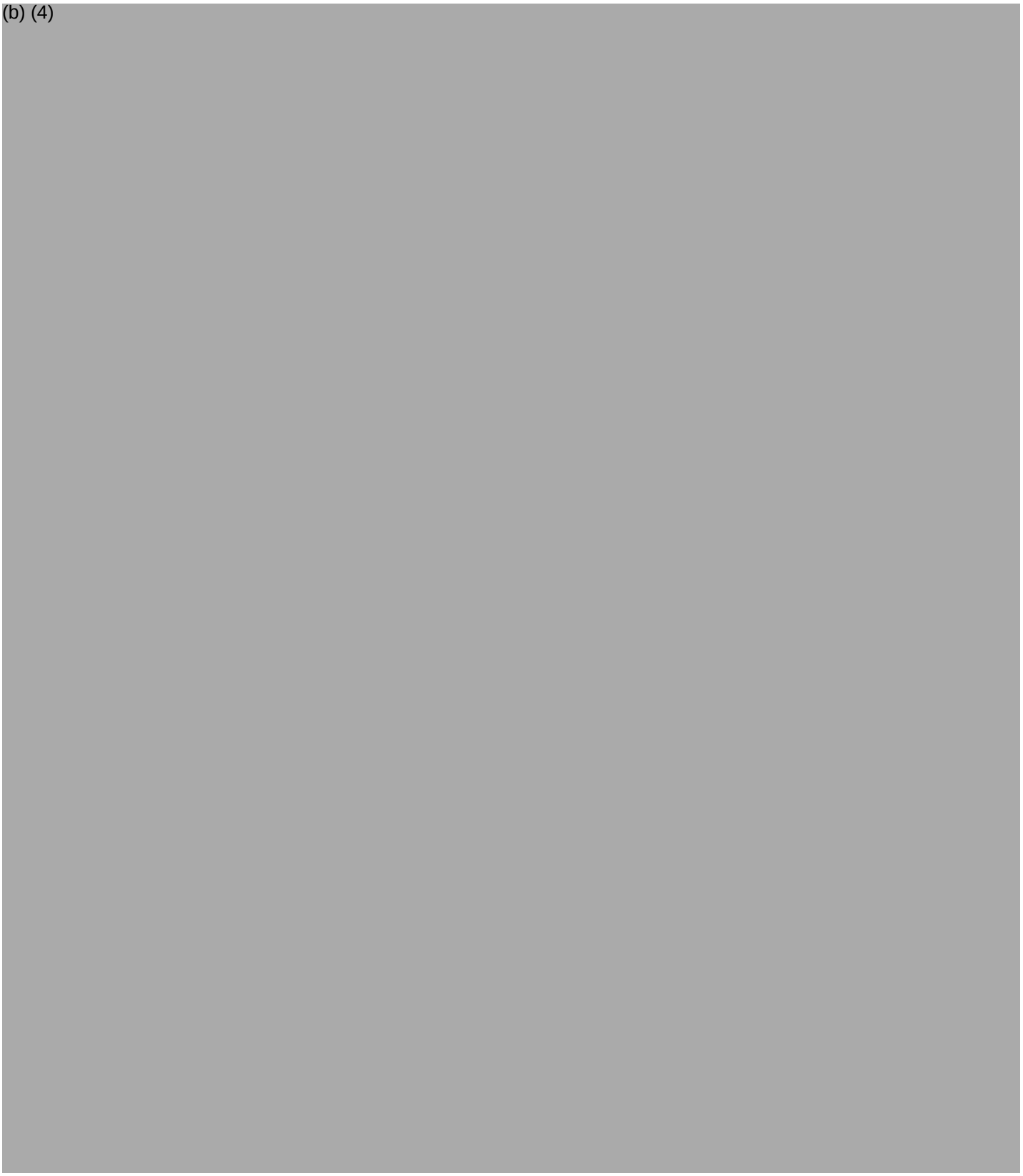
(b) (4)



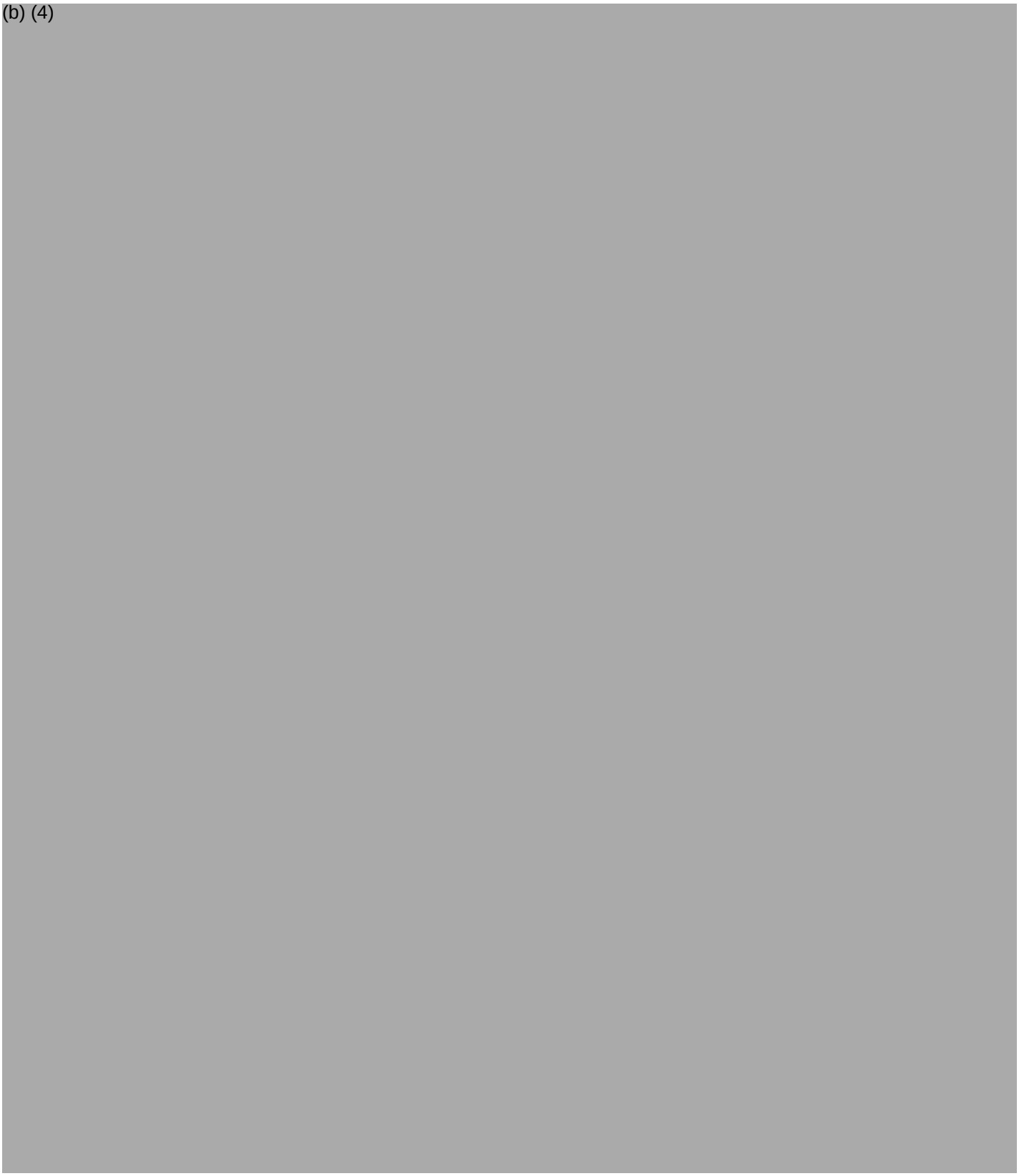
(b) (4)



(b) (4)



(b) (4)

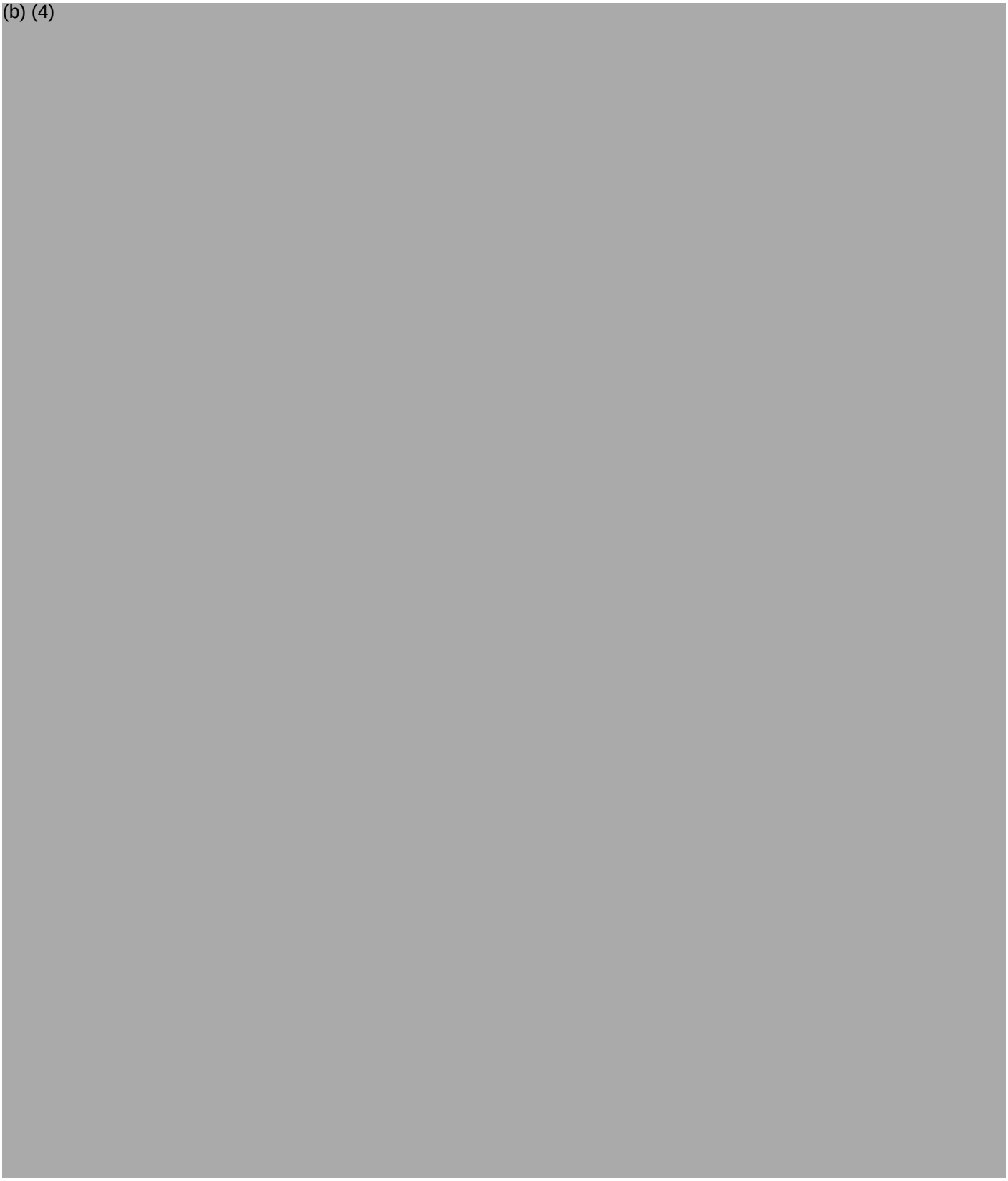


(b) (4)

6.3 Monitoring of Recall Effectiveness and Execution Progress

(b) (4)

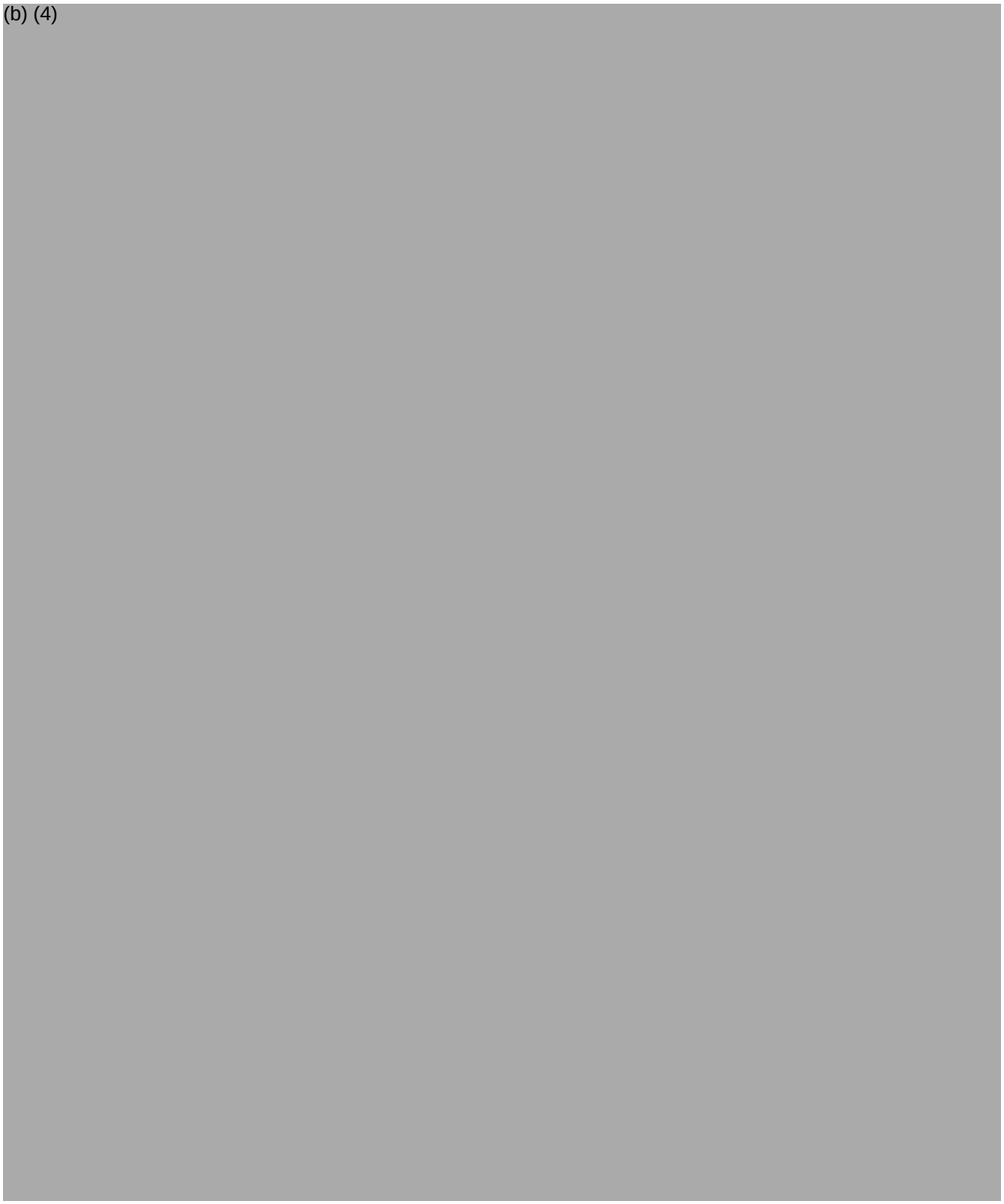
(b) (4)



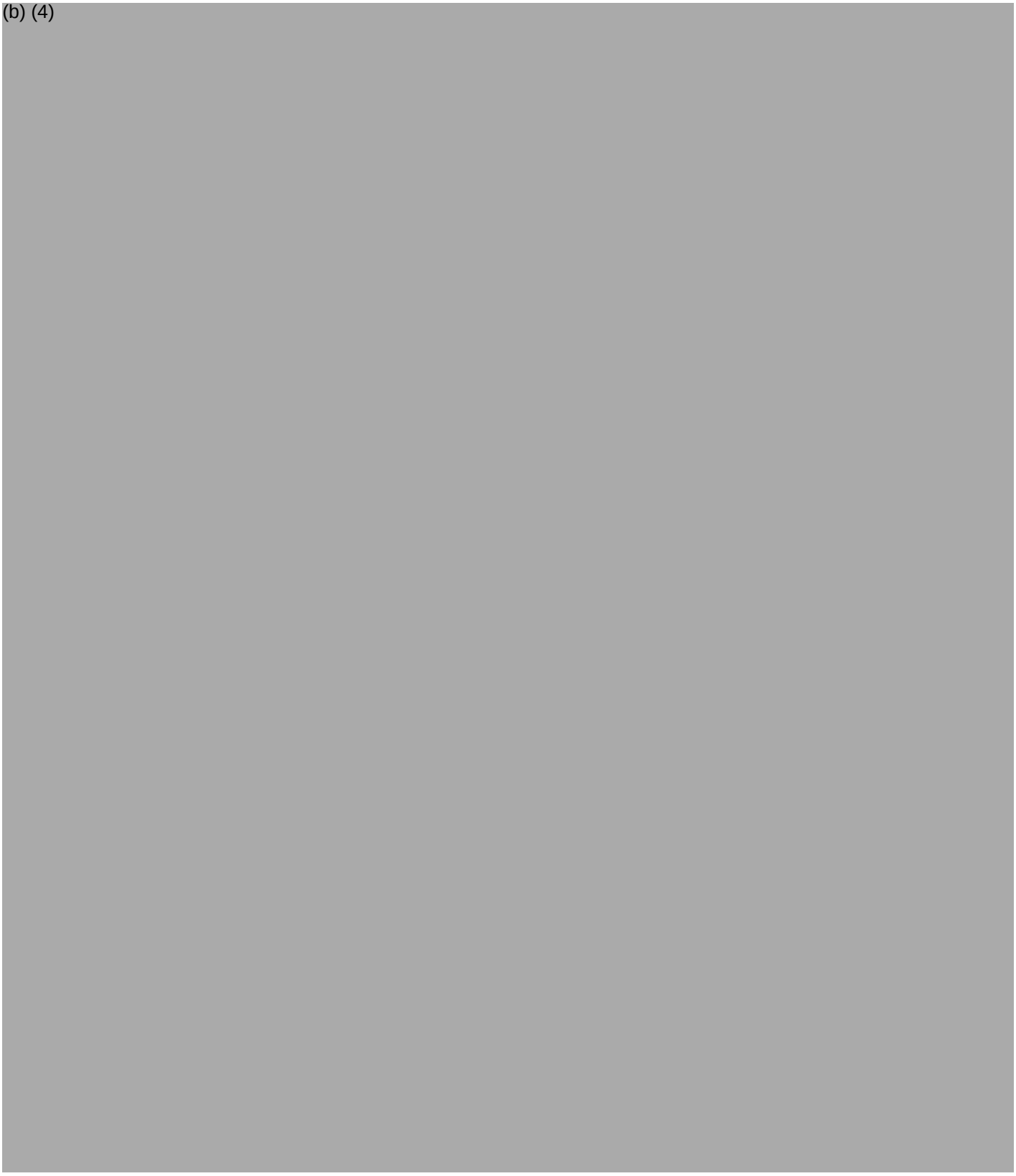
(b) (4)

(b) (4)

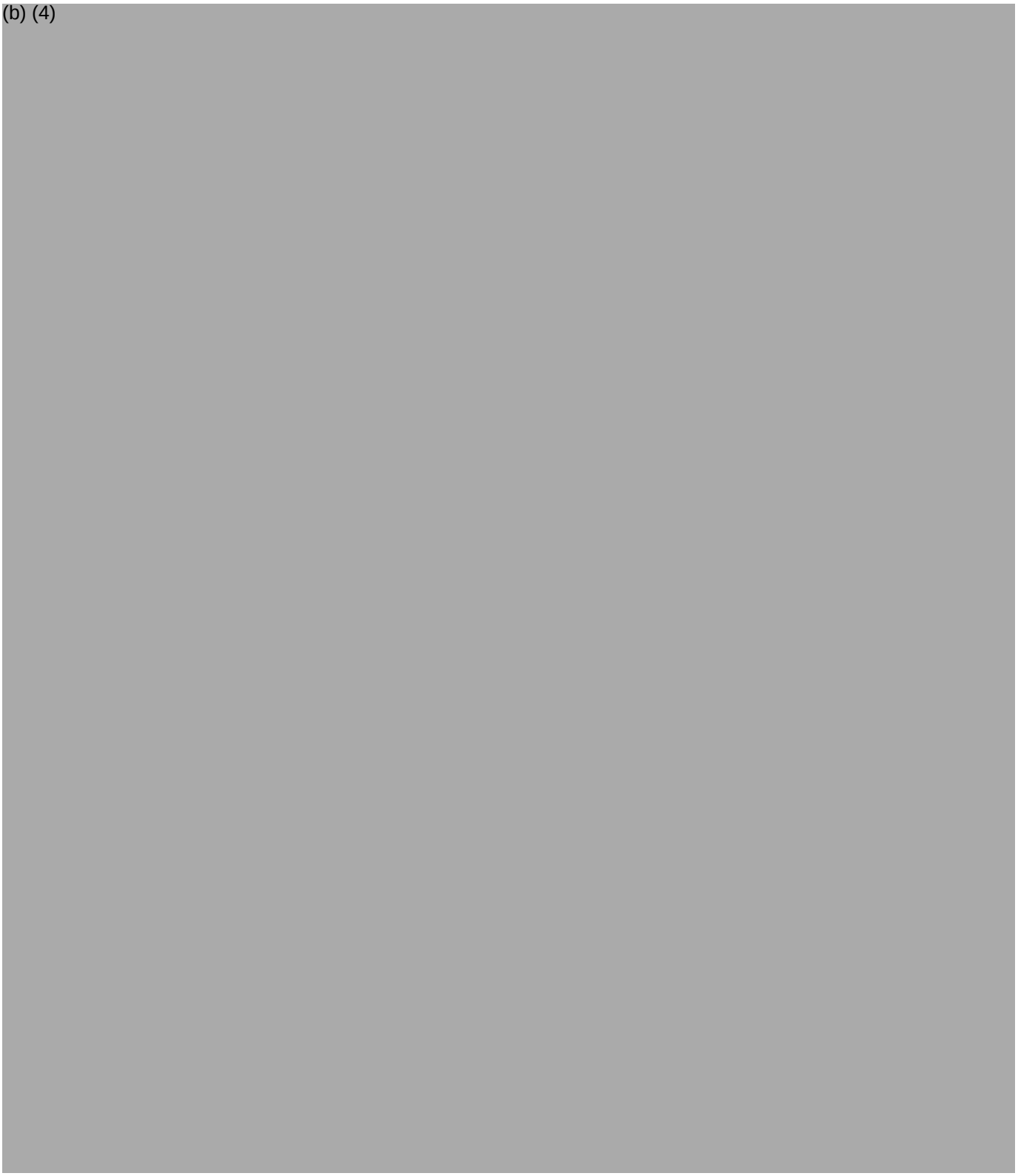
(b) (4)



(b) (4)



(b) (4)

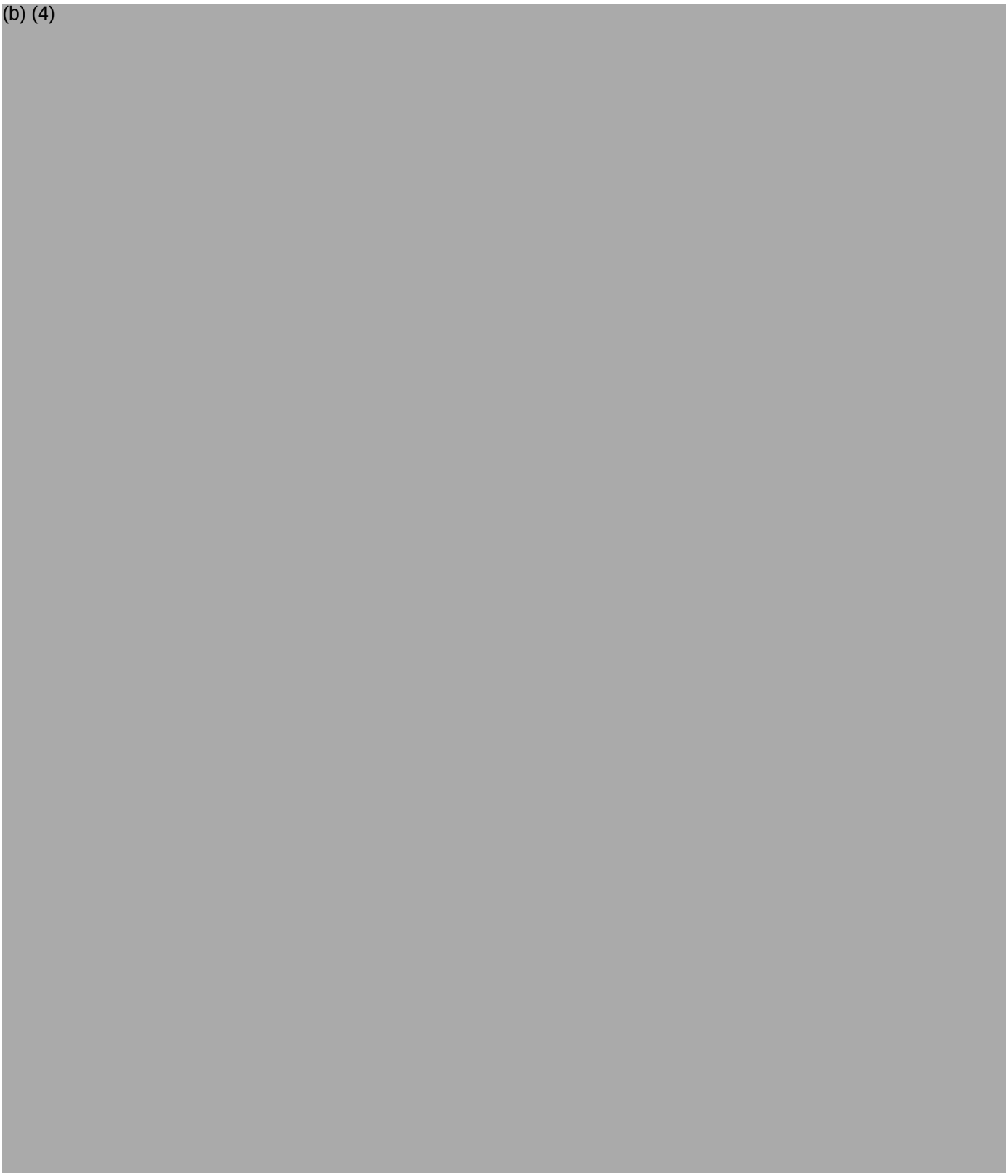


(b) (4)

6.4 External communications related to recall execution

(b) (4)

(b) (4)



(b) (4)

7 Glossary

Customer portal: Portal used by DMEs/Consignees to upload necessary information for recall execution

DME: Durable Medical Equipment; provider that supplies equipment and supplies ordered by a healthcare provider for everyday or extended use by patients

ECN: Engineering Change Notice; document authorizing and recording design changes throughout the prototyping and lifecycle phases of a product

HMV: Home Mechanical Ventilator; devices providing mechanical ventilation either invasively through a tracheotomy tube or noninvasively via a mask, used for long-term management of many forms of severe chronic respiratory failure in the home setting

Patient portal: Patient webpage to check device status for replacement/rework /financial compensation

PE-PUR: Polyester-based polyurethane; material used in sound abatement foam for devices affected by the Philips Respironics Class I recall that may break down and pose a risk to patients and/or users of the recalled devices

RAD: Respiratory Assist Device; devices intended to help patients in need of support for breathing, removal of carbon dioxide, and therapy to reduce disuse atrophy of abdominal wall muscles

Registration site: Website used by patients and DMEs to register for the recall

(b) (4)

8 Appendices

Appendix 1: (b) (4)

Appendix 2: "Patient Portal Images.pdf"

Appendix 3: "Cleaning inspection instructions.pdf"

Appendix 4: "Return instructions.pdf"

Appendix 5: "Customer portal for selection of remediation pathway.pdf"

Appendix 6: "DS CPAP-BiPAP-Patient Insert.pdf"

Appendix 7: "philips-fourth-quarter-results-2022-report.pdf"

Appendix 8: "Philips-recall-letter-2021-11-16-us-revised .pdf"

Appendix 9: Recall information home page
https://www.usa.philips.com/healthcare/e/sleep/communications/src-update

Appendix 10: Patient recall information page
https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/information-for-patients-and-caregivers

Appendix 11: DME/Consignee recall information page
https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/information-for-business-customers

Appendix 12: Clinician recall information page
https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/information-for-physicians-and-providers

Appendix 13: Recall news & updates web page
https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/news

Appendix 14: (b) (4)

Appendix 15: "US Recertified In BOM Letter to Patients.doc"

Appendix 16: (b) (4)

Appendix 17: "518(a) Summary Report – JAN-2023.pdf"

Appendix 18: "Patient Prioritization – Final Proposal 18-Nov.doc"

Appendix 19: "Patient Prioritization – Question Responses FINAL 29-Nov.doc"

Appendix 20: "Patient Prioritization – 18-Jan FDA Update FINAL.doc"

Appendix 21: "Remediation Completion Projections.pdf"

Appendix 22: (b) (4)

Appendix 23:
(b) (4)