

APR 08 2003

**510(k) Summary of Safety and Effectiveness**

**K030982**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

**I. GENERAL INFORMATION**

**Device Name and Classification**

|                       |   |
|-----------------------|---|
| Product Name:         | Syngo Colonography software package     |
| Common Name           | 3D Reconstruction Software              |
| Classification Name:  | Accessory to Computed Tomography System |
| Classification Panel: | Radiology                               |
| CFR Section:          | 21 CFR §892.1750 205D                   |
| Device Class:         | Class II                                |
| Product Code:         | 90 JAK LLZ                              |

**Establishment:**

**Importer/Distributor:**

Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway  
Malvern, PA 19355

**Registration Number:** 2240869

**Manufacturing Facility:**

Siemens AG  
Medical Solutions  
Henkestrasse 127  
D-91052 Erlangen, Germany  
***syngo* is a registered trademark of Siemens AG**

**Contact Person:** Mr. Jamie Yieh

Senior Technical Specialist  
Telephone: (610) 448-1785 Fax: (610) 448-1787

**Date of Preparation of Summary:** November 26<sup>th</sup> 2002

**II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION**

**Device Description and Intended Use:**

This premarket notification covers Siemens Syngo Colonography software package. It is based on Siemens *syngo* software platform.

*syngo* Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools

with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-luminal view), the wall and the outside (extra-luminal view) of the colon. With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.

Due to all these capabilities the syngo Colonography software has the advantage of non-invasive evaluation of colonic lesions as compared to conventional colonoscopy.

**General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

**Substantial Equivalence:**

The Syngo Colonography software package, addressed in this premarket notification, is substantially equivalent to the following commercially available software package:

| <i>Predicate Device Name</i>                             | <i>FDA Clearance Number</i> | <i>FDA Clearance Date</i> |
|--|-----------------------------|---------------------------|
| GE CT Colonography/Navigator 2 Workstation               | K012313                     | 08/07/01                  |
| Siemens Fly Through                                      | K971717                     | 09/03/97                  |
| Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso) | K973010                     | 11/10/97                  |

The Syngo Colonography software package described in this 510(k) has the same intended use and similar technical characteristics as the commercially available software listed above.

In addition, many of the image processing, display and evaluation components of syngo Colonography are currently available on software options like the Volume Rendering Technique option, K923524/S2, cleared on May 17<sup>th</sup> 1994 and workstations like the syngo Multimodality Workstation, K010938 cleared on 26<sup>th</sup> June 2001 wherein the Fly Thorough software algorithms were transferred over to the syngo software platform. syngo Colonography packages these image processing and image display components in an optimized workflow palette.

In summary, Siemens is of the opinion that Syngo Colonography software package does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate software components and the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 08 2003

Siemens Medical Solutions, Inc.  
% Mr. Heinz Joerg Steneberg  
Division Manager, Medical Division  
TUV Rheinland of North America  
12 Commerce Road  
NEWTON CT 06470

Re: K030982  
Trade/Device Name: Syngo Colongraphy  
Software Package  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communications system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: March 26, 2003  
Received: March 28, 2003

Dear Mr. Steneberg:

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

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

Page 2

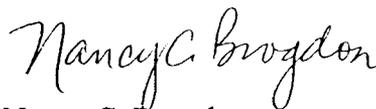
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

|                                  |                |
|----------------------------------|----------------|
| 8xx.1xxx                         | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx       | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx       | (301) 594-4654 |
| Other                            | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indication for use**

510(k) Number (if known):     K030982    

**Device Name:** syngo Colonography Software Package

syngo Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-luminal view), the wall and the outside (extra-luminal view) of the colon. With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.

Due to all these capabilities the syngo Colonography software has the advantage of non-invasive evaluation of colonic lesions as compared to conventional colonoscopy.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

*David R. [Signature]*

(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number     K030982    

Prescription Use  OR Over-The-Counter Use   
(Per 21 CFR 801.109)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 08 2003

Siemens Medical Solutions, Inc.  
% Mr. Heinz Joerg Steneberg  
Division Manager, Medical Division  
TUV Rheinland of North America  
12 Commerce Road  
NEWTON CT 06470

Re: K030982  
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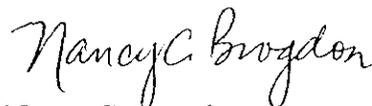
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Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indication for use**

510(k) Number (if known):     K030982    

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(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

*David R. Begeman*

(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number     K030982    

Prescription Use  OR Over-The-Counter Use   
(Per 21 CFR 801.109)

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

March 28, 2003

SIEMENS MEDICAL SOLUTIONS USA, INC.  
c/o TUV RHEINLAND OF NORTH AMERICA, 510(k) Number: K030982  
12 COMMERCE ROAD Received: 28-MAR-2003  
NEWTON, CT 06470 Product: SYNGO COLONOGRAPHY  
ATTN: HEINZ JOERG STENEGER SOFTWARE PACKAGE

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

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at <http://www.fda.gov/oc/mdufma>).

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

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

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Office of Device Evaluation  
Center for Devices and Radiological Health

K 030982

Food and Drug Administration  
Center for Devices and Radiological Health  
510(k) Document Mail Center (HFZ-401), Rm. T20  
Office of Device Evaluation - 510(k)  
9200 Corporate Blvd.  
Rockville, MD 20850

**Subject: 510(k) Notification reviewed by Third Party**

Dear Document Control Clerk:

(b)(4) as Third Party reviewer is submitting the previewed 510(k) of Siemens Medical Solutions for the Syngo Colonography Software Package.

The following information is being submitted in accordance with the Third Party Preview Manual.

1. Purpose of Submission:  
New submission
2. Name and Address of Third Party:  
(b)(4)
3. Name and Address of Manufacturer:  
Siemens Medical Solutions, Inc.  
51 Valley Stream Parkway  
Malvern, PA 19355  
  
Manufacturing Facility:  
Siemens Medical Solutions  
Bereich Med  
Siemensstrasse 1  
91301 Forchheim, Germany
4. Trade Name: syngo Colonography Software Package
5. Common Name: 3D Reconstruction Software
6. Classification Name: Accessory to Computed Tomography System
7. Classification No.: 21 CFR 892.1750
8. SE Recommendation:

(b)(4) (b)(4) is recommending that the syngo Colonography Software Package is Substantially Equivalent (SE) to the legally marketed devices.

2015 NOV 26 P 1:55

RA II

SK 26

9. Date documents were received:  
December 2, 2002 (initial submission)  
March 19, 2003 (completely revised submission)
10. Owner's letter authorizing (b)(4) to submit their 510(k) to FDA and discuss its content with FDA  
(See attachment 2)
11. Owner's 510(k) submission as reviewed by (b)(4)  
(See attachment 3)
12. Pre-Review documentation  
(See attachment 1)
13. Personnel Qualification and Prevention of Conflict of Interest Criteria Statement:  
(b)(4) will continue to meet the personnel qualification and prevention of conflict of interest criteria as reviewed by FDA.
14. True and accurate statement  
(b)(4) certifies that the preview is based on the submitted 510(k), that it is true and accurate to the best of our knowledge, and it is understood that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q)

(b)(6)

(b)(6)

Print Name

March 26, 2003  
Date

(b)(6)

Print Name

Division Manager Medical Division  
Title

March 26, 2003  
Date

## Table of Content

|              |                                  |
|--------------|----------------------------------|
| Attachment 1 | (b) (4) Pre-Review Documentation |
| Attachment 2 | Owner's Authorization Letter     |
| Attachment 3 | Owner's Submission               |
| Attachment 4 | Other Project Documentation      |

# Attachment 1

## **(b)(4)** Pre-Review Documentation

Third Party Review Checklist  
FDA Screening Checklist  
Attachment 1 of the FDA Preview manual  
Attachment 2 of the FDA Preview manual  
Attachment 3 of the FDA Preview manual  
Guidance document Checklists  
Predicate device documentation  
Pre-Review correspondence  
Notes

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

510(k) Number: \_\_\_\_\_

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

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

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

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

- \* - May not be applicable for Special 510(k)s.
- \*\* - Required for Class III devices, only.
- \*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

N/A

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

|  | Present | Inadequate or Missing |
|--|---------|-----------------------|
| For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.) |         |                       |
| For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, <b>SEE Required Elements for a Declaration of Conformity to a Recognized Standard</b> , which is posted with the 510(k) boilers on the <b>H drive</b> .]  |         |                       |
| For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.   |         |                       |
| For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.  |         |                       |
| For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.     |         |                       |
| Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.   |         |                       |

N/A

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

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

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

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

Passed Screening \_\_\_\_ Yes \_\_\_\_ No

Reviewer: \_\_\_\_\_

Concurrence by Review Branch: \_\_\_\_\_

Date: \_\_\_\_\_

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



4. Device Name:

Trade or Proprietary Syngo Colonography Software Package  
Classification Name Accessary to Computed Tomography System

5. CFR Classification Citation: 21 CFR § 92.1750 (see 21 CFR 862 through 892)

6. Classification Panel: Radiology

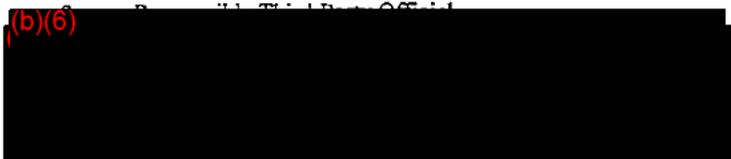
7. Based on my completion of pages 2 through 6 of this attachment, I recommend that this 510(k):

- Be accepted for substantive review
- Not be accepted for substantive review and I have listed the deficiencies on Attachment 1a

8. Primary Third Party Reviewer:

(b)(6)  
  
(b)(6)  
Print Name

March 26, 2003  
Date

(b)(6)  
  
Print Name

March 26, 2003  
Date

Division Manager, Medical Division  
Print Title

| Part II - Checklist   | YES | NO | Instructions   |
|---|-----|----|--|
| 1. Is the device one that FDA has determined as being acceptable for third party review?  | ✓   |    | If NO, telephone DSMA for instructions<br>---STOP REVIEW                           |
| 2. Is the device trade or proprietary name included?<br><i>Syngo Colonography</i>   | ✓   |    | If NO, note deficiency on Attachment 1a.   |
| 3. Is the device common or usual name included?<br><i>Accessory to CT system</i>  | ✓   |    | If NO, note deficiency on Attachment 1a.   |
| 4. Is the device classification name, class of the device, and regulation number (21 CFR 892.1750) included?  | ✓   |    | If NO, note deficiency on Attachment 1a.   |
| 5. Is the classification panel included?<br><i>Radiology</i>  | ✓   |    | If NO, note deficiency on Attachment 1a.   |
| 6. Has the applicant complied with Section 514 of the Act? (Section 514 relates to performance standards for class II devices. At this time, there are no 514 standards. Therefore, your answer should be yes.)   | ✓   |    | If NO, note deficiency on Attachment 1a.   |
| 7. Does the submission include proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (ODE Guidance Memorandum #G91-1)?  | ✓   |    | If NO, note deficiency on Attachment 1a.   |
| 8. Does the submission contain the "Indications for Use" form (See Attachment 1b)?  | ✓   |    | If YES, indicate page number: <u>8</u><br>If NO, note deficiency on Attachment 1a. |
| 9. Does the submission contain an acceptable <u>510(k) Summary</u> of Safety and Effectiveness or an acceptable <u>510(k) Statement</u> that safety and effectiveness information will be made available to any person upon request? For information on 510(k) Summaries and 510(k) Statements see Attachment 1c. | ✓   |    | If YES, indicate page number: _____<br>If NO, note deficiency on Attachment 1a.    |
| 10. Does the submission contain photographs of the device if applicable.  | N/A |    | If NO, note deficiency on Attachment 1a.   |

*software*

| Part II - Checklist  | YES | NO | Instructions                             |
|--|-----|----|--|
| 11. Does the submission contain drawings for the device with dimensions and tolerances if applicable?  | N/A |    | If NO, note deficiency on Attachment 1a. |
| 12. Does the submission identify the device to which equivalence is claimed?   | ✓   |    | If NO, note deficiency on Attachment 1a. |
| 13. If the answer to question 12 is YES, did the applicant identify:<br><br>a. Predicate device (referred to as marketed device)?<br>✓ b. Legally marketed device (referred to as marketed device)?<br><br>Note: A predicate device is a device that was legally in commercial distribution in the U.S. on or before May 28, 1976 (referred to as a preamendments device) or a device that was marketed after May 28, 1976 (referred to as a post amendments device) that was reclassified from class III to class I or II. A marketed device can be a predicate device but is most often a device that FDA has determined is SE to another marketed device (21 CFR 807.92(a)3). <u>IT IS YOUR RESPONSIBILITY TO MAKE SURE THAT THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE IDENTIFIED IS LEGITIMATE.</u> If it is not, the review must STOP. Telephone DSMA for assistance. | ✓   |    | K012313<br><br>K971717<br><br>K973010    |
| 14. Does the submission contain information about the marketed device(s) identified in questions 12 and 13 above to which equivalence is claimed, including labeling and a description of the device?  | ✓   |    | If NO, note deficiency on Attachment 1a. |
| 15. Does the submission contain a statement/comparison of similarities and/or differences between the new device and the marketed device? (The new device that is the subject of this 510(k) can be either a new device or a modification to the existing device.)   | ✓   |    | If NO, note deficiency on Attachment 1a. |

| Part II - Checklist  | YES                 | NO | Instructions   |
|--|---------------------|----|--|
| 16. Does the submission contain the Truthful and Accurate Statement (see Attachment 1d for information)?   | ✓                   |    | If YES, indicate page number: <u>6</u><br>If NO, note deficiency on Attachment 1a.   |
| 17. Does the submission contain the submitter's name, address, contact person, telephone number, and Fax number?   | ✓                   |    | If NO, or if unacceptable note deficiency on Attachment 1a.  |
| 18. If there is a representative or consultant, does the submission contain their name, address, contact person, telephone number, and Fax number?   | ✓                   |    | If NO, note deficiency on Attachment 1a.   |
| 19. Does the submission contain a table of contents with pagination?   | ✓                   |    | If NO, note deficiency on Attachment 1a.   |
| 20. If the submitter has a manufacturing facility (contract or owned), and/or a sterilization facility (contract or owned), is the address(es) contained in the submission?  | ✓                   |    | If deficient, note on Attachment 1a.   |
| 21. Does the submission contain a comparison table of the new device to the marketed device?   | ✓                   |    | If NO, note deficiency on Attachment 1a.   |
| 22. Does the submission contain information about the action taken to comply with voluntary standards?   | ✓<br><del>N/A</del> |    | If NO, note deficiency on Attachment 1a.   |
| 23. Does the submission contain performance data (can be bench or animal but not clinical), i.e.:<br><br>--- Is there performance data for the marketed device?<br><br>a. Bench Testing? ✓<br>b. Animal Testing? <del>N/A</del><br><br>--- Is there performance data for the new device?<br><br>a. Bench Testing? ✓<br>b. Animal Testing? <del>N/A</del> | 7-26-03<br>✓<br>✓   |    | If NO and data are necessary, note deficiency on Attachment 1a.<br><br>If NO and data are necessary, note deficiency on Attachment 1a. |

510(k) Summary.

US Import/Distribution.

Siemens AG  
Medical Solutions  
Henkestr. 127  
Erlangen, Germany

DICOM  
Compatible

| Part II - Checklist  | YES | NO | Instructions   |
|--|-----|----|--|
| 24. If the device is labeled as sterile, does the submission contain sterilization data?   | N/A |    | If NO, note deficiency on Attachment 1a.   |
| 25. Does the device incorporate a computer or computer software?<br><br>a. If YES, is there information about the hardware?<br>b. If YES, is there information about the software? | ✓   |    |  |
| 26. Is there a specific guidance document for this type of device?<br><i>No product specific guidance, software guide applicable.</i>  | N/A |    | If YES, continue review with checklist from the specific guidance document as required.<br><br>If NO, answer question 27.  |
| 27. Is this 510(k) sufficiently complete to allow substantive review?  | ✓   |    | If YES, continue review using specific guidance document or if no specific guidance document, continue the review using documentation forms.<br><br>If NO, note deficiency on Attachment 1a. |

*Software  
Guidance  
applicable*

Record of Deficiencies

| Checklist<br>Question Number | Describe in detail the additional information that is required. |
|------------------------------|---|
|                              | <p style="text-align: center;"><i>See attached.</i></p>         |

(Attach additional pages as needed. Please number.)



Attachment 1b

Page \_\_\_\_\_ of \_\_\_\_\_

510(k) Number (if known): \_\_\_\_\_

Device Name: \_\_\_\_\_

Indications For Use:

*See attached copy*

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

**Indication for use**

510(k) Number (if known): \_\_\_\_\_

**Device Name:** syngo Colonography Software Package

syngo Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-luminal view), the wall and the outside (extra-luminal view) of the colon. With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.

Due to all these capabilities the syngo Colonography software has the advantage of non-invasive evaluation of colonic lesions as compared to conventional colonoscopy.

(Please do not write below this line - continue on another page if needed)

-----  
Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

## REQUIREMENTS FOR A 510(k) SUMMARY OR 510(k) STATEMENT

### Definitions

A 510(k) summary means a summary, submitted under section 513(i)(3)(A) of the Act, of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based. The 510(k) statement in the format presented in this section is the same as the definition of the 510(k) statement. The 510(k) summary and 510(k) statement are defined in 21 CFR section 807.3.

A person submitting a premarket notification [510(k)] to FDA must include either:

- (1) a summary of the 510(k) safety and effectiveness information upon which the substantial equivalence determination is based; OR
- (2) a statement that the 510(k) safety and effectiveness information supporting the FDA finding of substantial equivalence will be made available by your firm (510(k) owner) to ANY person within 30 days of a written request.

If a 510(k) submitter chooses to provide a statement to satisfy the conditions in (2) above, written requests by any individual for a copy of the 510(k), excluding patient identifiers and trade secret and confidential commercial information, must be fulfilled by the statement certifier within 30 days of receipt of the request. FDA publishes the name of certifiers on the monthly list of 510(k) submissions for which substantial equivalence determinations have been made [807.93(b)]. 510(k) submitters may not charge requestors for compiling and disseminating this data.

Non compliance with the 510(k) statement will be deemed a prohibited act under section 301(p) of the FD&C Act and FDA may choose to use its enforcement powers to obtain compliance.

The choice between the 510(k) summary and 510(k) statement should be made before the 510(k) is submitted. However, a submitter may elect to change their choice between the summary or statement before the substantial equivalence determination is reached. After this determination is made, a submitter cannot change their choice of a 510(k) summary or 510(k) statement.

### Premarket Notification [510(k)] Summary

If you choose to meet the conditions for a 510(k) summary, then a summary must be submitted with your 510(k) submission and clearly marked as such in order for FDA to begin its scientific review of the 510(k) submission. A complete and correct summary as described below must be submitted in order for FDA to complete its review of the 510(k) submission. As required by section 807.92(a), FDA will accept summaries or amended summaries until FDA issues a determination regarding substantial equivalence.

Please make a copy of the following to use as a checklist and check off each item to make sure your summary is adequate and complete.

- The summary is a separate section of the submission, beginning on a new page and ending on a page not shared with any other part of the premarket notification submission, and is clearly identified as "510(k) Summary" as required by section 807.92(c).
- The summary contains on the first page, preferably on your letterhead paper, the submitter's name, address, phone and fax numbers, name of contact person, and date the summary was prepared [807.92(a)(1)].
- The summary includes the name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known [807.92(a)(2)].

Example:

- Trade name - DRAG@N LATEX EXAMINATION GLOVES
- Common name - exam gloves
- Classification name - patient examination glove (per 21 CFR section 880.6250)

- The summary identifies the legally marketed device to which your firm is claiming equivalence [807.92(a)(3)].
- The summary includes a description of the device [807.92(a)(4)].
- The summary describes the intended use of the device [807.92(a)(5)].
- Per section 807.92(a)(6), the 510(k) summary contains a summary of the technological characteristics of your device compared to the predicate device. If your device has different technological characteristics from the predicate device, the 510(k) summary contains a summary of how the technological characteristics of your device compare to a legally marketed device to which you are claiming equivalence.
- If the determination of substantial equivalence is also based on an assessment of non-clinical performance data, the summary includes a brief description of the nonclinical tests and how their results support a determination of substantial equivalence [807.92(b)(1)].
- NA If the determination of substantial equivalence is also based on an assessment of clinical performance data, the summary includes a brief discussion of clinical tests and how their results support a determination of substantial equivalence [807.92(b)(2)]. Clinical data is not needed for most devices cleared by the 510(k) process.
- Per section 807.92(b)(3), the summary includes the conclusions drawn from the nonclinical and clinical tests in (b1) and (b2). (See steps 8 and 9 above.)

NA [ ] Per section 807.92(d), the summary includes any other information reasonably deemed necessary by FDA. Such requests will be made directly to the applicant by FDA or the requirements will be published in guidance documents such as this document. Additional information requested by FDA during review of the 510(k) may include additional safety and effectiveness information which may necessitate an update of your summary if requested by FDA.

Please make sure you have included all of the information listed above and verify that the following criteria have been met.

- The summary includes only information that is also covered in the body of the 510(k).
- The summary does not contain any puffery or unsubstantiated labeling claims.
- The summary does not contain any raw data, i.e., contains only summary data.
- The summary does not contain any trade secret or confidential commercial information.
- The summary does not contain any patient identification information.

Make a copy of your complete 510(k) including the summary for your records. Submit the complete original 510(k) including the summary and a complete copy of the 510(k) including the summary to FDA.

In instances where a 510(k) submitter provides a 510(k) summary of the safety and effectiveness information upon which the SE determination is based with the 510(k) submission to FDA, written requests by individuals for copies of the 510(k) summary will be furnished by FDA through the Freedom of Information (FOI) process within 30 days after determining that the device is substantially equivalent to another device.

#### Premarket Notification [510(k) Statement]

NA For persons who choose to submit a 510(k) statement with their 510(k), the specific statement shown below must be submitted with the 510(k) in order for FDA to begin the review process. The statement should be clearly identified as "510(k) Statement," signed by the certifier -- NOT a consultant to the 510(k) submitter, and must include the specific language beginning with "I certify ...", shown in the following sample as required by 21 CFR section 807.93:

*NA*

*Summary provided!*

PREMARKET NOTIFICATION STATEMENT  
(As Required By 21 CFR 807.93)

*MMZ*

I certify that, in my capacity as [*The Position Held In Company By Person Required To Submit The Premarket Notification, Preferably The Official Correspondent In The Firm*], of [*Company Name*], I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

\_\_\_\_\_  
(Signature of certifier)

\_\_\_\_\_  
(Typed Name)

\_\_\_\_\_  
(Dated)

\_\_\_\_\_  
\*(Premarket Notification [510(k)] Number)

\*For a new submission, leave the space for the 510(k) number blank. You will receive your 510(k) number in your 510(k) acknowledgment letter. The 510(k) document control number begins with the letter K followed by digits.

Make a copy of your complete 510(k) including your signed statement for your records. Submit the complete original 510(k) including the statement and a complete copy of the 510(k) including the statement to FDA.

**ATTACHMENT 1c**  
**510(k) Summary or 510(k) Statement**

*See attached copy*



COP

### 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

#### I. GENERAL INFORMATION

##### Device Name and Classification

|                       |   |
|-----------------------|---|
| Product Name:         | Syngo Colonography software package     |
| Common Name           | 3D Reconstruction Software              |
| Classification Name:  | Accessory to Computed Tomography System |
| Classification Panel: | Radiology                               |
| CFR Section:          | 21 CFR §892.1750                        |
| Device Class:         | Class II                                |
| Product Code:         | 90 JAK                                  |

##### Establishment:

##### **Importer/Distributor:**

Siemens Medical Solutions USA, Inc.  
 51 Valley Stream Parkway  
 Malvern, PA 19355

**Registration Number:** 2240869

##### **Manufacturing Facility:**

Siemens AG  
 Medical Solutions  
 Henkestrasse 127  
 D-91052 Erlangen, Germany  
**syngo is a registered trademark of Siemens AG**

##### **Contact Person:** Mr. Jamie Yieh

Senior Technical Specialist  
 Telephone: (610) 448-1785 Fax: (610) 448-1787

**Date of Preparation of Summary:** November 26<sup>th</sup> 2002

#### II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

##### **Device Description and Intended Use:**

This premarket notification covers Siemens Syngo Colonography software package. It is based on Siemens *syngo* software platform.

syngo Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools

36

COPY

with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-luminal view), the wall and the outside (extra-luminal view) of the colon. With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.

Due to all these capabilities the syngo Colonography software has the advantage of non-invasive evaluation of colonic lesions as compared to conventional colonoscopy.

**General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

**Substantial Equivalence:**

The Syngo Colonography software package, addressed in this premarket notification, is substantially equivalent to the following commercially available software package:

| <i>Predicate Device Name</i>                             | <i>FDA Clearance Number</i> | <i>FDA Clearance Date</i> |
|--|-----------------------------|---------------------------|
| GE CT Colonography/Navigator 2 Workstation               | K012313                     | 08/07/01                  |
| Siemens Fly Through                                      | K971717                     | 09/03/97                  |
| Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso) | K973010                     | 11/10/97                  |

The Syngo Colonography software package described in this 510(k) has the same intended use and similar technical characteristics as the commercially available software listed above.

In addition, many of the image processing, display and evaluation components of syngo Colonography are currently available on software options like the Volume Rendering Technique option, K923524/S2, cleared on May 17<sup>th</sup> 1994 and workstations like the syngo Multimodality Workstation, K010938 cleared on 26<sup>th</sup> June 2001 wherein the Fly Thorough software algorithms were transferred over to the syngo software platform. syngo Colonography packages these image processing and image display components in an optimized workflow palette.

In summary, Siemens is of the opinion that Syngo Colonography software package does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate software components and the predicate device.

ATTACHMENT 1d  
510(k) Truthful and Accurate Statement

PREMARKET NOTIFICATION  
TRUTHFUL AND ACCURATE STATEMENT  
(As Required By 21 CFR 807.87(j))

I certify that, in my capacity as *[the position held in company]* of  
*[company name]*, 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.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Typed Name)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
\*(Premarket Notification [510(k)] Number)

\*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification  
[e.g., not a consultant for the 510(k) submitter].

*See attached copy*

*VJB*

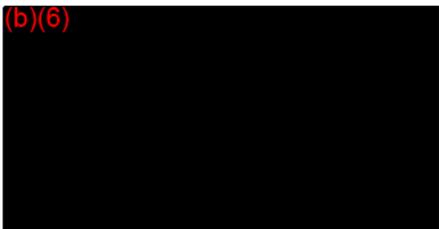
Premarket Notification

Records processed under FOIA Request # 2015-4839, Released by CDRH on 10-21-2015

(As required by 21 CFR 807.87(j))

I certify that, in my capacity as the Manager, Regulatory Submissions of Siemens AG Medical Solutions CT, Forchheim, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)



*Nov 26, 2002*  
Date

Manager Regulatory Submissions CT

*COPY*

**ATTACHMENT 2**

**Third Party "Substantial Equivalence" (SE) Decision Making  
Documentation (Referred to as SE Documentation)**

Revised: 7/1/96

**THIRD PARTY "SUBSTANTIAL EQUIVALENCE" (SE)  
DECISION MAKING DOCUMENTATION**

• 510(k) Holder's Name:  
• Primary Third Party Reviewer:  
(b)(6) March 26, 2003  
Date  
(b)(6)  
Print Name

• Responsible Official:  
(b)(6) March 26, 2003  
Date  
(b)(6)  
Print Name and Title  
(b)(4)  
Print Third Party Name

|  | Yes*                                | No*                                 |                                      |
|--|-------------------------------------|-------------------------------------|--------------------------------------|
| 1. Is product a device?  | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | If NO = Stop                         |
| 2. Is device subject to 510(k)?  | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | If NO = Stop                         |
| 3. Same indication statement?  | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | If YES = Go To 5                     |
| 4. Do differences alter the effect or raise new issues of safety or effectiveness? | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | If YES = Stop NE                     |
| 5. Same technological characteristics?   | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | If YES = Go To 7                     |
| 6. Could the new characteristics affect safety or effectiveness?                   | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | If YES = Go To 8                     |
| 7. Descriptive characteristics precise enough?                                     | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | If NO = Go To 10<br>If YES = Stop SE |
| 8. New types of safety or effectiveness questions?                                 | <input type="checkbox"/>            | <input type="checkbox"/>            | If YES = Stop NE                     |
| 9. Accepted scientific methods exist?  | <input type="checkbox"/>            | <input type="checkbox"/>            | If NO = Stop NE                      |
| 10. Performance data available?  | <input type="checkbox"/>            | <input type="checkbox"/>            | If NO = Request Data                 |
| 11. Data demonstrate equivalence?  | <input type="checkbox"/>            | <input type="checkbox"/>            | Final Decision:                      |

\*Note: In addition to completing page 2, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation on page 3.

ATTACHMENT  
2a STATUS  
TRY AND  
SIMILAR  
NO

NARRATIVE DEVICE DESCRIPTION

1. Intended Use:

*see page 8 of submission*

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

Summary:

*see attachment 2a  
- Review Memo -*

**Siemens Medical Solutions USA, Inc.**  
Syngo Colonography Software Package

510 (k) Submitter: Siemens Medical Solutions USA, Inc.  
Type of Submission: Traditional  
Product: Syngo Colonography Software Package  
Classification: 21CFR 892.1750  
Product Code: 90 JAK  
Classification name: Accessory to Computed Tomography System  
Legally marketed device(s): Siemens Fly Through (K971717)  
Siemens RealTime 3D Diagnostic Workstation (K973010)  
GE CT Colonography/Navigator 2 Workstation (K012313)

### 1. General Description

The Siemens Syngo Colonography Software Package is a self-contained image analysis software for evaluating CT volume data sets. The software can also be used for Magnetic Resonance Imaging (MR) data sets.

The software is designed to support the physician in studying the inside, wall and outside of the colon. Datasets can be viewed from the prone and supine positions to facilitate the detection of colonic lesions in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning.

This evaluation allows for the volumetric analysis of colonic polyps or lesion size over time.

The syngo software package is based on the Siemens syngo software platform. The Syngo Colonography Software Package utilizes a workstation with a Microsoft Windows NT 4.0/2000 operating platform.

### 2. Comparison

Attachment 7 of the submission contains the substantial equivalence information.

The Syngo Colonography Software Package has been compared to the Siemens Fly Through (K971717), the Siemens RealTime 3D Diagnostic Workstation (K973010) and the GE CT Colonography/Navigator 2 Workstation (K012313).

The indications for use statements for these software packages are similar. The software packages are intended to provide the medical personnel with three dimensional reconstructions of anatomic characteristics. Based on the documentation provided in the submission the GE CT Colonography/Navigator 2 Workstation (K012313) and the Syngo Colonography Software Package are intended to allow the user to study the inside wall and outside of the colon and to view datasets from both, prone and supine positions to facilitate the detection of colonic lesions. Both systems allow for marking of lesions and for linear measurements. Thus, the intended use for both devices is the deemed to be the same.

All software packages utilize a workstation, differences between the Sun Sparc (GE CT Colonography/Navigator 2 Workstation) and the Syngo Colonography Software Package are not deemed to raise new questions regarding safety and efficacy.

**Siemens Medical Solutions USA, Inc.**  
Syngo Colonography Software Package

The Image Processing and Evaluation functions for all devices are similar and do not raise any new questions regarding safety and efficacy.

User Interface are GUI based for all Software Packages, the archiving and storing system for all Siemens Software Packages is identical.

All Software packages are DICOM compatible.

**3. Software**

The Syngo Colonography Software Package description is provided in attachments 4 and 5 of the submission. The level of concern has been determined as minor. The information required per guidance document "Guidance for the Content of Pre-Market Submissions for Software contained in Medical Devices" for this level of concern is deemed to be available.

**4. Hazard Analysis**

A hazard analysis Syngo Colonography Software Package was included in attachment 5 of the submission. All identified hazards are deemed be addressed in a manner consistent with recognized methods.

**5. Labeling Review**

Labeling was provided in form of draft promotional literature and draft manual Labeling and promotional material for the legally marketed device was also provided in attachment 8 of the submission.

**6. Additional Information**

The following documents requested after receiving the submission are considered as sufficient to support the SE decision:

Document/Date:

Documentation received from Siemens Medical Solutions on December 2, 2002

Revised submission received from Siemens Medical Solutions on March 19, 2003

**7. Review Summary**

The comparison (see attachments 7 and 8 of the submission) shows that the Syngo Colonography Software Package has similar features as the legally marketed devices.

The differences do not affect the intended use or raise new questions regarding safety and effectiveness.

The requirements of applicable guidance documents are deemed to be fulfilled.

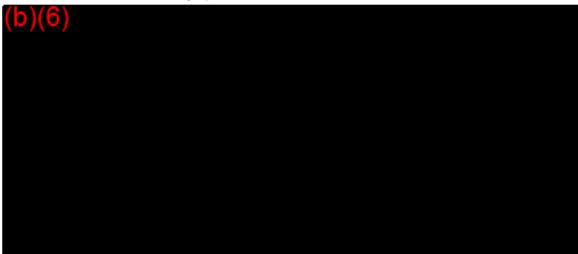
**Siemens Medical Solutions USA, Inc.**  
Syngo Colonography Software Package

**8. Conclusion**

The documents submitted allow for the decision that the received from Siemens Medical Solutions that the Syngo Colonography Software Package is substantially equivalent to the legally marketed devices Siemens Fly Through (K971717), Siemens RealTime 3D Diagnostic Workstation (K973010), GE CT Colonography/Navigator 2 Workstation (K012313).

Reviewer(s):

(b)(6)



*March 26, 2003*

Title: Division Manager, Medical Division

**Explanations To "YES" And "NO" Answers To Questions On Page 1 As Needed**

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

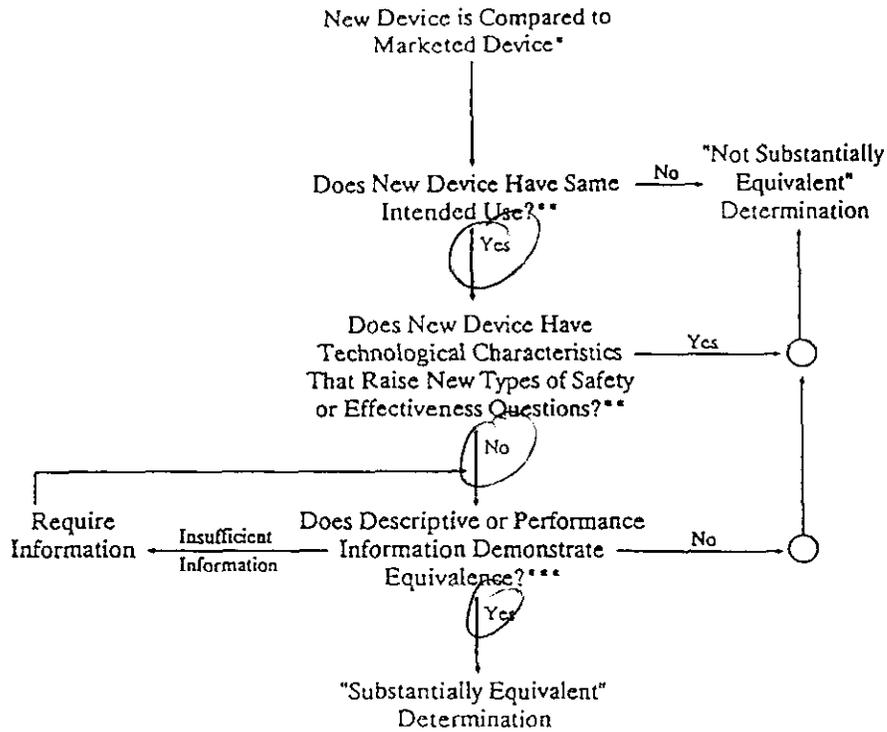
**Record of Deficiencies**

Describe in detail the additional information that is required:

N/A

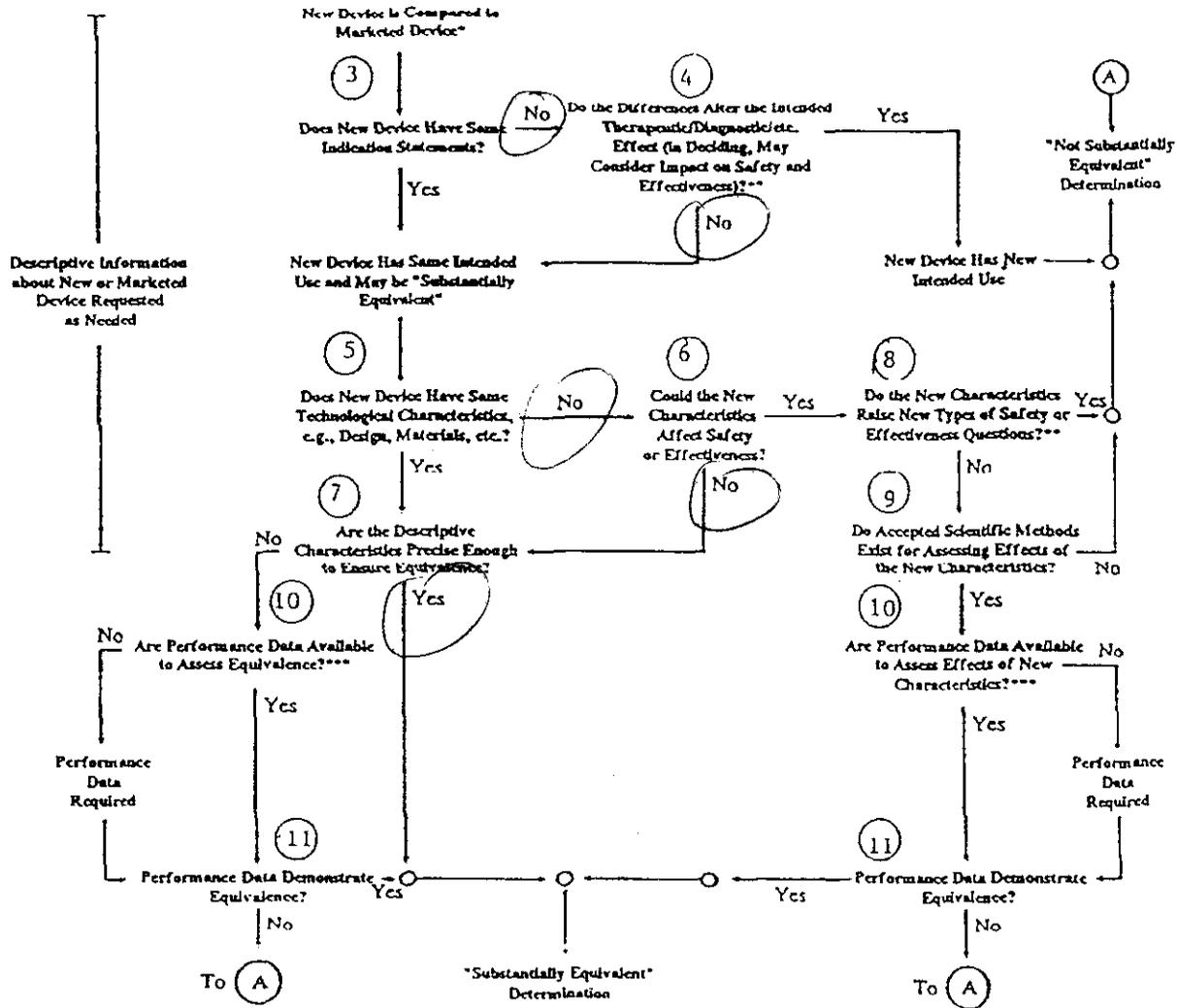
(Attach additional pages as needed. Please number.)

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



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

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



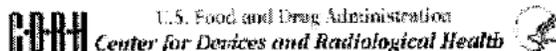
- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing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

| SECTION NUMBER | SOFTWARE DOCUMENTATION                      | MINOR CONCERN  | MODERATE CONCERN  | MAJOR CONCERN  |
|----------------|---|--|---|--|
| 2, 3.1         | Level of Concern                            | All levels of concern  |   |  |
| 3.2            | Software Description                        | All levels of concern  |   |  |
| 3.3, 4.3       | Device Hazard Analysis                      | All levels of concern  |   |  |
| 3.4, 4.2       | Software Requirements Specification (SRS)   | Software functional requirements from SRS  | SRS   |  |
| 3.5            | Architecture Design Chart                   | A chart depicting the partitioning of the software system into functional subsystems | A chart depicting the partitioning of the software system into functional subsystems, listing of the functional modules and a description of how each fulfills the requirements.  |  |
| 3.6            | Design Specification                        | No documentation is necessary in the submission.                                     | Software design specification document  |  |
| 3.7            | Traceability Analysis                       | No documentation is necessary in the submission.                                     | Traceability among requirements, identified hazards, and Verification and Validation testing.   |  |
| 3.8, 4.1       | Development                                 | No documentation is necessary in the submission.                                     | Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities.  | Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the configuration management and maintenance plan documents.    |
| 3.9            | Validation, Verification and Testing (VV&T) | Software functional test plan, pass / fail criteria, and results                     | Description of VV&T activities at the unit, integration and system level. System level test protocol including pass/fail criteria, and tests results.                             | Description of VV&T activities at the unit, integration and system level. Unit, integration and system level test protocols including pass/fail criteria, test report, summary, and tests results. |
| 3.10           | Revision Level History                      | No documentation is necessary in the submission.                                     | Revision history log  |  |
| 3.11           | Unresolved anomalies (bugs)                 | No documentation is necessary in the submission.                                     | List of errors and bugs which remain in the device and an explanation how they were determined to not impact safety or effectiveness, including operator usage and human factors. |  |
| 3.12           | Release Version Number                      | Version number and date for all levels of concern.                                   |   |  |

*Section*

5.1 ✓  
 4.1 ✓  
 5.11 ✓  
 5.2 ✓  
 5.3 ✗  
 5.4 ✓  
 ✓  
 4.2 ✓  
 5.6 ✓  
 5.0 ✓  
 5.6 ✓  
 5.7 ✓  
 5.60  
 NA  
 NA  
 Lj Letke  
 Somaris  
 VA 70p

**Table 1 Documentation in a Premarket Submission**



Prototype - for testing only

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

[New Search](#)

[Back To Search Results](#)

### Product Classification Database

**Device** SYSTEM, X-RAY, TOMOGRAPHY, COMPUTED  
**Medical Specialty** Radiology  
**Product Code** JAK  
**Device Class** 2  
**510(k) Exempt?** No  
**Regulation Number** 892.1750  
**Third Party Review** Eligible for *Mutual Recognition Agreement Program*  
Eligible for *Accredited Persons Program*  
[Accredited Persons and Third Party Program Information](#)  
[Mutual Recognition Agreement Program Information](#)

#### Accredited Persons

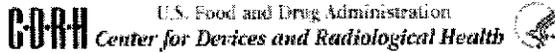
- [BRITISH STANDARDS INSTITUTION](#)
- [CENTER FOR MEASUREMENT STANDARDS OF INDUSTRIAL](#)
- [CHEIROON BV](#)
- [CITECH](#)
- [ENTECLA, INC.](#)
- [INTERTEK TESTING SERVICES](#)
- [N.V. KEMA](#)
- [TUV AMERICA, INC.](#)
- [TUV RHEINLAND OF NORTH AMERICA, INC.](#)
- [UNDERWRITERS LABORATORIES, INC.](#)

Database Updated 3/5/2003

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Prototype - for testing only

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

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[Code of Federal Regulations]  
 [Title 21, Volume 8]  
 [Revised as of April 1, 2002]  
 From the U.S. Government Printing Office via GPO Access  
 [CITE: 21CFR892.1750]

[Page 511]

TITLE 21--FOOD AND DRUGS

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

PART 892--RADIOLOGY DEVICES--Table of Contents

Subpart B--Diagnostic Devices

Sec. 892.1750 Computed tomography x-ray system.

(a) Identification. A computed tomography x-ray system is a diagnostic x-ray system intended to produce cross-sectional images of

the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) Classification. Class II.

Database Updated April 1, 2002

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG - 7 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

General Electric Medical Systems  
% Mr. Reiner Krumme  
Manager, Medical Division  
TUV Rheinland of North America  
12 Commerce Road  
NEWTON CT 06470

Re: K012313  
CT Colonography/Navigator 2 (CT Navigation software package)  
Dated: July 18, 2001  
Received: July 23, 2001  
Regulatory Class: II  
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

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

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

Sincerely yours,

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known):

Device Name: CT Colonography

Indications for Use

CT Colonography/Navigator2 is an image analysis software package that contains CT Colonography and Navigator2.

CT Colonography allows the user to study the inside, wall and outside of the colon. It provides the user with an ability to view datasets from both, prone and supine positions, facilitating detection of colonic lesions. In comparison to colonoscopy, this tool has an advantage of non-invasive depth penetration due to its 3D presentation capability.

Navigator2 provides endoluminal views of anatomical structures. Navigator2 is designed to enhance and modify current image quality, tools, speed and user interface of Navigator for improved productivity. Navigator2 provides a visualization tool to investigate structures (such as polyps, tumors, stones, calcification etc.) within anatomy, airways and organs. Thus, its viewing capability of the inner and outer surfaces of organs as well as within their walls provides additional supplemental information, complementing endoscopy/colonoscopy, to support interpretation and treatment planning. Navigator2 is applicable to X-ray as well as CT/MR.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801-109)

OR Over-The-Counter Use \_\_\_\_\_

*Nancy C. Brogdon*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number     K012313

AUG - 7 2001



**GE Medical Systems**  
General Electric Company  
P O Box 414 Milwaukee, WI 53201

K012313

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

**Submitter**            Larry A. Kroger, Ph.D.  
Senior Regulatory Program Manager  
Telephone: (262) 544-3894, FAX: (262) 544-3863  
Date Prepared: June 12, 2001

**PRODUCT IDENTIFICATION**

Name:                    CT Colonography/Navigator2

Classification Name: Accessory to Computed Tomography System

Manufacturer :        General Electric Medical Systems  
283, rue de la Miniere  
78533 Buc Cedex, FRANCE

Distributor:            General Electric Medical Systems, Milwaukee, WI

**Marketed Devices**    The CT Colonography/Navigator2 is substantially equivalent to the device listed below:

Model:                    Navigator  
Manufacturer:          General Electric Medical Systems, Milwaukee, WI  
510(k) #:                K954355

**Device Description:**

CT Colonography/Navigator2 (CTC/Nav2) is an image analysis software package that allows the user to study the inside, wall, and outside of the colon using CT-acquired helical images. The tool is laid out to facilitate the detection of colonic lesions. CT Colonography requires Navigator2 for its operation however, Navigator2 can also be utilized as a stand-alone option. Navigator2 is an advanced visualization software option that provides endoluminal views of anatomical structures. The flexibility of this software allows the user to move interactively from air paths to inner vessels visualization and thus, it is not limited to inner navigation of structures as lungs and sinuses. Volume Analysis (includes both, CT/MR Windows Workstation, K913770 and 3D & Dentascan for Windows K923077) provides the base for CTC/Nav2 and Nav2 alone, which allows an increase in the ease of use and productivity. CTC/Nav2 and Nav2 alone, also use some options of Volume Rendering (AW Volume Render Option

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K972399), which allows the user to quickly isolate structure of interest and render volumetric data in three dimensions.

**Indications for Use :**

CT Colonography/Navigator2 is an image analysis software package that contains CT Colonography and Navigator2.

CT Colonography allows the user to study the inside, wall and outside of the colon. It provides the user with an ability to view datasets from both, prone and supine positions, facilitating detection of colonic lesions. In comparison to colonoscopy, this tool has an advantage of non-invasive depth penetration due to its 3D presentation capability.

Navigator2 provides endoluminal views of anatomical structures. Navigator2 is designed to enhance and modify current image quality, tools, speed and user interface of Navigator for improved productivity. Navigator2 provides a visualization tool to investigate structures (such as polyps, tumors, stones, calcification etc.) within anatomy, airways and organs. Thus, its viewing capability of the inner and outer surfaces of organs as well as within their walls provides additional supplemental information, complementing endoscopy/colonoscopy, to support interpretation and treatment planning. Navigation2 is applicable to X-ray as well as CT/MR.

**Comparison with Predicate:**

CT Colonography/Navigator2 is an image analysis software built on Navigator 2 features that allows the user to study the inside, wall, and outside of the colon using CT acquired helical images. The tool is laid out to facilitate the detection of colonic lesions. Navigator 2 is a new version of the current GE Navigator, it has improved performance and usability. The functional features of this package are substantially equivalent to that of the following device:

| Device Name                                 | FDA Clearance Number |
|---|----------------------|
| Advantage Windows 3D with Navigator Option* | K 954355             |
|   |                      |

*\*referred as Navigator in this application*

**Adverse Effects on Health :**

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

**Conclusions:**

The CT Colonography/Navigator2 does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the CT Colonography/Navigator2 to be equivalent to those of Navigator (K954355).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP - 3 1997

Kathleen Rutherford  
Manager, Regulatory Submissions  
Siemens Medical Systems, Inc.  
186 Wood Ave. South  
Iselin, NJ 08830

Re: K971717  
Fly Through (3D CT/MR Reconstruction Software)  
Dated: August 7, 1997  
Received: August 8, 1997  
Regulatory class: II  
21 CFR 892.1750/Procode: 90 JAK

Dear Ms. Rutherford:

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian Yin".

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**ATTACHMENT 1**

**Indications For Use**

510(k) Number (if known): K971717  
Device Name: Fly Through Software Package

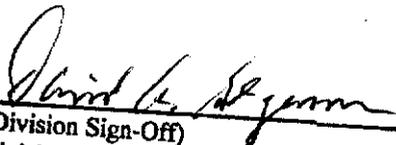
**Indications For Use:**

From user specified sets of CT or MR images, Fly Through can be used for

- 3D presentation of segmented anatomic models (e.g., tracheas, bones, vessels, colon, etc.);
- navigating interactively through 3D segmented models that represent body cavities (e.g., vessels, colon, spine, lung, etc.);
- for viewing the inner surface of organ models (vessels, colon, etc.). Fly Through offers advantages over real endoscopy. For example, Fly Through can be performed within models of organs or blood vessels inaccessible to a real endoscope;
- a training tool for surgeons to practice endoscopic procedures;
- surgical planning;
- feasibility study of an actual endoscopic procedure; and
- a 3D positioning and orientation tool for Multiplanar reconstruction, thus assisting diagnosis from Multi-Planar-Reconstructions (MPRs): the Fly Through tool can help the user to position and visualize the 3-dimensional location of the MPR within the segmented dataset.

( please do no write below this line- continue on another page if needed )

Concurrence of the CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K971717

Prescription Use X OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

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**SIEMENS**

SEP - 3 1997

ATTACHMENT 11

K971717

510(k) Summary

Siemens Fly Through Software Package

May 8, 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. General Information.

Establishment

- **Address:** Siemens Medical Systems, Inc.  
186 Wood Avenue South  
Iselin, NJ 08830
- **Contact Person:** Kathleen M. Rutherford  
Manager, Regulatory Submissions  
(908) 321-4779 phone  
(908) 321-4841 fax

Device Name

- **Trade Name:** Fly Through
- **Common Name:** PACS software
- **Classification Name:** Picture Archiving and Communication System (PACS)
- **Classification:** Class II
- **Performance Standards:** None established under Section 514 of the Food, Drug, and Cosmetic Act.

II. Information Supporting Substantial Equivalence Determination.

• **Device Description:**

The Siemens Fly Through is a software package that provides 3D, MPR of anatomic structures, and interactive endoscopic views of organs with cavities. By navigating within the 3D imaging data, the user can tour the patient anatomy and make adjustments to provide the best view.

Fly Through can be installed onto medical viewing and post-processing workstations that meet minimum system requirements such as patient database, filming, and networking, 24 bits true color graphics display, real-time polygon rendering graphics, and real-time texture mapping graphics.

# SIEMENS

- **Intended Use:**

The Fly Through application is intended to provide physicians with a training tool, and means to help evaluate from CT or MR datasets the feasibility of conducting actual endoscopic procedures. The application is also intended to assist diagnosis from Multi-Planar-Reconstructions (MPRs): the Fly Through tool can help the user to position and visualize the 3-dimensional location of the MPR within the segmented dataset.

- **Technological Characteristics as compared to the Predicate Device:**

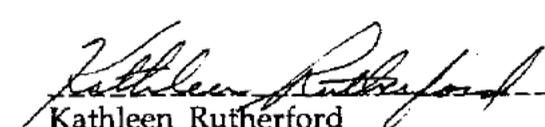
The Fly Through has the same technological characteristics as GE's Navigator. They both provide the user with 3D and MPR of anatomic structures. They both provide the user with a navigation tool that can be used to view the anatomy in different viewpoints. Siemens Fly Through also provides the MPR in relation to the 3D model thus making it easier for the user to position and visualize the 3-dimensional location of the MPR within the segmented dataset.

The Fly Through has the same technological characteristics as the Prominence Workstation. FT is installed as an option on the Prominence. They share the same segmentation module, patient data, MPR, user interface, filming, and storage. FT has the added ability to show 3D surface shading and tetrahedral models.

- **Substantial Equivalence:**

Siemens Fly Through is substantially equivalent to the following devices:

1. Advantage Windows 3D with Navigator  
GE
2. Prominence Workstation (Silhouette)  
ISG Technologies

  
-----  
Kathleen Rutherford  
Manager, Regulatory Submissions  
Imaging Systems Group, Siemens Medical Systems

5/8/97  
-----  
Date

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 10 1997

Kathleen Rutherford  
Manager, Regulatory Submissions  
Siemens Medical Systems, Inc.  
186 Wood Avenue South  
Iselin, NJ 08830

Re: K973010  
Realtime 3D Diagnostic Workstation  
Dated: August 8, 1997  
Received: August 13, 1997  
Regulatory class: Unclassified  
Procode: 90 LLZ

Dear Ms. Rutherford:

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K973010

# SIEMENS

## ATTACHMENT 10

### 510(k) Summary

#### Siemens Realtime 3D Software Package

NOV 10 1997

August 8, 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

#### I. General Information.

##### Establishment

- **Address:** Siemens Medical Systems, Inc.  
186 Wood Avenue South  
Iselin, NJ 08830
- **Contact Person:** Kathleen M. Rutherford  
Manager, Regulatory Submissions  
(908) 321-4779 phone  
(908) 321-4841 fax

##### Device Name

- **Trade Name:** Realtime 3D Diagnostic Workstation
- **Common Name:** 3D CT/MR Post-processing Workstation
- **Classification Name:** Picture Archiving and Communication System (PACS)
- **Classification:** Class II
- **Performance Standards:** None established under Section 514 of the Food, Drug, and Cosmetic Act.

#### II. Information Supporting Substantial Equivalence Determination.

##### • Device Description:

Realtime 3D (RT3D) Diagnostic Workstation includes all the necessary hardware and software components for a medical imaging workstation that allows 3D visualization of tomographic dataset from either a CT or MR scanner together with Multiplanar Reconstructions (MPR), and allows the user to fly through or around the 3D image(s) in real time. The user can also view the 3D images in stereo and make measurements in the 3D images.

##### • Intended Use:

The Realtime 3D application is intended to provide the physician with additional diagnostic information through displaying the

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# SIEMENS

tomographic dataset in 3 dimensional space which can show the spatial relationship among different anatomical structures. It can also be used for pre-surgical and post-surgical evaluation by surgeons. Due to its real time performance, Realtime 3D provides the user with fast case-turnaround time which leads to improved patient care and cost savings.

• **Technological Characteristics as compared to the Predicate Device:**

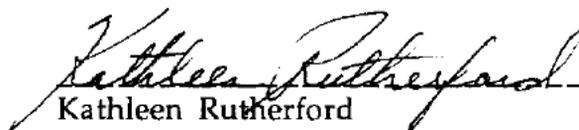
The Realtime 3D has the same technological characteristics as Vitrea™ 3D Medical Visualization System. They both provide the user with 3D and MPR of anatomic structures. They both provide the user with a navigation tool that can be used to "Fly around" or "Fly through" the anatomy of interest. Siemens Realtime 3D offers, in addition, interactive clip planes which provides the user with real time MPR, stereo display, 3D measurement, and an orientation view during Fly-through and fly-around for better orientation and navigation.

The Realtime 3D has the same technological characteristics as the MagicView Workstation. They have substantially similar MPRs, MIPs, and volume rendering algorithm. RT3D has the added ability to show 3D images in real time.

• **Substantial Equivalence:**

Siemens Realtime 3D is substantially equivalent to the following devices:

- Vitrea™ 3D Medical Visualization System  
Vital Images
- MagicView Diagnostic Workstation  
Siemens Medical Systems, Inc.



-----  
Kathleen Rutherford  
Manager, Regulatory Submissions  
Imaging Systems Group, Siemens Medical Systems

8/7/97  
-----  
Date

**ATTACHMENT 1(revision)**

**Indications For Use**

510(k) Number (if known): K973010  
Device Name: Realtime 3D Diagnostic Workstation

**Indications For Use:**

From user specified sets of CT or MR images, Realtime 3D can be used for

- 3D presentation of the complete anatomic structure (i.e. head, chest, abdomen) covered by the original CT or MR images for diagnosis and use in treatment planning;
- diagnosing as well as treatment planning from real time Multi-Planar-Reconstruction (MPR):the Realtime 3D tool can help the user to position and visualize the 3-dimensional location of the MPR within the 3D volume by using interactive clip planes in real time;
- CTA and MRA displaying enhanced vessels;
- measurement of anatomical structures in the 3D volume. Important for quantitative measurement of geometry and length of anatomy indices;
- displaying the position of anatomical structures in relationship to each other;
- navigating interactively through anatomical structures (e.g., vessels, colon, spine, lung, etc.) or inside the 3D volume;
- depth perception using the Sterco display option to visualize i.e. overlaying and underlying vessels;
- for viewing the inner surface of organs (vessels, colon, etc.);

( please do no write below this line- continue on another page if needed )

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

David G. Ferguson  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number 973010

# SIEMENS

March 17, 2003

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

Subject: Reply on (b)(4) Review and Record of Deficiencies (syngo Colonography)

Dear Mr. (b)(6),

As discussed on March 13, 2003, Siemens Medical Solutions would like to provide you with one copy of the modified Pre-Market Notification for Siemens syngo Colonography Software Package which was submitted to (b)(4), on November 27, 2002.

These modifications are related to the Record of Deficiencies (syngo Colonography) which (b)(4) sent to Siemens on December 6, 2002

The following items were in the record and below is the replies:

(b)(4)

**Siemens Medical Solutions USA, Inc.**

Regulatory Affairs

51 Valley Stream Parkway

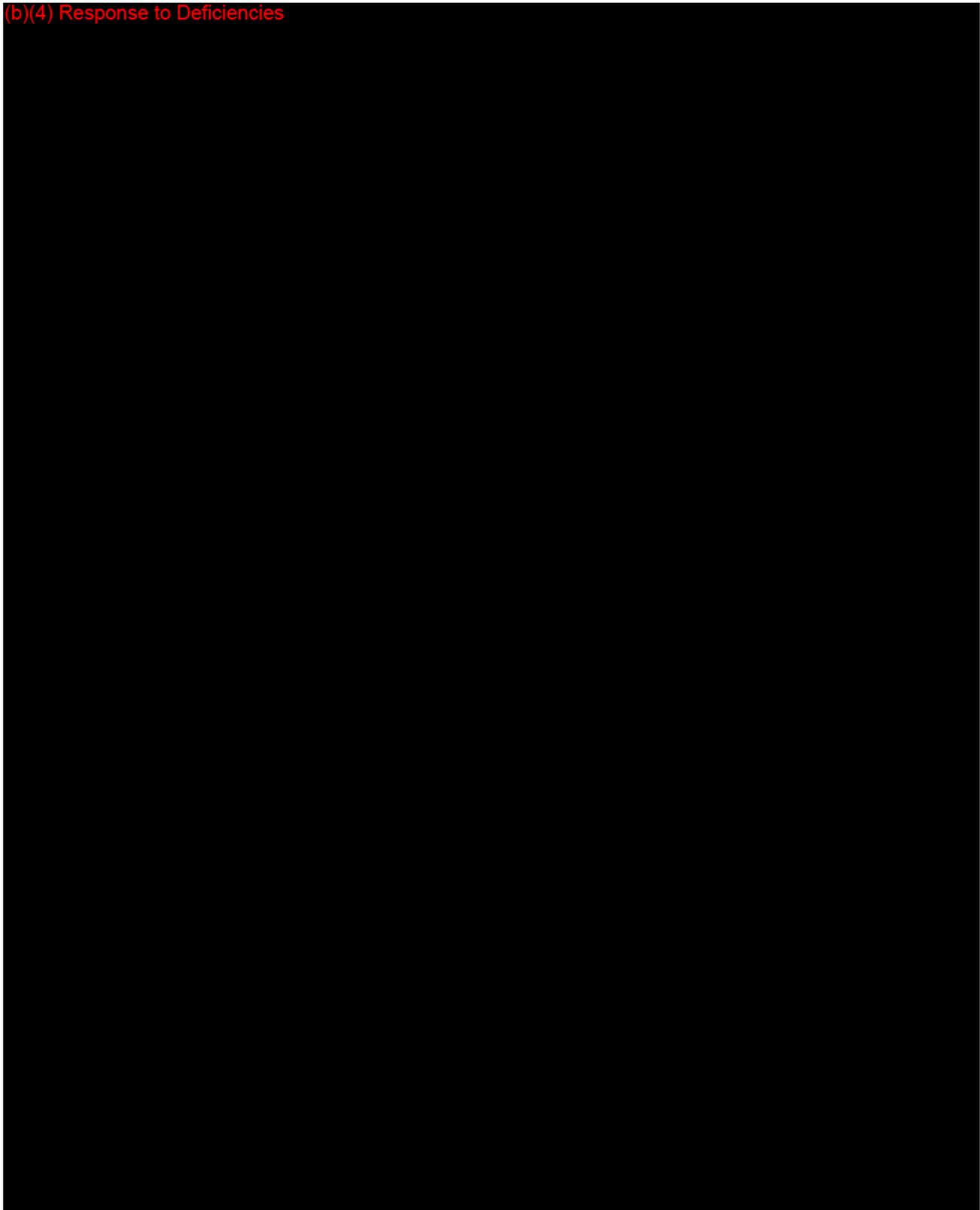
Tel: (610) 448-1777

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

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# SIEMENS

(b)(4) Response to Deficiencies



# SIEMENS

I hope that these answers resolve your questions with the current Siemens syngo Colonography Software Package. Please feel free to contact me directly, if there are any further issues.

Sincerely,



Mr. Jamie Yieh  
Senior Technical Specialist  
Regulatory Affairs  
Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway  
Malvern, PA 19355  
Tel: 610-448-1785  
Fax: 610-448-1787

# Attachment 2

## Owner's Authorization

SIEMENS

November 27, 2002

Mr. (b)(6)  
(b)(4)

**Subject: Third Party Review of Siemens syngo Colonography software package  
Premarket application**

Dear Mr. (b)(6)

Siemens Medical Systems, Inc., authorizes (b)(4) to review and thereafter submit the premarket application for the Siemens syngo Colonography software package to the U.S. Food and Drug Administration and, as necessary to discuss its content with the FDA.

Sincerely,

Siemens Medical Systems, Inc.,

(b)(6)

Regulatory Submissions

Enclosure

**Siemens Medical Solutions USA, Inc.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118  
Sales and Service: One Wood Avenue South, Iselin, NJ 08830 Tel: (732) 271-6500 Fax: (732) 321-4841

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# Attachment 3

## Owner's Submission

Pre-market Notification  
For  
**Siemens**  
**syngo Colonography**  
**Software Package**

November 26<sup>th</sup> 2002  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Document Control Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, MD 20850

**Subject: Traditional 510(K) Submission for Siemens syngo Colonography Software Package**

Dear Document Control Clerk:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, Siemens Medical Solutions, Inc. is submitting, in duplicate, a **traditional Premarket Notification [510(k)]** for the Siemens Medical Systems, Inc., **syngo Colonography Software Package**. The following information is provided in accordance with 21 CFR §807.87 and the guidance document "Addendum: How to Submit a Premarket Notification [510(k)] March 1995" from the Center for Devices and Radiological Health.

**1. Reason for Submission:**

Siemens Medical Solutions intends to market the syngo Colonography software package.

**2. Device Name and Classification:**

|                       |                                     |
|-----------------------|-------------------------------------|
| Product Name:         | syngo Colonography software package |
| Classification Name:  | 3D Reconstruction Software          |
| Classification Panel: | Radiology                           |
| CFR Section:          | 21 CFR §892.1750                    |
| Device Class:         | Class II                            |
| Product Code:         | 90 JAK                              |

The Software Certification statement is provided in Attachment 3. A software description is provided in Attachment 4 and software development is described in Attachment 5.

**3. Importer/Distributor Establishment Registration Number: 2240869**

Siemens Medical Solutions, Inc.  
51 Valley Stream Parkway  
Malvern, PA 19355

**4. Manufacturing Facility:**

Siemens Medical Solutions  
Bereich Med  
Siemensstrasse 1  
91301 Forchheim, Germany  
**syngo is a registered trademark of Siemens AG**

**5. Contact Person:**

Mr. Jamie Yieh  
Senior Technical Specialist  
Phone: (610) 448-1785 Fax: (610) 448-1787

**6. Substantial Equivalence:**

The syngo Colonography Software package is substantially equivalent to the following devices:

| <i>Predicate Device Name</i>                             | <i>FDA Clearance Number</i> | <i>FDA Clearance Date</i> |
|--|-----------------------------|---------------------------|
| GE CT Colonography/Navigator 2 Workstation               | K012313                     | 08/07/01                  |
| Siemens Fly Through                                      | K971717                     | 09/03/97                  |
| Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso) | K973010                     | 11/10/97                  |

In addition, many of the image processing, display and evaluation components of syngo Colonography are currently available on software options like the Volume Rendering Technique option, K923524/S2, cleared on May 17<sup>th</sup> 1994 and workstations like the syngo Multimodality Workstation, K010938 cleared on 26<sup>th</sup> June 2001 wherein the Fly Thorough software algorithms were transferred over to the syngo software platform. syngo Colonography packages these image processing and image display components in an optimized workflow palette.

Detailed Substantial Equivalence Information is provided in Attachment 7.  
The Predicate Device Literature is provided in Attachment 8.

**7. 510(k) Summary:**

The 510(k) Summary is provided in Attachment 10.  
The Reviewers Checklist is provided in Attachment 11.

**8. Indications for Use:**

The Indications for Use is provided in Attachment 2.  
Clinical and non-clinical information supporting the Indications for Use is provided in Attachment 6.

**9. Truthful and Accurate Statement:**

A signed Truthful and Accurate Statement is provided in Attachment 1.

**10. Labeling:**

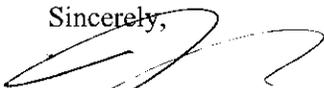
The Draft Promotional Literature is provided in Attachment 9.

**Confidentiality**

All items marked "CONFIDENTIAL" may be trade secret, confidential commercial or financial information as defined in 21 CFR §20.61. Siemens requests that FDA not make public disclosure of this information without prior consultation with Siemens as provided by 21 CFR §20.45.

If you have any additional questions, please contact me at (610) 448-1785. My fax number is (610)448-1787.  
Thank you for your attention.

Sincerely,



Mr. Jamie Yieh  
Regulatory Affairs  
Attachments

**Table of Contents**

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**ATTACHMENT 1 TRUTHFUL AND ACCURATE STATEMENT ..... 5**

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**ATTACHMENT 3 SOFTWARE CERTIFICATION STATEMENT ..... 9**

**ATTACHMENT 4 SOFTWARE DESCRIPTION ..... 11**

**ATTACHMENT 5 SOFTWARE DEVELOPMENT DESCRIPTION ..... 28**

**Inserts:**

Risk Analysis Certification to (b)(4) .....41 Pages

CT Applications (b)(4) .....51 Pages

Risk Analysis (2 Risk Management) (b)(4) .....6 Pages

(b)(4) Test Specification .....269 Pages

(b)(4) Test Results .....4 Pages

**ATTACHMENT 6 SCIENTIFIC INFORMATION SUPPORTING CT COLONOGRAPHY ..... 54**

**Inserts:**

(b)(4) .....6 Pages

(b)(4) .....4 Pages

**ATTACHMENT 7 SUBSTANTIAL EQUIVALENCE INFORMATION ..... 56**

**ATTACHMENT 8 PREDICATE DEVICE LITERATURE ..... 63**

**Inserts:**

GE CT Colonography/Navigator 2 pre-market notification clearance.....4 Pages

GE CT Colonography/Navigator 2 promotional literature.....3 Pages

Siemens *syngo* Fly Through Software Datasheet.....2 Pages

Siemens 3D Virtuosos Datasheet.....10 Pages

**ATTACHMENT 9 DRAFT PROMOTIONAL LITERATURE..... 64**

**Inserts:**

Syngo Colonography datasheet.....2 Pages

User Manual for syngo Colonography (option).....71 Pages

**ATTACHMENT 10 510(K) SUMMARY ..... 65**

**ATTACHMENT 11 REVIEWERS CHECKLIST ..... 68**

**Inserts:**

Reviewers Checklist.....4 Pages

**Attachment 1**  
**Truthful and Accurate Statement**

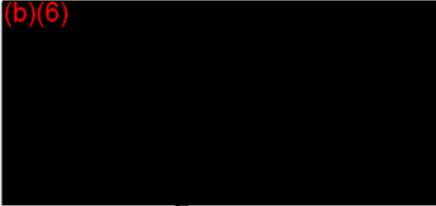
**Premarket Notification**

**Truthful and Accurate Statement**

**(As required by 21 CFR 807.87(j))**

I certify that, in my capacity as the Manager, Regulatory Submissions of Siemens AG Medical Solutions CT, Forchheim, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)



*Nov 26, 2002*  
Date

Manager Regulatory Submissions CT

**Attachment 2**  
**Indications for Use**

**Indication for use**

510(k) Number (if known): \_\_\_\_\_

**Device Name:** syngo Colonography Software Package

syngo Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-luminal view), the wall and the outside (extra-luminal view) of the colon. With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.

Due to all these capabilities the syngo Colonography software has the advantage of non-invasive evaluation of colonic lesions as compared to conventional colonoscopy.

(Please do not write below this line - continue on another page if needed)

-----  
Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

SO

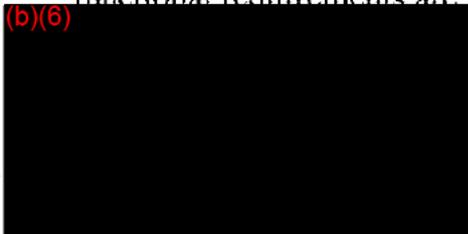
**Attachment 3**  
**Software Development Certification**

Software Certification Statement

Records processed under FOIA Request # 2015-4839; Released by CDRH on 10-21-2015

Siemens affirms that the syngo Colonography Software Package has been developed, manufactured and tested according to the same principles regarding procedures, guidelines and Quality System Regulation (QSR) followed for the existing Somatom CT software systems, and prior to commercial distribution test results will demonstrate that the software specifications and functional requirements are met.

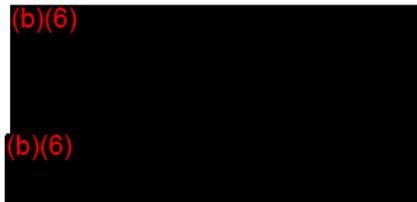
(b)(6)



*Nov. 24, 2002*

Date

(b)(6)



(b)(6)

*Nov. 26 2002*

Date

Quality Management CT

**Attachment 4**  
**Software Description**

## Software Description

### 4.1 Introduction

syngo Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-luminal view), the wall and the outside (extra-luminal view) of the colon. With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.

Due to all these capabilities the syngo Colonography software has the advantage of non-invasive evaluation of colonic lesions as compared to conventional colonoscopy.

To understand the next workflow related paragraphs some terms have to be briefly introduced that will be explained in detail later.

- **View:** In this context a view is a segment showing an image that uses a certain type of rendering to display the volume data and that offers a set of special interactions to the user.

There can be several different views at a time or several instances of the same view.

- **Global View:** This view shows the un-obscured colon.
- **Scroll View:** This view shows MPR or VRT slabs in the volume that can be moved (scrolled) very fast through the volume.
- **Endo View:** Shows a view into the lumen of the colon (virtual endoscope). Similar to that which can be seen through an endoscope but enriched with 3D rendering capabilities.

When performing an evaluation with syngo Colonography the user will normally proceed step-by-step as follows:

a. Start syngo Colonography

- The application can be started as a dynamic task card within the syngo operating system.

b. Loading and displaying images

- The required examination data is transferred from the local database to the syngo Colonography task card.
- User has the ability to zoom, pan, window parts of images and change the display mode.

c. Preparing for evaluation

- The images are initially displayed in "Survey Mode"
- The user then has to manually locate and mark lesions (eg. Colon polyps) relevant to the examination.

d. Performing evaluation

The user conducts a per lesion examination of the marked lesions encompassing but not limited to:

- Classifying the lesion
- Adding comments
- Applying length measurements to it in the scroll views

- Assign images to it for reporting
- e. Documenting the results
- Each lesion is documented and a final examination report is produced.

**4.2 syngo Colonography Task Card**

syngo Colonography is designed as a dynamic taskcard application following the *syngo* style guide. A Taskcard is similar to a browser window in the Microsoft Windows™ operating system environment and has image display and image manipulation functionalities implemented via on-screen control buttons. *syngo* is a marketing name for a set of medical technologies and services of Siemens Medical Solutions based on Windows NT™ or Windows 2000™ operating systems and is a registered trademark of Siemens AG, Germany and was described in the *syngo* Multimodality Workstation premarket application, K010938 cleared on 26<sup>th</sup> June 2001.

**Figure 1: syngo Colonography Task Card**

|                                     |                                      |  |              |
|-------------------------------------|--------------------------------------|--|--------------|
| Main Menu                           |                                      |  | Colonography |
| Image Area<br>(top-left segment)    | Image Area<br>(top-right segment)    | Patient Folder                         |              |
|                                     |                                      | 2 Rows of Buttons                      |              |
|                                     |                                      | Orientation<br>Image<br>Sub-Task Cards |              |
| Image Area<br>(bottom-left segment) | Image Area<br>(bottom-right segment) | Evaluation<br>Card                     |              |
|                                     |                                      | 2 Rows of Buttons                      |              |
| Status Bars                         |                                      |  |              |

The syngo Colonography task card is subdivided into the four following main areas as shown in Figure 1 on the preceding page:

- (1) Main menu
- (2) Image area
- (3) Control area - Functions for displaying and evaluating the loaded images
- (4) Status bar - System messages are displayed

**4.2.1 Image Area Layout**

The image area consists of four image segments in which, the original images that have been loaded, selected partial volumes and evaluation images are displayed.

If there is only one data set loaded all segments of the image area are assigned to this data set (single-data-set mode).

If there are two data sets loaded:

- Either the four segments are all assigned to the first of the data sets (single-data-set mode) and the user can arbitrarily switch between the two data sets OR

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- The four segments are all assigned to the second data set (single-data-set mode) and the user can arbitrarily switch between the two data sets OR,
- Two segments are assigned to the first data set and the other two are assigned to the second data set (side-by-side mode) and

The user can arbitrarily switch between single-data-set and side-by-side mode.

In any of the modes the user can blow up any of the segments to a 1 on 1 layout and deflate it back to a 4 on 1 layout.

The same layouts are used for CT and MR data sets.

#### 4.2.1.1 Layout in Single Data Set Mode

The basic image types are:

- Global View
- Axial scroll view
- Sagittal scroll view
- Coronal scroll view
- Endoscopic view
- Oblique MPR

In single-data-set mode the layout comprises two scroll view segments, one endo view segment, and one global view segment.

**Figure 2: Layout for Single Data Set Mode**

|                                |                                   |
|--------------------------------|-----------------------------------|
| Sagittal<br>MPR<br>Scroll View | Transversal<br>MPR<br>Scroll View |
| Global View                    | Endo View                         |

If an image is blown-up when the user switches to the other data set the corresponding image of the other set is displayed blown-up too. But if the user switches to side-by-side mode a 4 on 1 layout is used.

Zoom and pan parameters stick with the image (resp. image stack), they are not applied to the corresponding image of the other data set. But if the user switches to side-by-side mode the zoom and pan parameters remain with the particular scroll and endo view images.

#### 4.2.1.2 Layout for Side-by-Side-Mode

In side-by-side mode there is a scroll and an endo view for each data set.

**Figure 3: Layout for SideBy Side Mode**

|                                  |                                  |
|----------------------------------|----------------------------------|
| MPR<br>Scroll View<br>data set 1 | MPR<br>Scroll View<br>data set 2 |
| Endo View<br>data set 1          | Endo View<br>data set 2          |

When the user switches to side-by-side mode the top-right (scroll view), and the bottom-right (endo view) images of both data sets will be displayed side by side.

While switching between side-by-side and single-data-set modes the input focus remains with the segment where it was before switching.

If the user switches from a blown-up image in side-by-side mode to single-data-set mode the image remains blown-up.

If the user switches from side-by-side mode to single-data-set mode the zoom and pan parameters remain with the particular images.

### 4.2.2 **Control Area**

The next paragraphs describe the control area top-down.

All buttons are dimmed until valid data are loaded into the application. From then onwards special dimming rules are applied to each of them.

#### 4.2.2.1 Patient folder

The standard patient folder icon with the patient's name in its tooltip is displayed.

#### 4.2.2.2 Button Row 1

With the buttons in this row the user selects what data set(s) to display.

The buttons are arranged from left to right as follows:

- Data Set 1: All segments are assigned to the first data set loaded (single-data-set mode).
- Data Set 2: All segments are assigned to the second data set loaded (single-data-set mode).
- Side by Side: Images from both data sets are displayed side by side (side-by-side mode).

The buttons behave as radio buttons (i.e. exactly one is pressed at a time).

If only a single data set is loaded all buttons are dimmed. They become undimmed as soon as a second data set is successfully loaded. After loading of the second data set the button Data Set 2 is pressed and the images for data set 2 are displayed in single-data-set mode.

#### 4.2.2.3 Button Row 2

On setting a lesion marker the system provides a default unique name for this marker. The buttons in this row are for actions, which the user will perform very often with respect to these lesion markers.

The buttons are arranged from left to right as follows:

- **Set Lesion Marker:** After clicking this button the mouse pointer changes its shape and the user can place a new lesion marker. After placing the marker the button is automatically released.

On setting a lesion marker syngo Colonography assigns it a number as its default name. Numbering starts with 1 and is incremented for each marker set. Numbering is independent from the data set.

This lesion marker becomes the selected one.

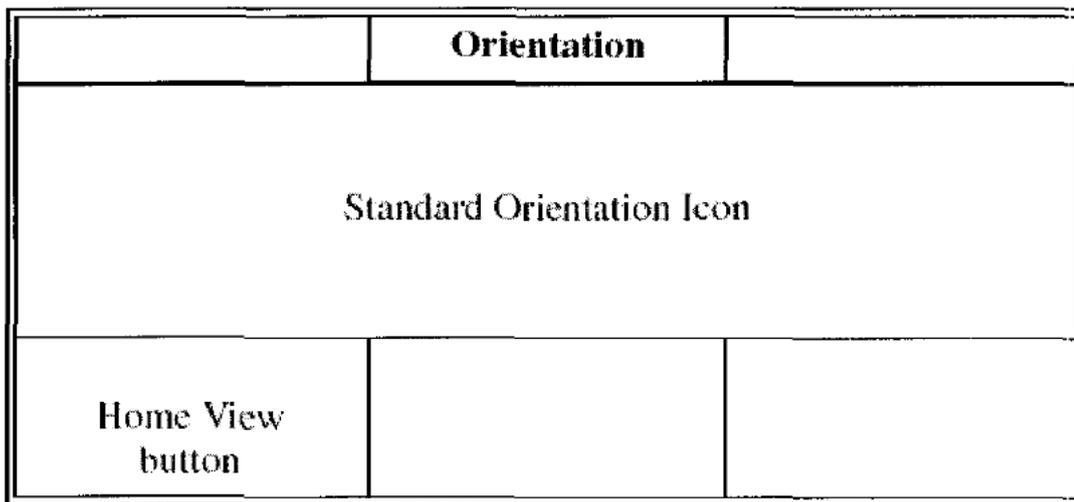
- **Set Virtual Endoscope:** After clicking this button the mouse pointer changes its shape (same shape as for Set Lesion Marker) and the user can move the virtual endoscope to a new location.

After placing the marker the button is automatically released.

A button stays in pressed state until the corresponding action was performed or it is clicked again or another button that is connected with Left Mouse Button-click (e.g. one of this row) or Left Mouse Button-move (e.g. Zoom/Pan) is clicked.

#### 4.2.2.4 Orientation Sub-task Card

**Figure 4: Orientation Sub-task Card**



This is the standard syngo orientation icon with its six buttons to change the view directions of a scroll view.

There is a Home View button (push button behavior) to let all views return to appropriate initial states

4.2.2.5 Image Sub-task Card

**Figure 5: Image Sub-task Card**

|                         |                 |                 |
|-------------------------|-----------------|-----------------|
|                         |                 | <b>Image</b>    |
| Zoom/Pan button         | Home Z/P button |                 |
| Rotate button           |                 |                 |
| Single Windowing button | Window 1 button | Window 2 button |

On this sub-task card there are standard buttons as on the syngo 3D task card described in syngo multimodality workstation 510(K), K010938 cleared on 26<sup>th</sup> June 2001. Whether an action can be applied to a view depends on the capabilities of the particular view.

4.2.2.6 Evaluation Sub-task Card

The system provides the user the ability to delete a selected marker.  
 The system also preserves the order in which lesion markers were set  
 In evaluation mode the system provides the user the ability to draw at least 5 distance lines on all oblique Multi Planar Reconstructions together assigned as attributes to the selected lesion marker.

**Figure 6: Evaluation Sub-task Card**

|                                  |                             |
|----------------------------------|-----------------------------|
| <b>Evaluation</b>                |                             |
| Drop list containing all markers | Distance button             |
|                                  | Evaluation Dialog button    |
|                                  | Delete Lesion Marker button |

- **Drop list:** The drop list lists all lesion markers found for the data set(s) under evaluation. They are listed with their names in the order they have been set independently from the data set where they belong. If the user clicks on a name in the list this marker becomes selected and the endo view becomes re-displayed as when the marker was set (i.e. marker is visible in the endo view), the scroll views are synchronized to the marker location. The scroll views return to the view direction, zoom, and pan as when the marker was set. The current layout remains (single-data-set or side-by-side). If the user selects a marker in a scroll or endo view or in the Evaluation dialog the selection in the drop list changes accordingly.
- **Distance button:** Enables drawing of Distance lines, which are assigned to the selected marker, in the scroll views and switches the layout to single-data-set mode for the data set with this marker. The button has check-box like behavior. Additionally it becomes released if the user clicks another button that is connected with LMB-click (e.g. Set Lesion Marker) or LMB-move (Zoom/Pan), or if the user changes the layout, or switches to the other data set.

The number of distance lines per marker is restricted to 10. If this maximum number is reached the button becomes dimmed until the user deletes a distance line or its entry in the Evaluation dialog. Drawing and manipulation (changing length, moving, deleting) of the distance lines is the same as on the Viewing task card but the lines have no context menu and there are no applicable entries in the Edit menu. The distance lines are transient, which means they disappear if the user changes the view direction of the scroll view (either on the Orientation sub-task card or by rotating the reference lines). This means the user can draw a distance line, scroll away from this image, scroll back to it, and the distance line is re-displayed.

But, if he changes the view direction, the distance line is lost. The reason for this behavior is that it is very hard to return to a distance line in an oblique scroll view if its tilt angle has changed. Therefore and consequently distance lines are deleted if the view direction changes in any way. Images together with their distance lines can be made persistent in the Local database and can be sent to the virtual film sheet and to the report.

- **Evaluation Dialog button:** Opens the Evaluation dialog for the selected marker (see 5.1.2.5) and switches the layout to single-data-set mode for the data set with this marker. The button is dimmed if there is no lesion marker. The button has push button behavior. If it is clicked while the Evaluation dialog is already open nothing happens.
- **Delete Lesion Marker button:** Deletes the currently selected marker together with all the information assigned to it. The button has push button behavior. The button is dimmed if there is no lesion marker. If the user has already added information to the marker he has to confirm the request for deletion (it should be easy to delete a marker just set, but confirmation is requested if the user has already added information to the marker).

Deleting a marker does not change the numbers or names of the other markers.

#### 4.2.2.7 Button row 3

- **Save:** Saves the image with the input focus to the Local database into the series defined by the application.
- **Copy to Film Sheet:** Sends the image with the input focus to the virtual film sheet.
- **Copy to Report:** Sends the image with the input focus to the report information for the selected marker and saves it in the Local database (with no special flags). The number of images per lesion is restricted to 4. If this maximum number is reached the button

becomes dimmed for this marker. Its stays dimmed until the user excludes an image from being reported, or the user selects another marker.

#### 4.2.2.8 Button row 4

The buttons in this row are the standard buttons:

**Save As:** Saves the image with the input focus to the Local database into the series defined by the user.

**Report Wizard:** This push button starts the Report Wizard dialog. It is dimmed if there are no lesion markers. If it is clicked while the Report Wizard dialog is already open nothing happens.

### 4.2.3 **Main Menu**

Colonography extends the main menu. This chapter describes these extensions.

#### 4.2.3.1 Patient

The entries

- Open Series List
- Close Patient
- Save
- Save As
- Copy to Film Sheet

are added to the Patient menu.

#### 4.2.3.2 Edit

The application adds an Edit menu to the main menu. The entries are:

- Hide Reference Lines: Reference lines are globally hidden/displayed.
- Hide Flight Path: Flight path is globally hidden/displayed
- Hide Graphics: Markers, virtual endoscope icons (location, view direction, field of view) and flight paths are globally hidden/displayed.

#### 4.2.3.3 View

The application adds a View menu to the main menu. The entries are:

- No Text: Hide text in all images.
- All Text: Show text in all images.
- --- Separator ---
- Blow Up Segment: same as double-click (expand image to 1 on 1 layout).

#### 4.2.3.4 Orientation

The application adds an Orientation menu to the main menu. The entries are:

- Front to Back
- Back to Front
- Left to Right
- Right to Left
- Head to Feet
- Feet to Head
- --- Separator ---
- Home View
- --- Separator ---

- Rotate Images

#### 4.2.3.5 Image

The application adds an Image menu to the main menu. The entries are:

- Single Windowing
- Window 1
- Window 2
- --- Separator ---
- Zoom/Pan
- Home Zoom/Pan

#### 4.2.4 **Evaluation dialog**

The user collects and enters the information for a particular lesion in the Evaluation dialog.

The dialog appears as a floating window over the control area and has a narrow shape so that it does not obstruct image segments.

The dialog is application dependant.

The system provides the user the ability to assign attributes to the selected lesion marker.

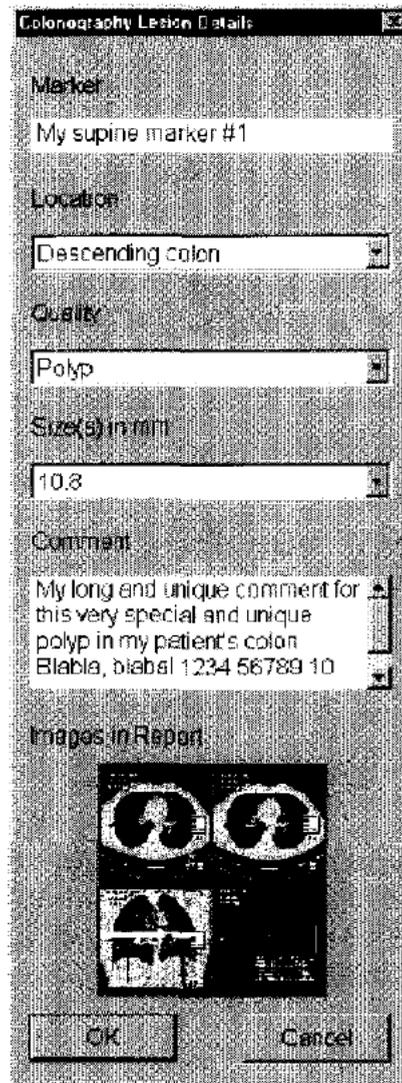
The system also provides the user the ability to edit attributes of the selected marker.

He can:

- Assign a short name (up to 10 characters) to a lesion. The default name proposed by the application is its number in the order of markers set. Names (or numbers) remain with a lesion marker, they are not shifted if a marker has been deleted.
- Select the Quality of finding from a drop-list (Polyp, Indeterminate).
- Select the Location of the finding from a drop-list (Rectum, Sigmoid, Ascending colon, Descending colon, Transverse colon, Splenic flexure, Hepatic flexure, Caecum).
- Edit or delete (lesion) size strings. Initially the strings are the length values retrieved from the distance lines drawn for this lesion. The user can edit these strings (e.g. add a prefix like 'max.' or 'diameter') or delete one by clearing it. If the user changes a distance line in an image (e.g. adjusted one of its end points) after he has modified its text, the modified text is replaced by the new length value. The length of a size string is restricted to 20 characters.
- Enter a comment for this lesion.
- Exclude images from being reported. With the Copy to Report button on the application's task card the user has added images to the report for the selected lesion.

These images are displayed as image icons on the dialog (in the order they have been added: top-left, top-right, bottom-left, bottom-right). The user can select an icon (LMB-click on it) and exclude it from being reported with the Delete-key on the keyboard. Then the icon becomes cleared. This does not delete the corresponding image in the Local database.

**Figure 7: Evaluation Dialog (Schematic)**



- OK button: Closes the dialog and makes changes valid for the report.
- Cancel button: Discards changes and closes the dialog.

There is no Help button on this dialog (no space) but F1 key displays online-help for this dialog.

#### **4.2.5 Report Wizard dialog**

In the Report Wizard dialog the user can review the elements comprising the report and he can add some report-global information.

On the Report Wizard dialog there are two tab cards:

- • Lesion information: Lists all lesions reported for this examination.
- • General: The user can enter an introduction comment (e.g. disease history) and a comment for other abnormalities found during the examination.

On the dialog the user can:

- Select the template for the report from a drop-list.
- Enter the referring physician's name (max. 64 characters)
- Enter the reading physician's name (max. 64 characters). As default the name most-recently entered is offered.

**Figure 8: Report Wizard Dialog**

Colonoscopy Report Wizard

Report Template: Long Report

Patient With A Long Name: Johannes      31-Dec-1950      aPatient With A Long Name

Abdomen Routine: Supine      01-Jan-2002      Colon Supine: 1      CT

Abdomen Routine: Prone      01-Jan-2002      Colon Prone: 12      CT

Referring Physician: Dr. Nowhere      Reading Physician: Dr. Anywhere

| Lesion Information |                  | General       |               |
|--------------------|------------------|---------------|---------------|
| Marker             | Location         | Size in mm    | Quality       |
| supine1            | Ascending Colon  | 10.3/7.4      | Polyp         |
| supine2            | Descending Colon | 8.5           | Indeterminate |
| prone 3            | Sigmoid          | 10.3/7.4/15.8 | Polyp         |

Details

Conclusion: Send to colonoscopy for polyp removal

OK      Report      Cancel      Help

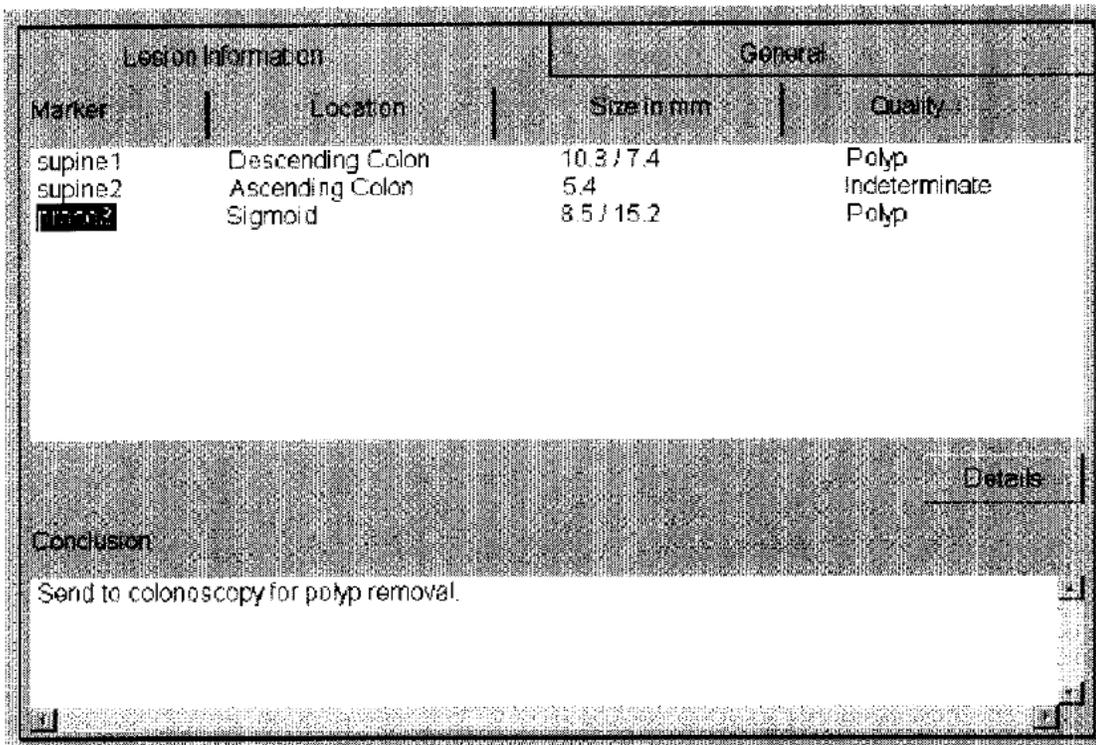
The buttons are:

- OK: Close the dialog and accept the changes.
- Report: Starts the reporting tool.
- Cancel: Close the dialog and discard changes.
- Help: on-line help for the dialog.

#### 4.2.5.1 Lesion Information Tab Card

This dialog gives an overview of the per lesion information that is going into the report.

**Figure 9: Lesion Information Tab Card (schematic)**



The tab card is split into a list-box displaying information for each marked lesion and a comment field for the conclusion of the examination.

In the list-box the information per line is

- marker name,
- lesion location,
- lesion size concatenated to a single string,
- and quality.

The content is the one entered in the evaluation dialog. The list-box becomes scrollable if there are more entries than lines available. The user can adjust column width. The user can select a marker name and click on the Details button in order to get the evaluation dialog for this finding displayed.

#### 4.2.5.2 General tab card

It is possible to store patient history information such as family disease history.

This dialog offers two text fields:

- Introduction: Here the user can enter global information like patient's disease history or family disease history.
- Other Abnormalities: Here he can report extra-colonic findings.

#### 4.2.6 Report Template Administration Dialog

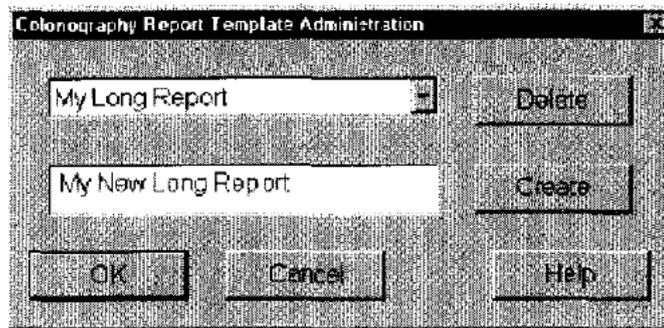
The system provides the user the ability to include the patient name and identification, date of birth, physician, scan date and time, technique factors, and comments in the paper report.

The system also provides the user the ability to configure the paper report site and/or user specific adding the resp. information.

In this dialog the user can create, modify, and delete report templates. Creation and modification of templates is done with a template editor which is automatically started.

The dialog is application-modal.

**Figure 10: Report Template Administration Dialog (schematic)**



- Delete: With this button the user can delete the template selected in the drop-list.
- Create / Modify: The user can enter a name for a new template or for a template to be modified.

If the entered name matches the name of an existing template the caption of the button reads 'Modify' otherwise it reads 'Create'. In both cases clicking on the button starts the template editor either with an empty template or with the one to be modified.

- OK: Close the dialog and accept changes.
- Cancel: Close dialog without applying any changes.
- Help: on-line help for the dialog.

#### **4.3 Image text**

The system displays the image text in all image windows according to the rules for the image type and the embedding software platform .

The system also displays an orientation cube for 3D images and oblique Multi Planar Reconstructions looking the same as on 3D task card.

The system uses the three letter convention for orientation markers according to DICOM.

The image text is the same as for the 3D task card.

#### **4.4 Marker icons**

Lesion markers are small arrows with a text label. The selected marker has a different color than the others.

While moving through scroll or endo views markers are displayed simplified.

#### **4.5 Native language support**

The system shall use native language support based on syngo .

Colonography uses the syngo concept for native language support. Therefore no special programming is required.

Date and time information is formatted according to the rules set for the system.

#### **4.6 Online-Help**

The system provides online help according to the syngo rules .

Colonography offers Help buttons and F1-help.

Unique entry points for on-line help are provided for:

- the task card (F1)
- dialogs with a Help button

#### **4.7 Message boxes**

Message boxes behave application-modal, which means the user cannot interact with the application until he confirmed the message box. But he can switch to other task cards, come back to the application, and still sees the message box.

#### **4.8 Dialogs**

Usually dialogs are modeless unless another behavior is explicitly specified.

#### **4.9 Status Bar messages**

Colonography shows certain information in the middle slot of the status bar. Status bar messages for a current activity (e.g. 'Printing') are displayed for the whole time of the activity. If the user switches to another task card and returns to Colonography later the status bar shows the correct message for the actual state of the activity (e.g. either still 'Printing' or 'Printed').

#### **4.10 Hardware interfaces**

There is no direct hardware interface. But Colonography needs a fast OpenGL graphics card with at least 64 MB of memory.

#### **4.11 Software interfaces**

##### **4.11.1 3D Framework**

Colonography extends the 3D framework.

##### **4.11.2 IVT**

The Interactive Visualization Toolkit (IVT) encapsulates the visualization for syngo Colonography. It allows high-performance calculation and display of special graphics with interactive user access like e.g. reference lines, real-time Muliplanar Reconstruction (MPRs). The algorithmic part provides excellent image quality for both 2D imaging and 3D volume rendering techniques.

##### **4.11.3 Local Database**

The interface to the Local Database is completely encapsulated by the embedding 3D framework.

##### **4.11.4 Filming**

Colonography embeds the 'Copy to Film Sheet' button into its task card. Interaction with the Filming application is completely encapsulated by the embedding 3D framework.

##### **4.11.5 3D Series List**

The application extends the 3D Series List in order to get user selections of images pre-validated and sorted as a volume data set.

#### **4.11.6 MedDynamics**

The application uses MedDynamics to get its buttons and menu entries embedded into the User Interfaces of other components (Patient Browser and Main Menu) and become started and ended as a dynamic task card.

The application claims its state as 'have unsaved data' if:

- If there are is at least one marker set and no report has been created yet (Report has not been clicked on the Report Wizard dialog).
- After report creation data have been changed. Changed means:
  - A new marker has been set.
  - A marker has been deleted.
  - A new distance line has been drawn.
  - An existing distance line has been modified.
  - An existing distance line has been deleted.
  - An image has been sent to the report.
  - At least one item on the evaluation dialog has been changed and the dialog has been closed with OK (this includes removal of an image from the report).
  - At least one item on the Report Wizard dialog has been changed and the dialog has been closed with OK (this includes selection of another template).

#### **4.11.7 Component Manager**

Colonography is technically started and ended by the syngo Component Manager. If the Component Manager sends a shutdown request the response of the application depends on whether there are unsaved data (which means unreported data) or not.

#### **4.11.8 Patient Browser**

Via MedDynamics Colonography's button and menu entries are put into the Patient Browser User Interface.

#### **4.11.9 Archiving and Networking**

Colonography has no direct interface to Archiving and Networking. Result images are saved to the Local database and from there the user can export or send them.

Colonography has to fill the header information of result images properly so that these results can be exported and imported again to/from off-line media or can be sent and received to/from other syngo-based network nodes.

#### **4.11.10 Configuration**

The application uses the syngo Configuration Library in order to read and write configuration information.

There is no independent configuration dialog (as a .exe of its own) and therefore also no applet for Colonography.

#### **4.11.11 Reporting Engine**

The application uses the 3rd party tool 'List & Labels' as reporting engine. The reporting engine compiles reports from the information collected through the examination (content) and a template (layout) and sends them to paper printers or to the file system in the selected format.

The template editor is part of the reporting engine.

The reporting engine is a DLL running in the process context of Colonography.

#### **4.11.12 Win32**

Win32 APIs are used to manage bitmaps for reporting purposes as temporary files in the file system.

#### **4.12 Communication interfaces**

Not Available

#### **4.13 Hook for MR data**

The system is able to automatically adapt to the homogeneity of MR images after loading. Colonography provides a hook in its BE that can be used for image preprocessing. The preprocessing unit is encapsulated in a DLL of its own.

For a detailed outline of the software functionality please refer to attachment 8, Draft User Manual.

**Attachment 5**  
**Software Development Description**

**Overview**

A general description of the software development process for Siemens Somaris 5 software is included in this section of the 510(k). Following this discussion is the software development process specifics (e.g. risk analysis, software structure chart, etc.).

There are several phases in the software development process: requirements, concept, design, implementation, integration, validation and maintenance. The existence of these phases allows reviews to be conducted at distinct points during the software development process. This assures that the output of each phase is complete, correct and consistent with the output of the corresponding phase. Depending on the size of the defined function clusters or its complexity, development processes may be processed concurrently. Reviews are performed throughout the development process and may be conducted on isolated portions of the overall development and not necessarily on the project as a whole. To perform a complete system test for the Syngo Colonography software package, all software modules shall be signed off from integration test by the responsible software development group.

The documentation resulting from each stage will be placed in the Engineering History Record and the responsibility for submitting the required documents will fall upon the software development groups responsible for creating them.

Siemens affirms that the described software development process has been and will be followed prior to commercial distribution and that the system specifications and functional requirements are met. This software development process will be followed for all changes made to the software. Modified software is retested and revalidated in accordance with quality management process prior to commercial distribution.

### **5.1 Level of Concern**

Siemens considers the syngo Colonography software package to be of a minor level of safety concern, since:

- failures or latent design flaws would not result in death or serious injury to the patient; and
- images are interpreted by trained medical personnel, competent to ascertain whether the images provide information that can be useful in the determination of a diagnosis.

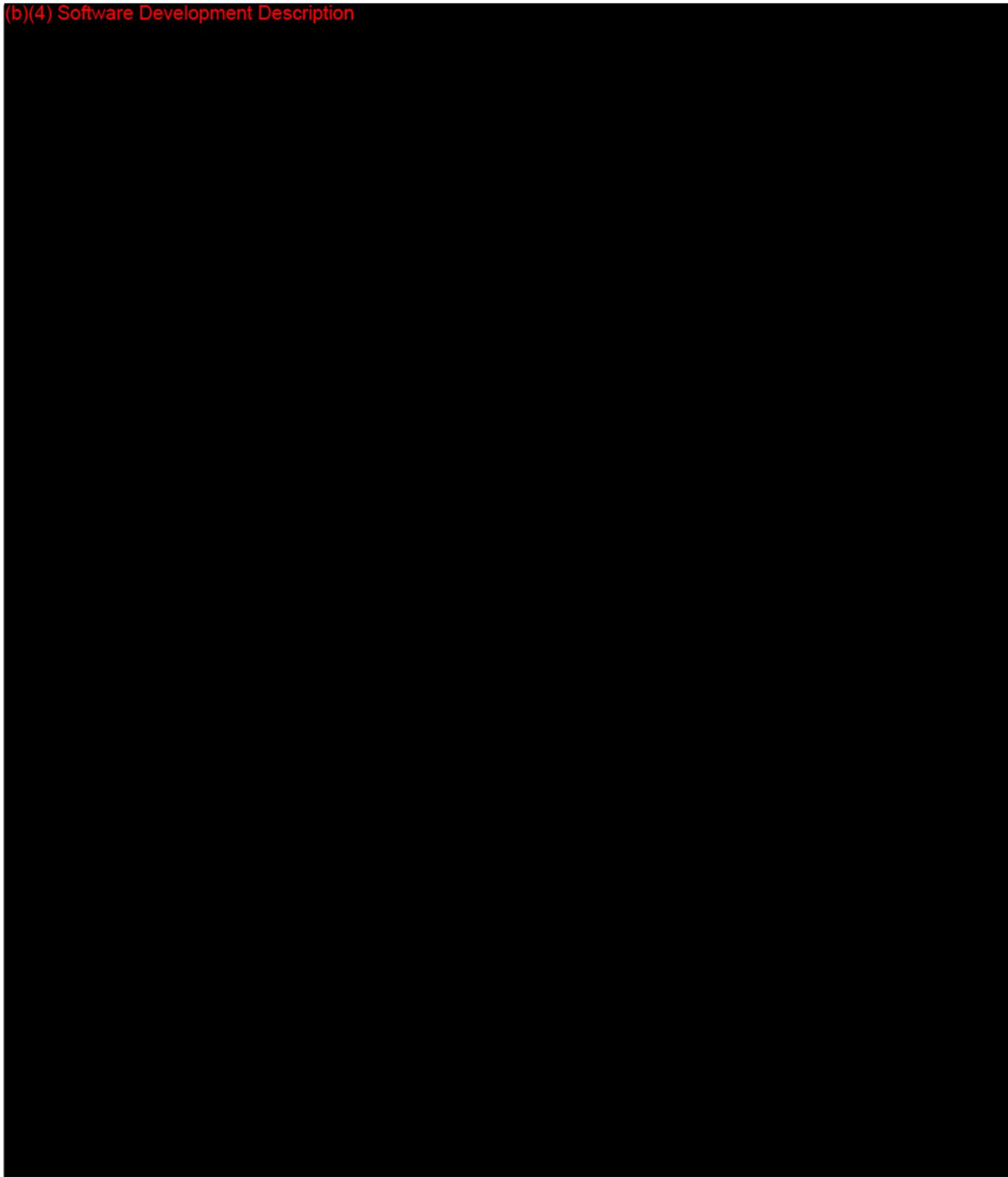
To avoid or minimize the additional risks documented by the risk analysis corresponding requirements were considered by the concept, the design, and the implementation of the software.

This goal is improved by a detailed traceability of requirements, with the major focus on the safety relevant requirements.

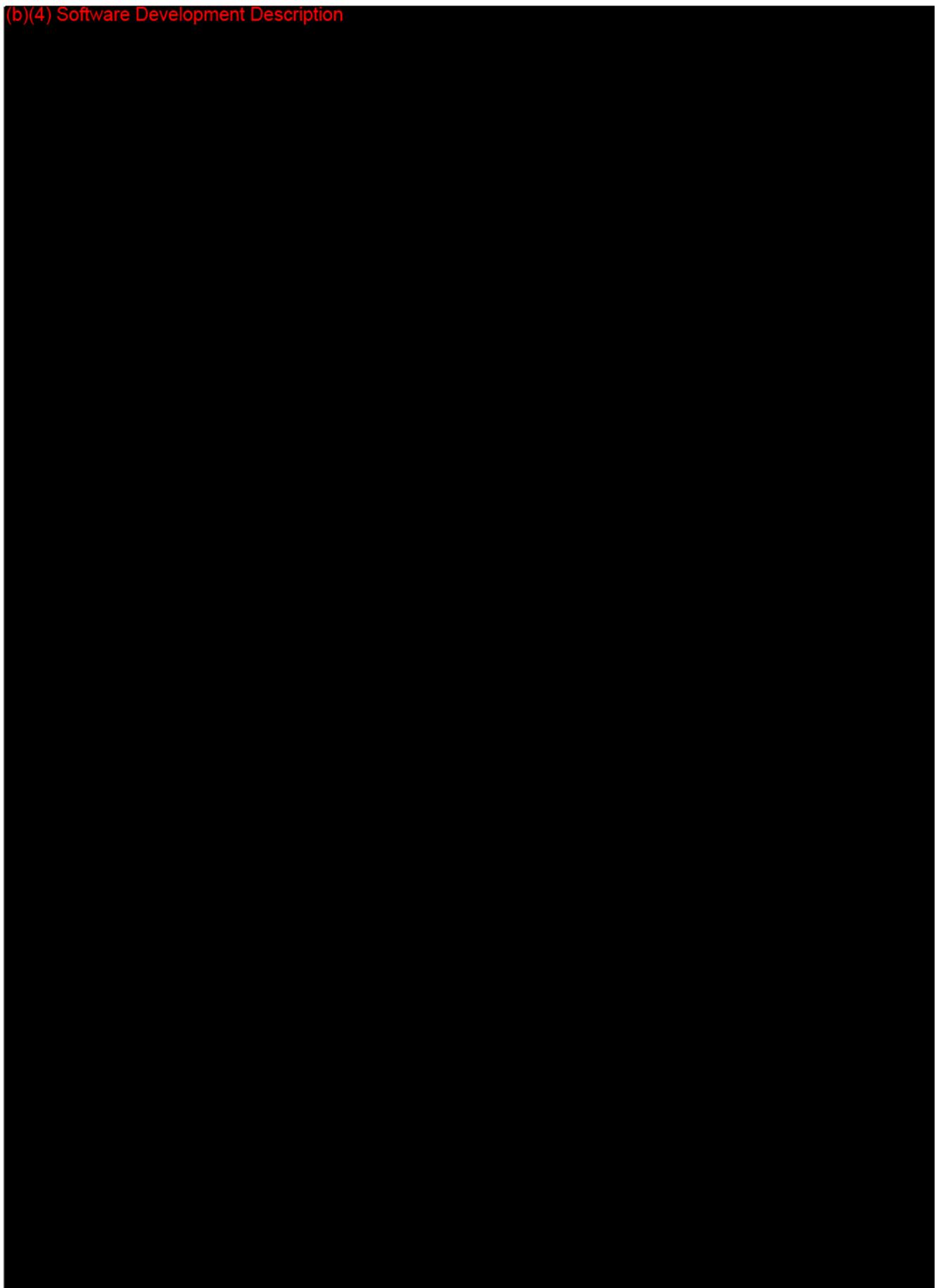
## 5.2 System and Software Requirements:

### 5.2.1 System Requirements

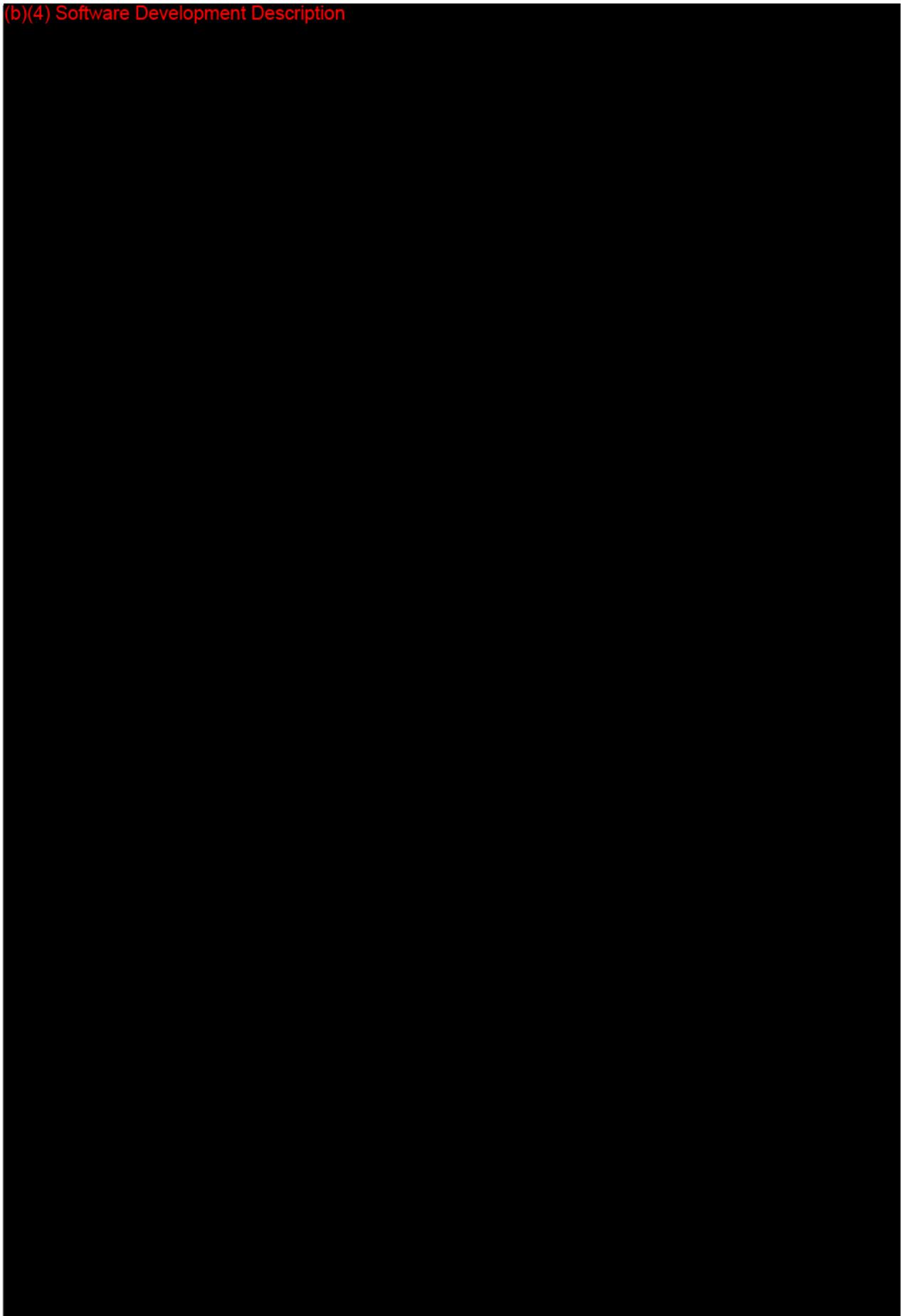
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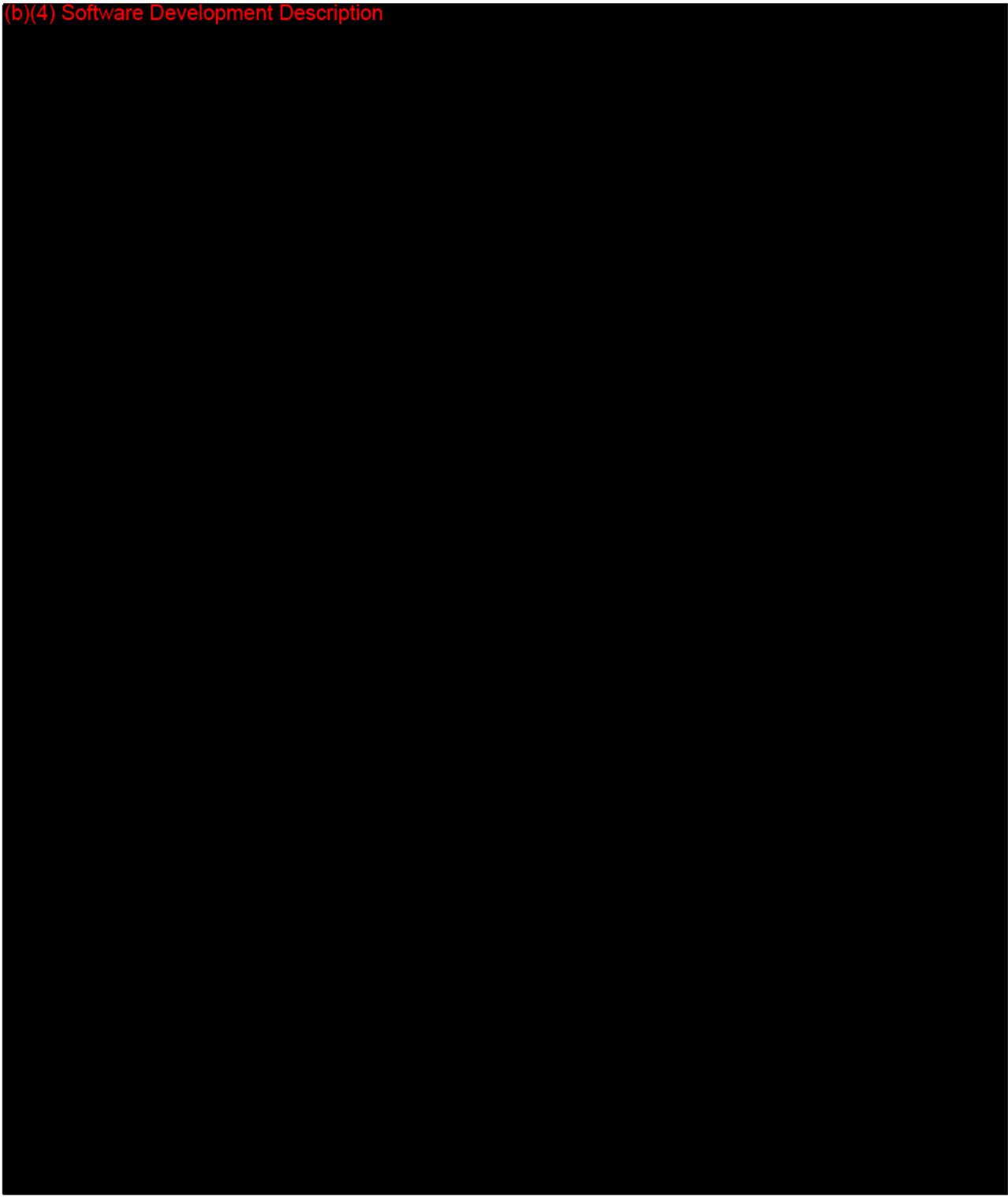
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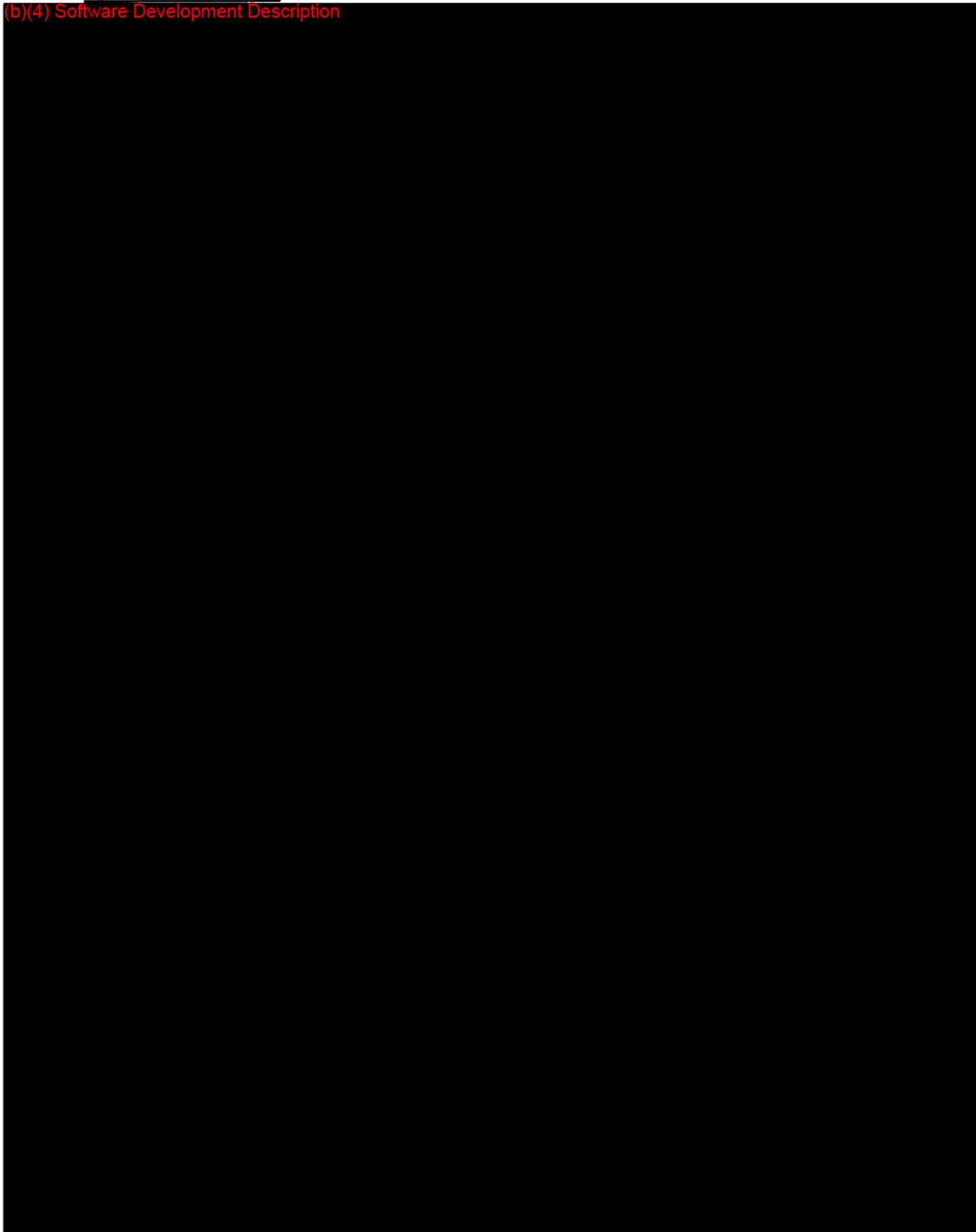


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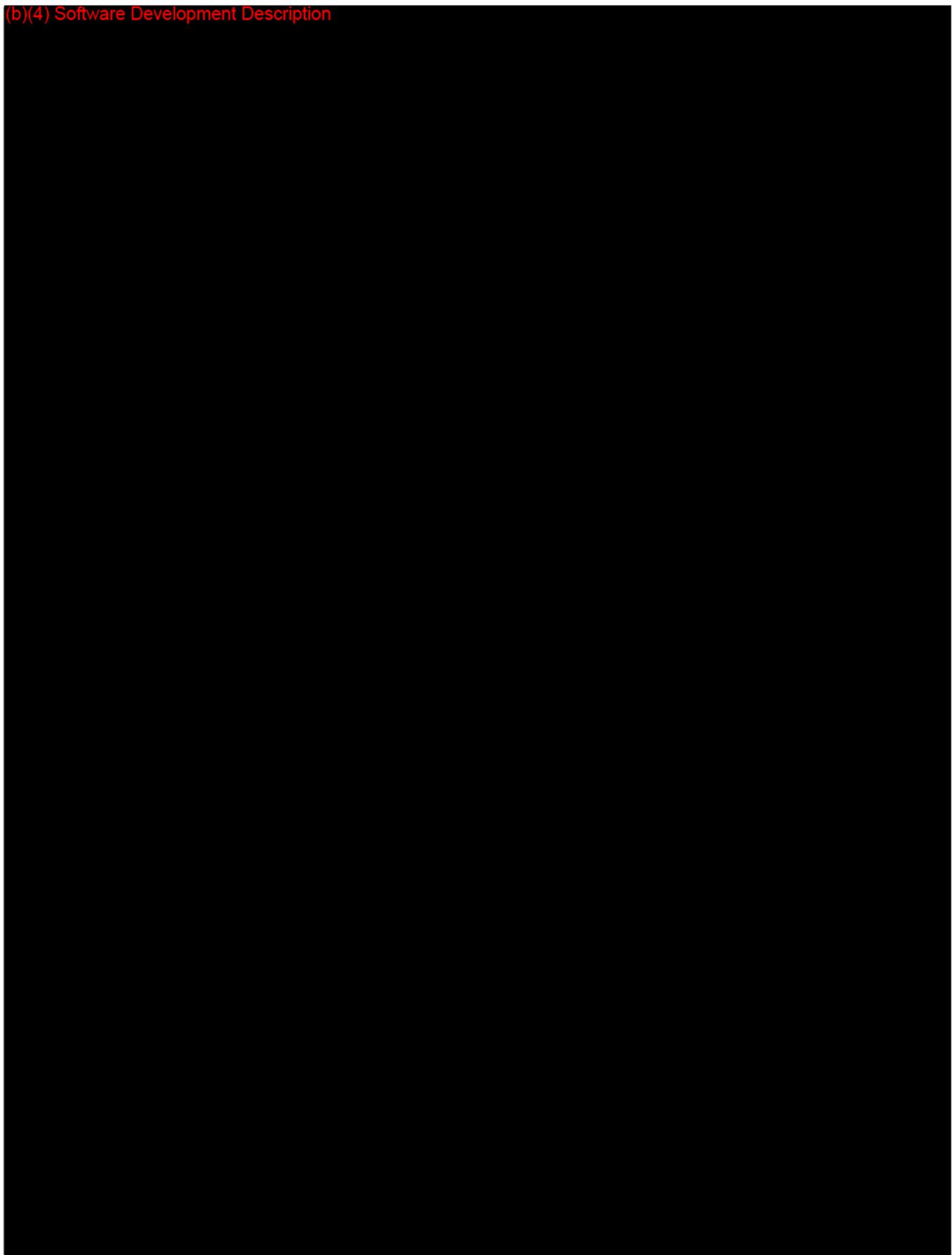


### **5.3 System Architecture**

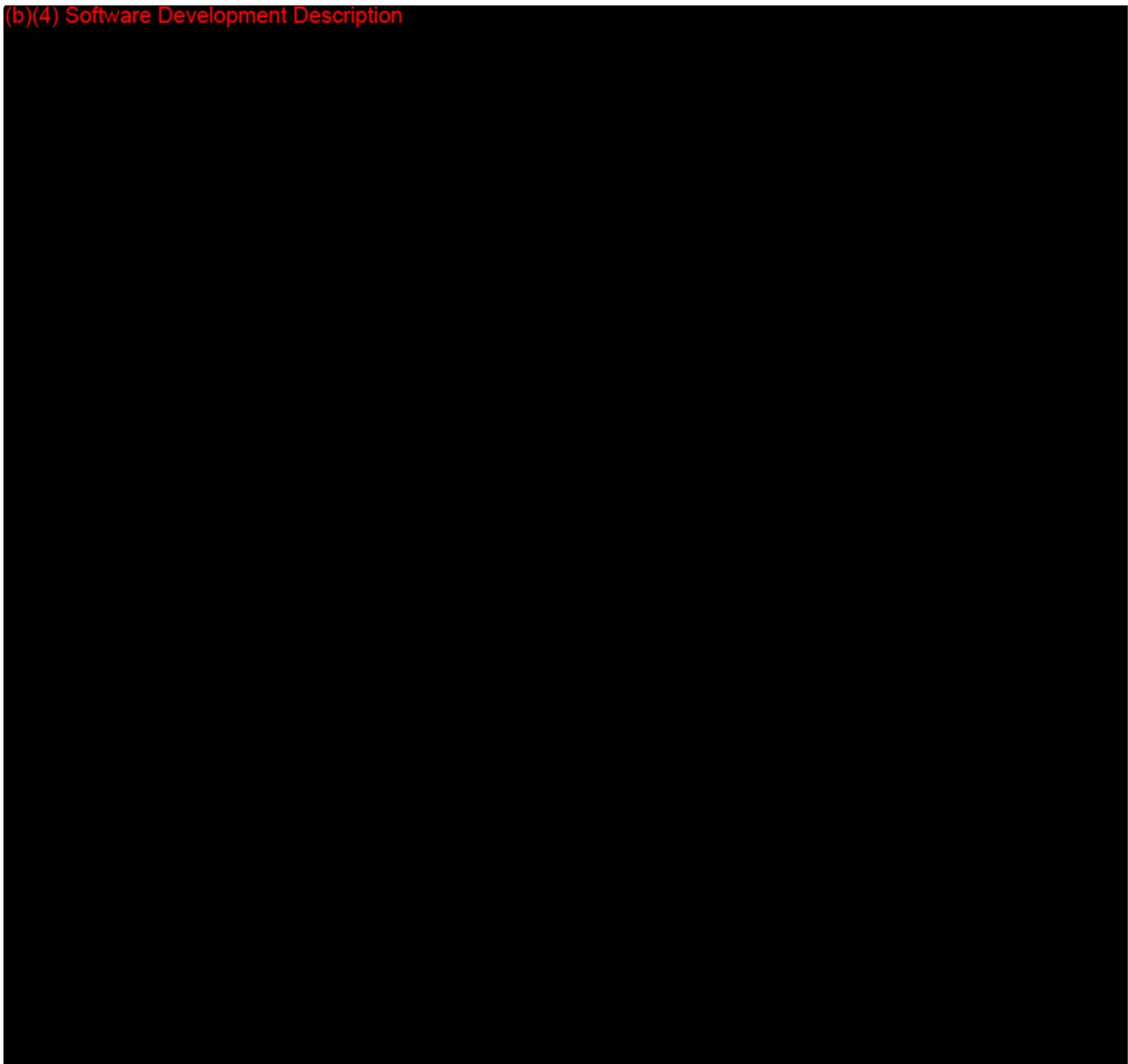
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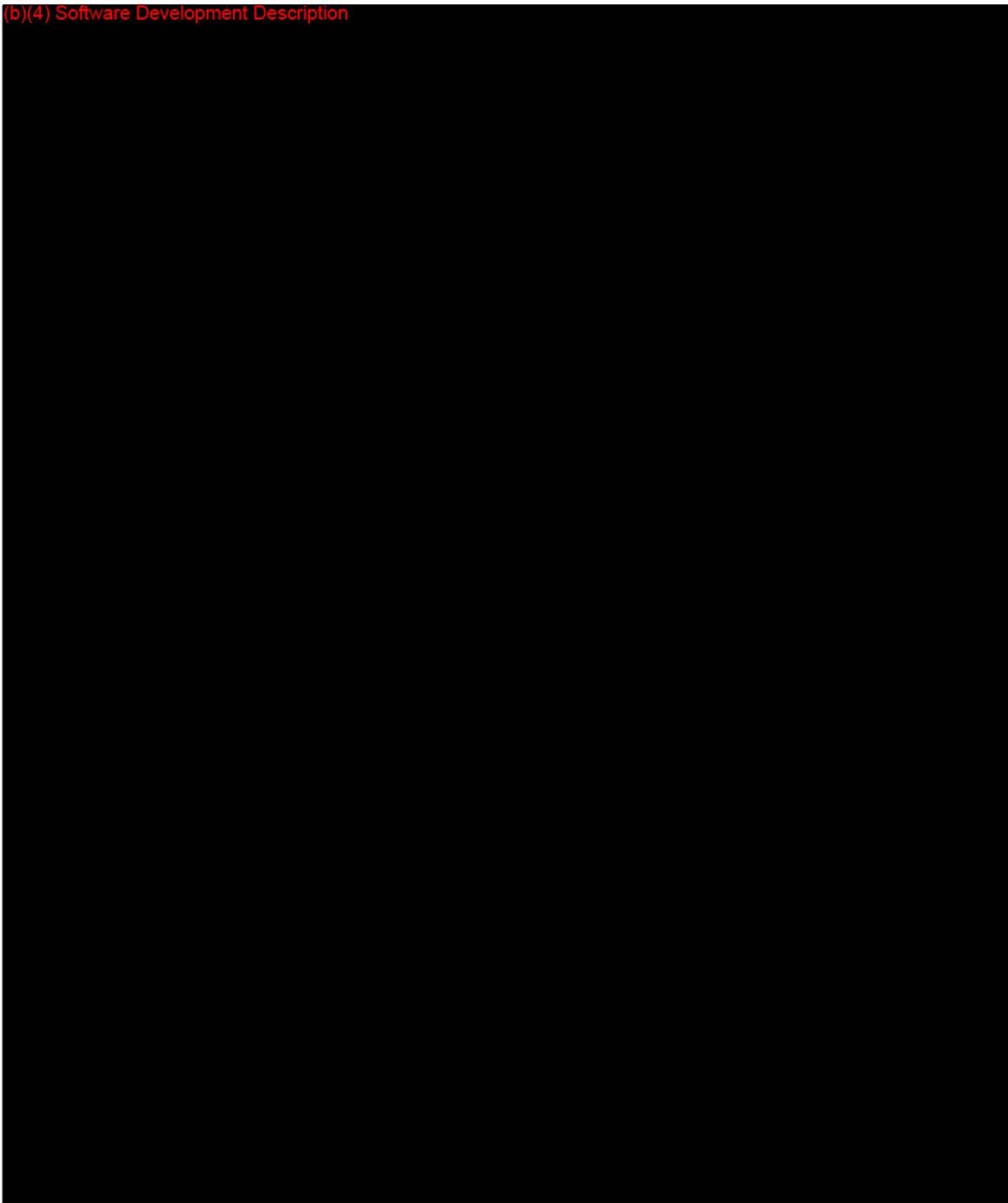
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### 5.6.1 Structure

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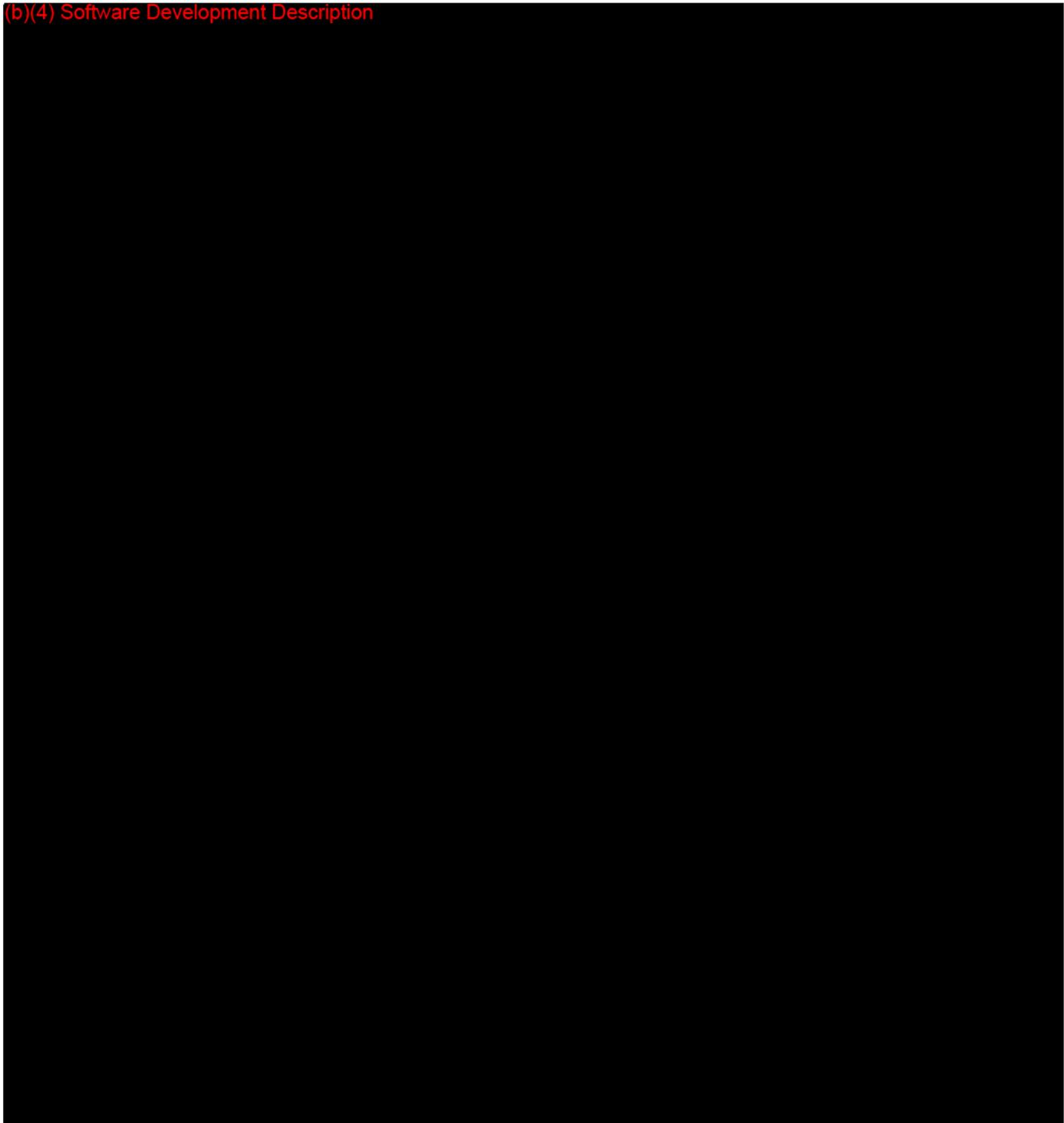


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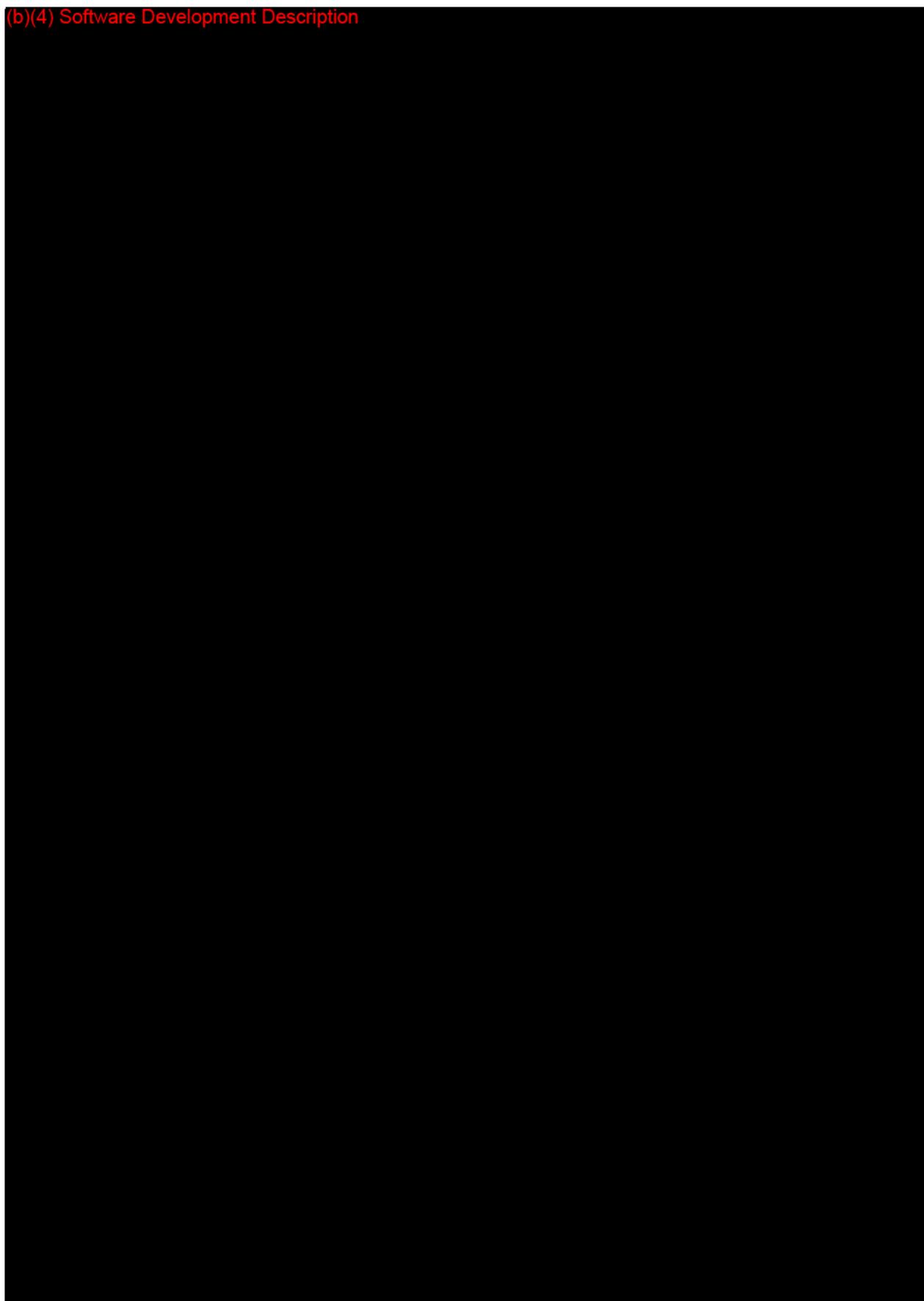


**5.7 Software Development Process**

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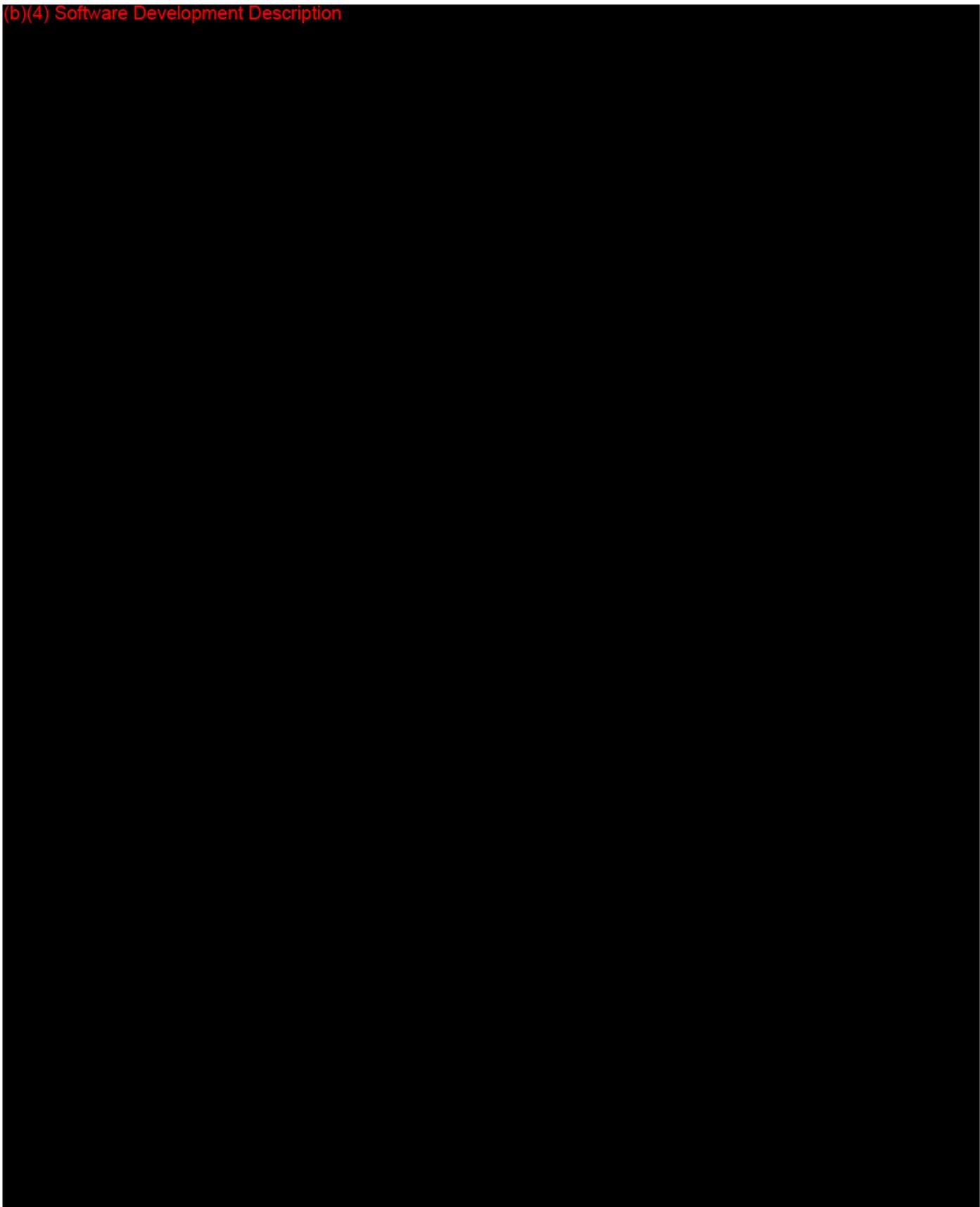
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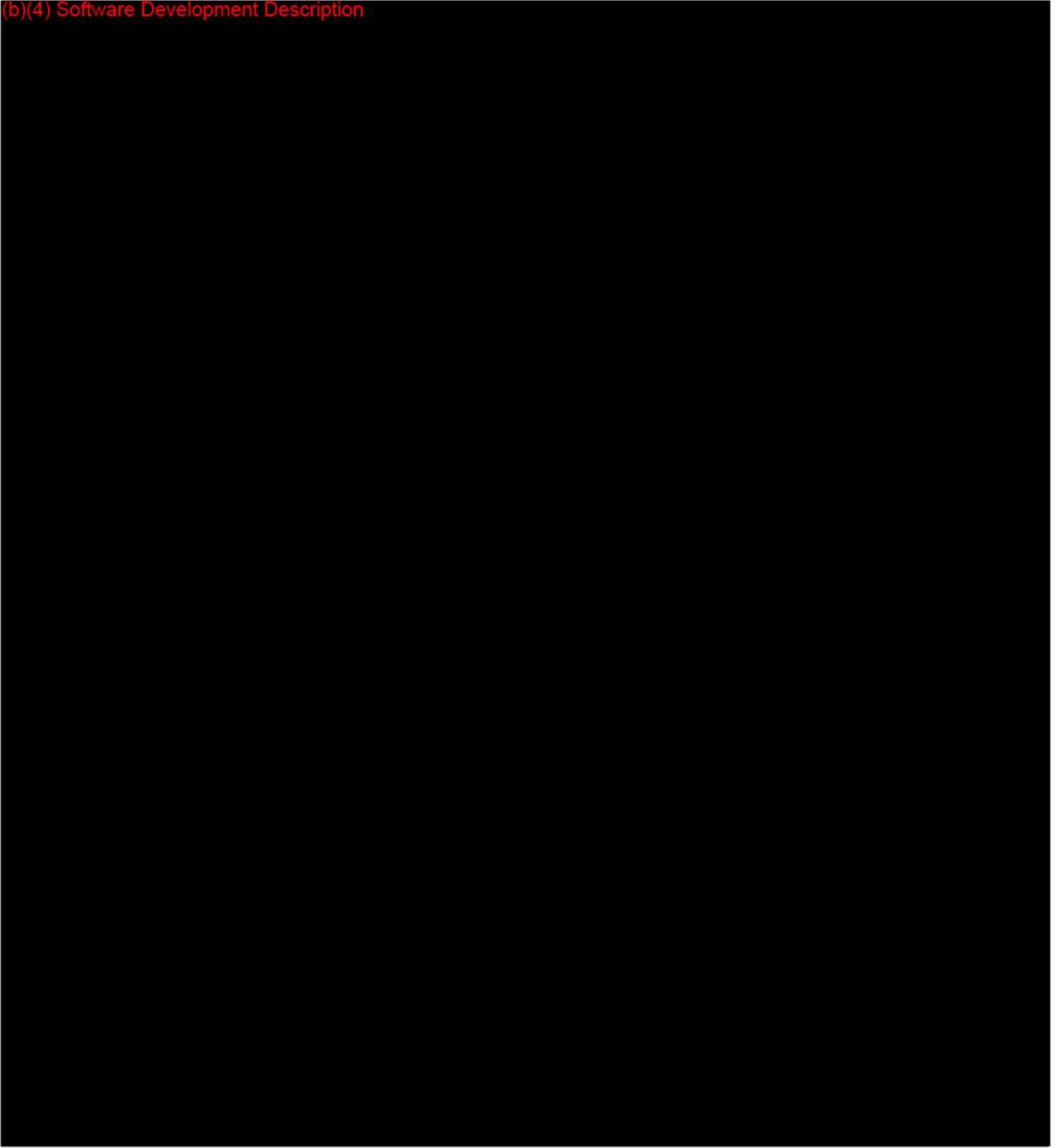
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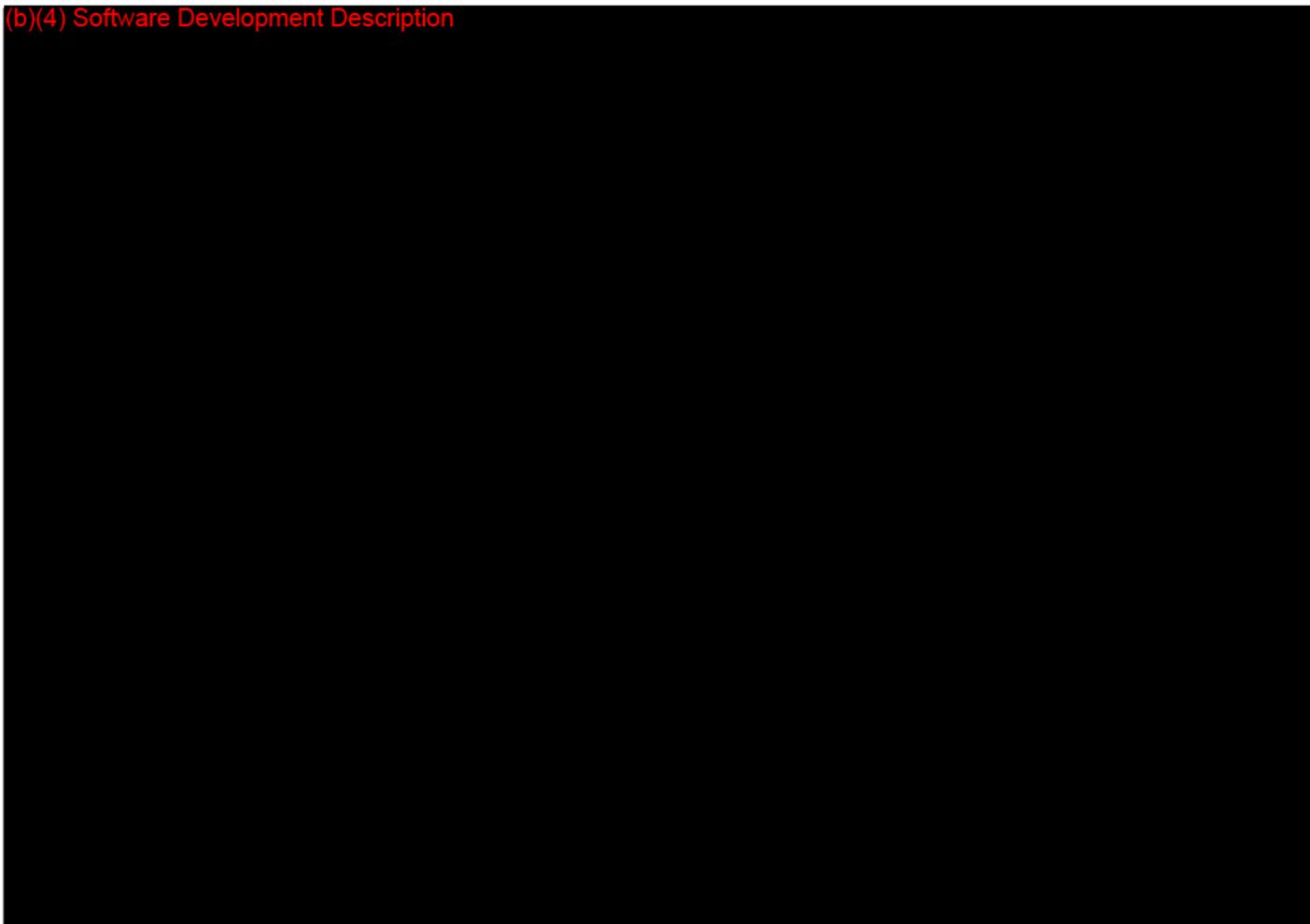
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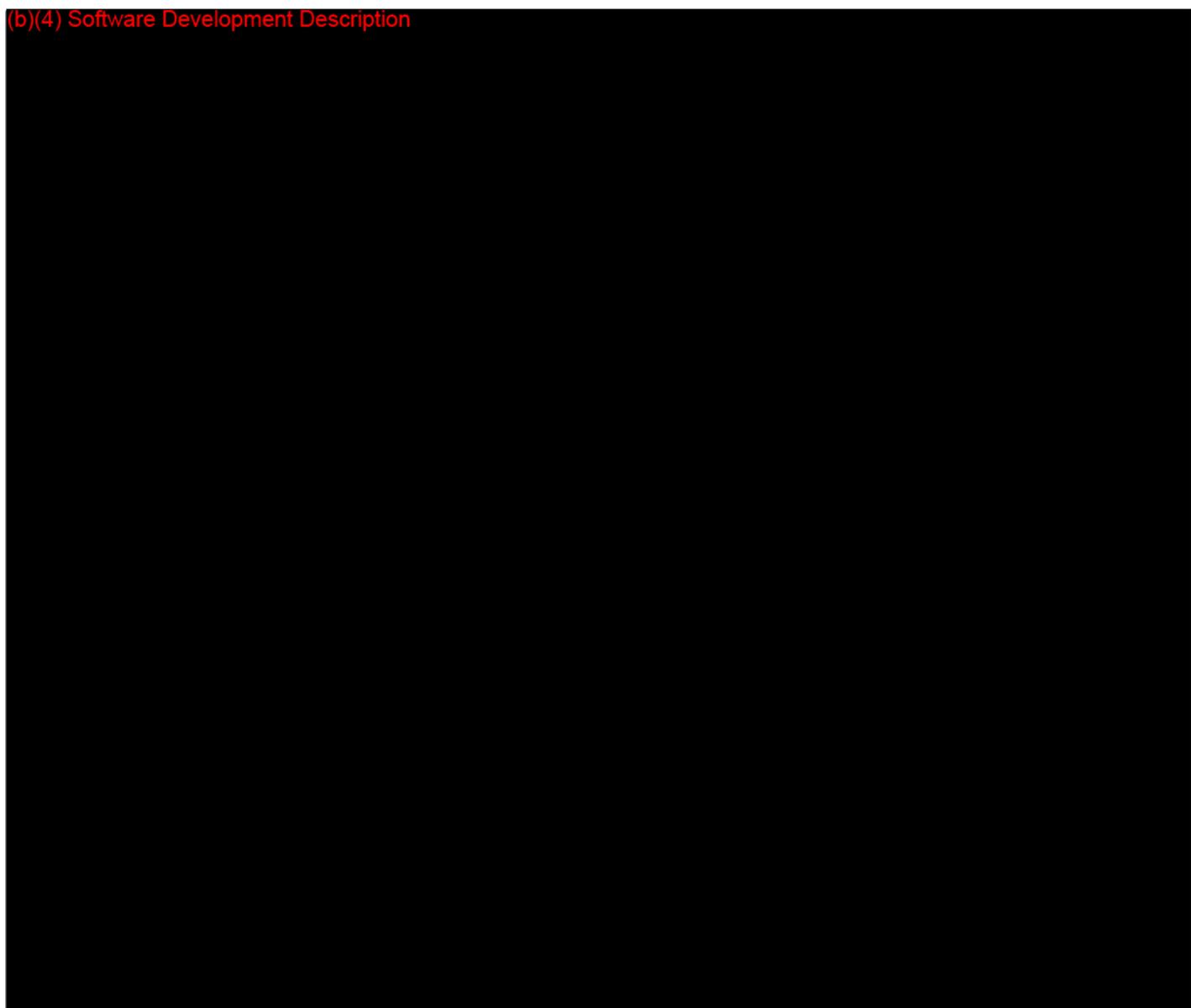
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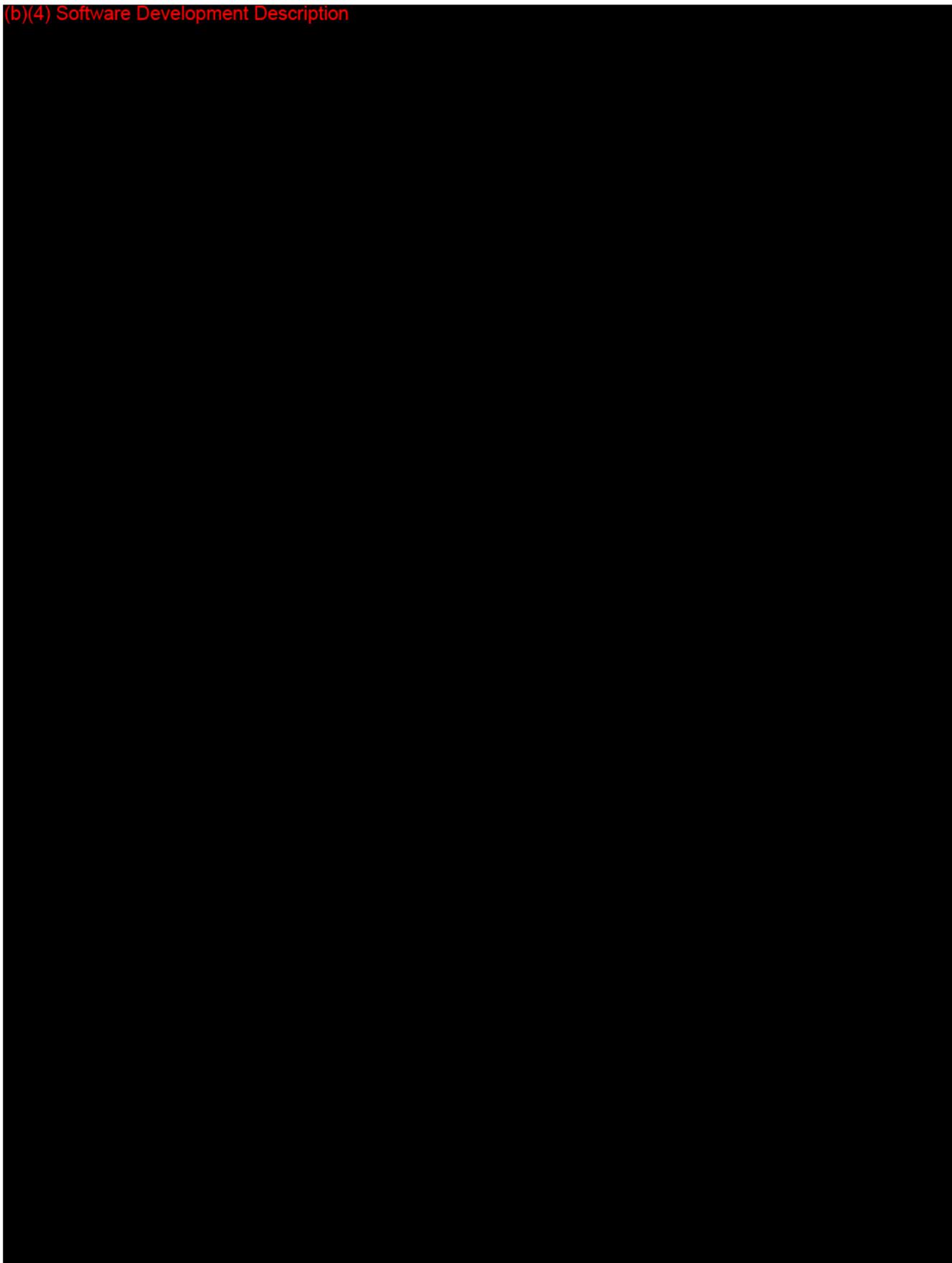
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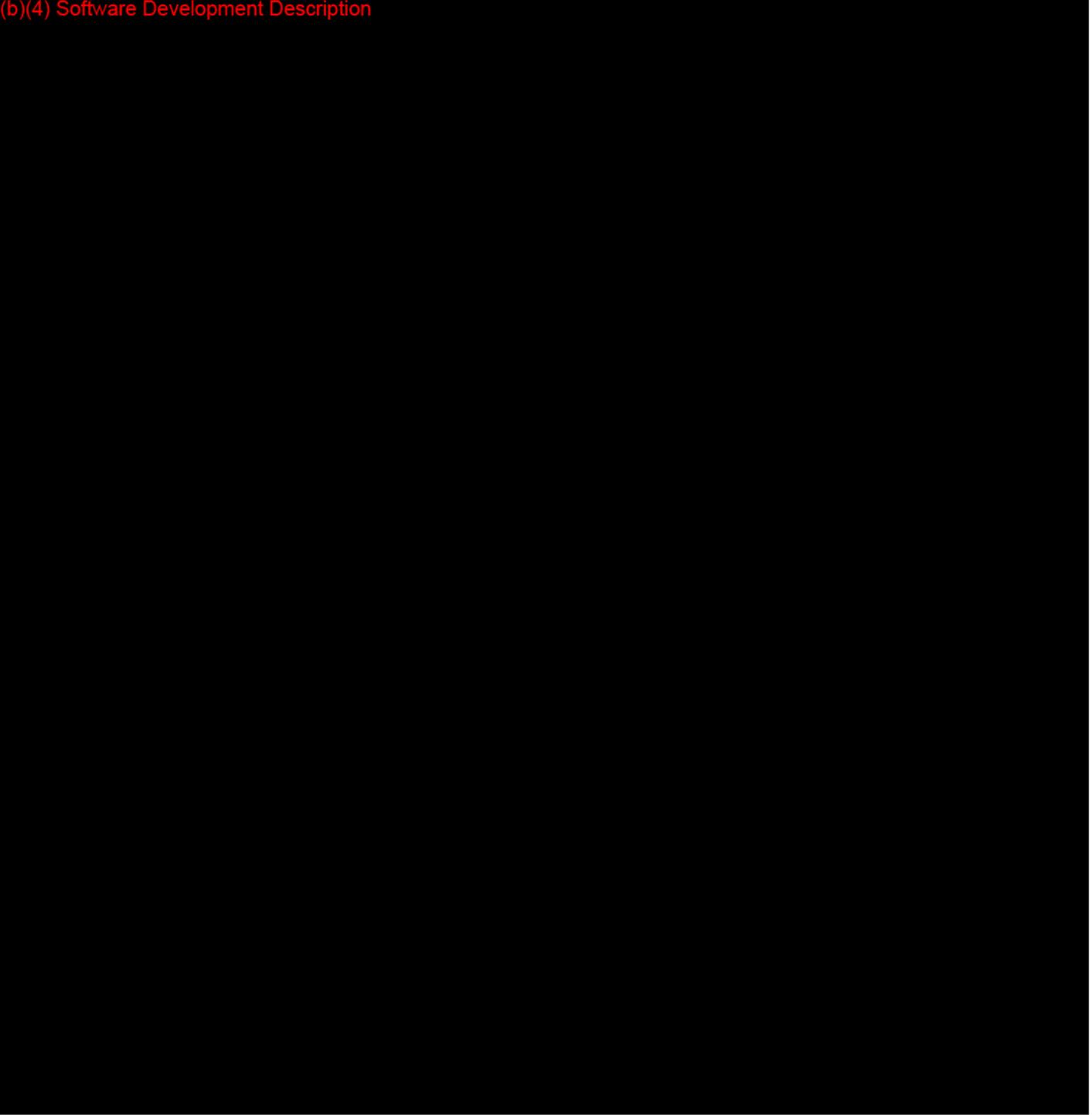
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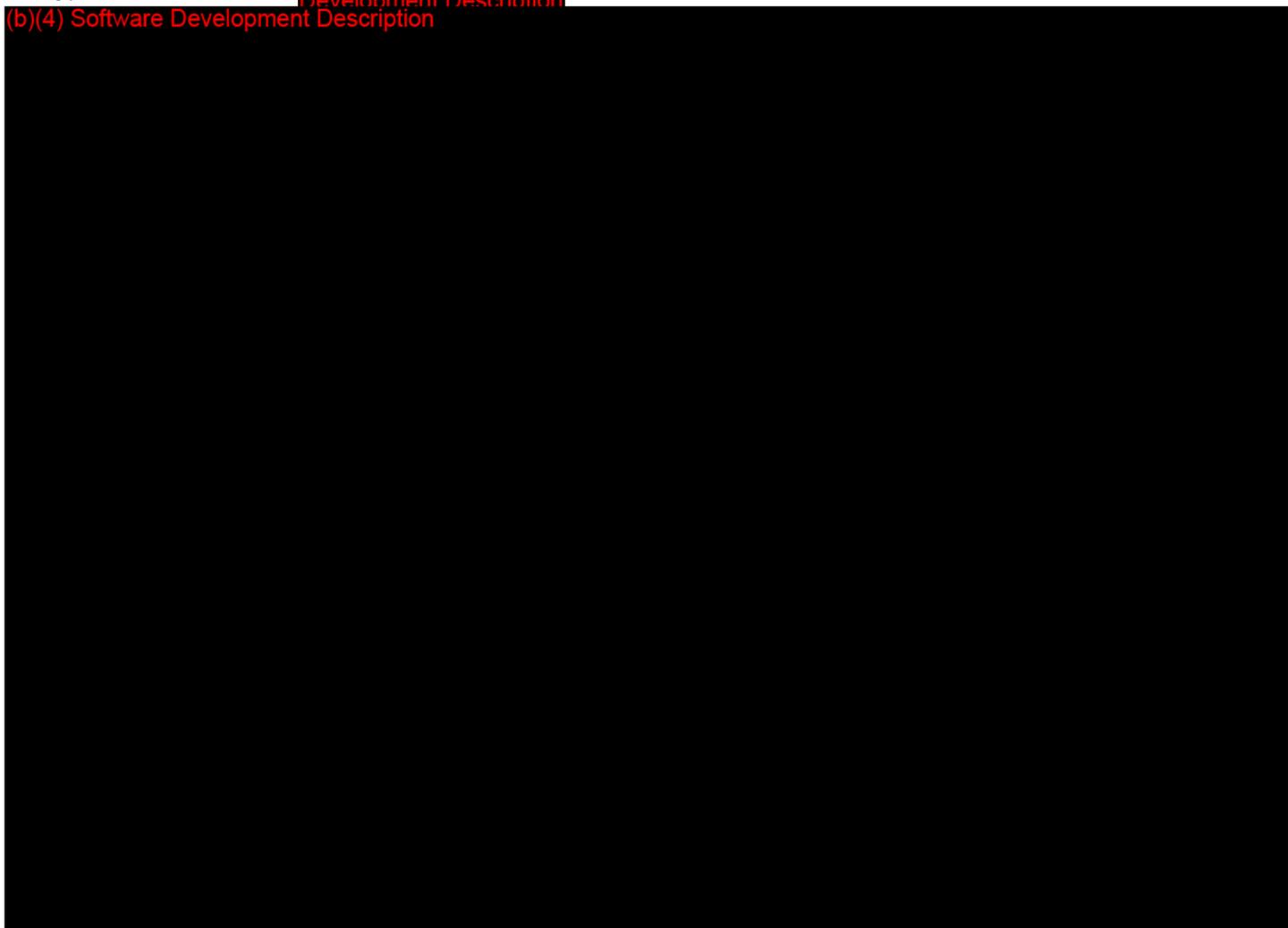


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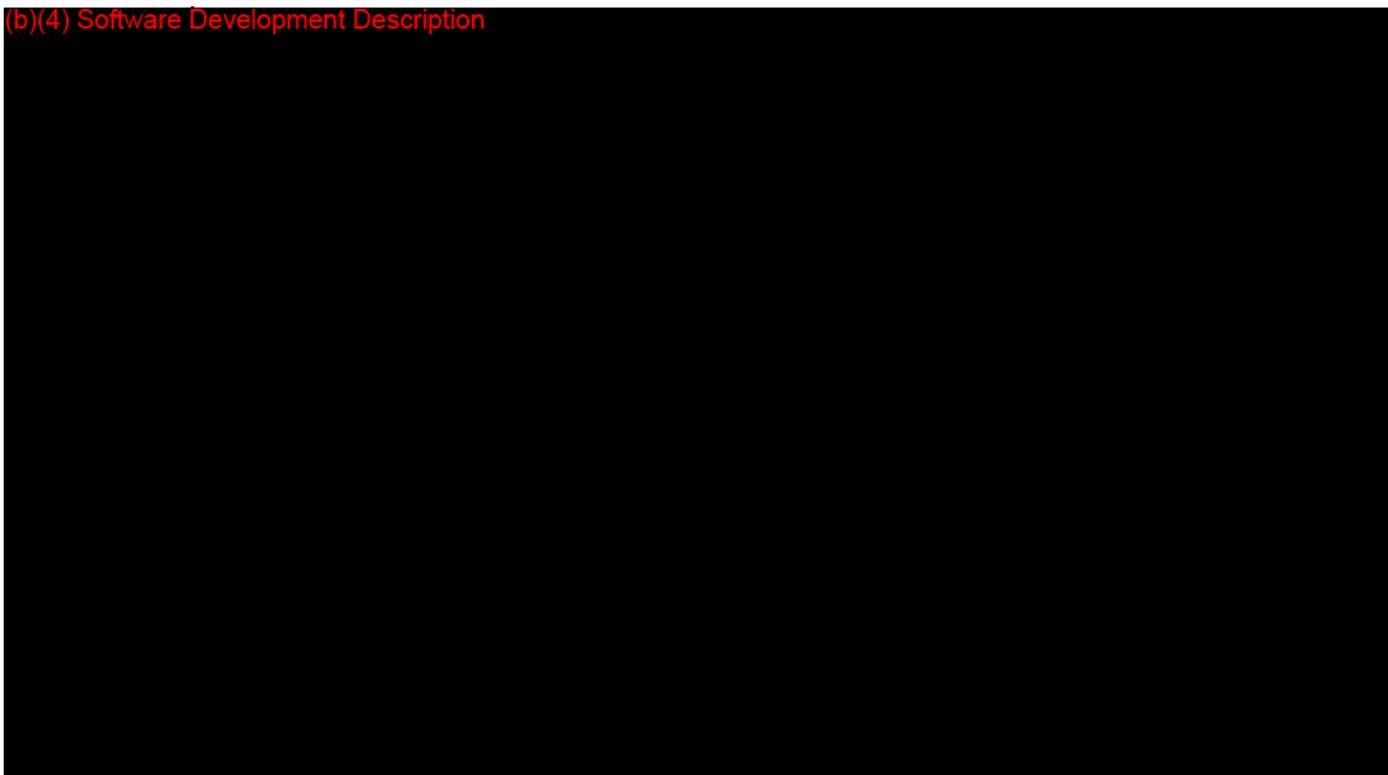


**5.10.2 Test Results**

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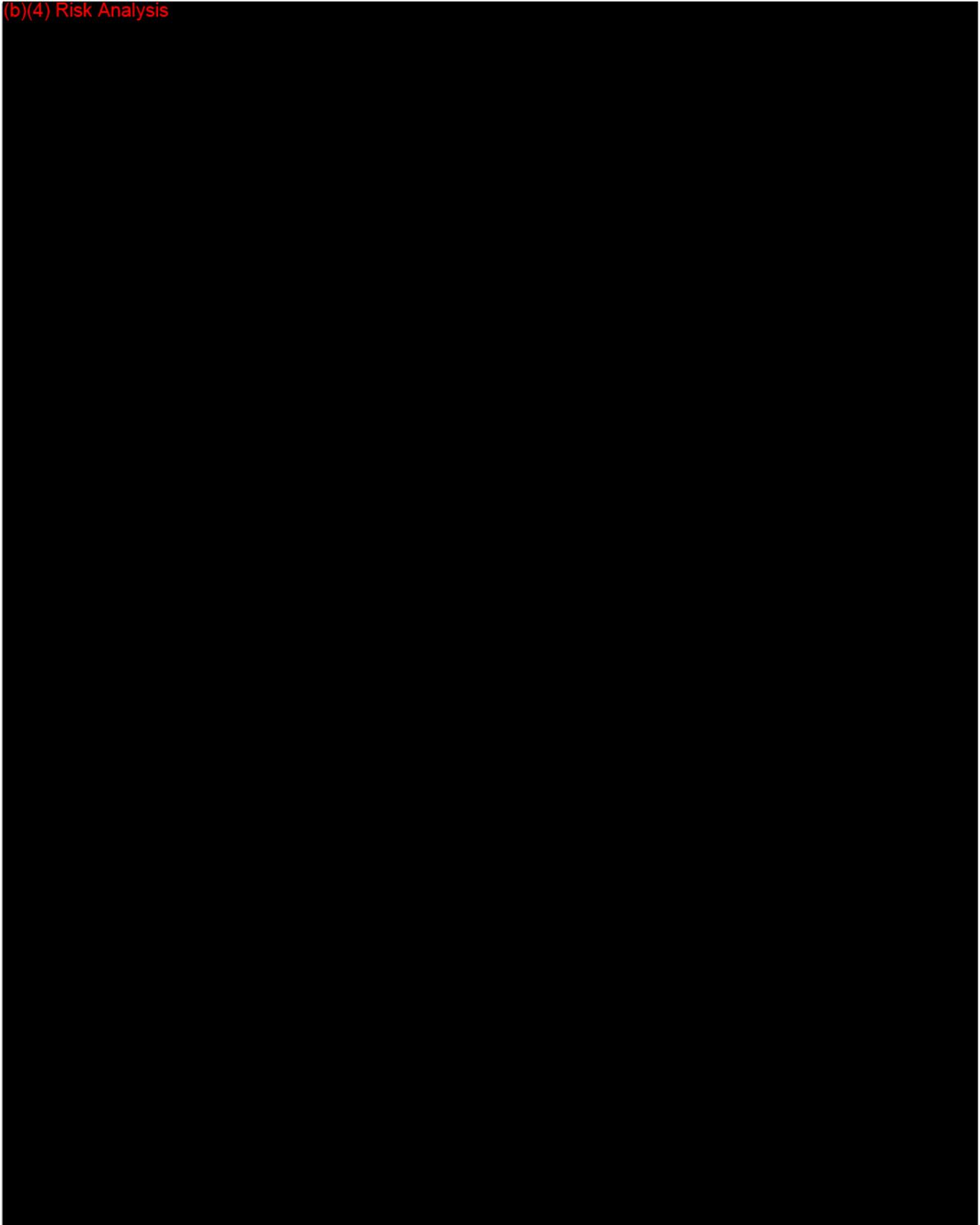
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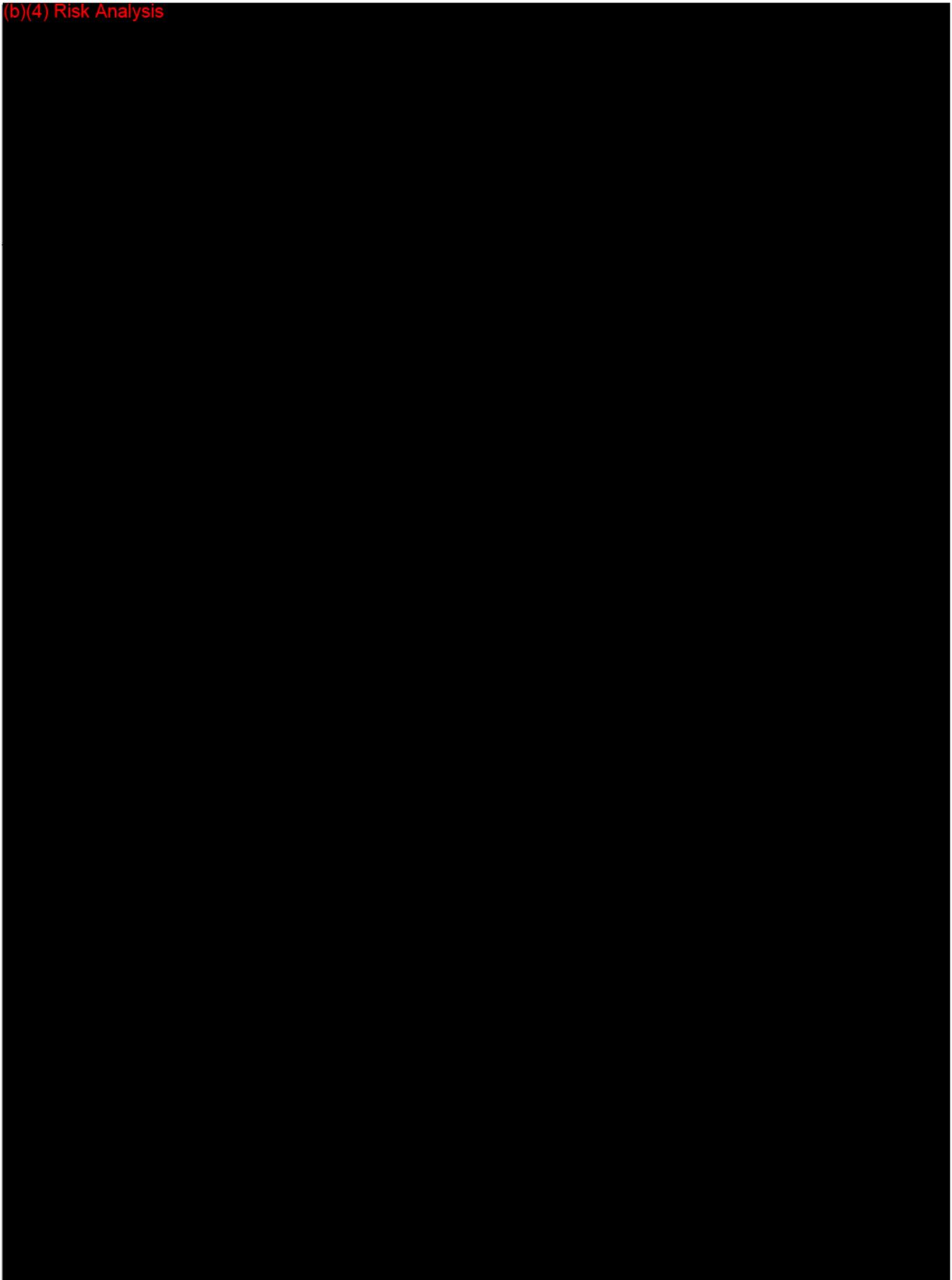
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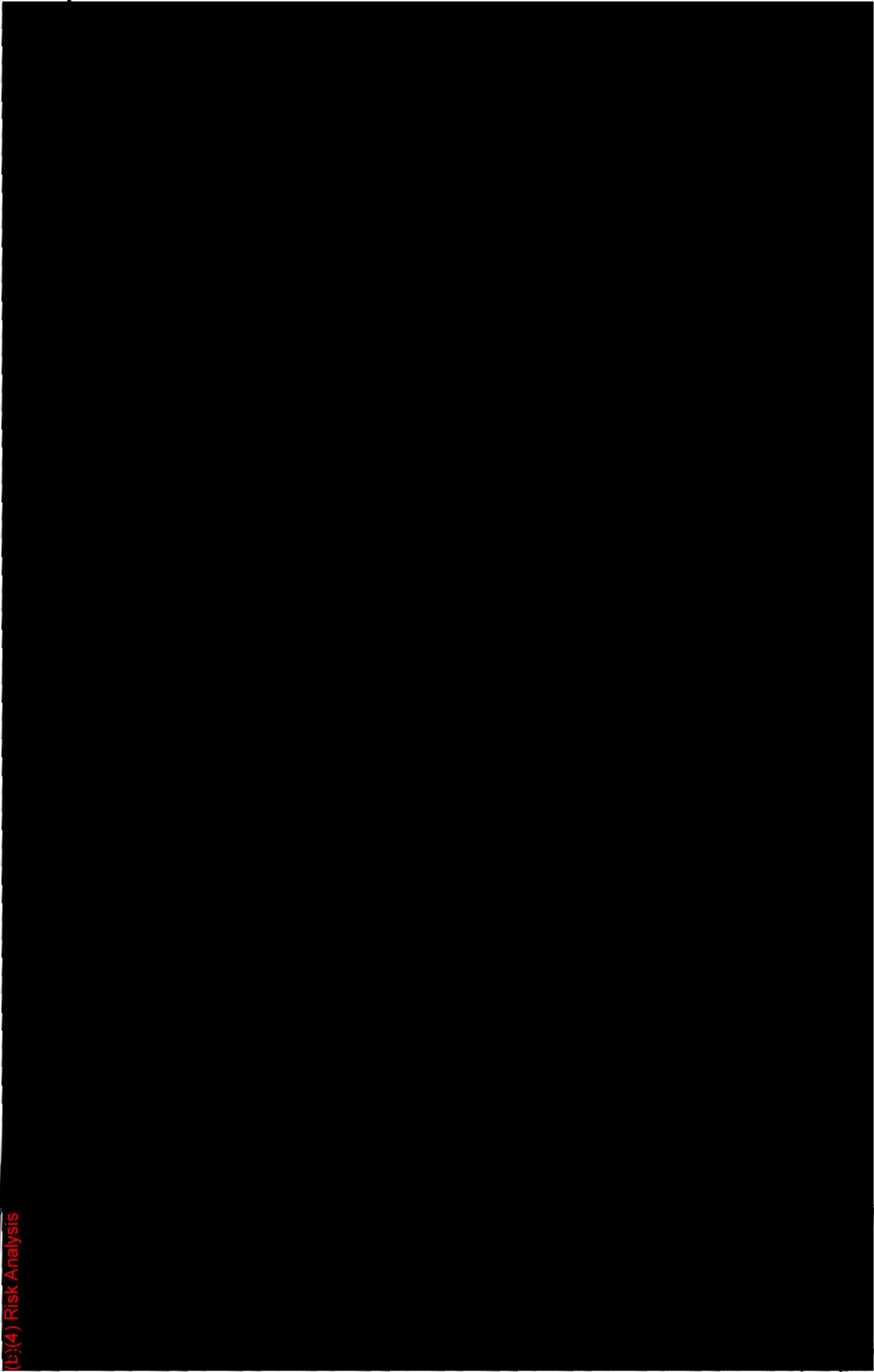
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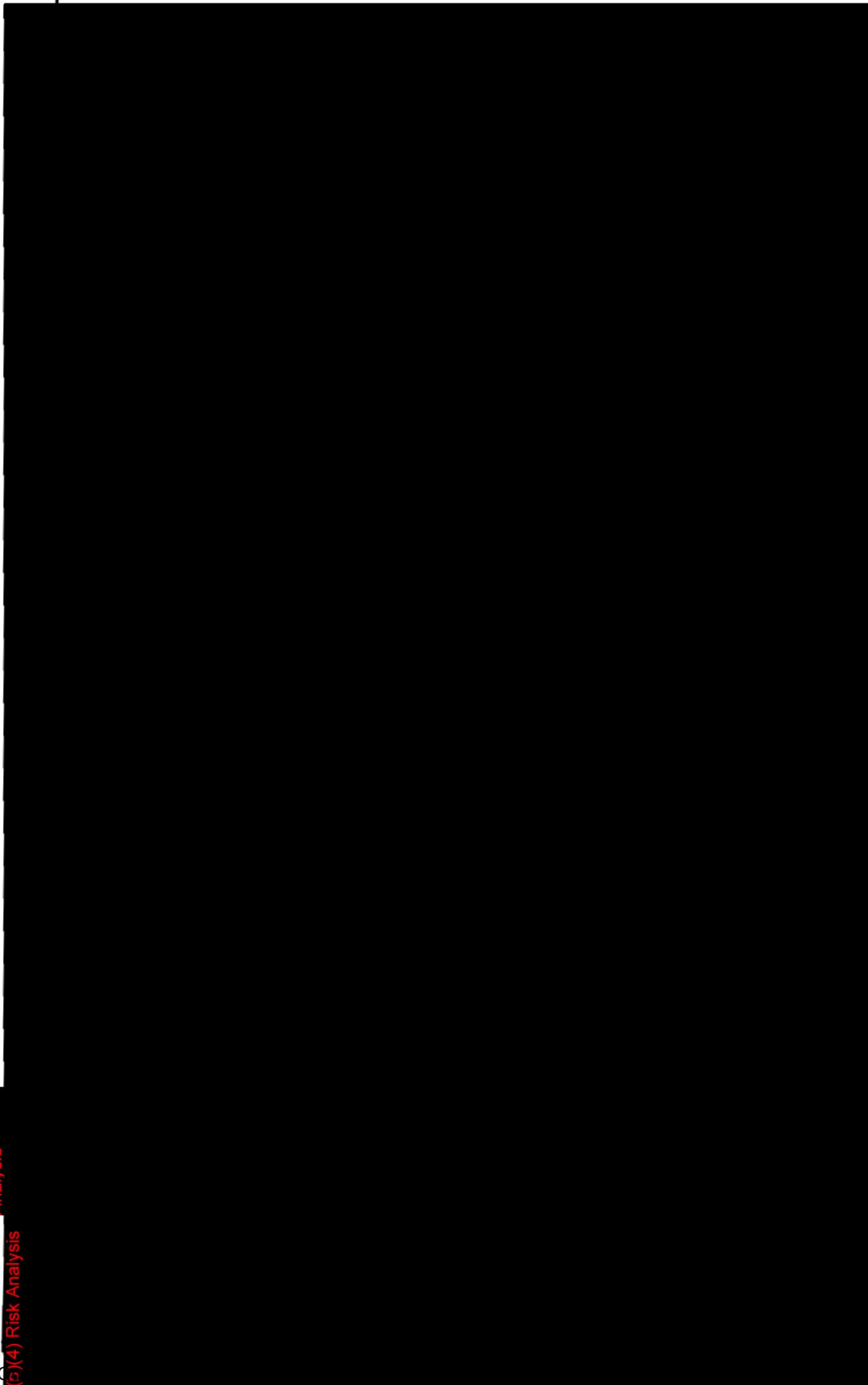
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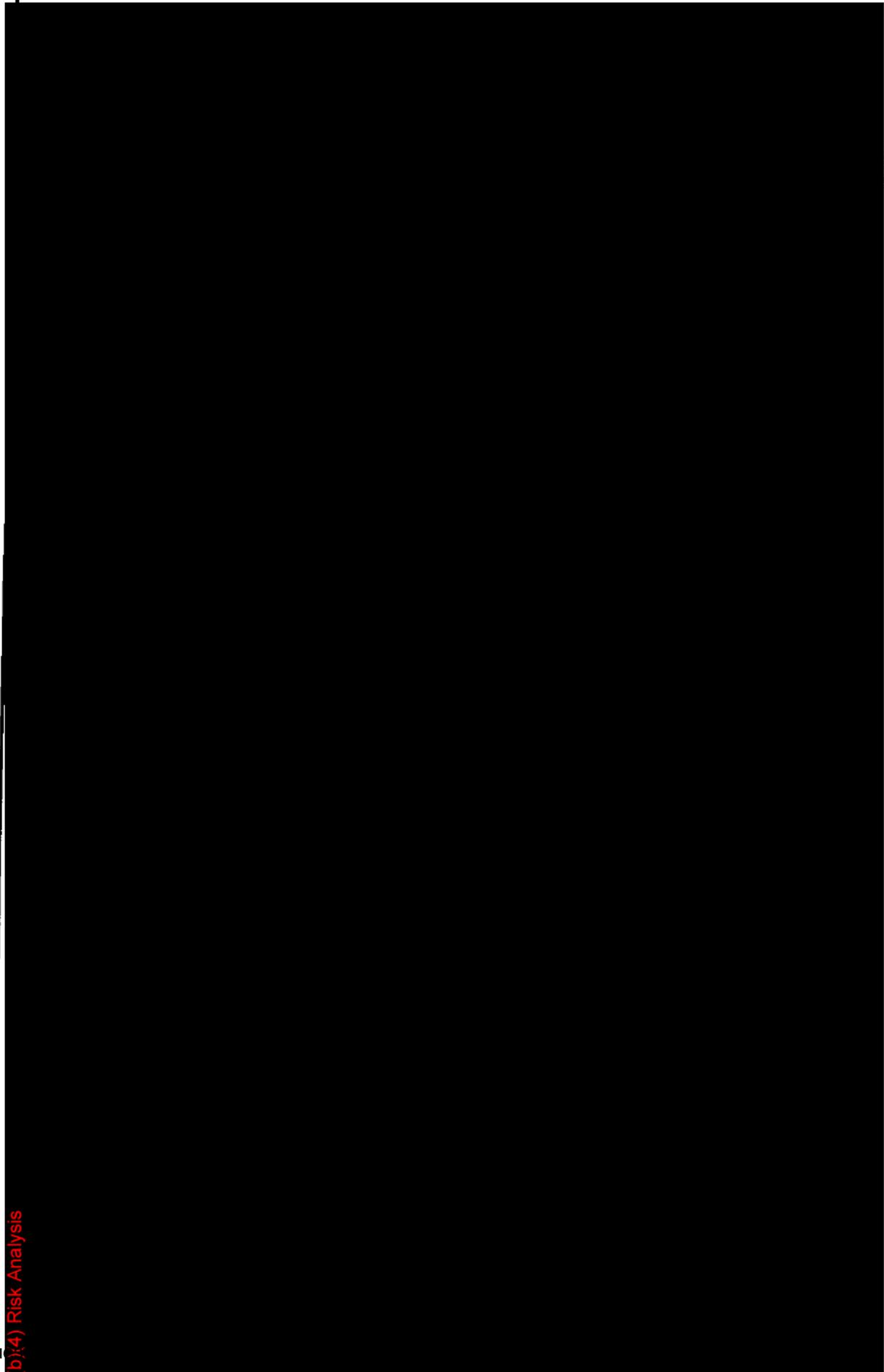
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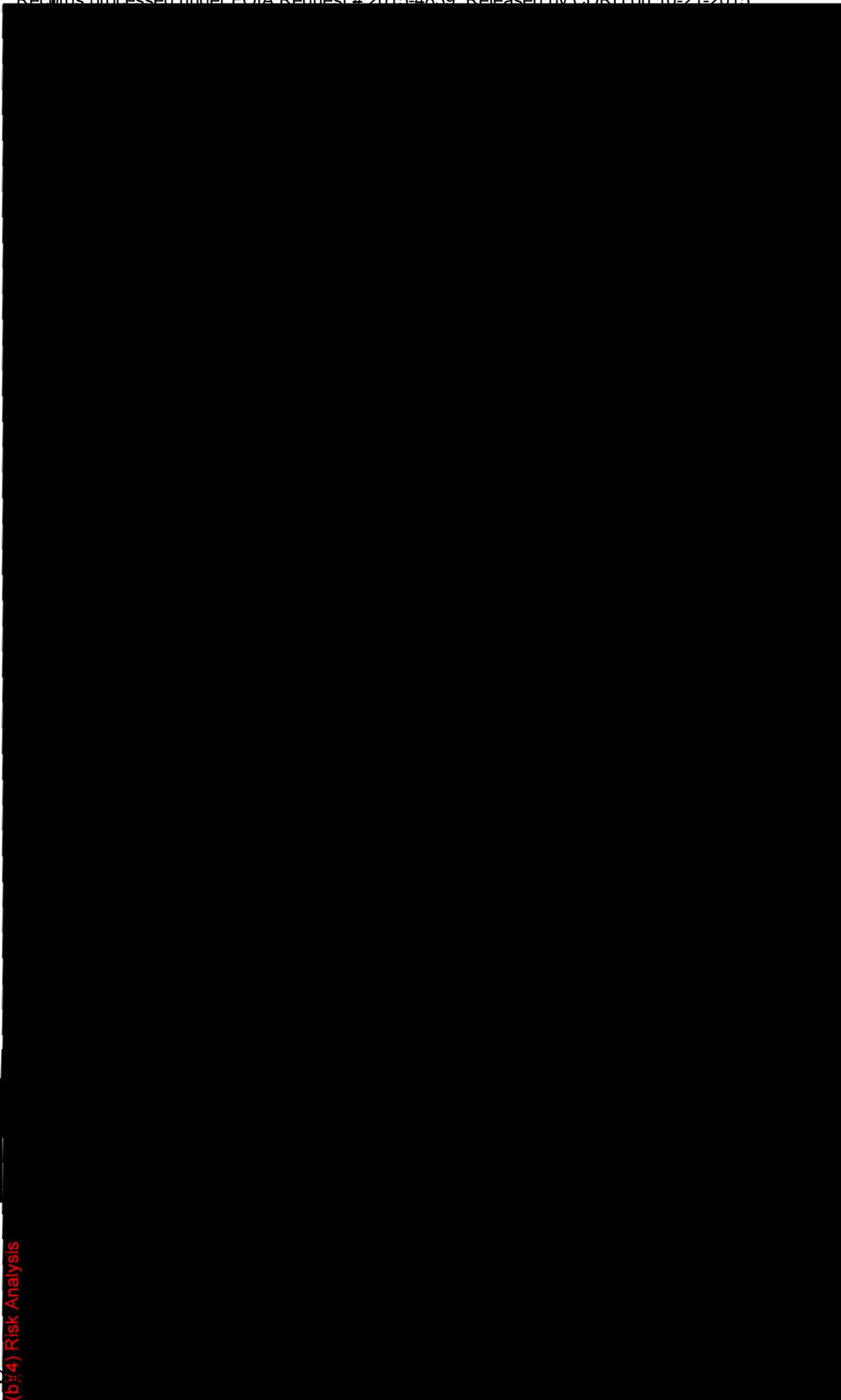
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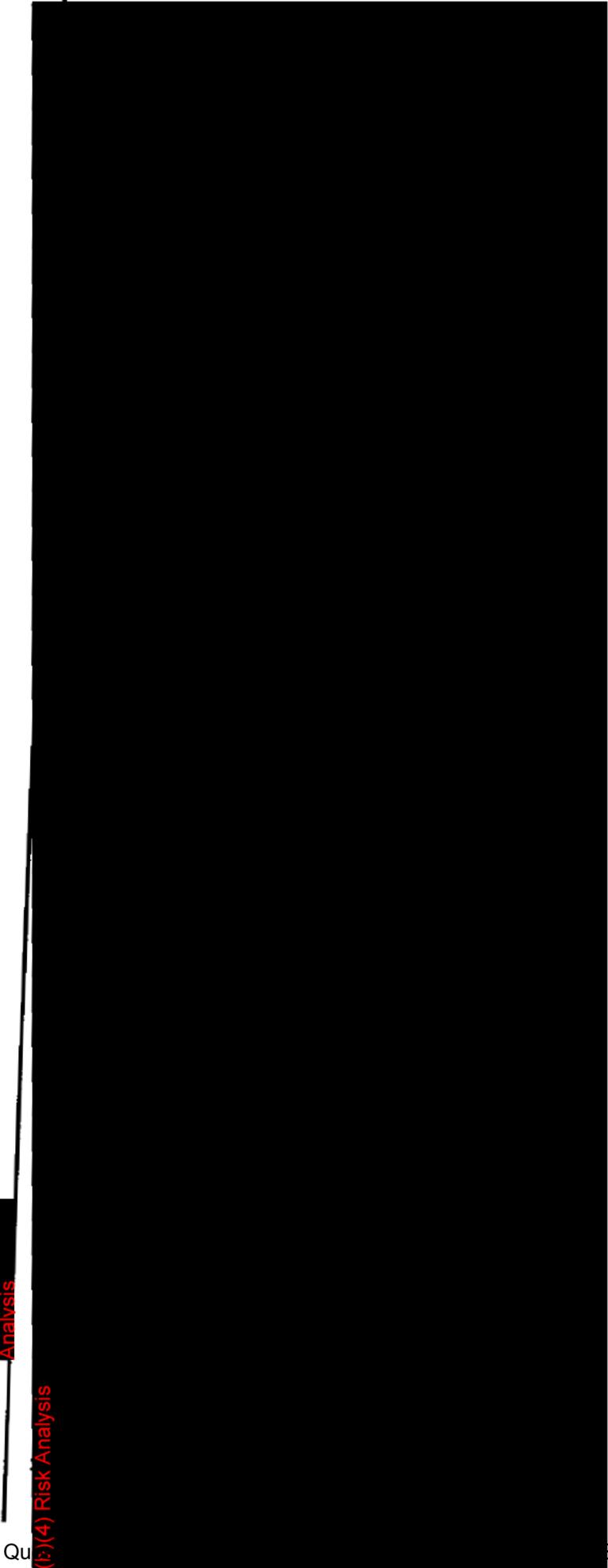
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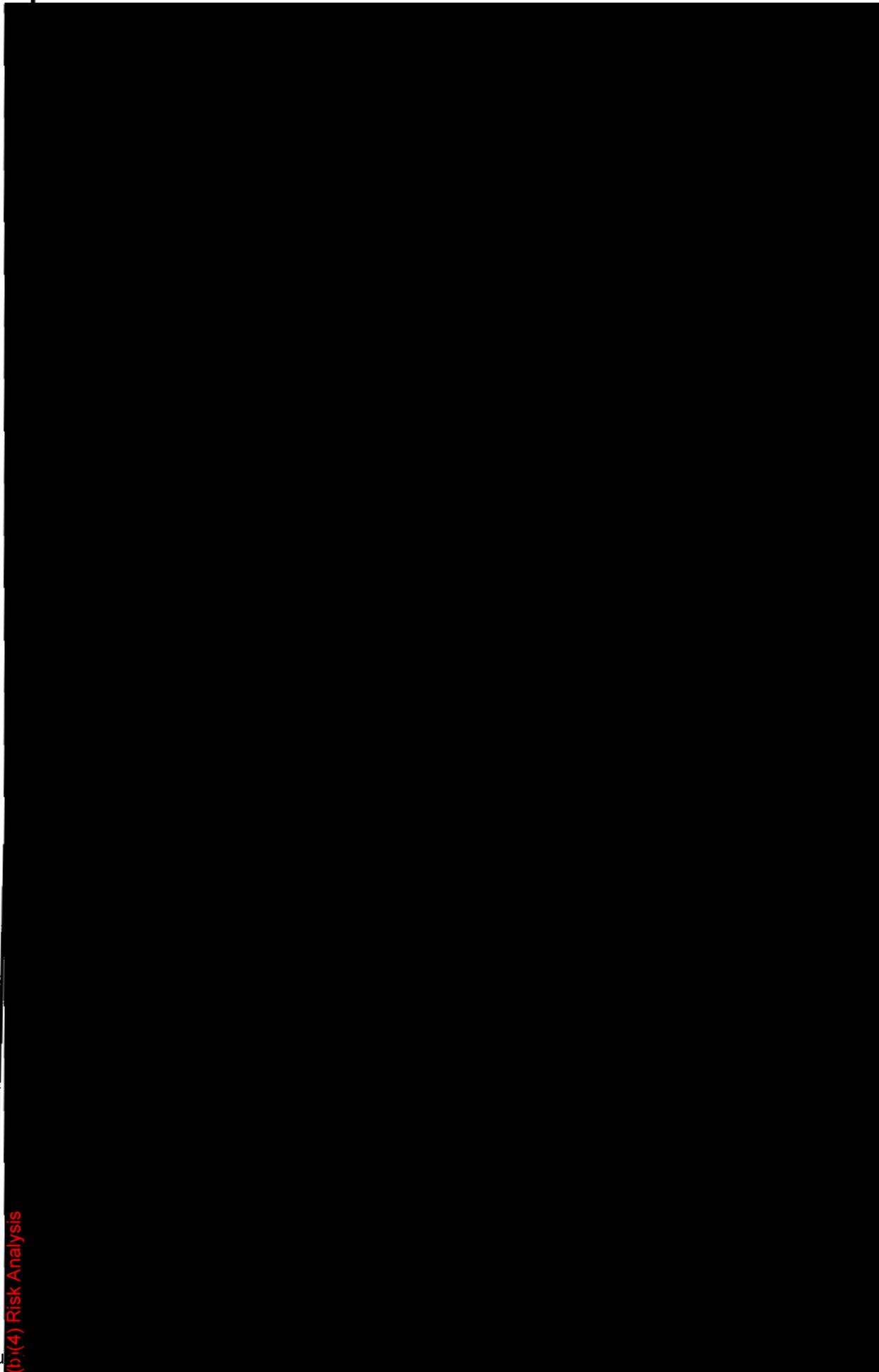
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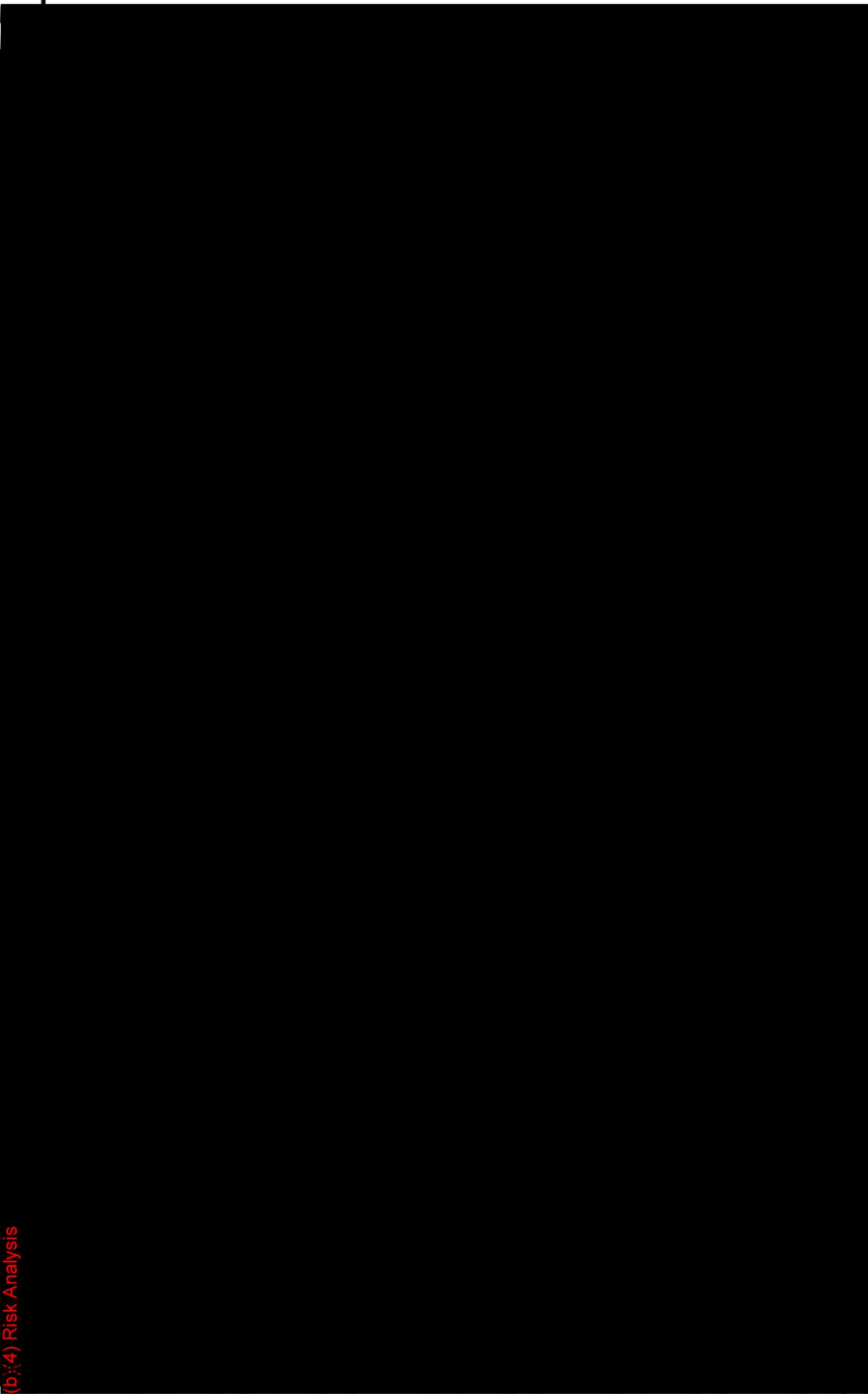
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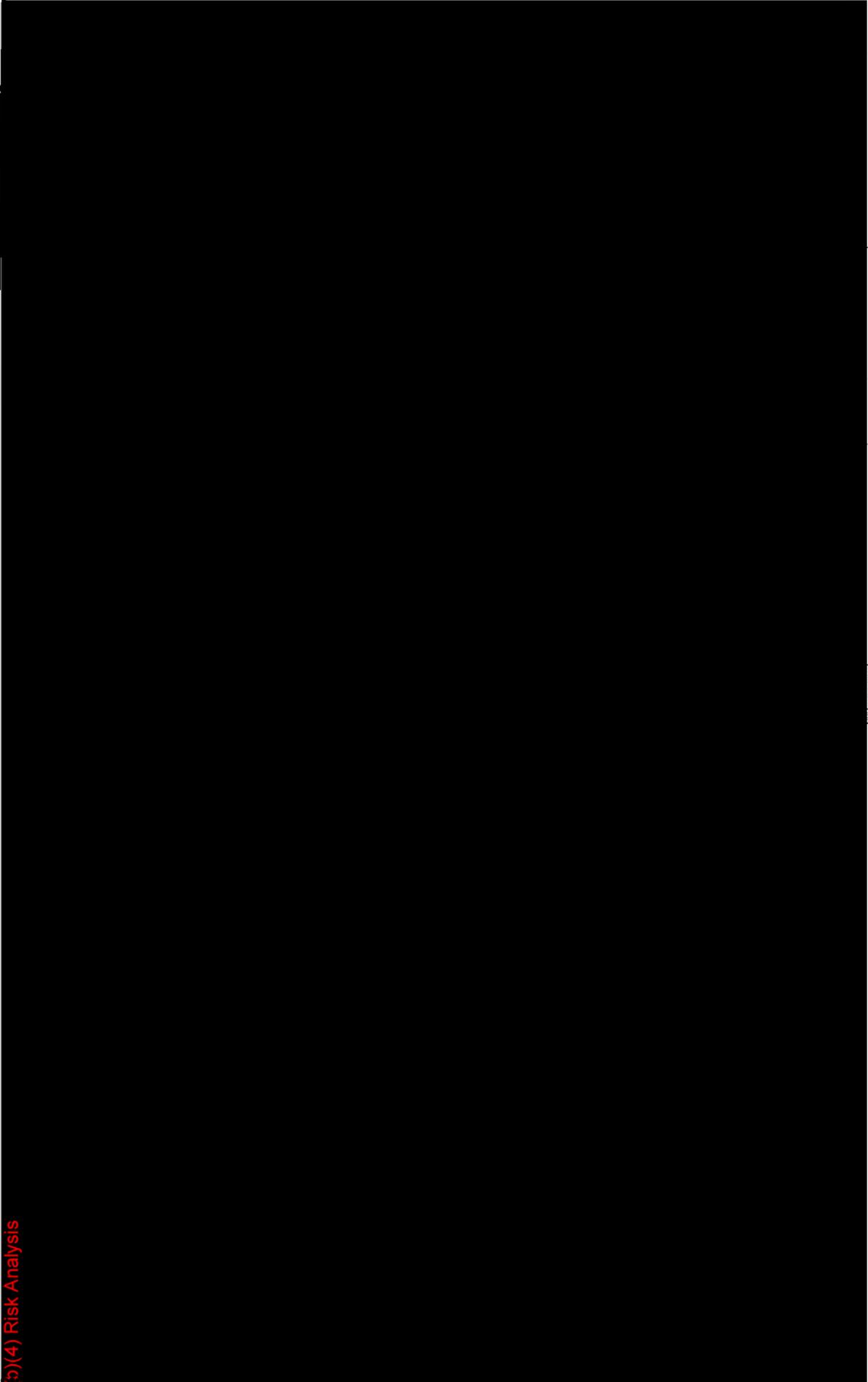
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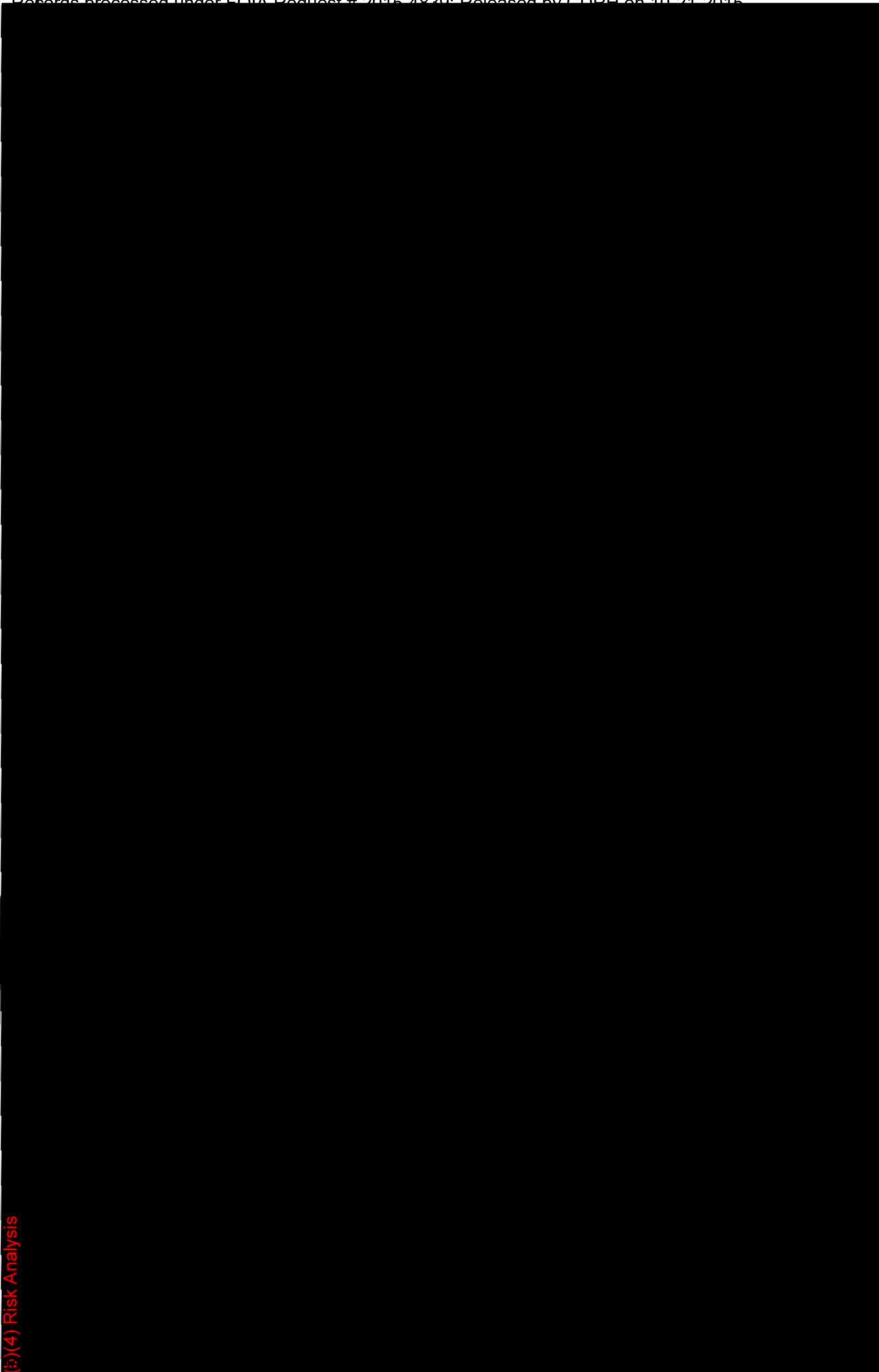
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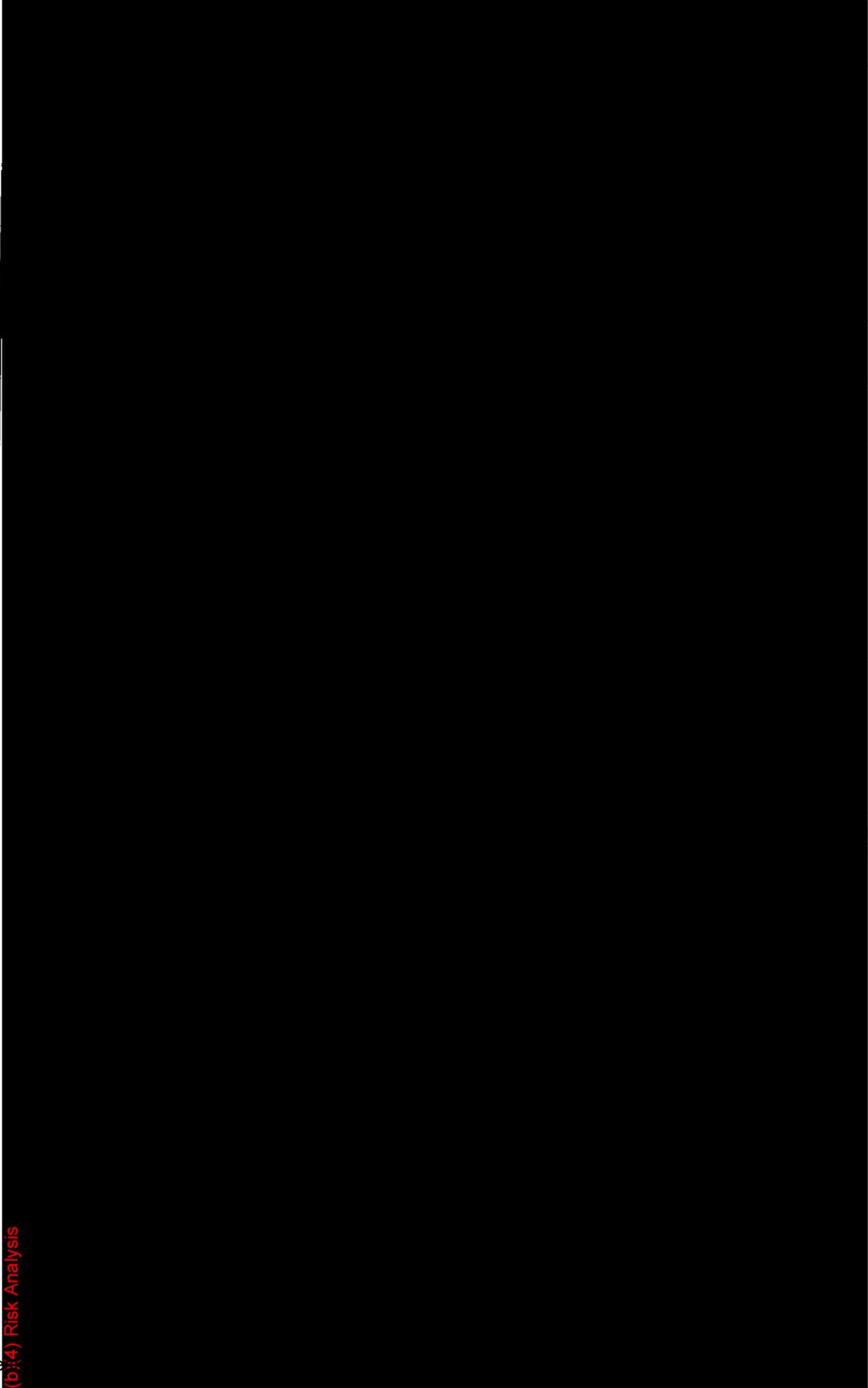
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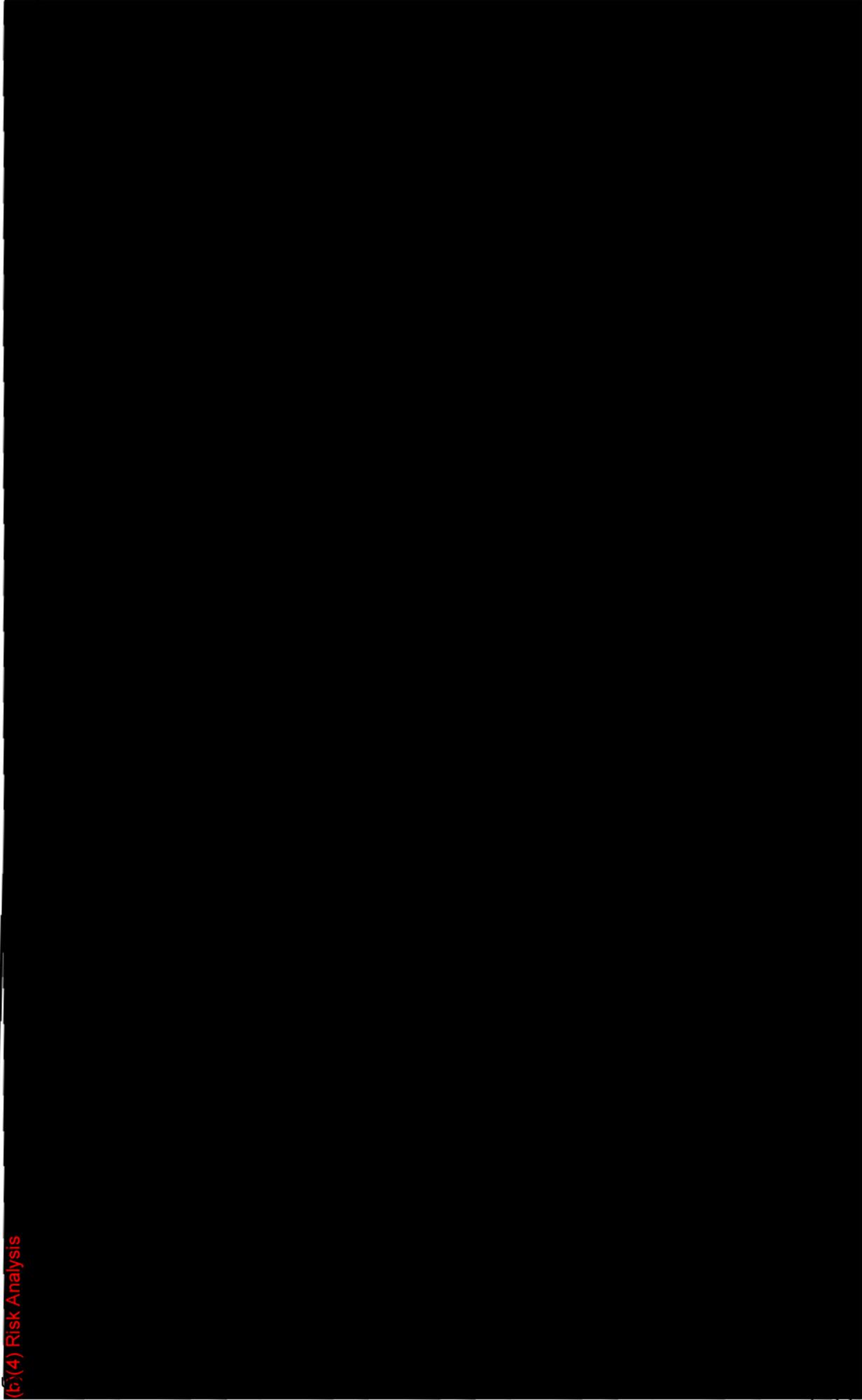
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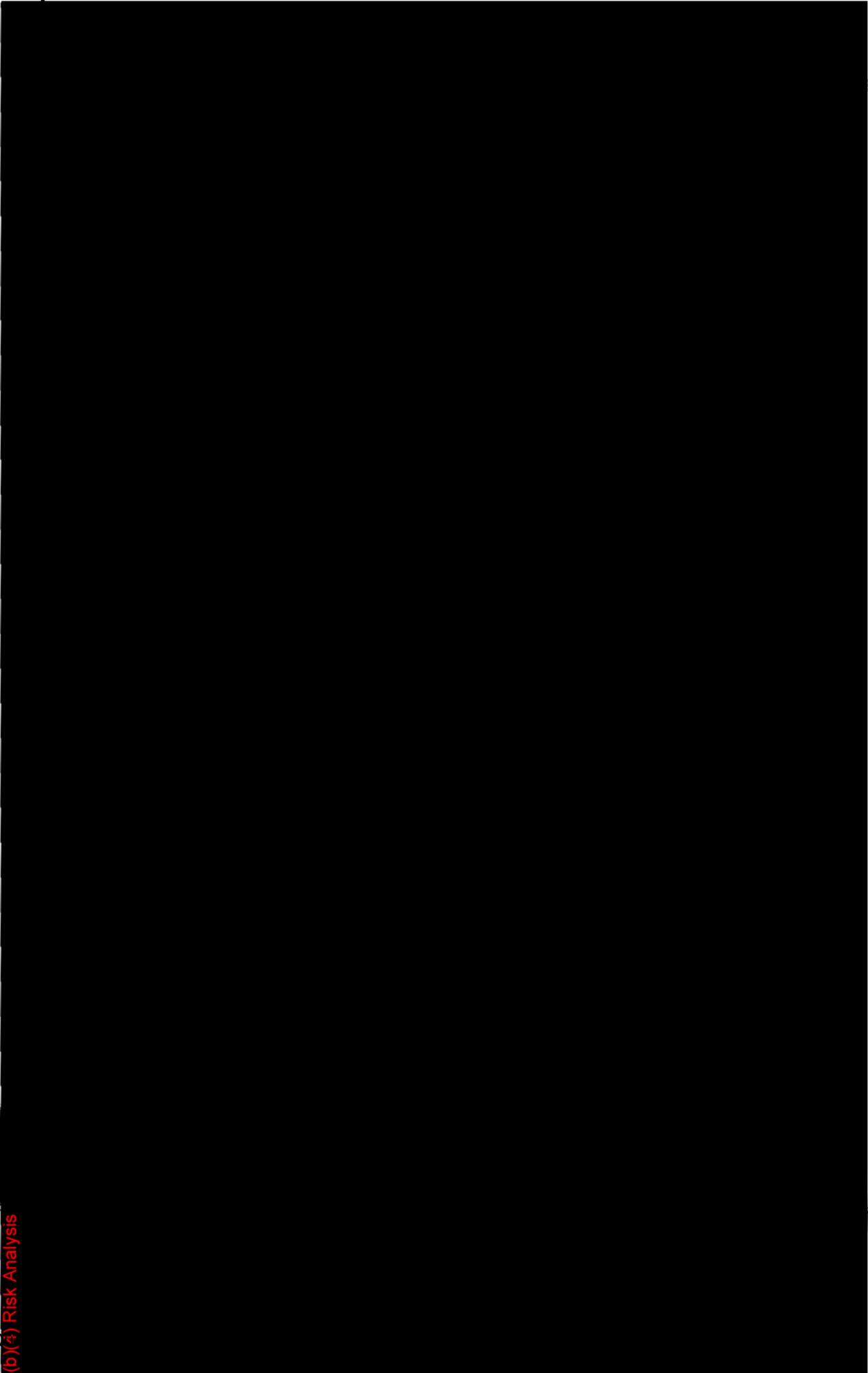
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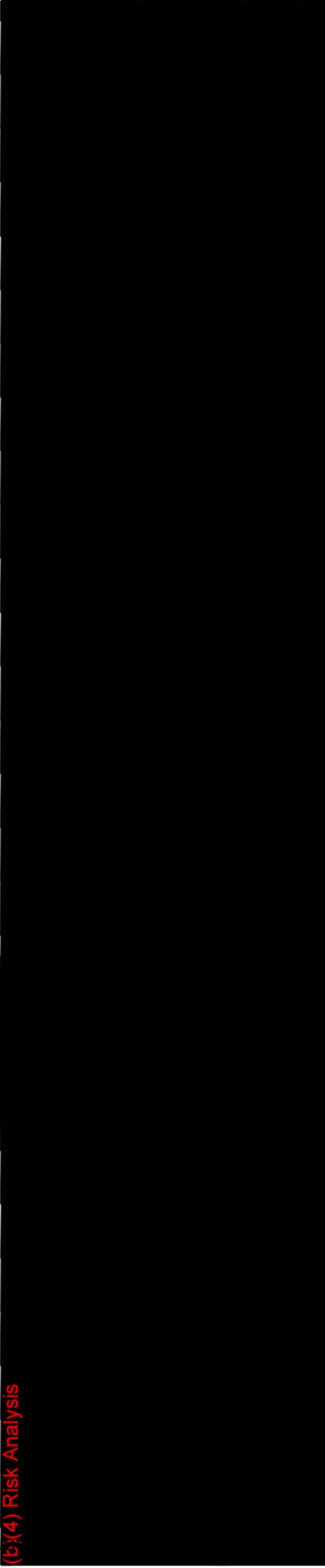
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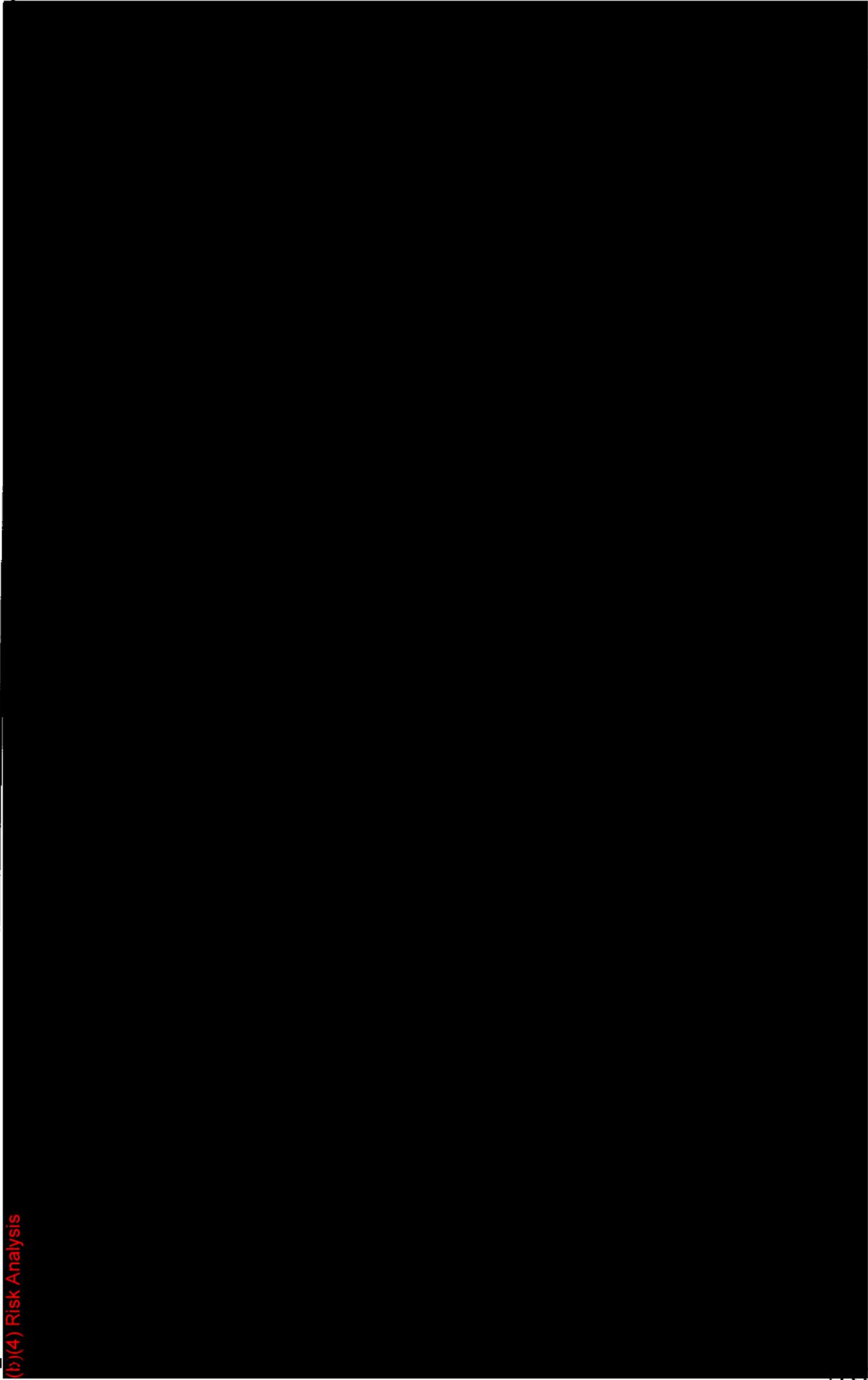
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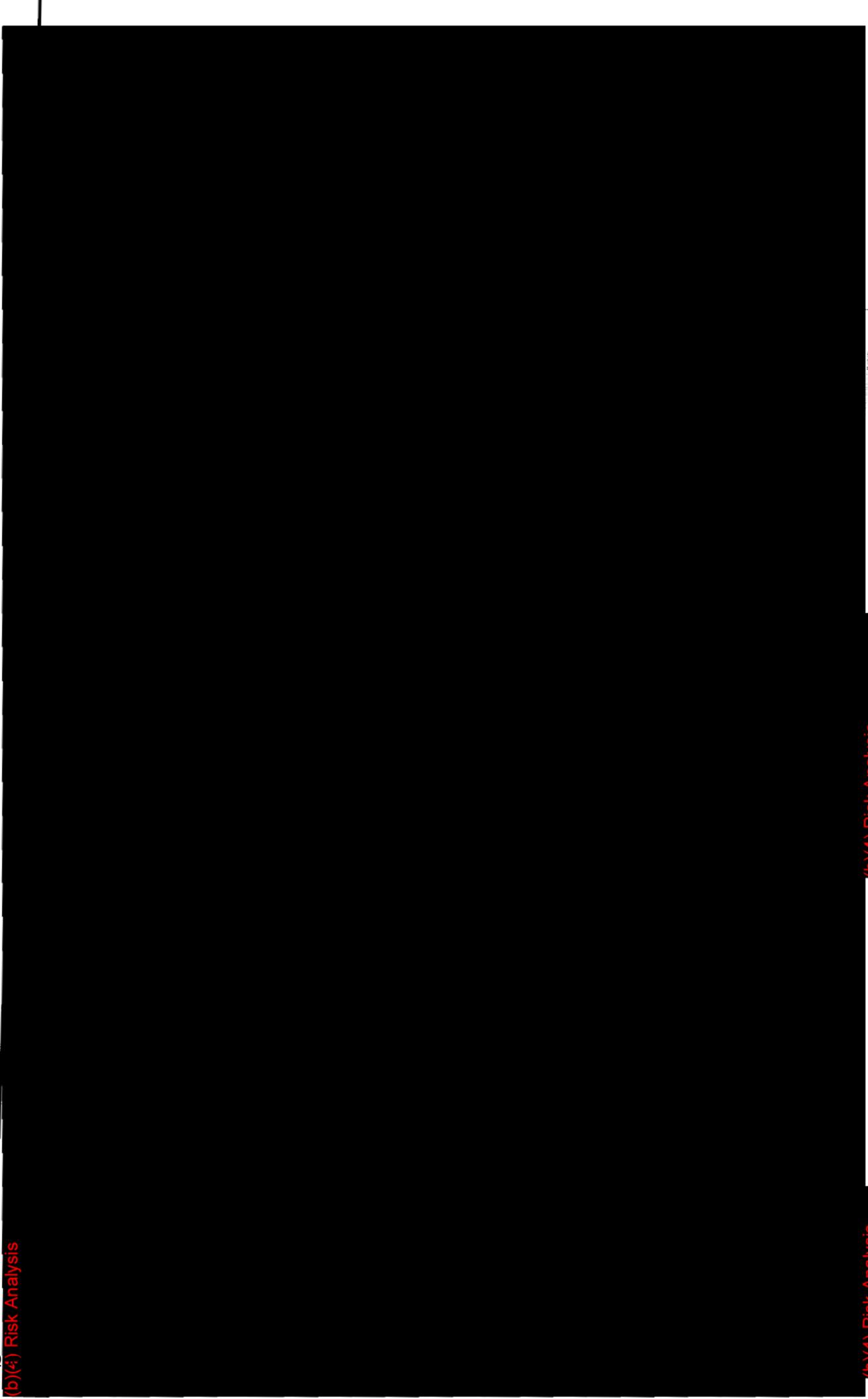
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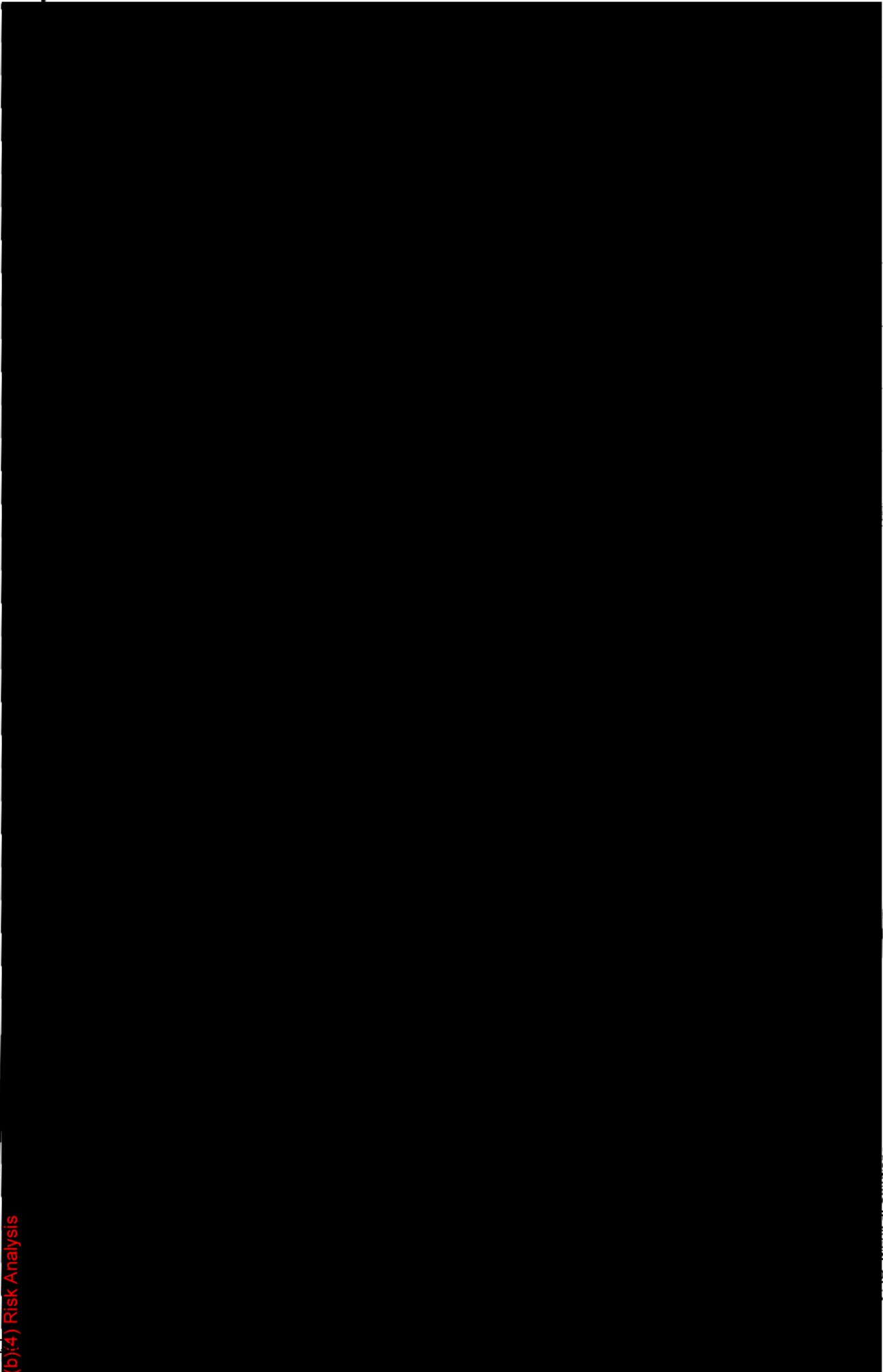
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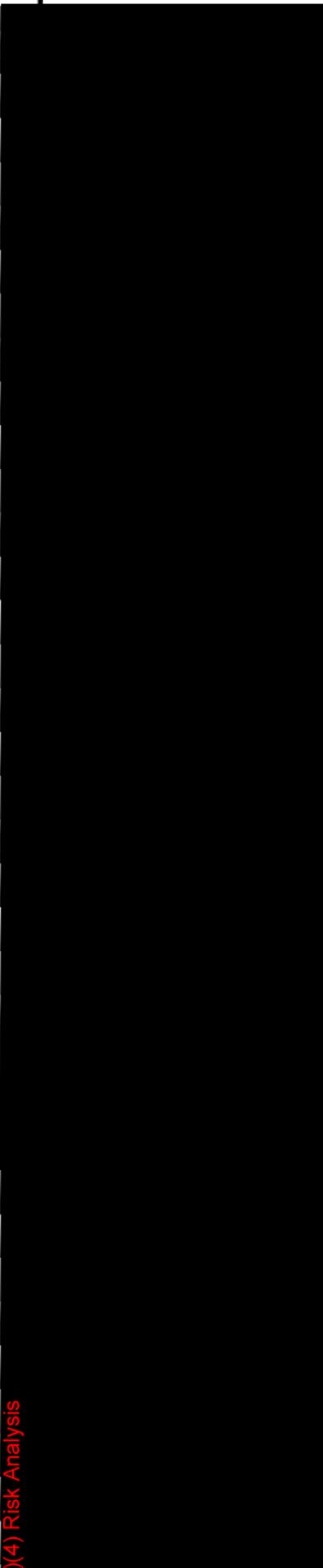
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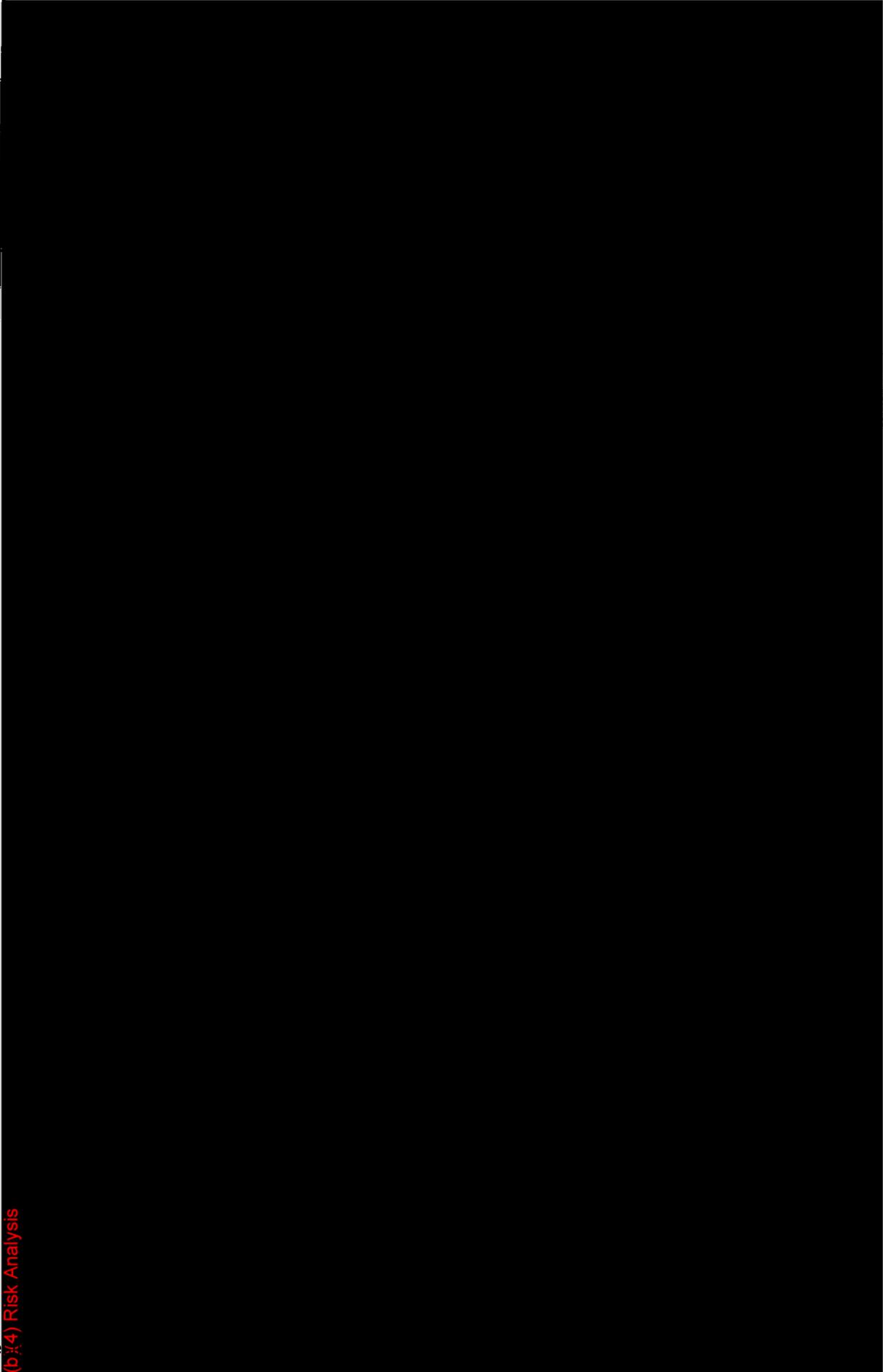
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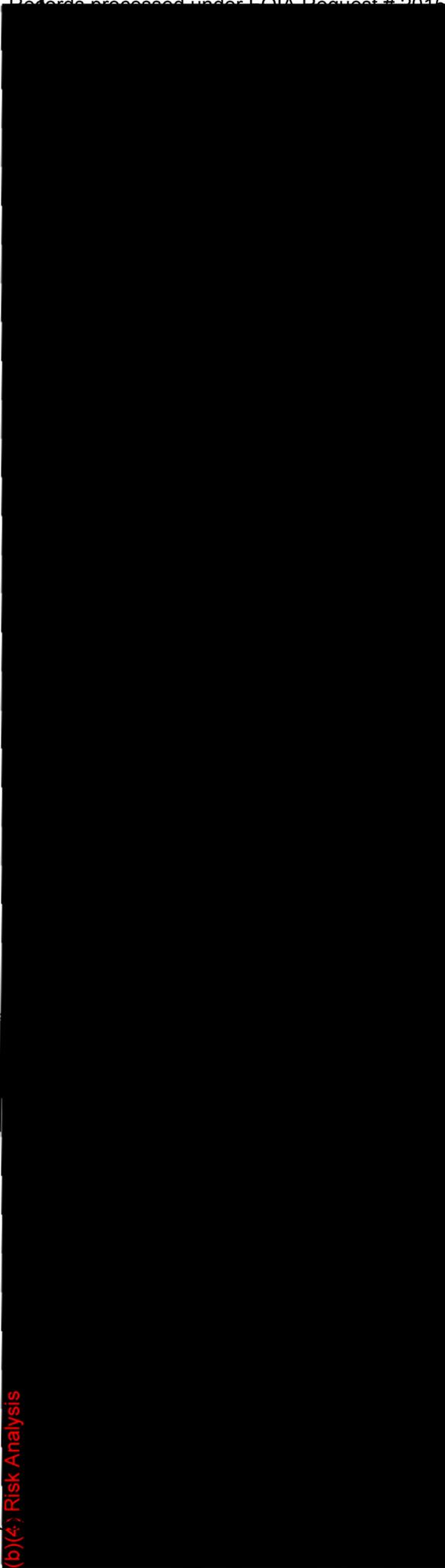
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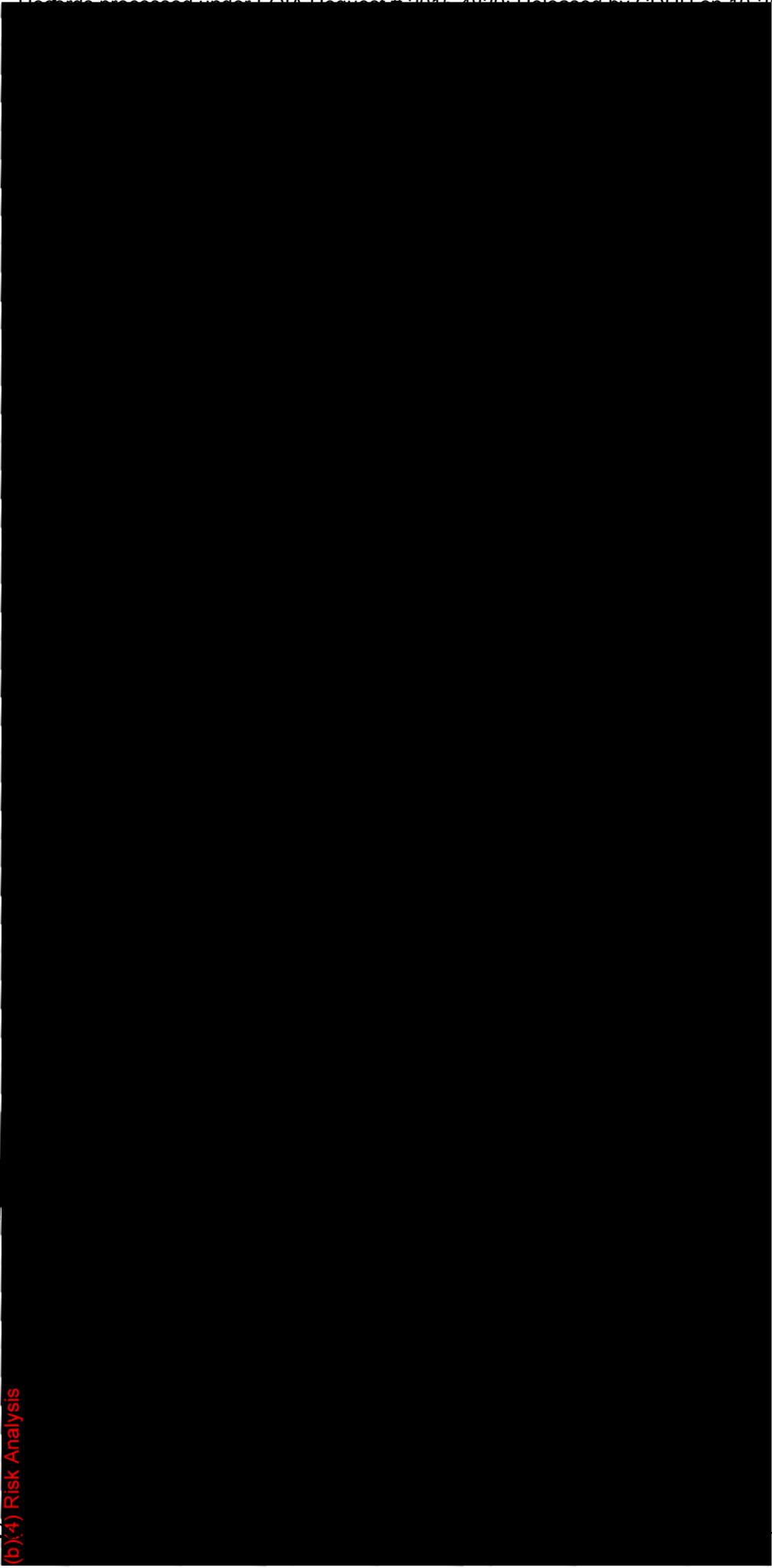
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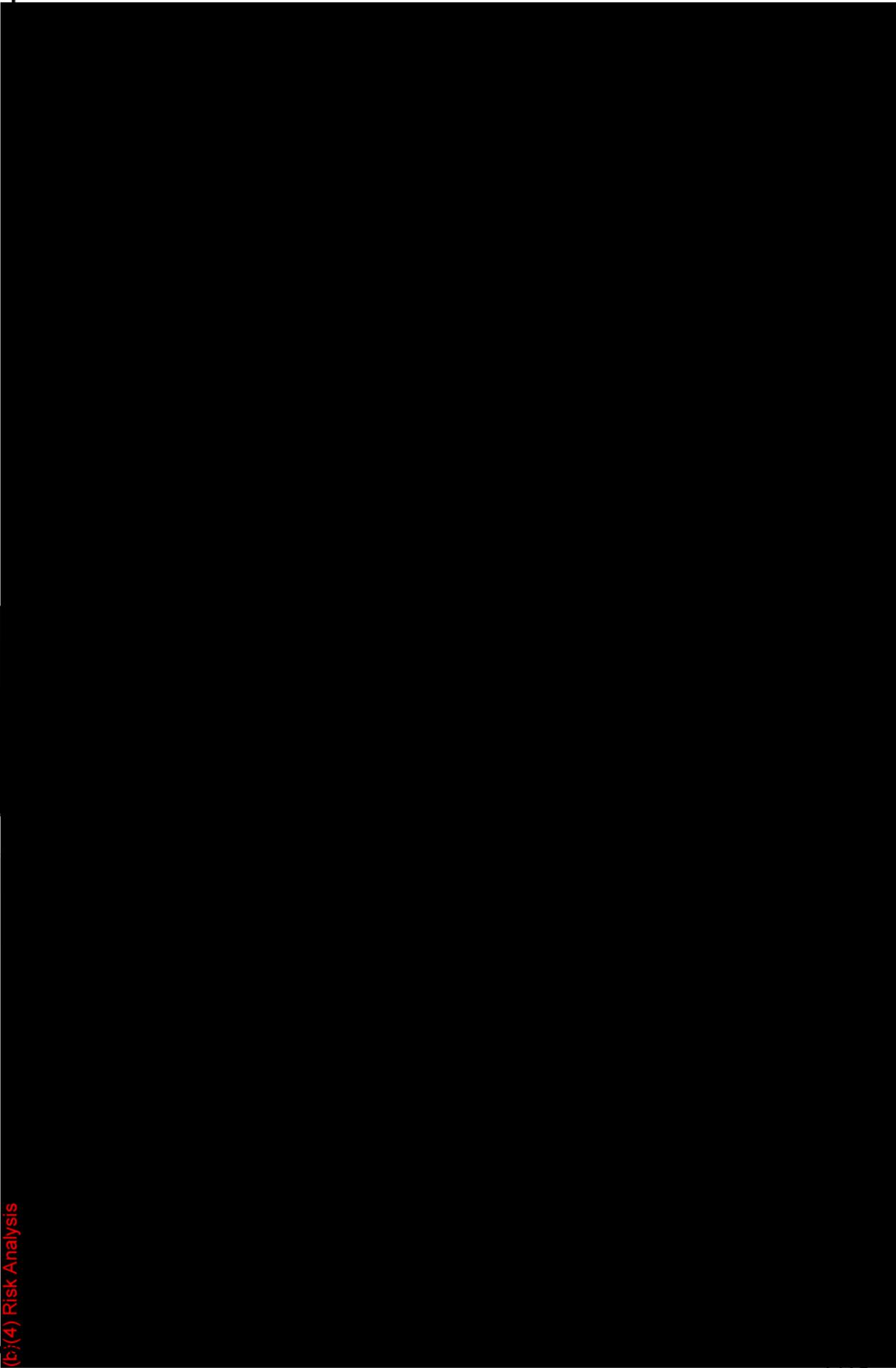
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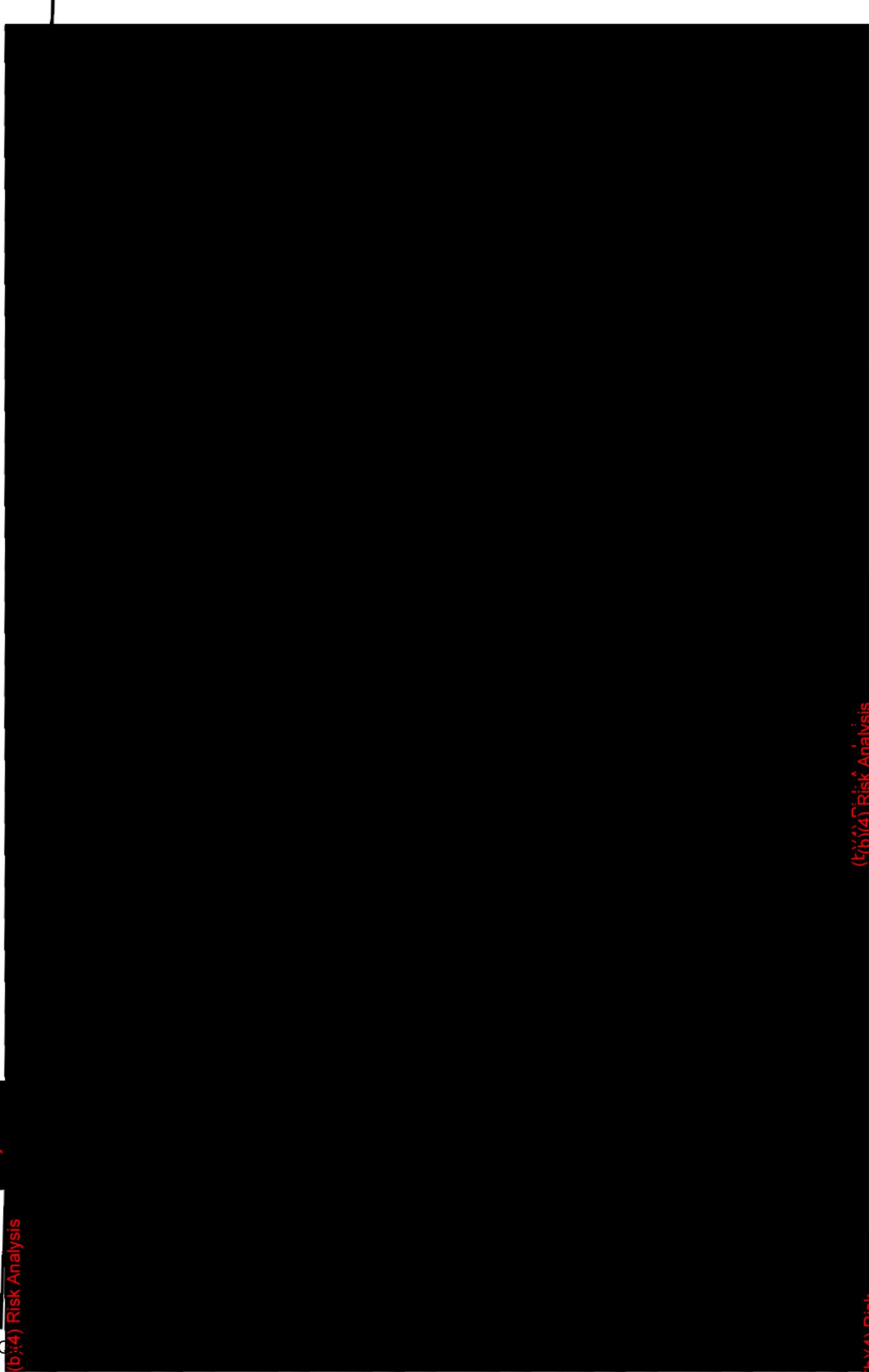
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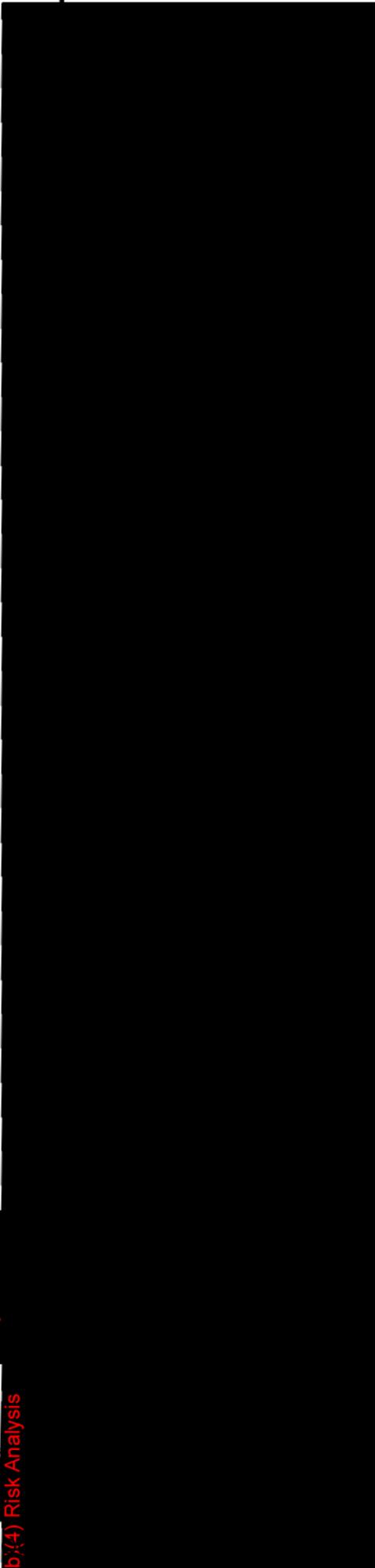
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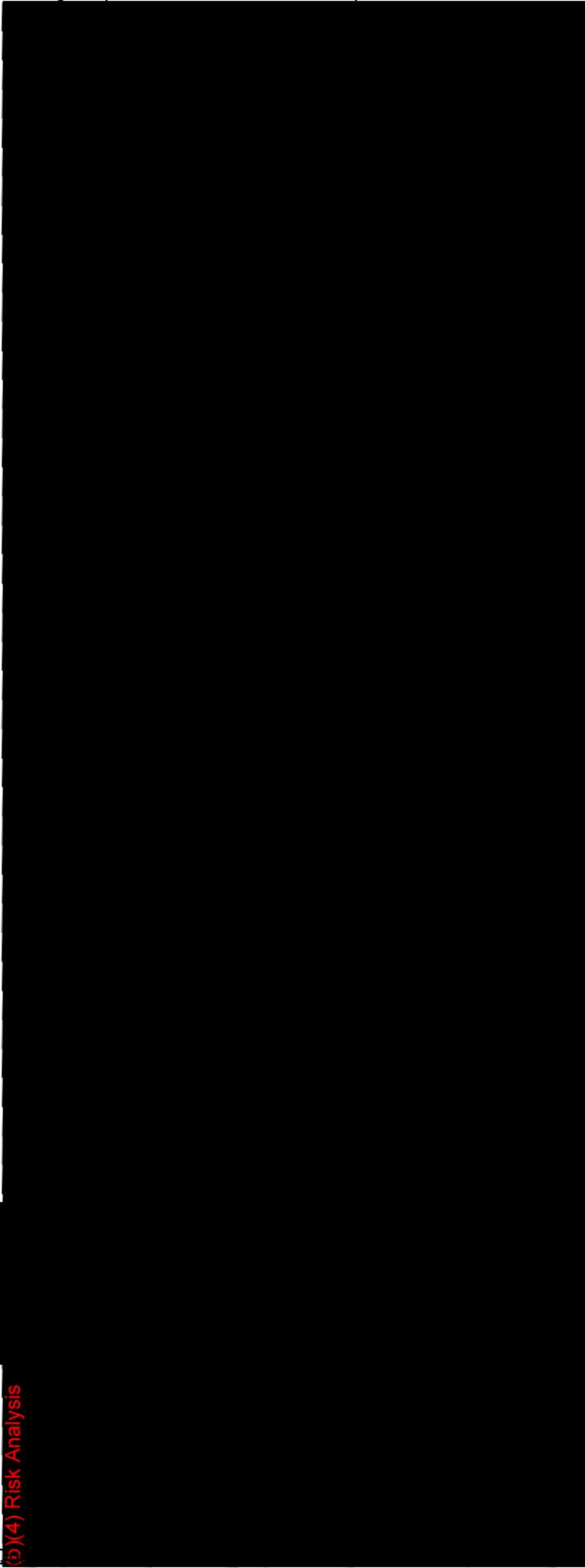
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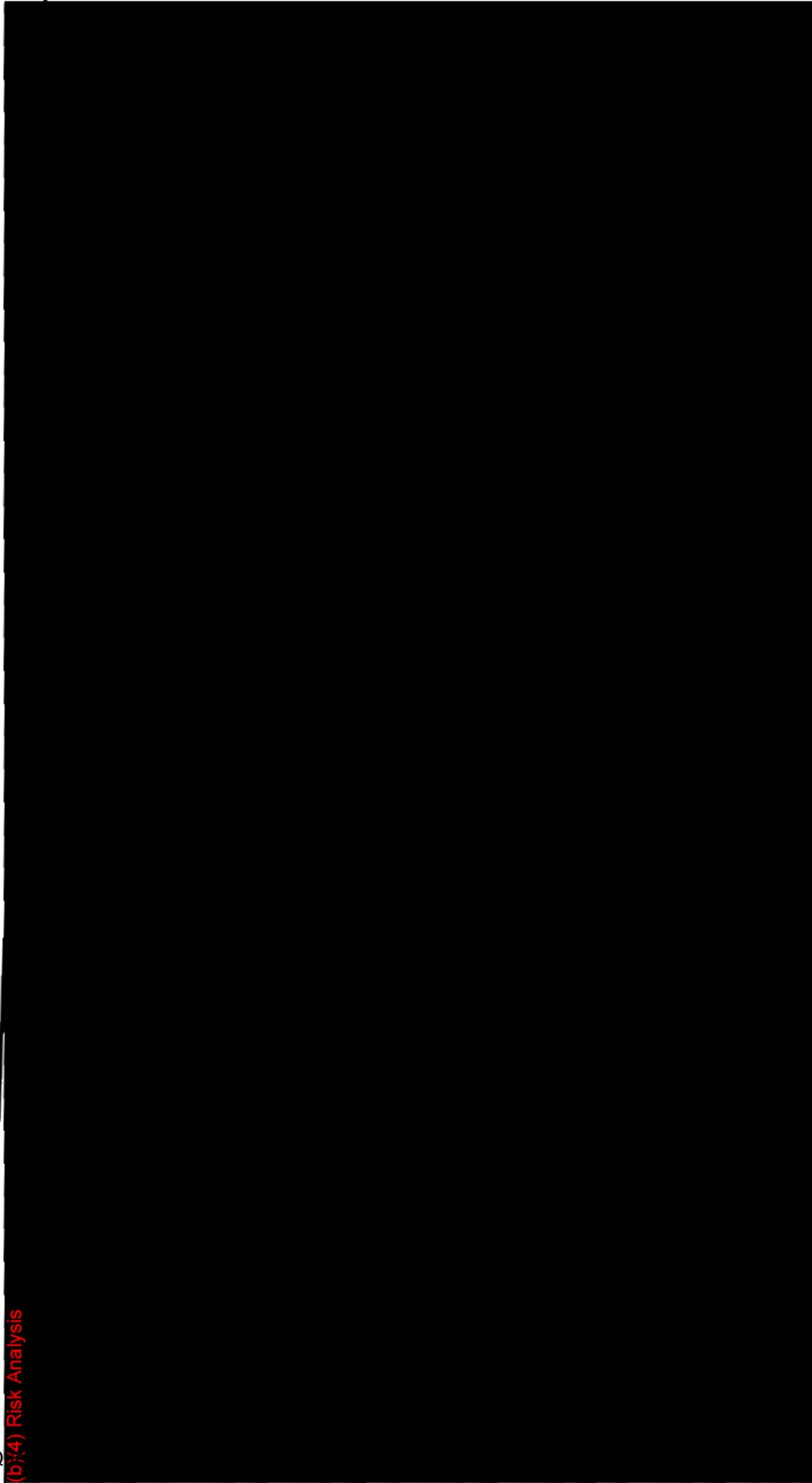
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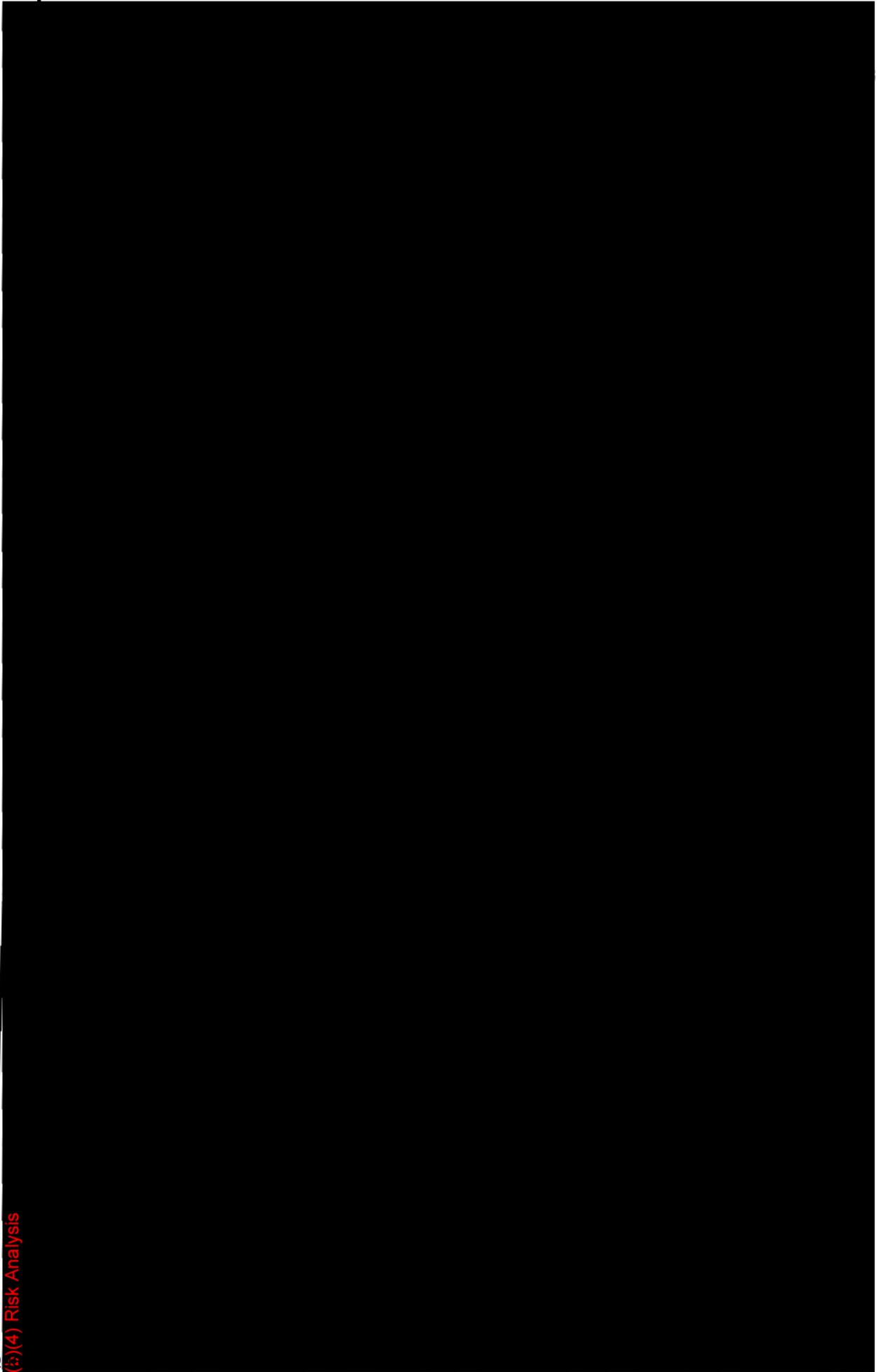
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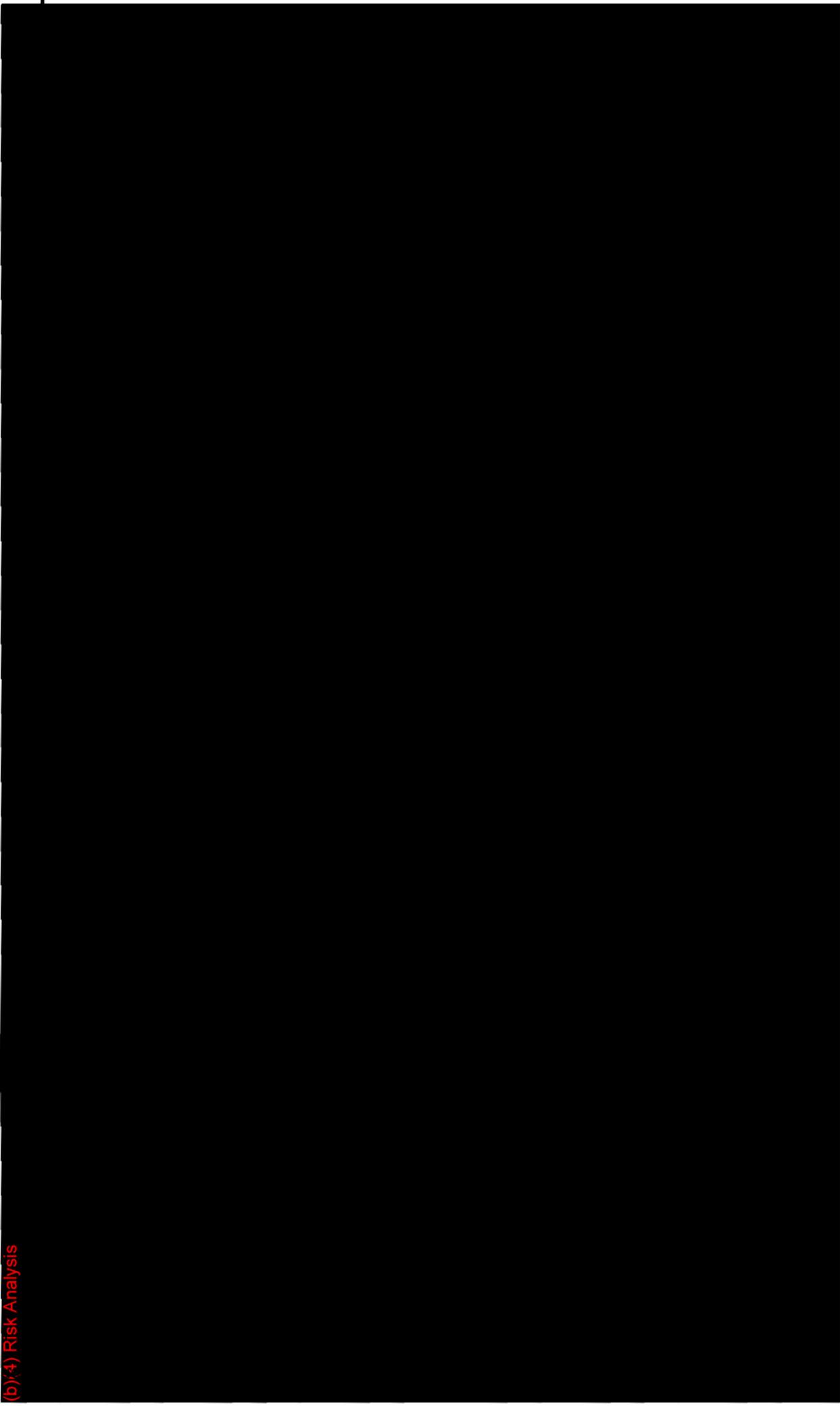
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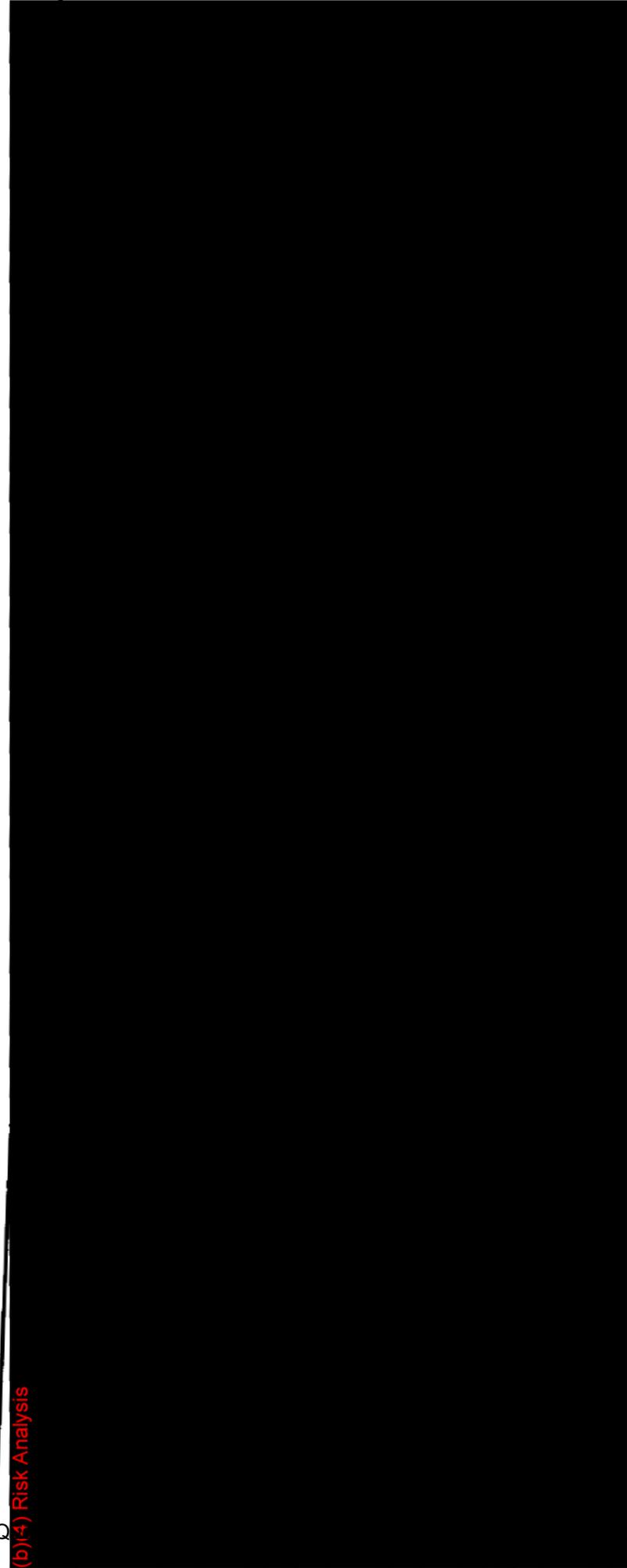
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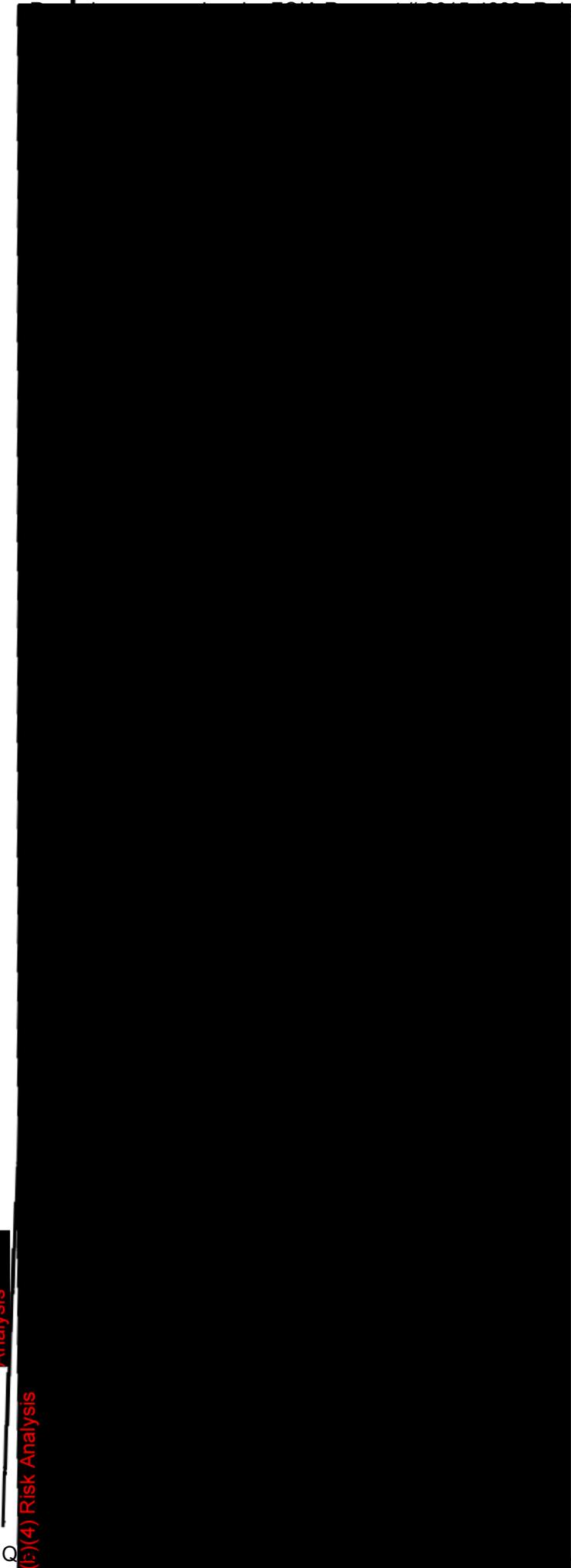
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| Date:         |            |            |            | Date:              |            |            |
| Signature:    |            |            |            | Signature:         |            |            |

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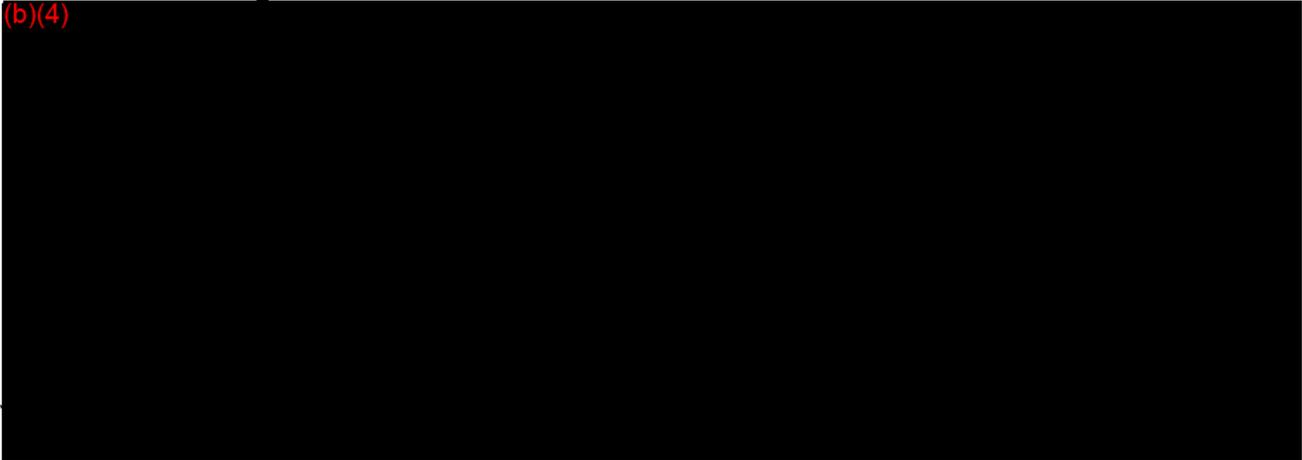
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# 1 Introduction

## 1.1 Purpose

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## 1.2 Scope

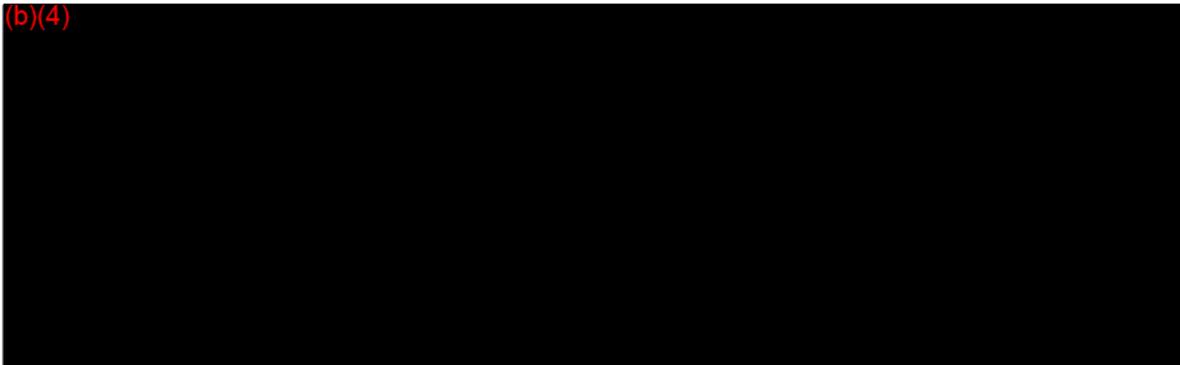
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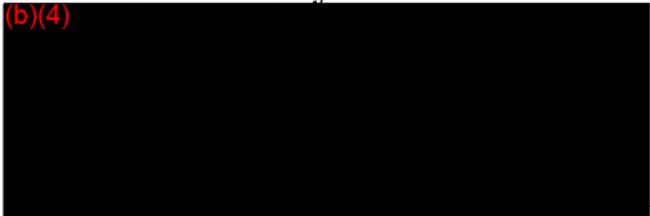
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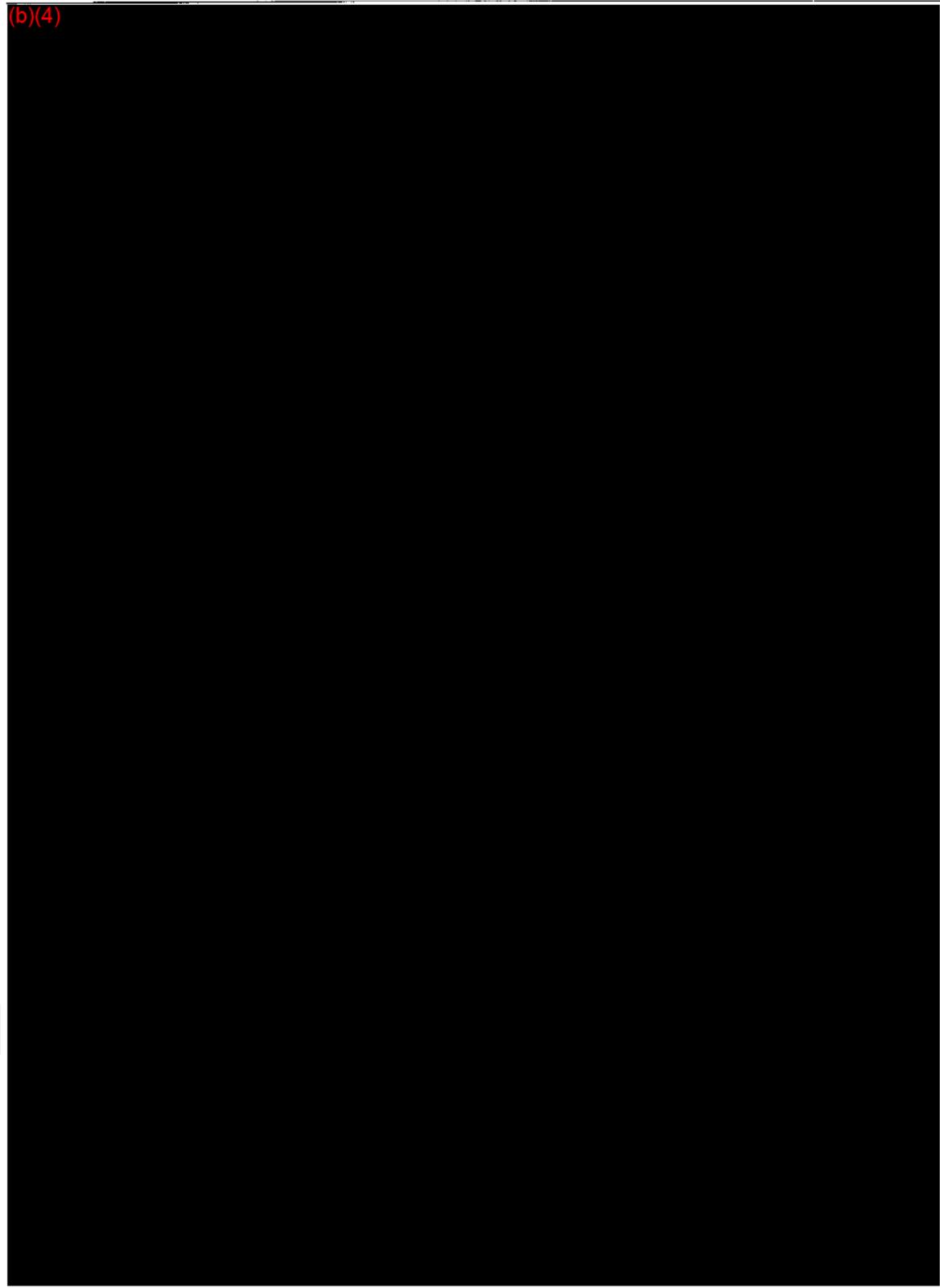
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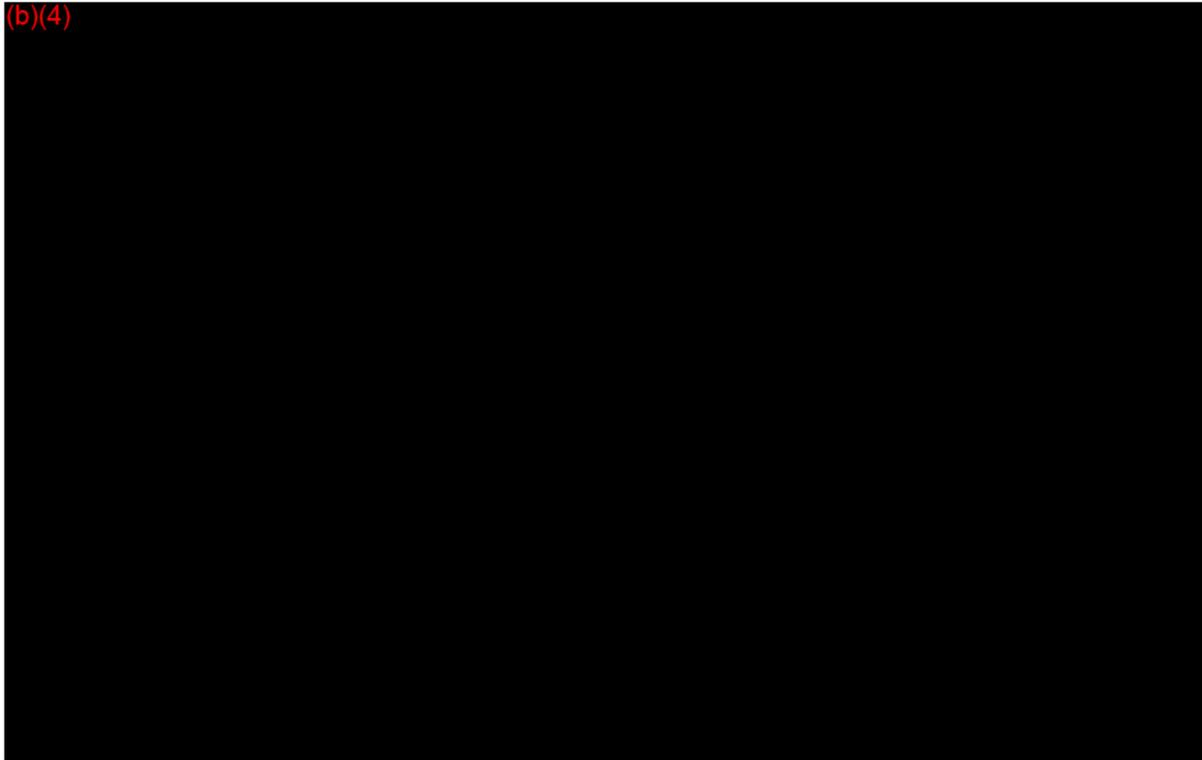


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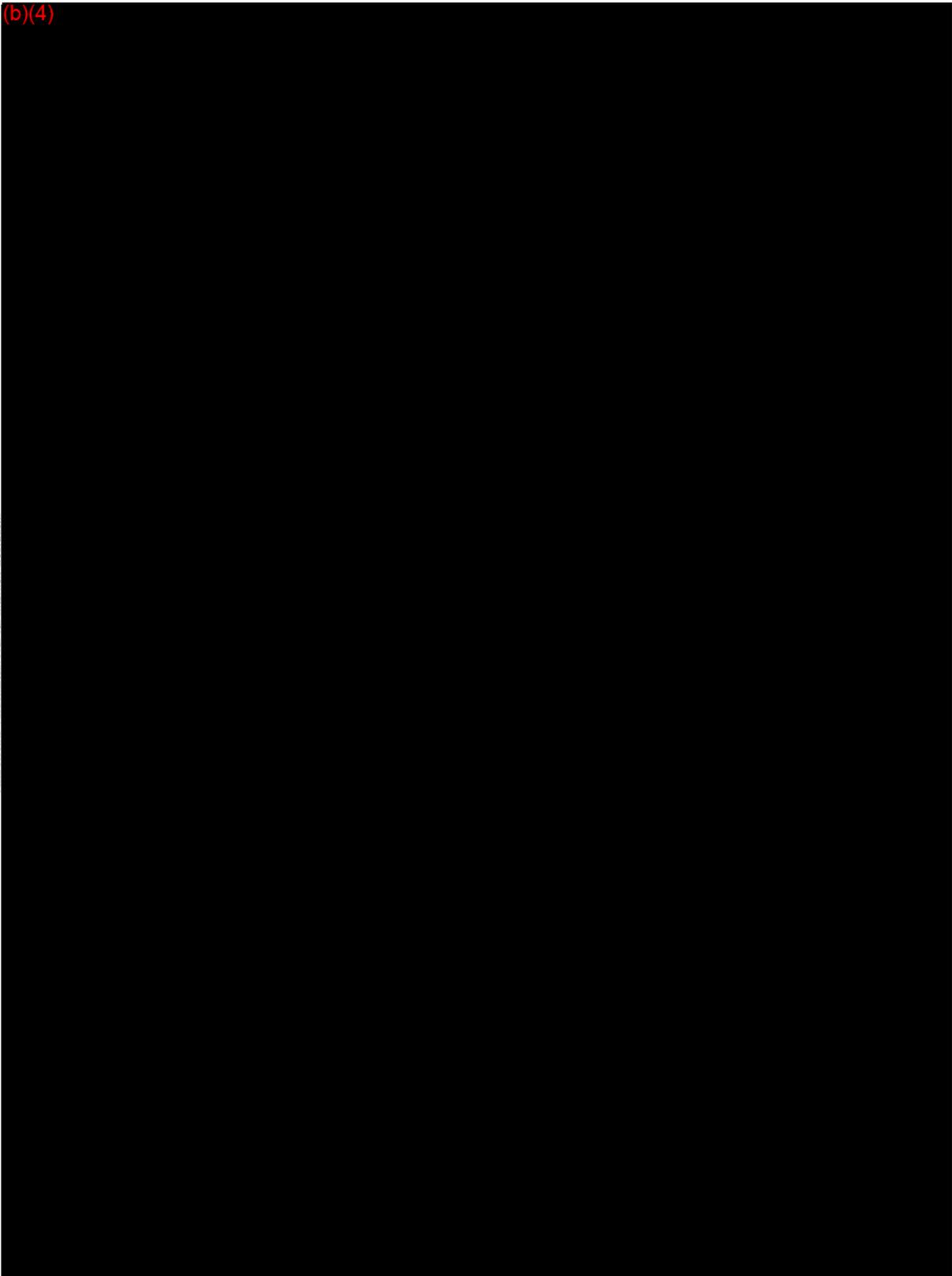
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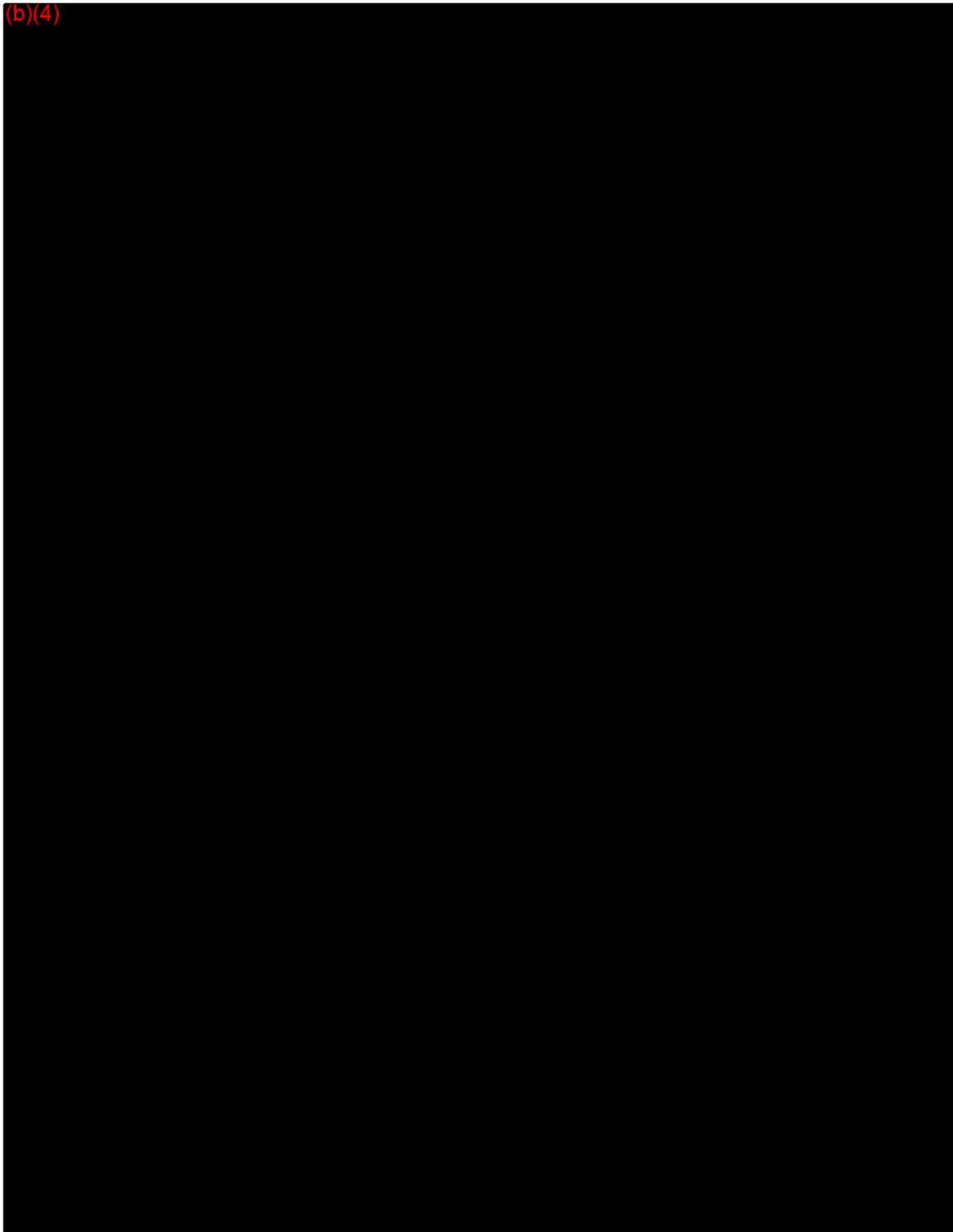
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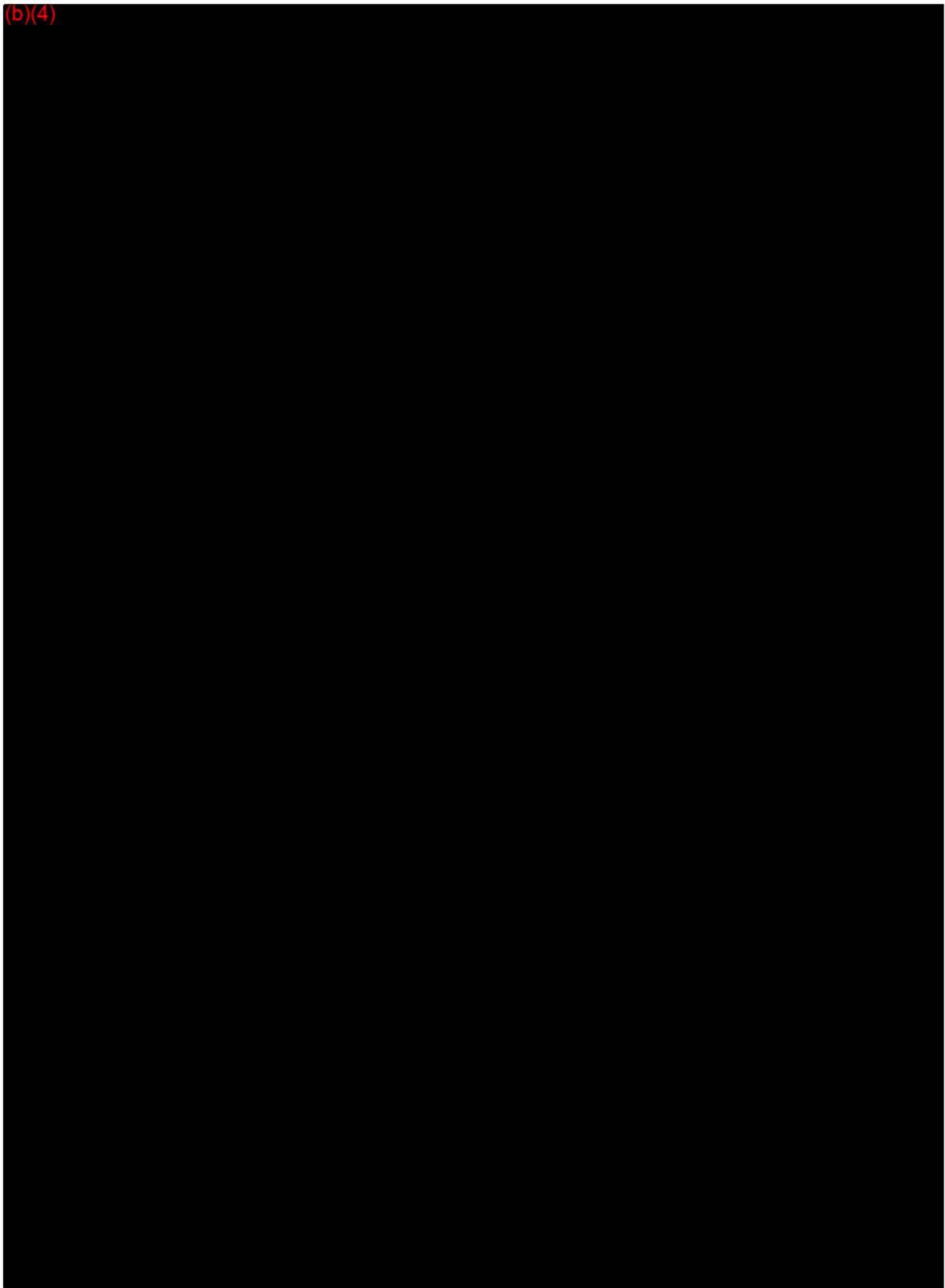
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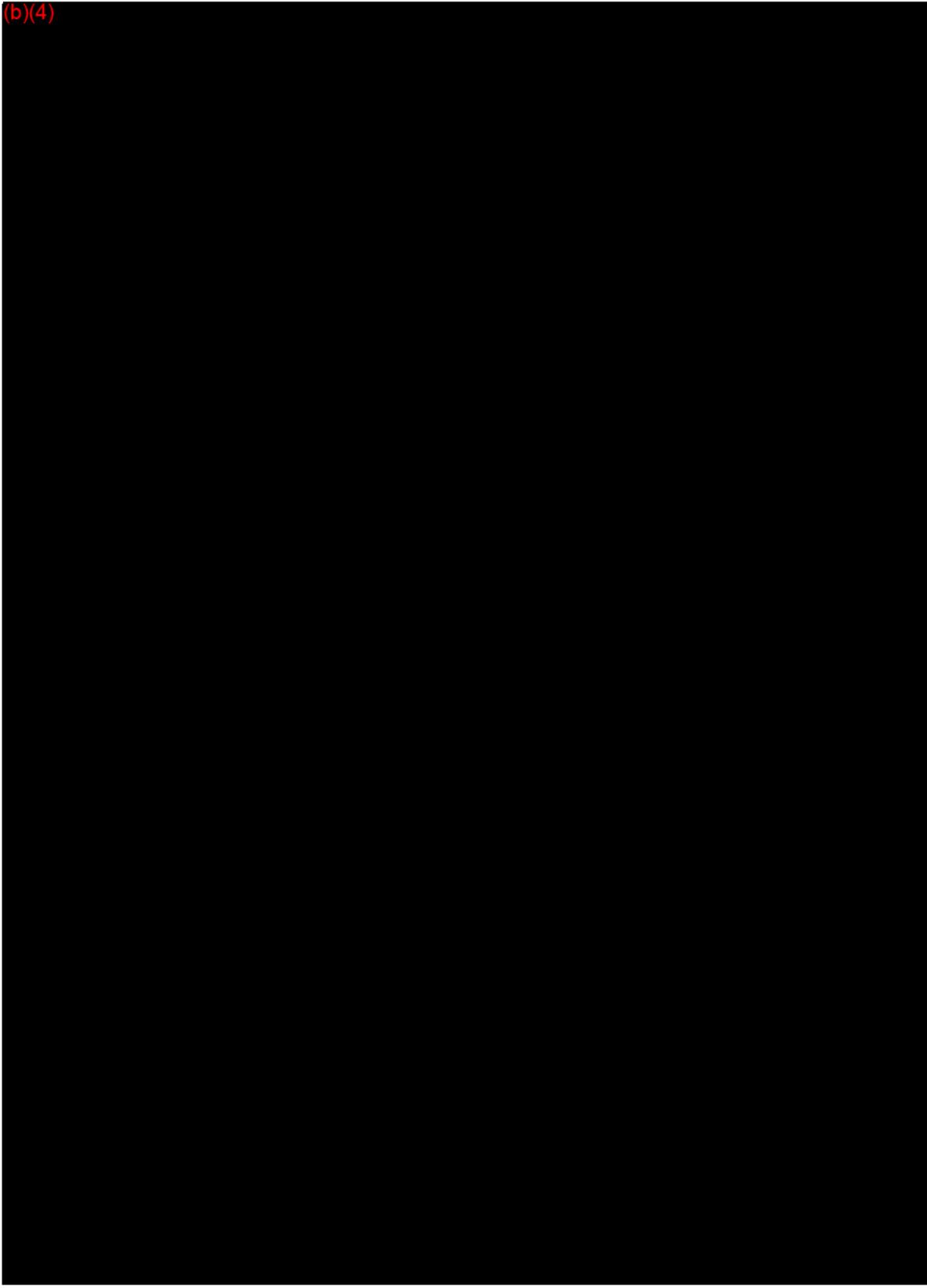


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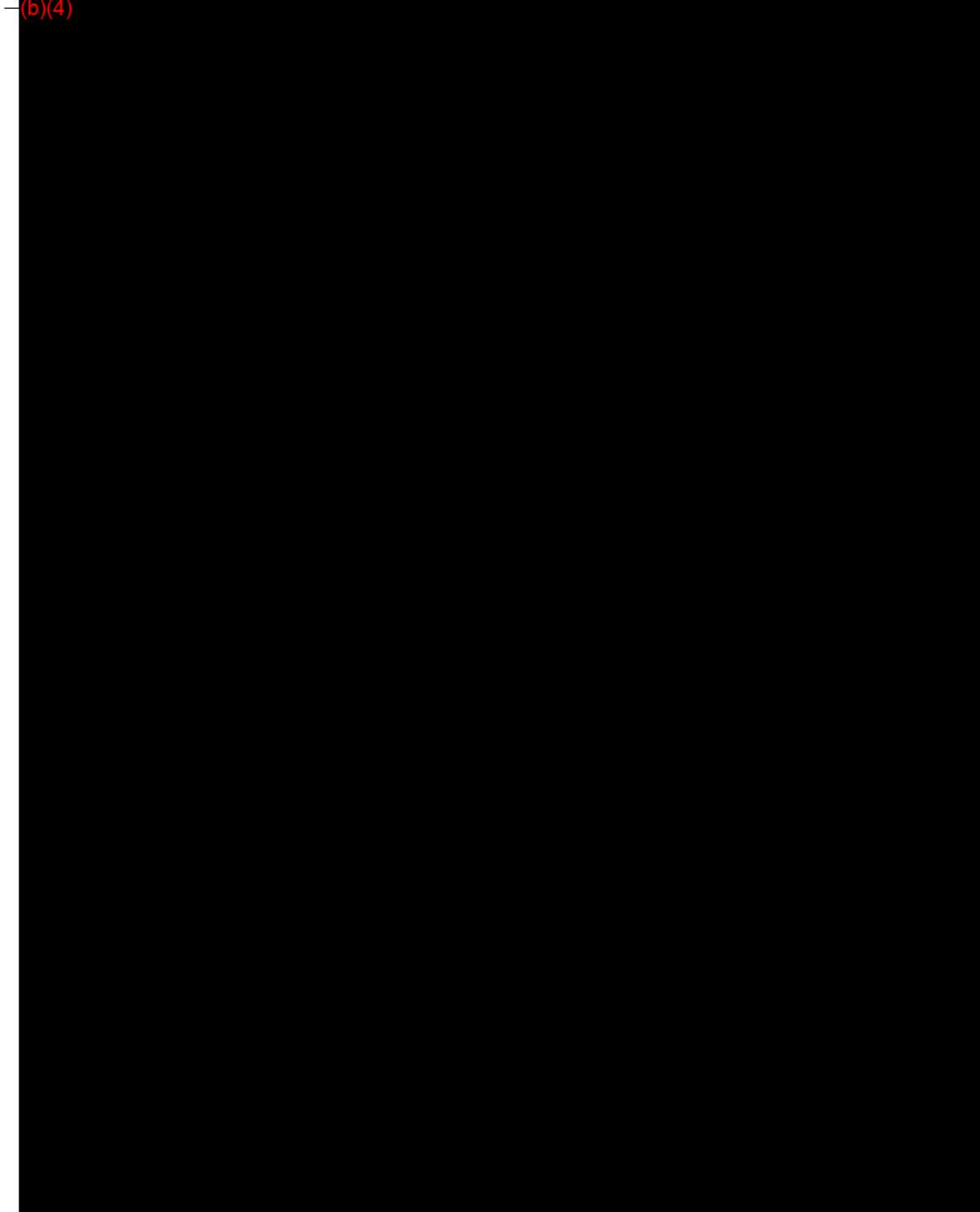
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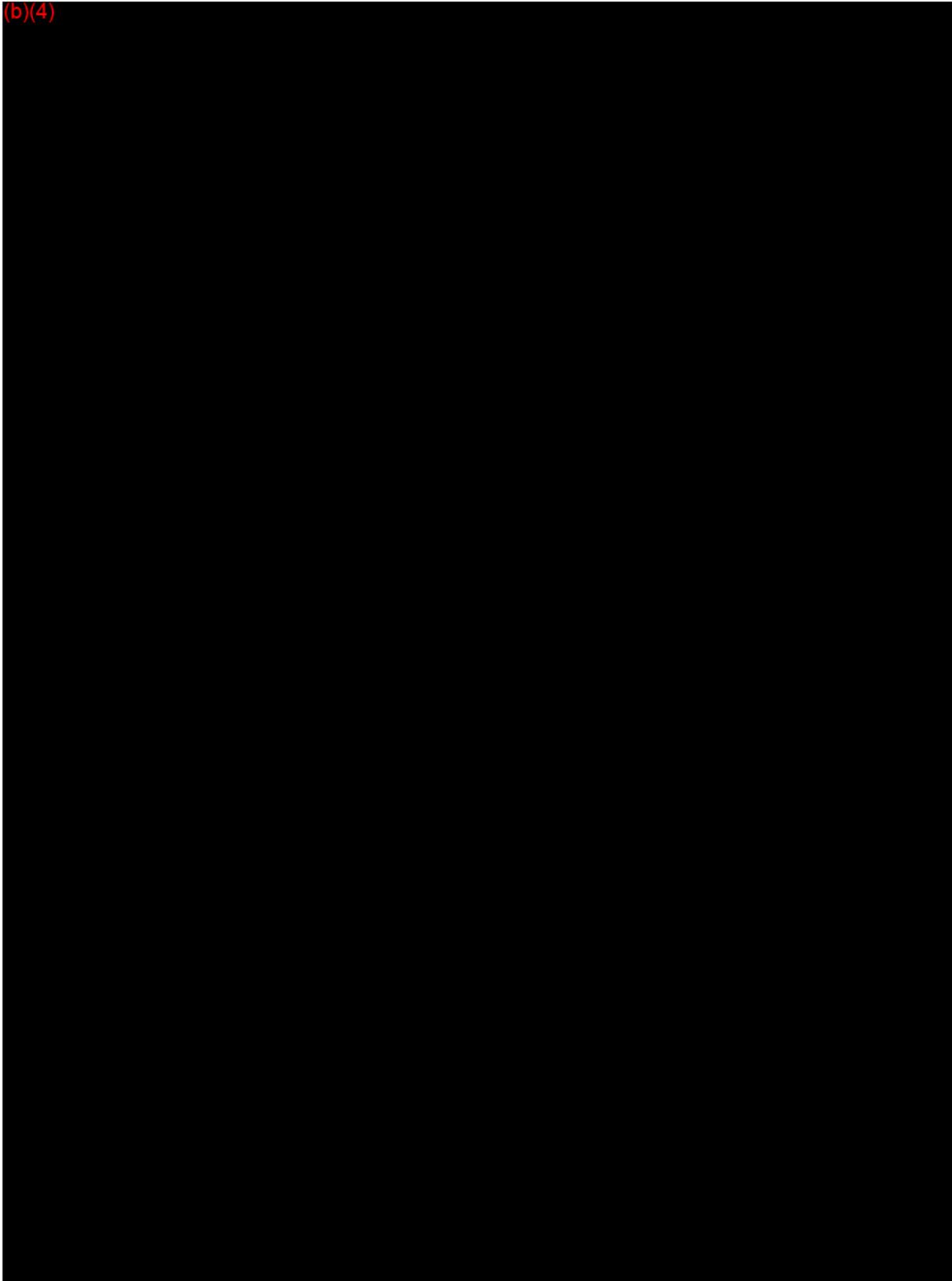
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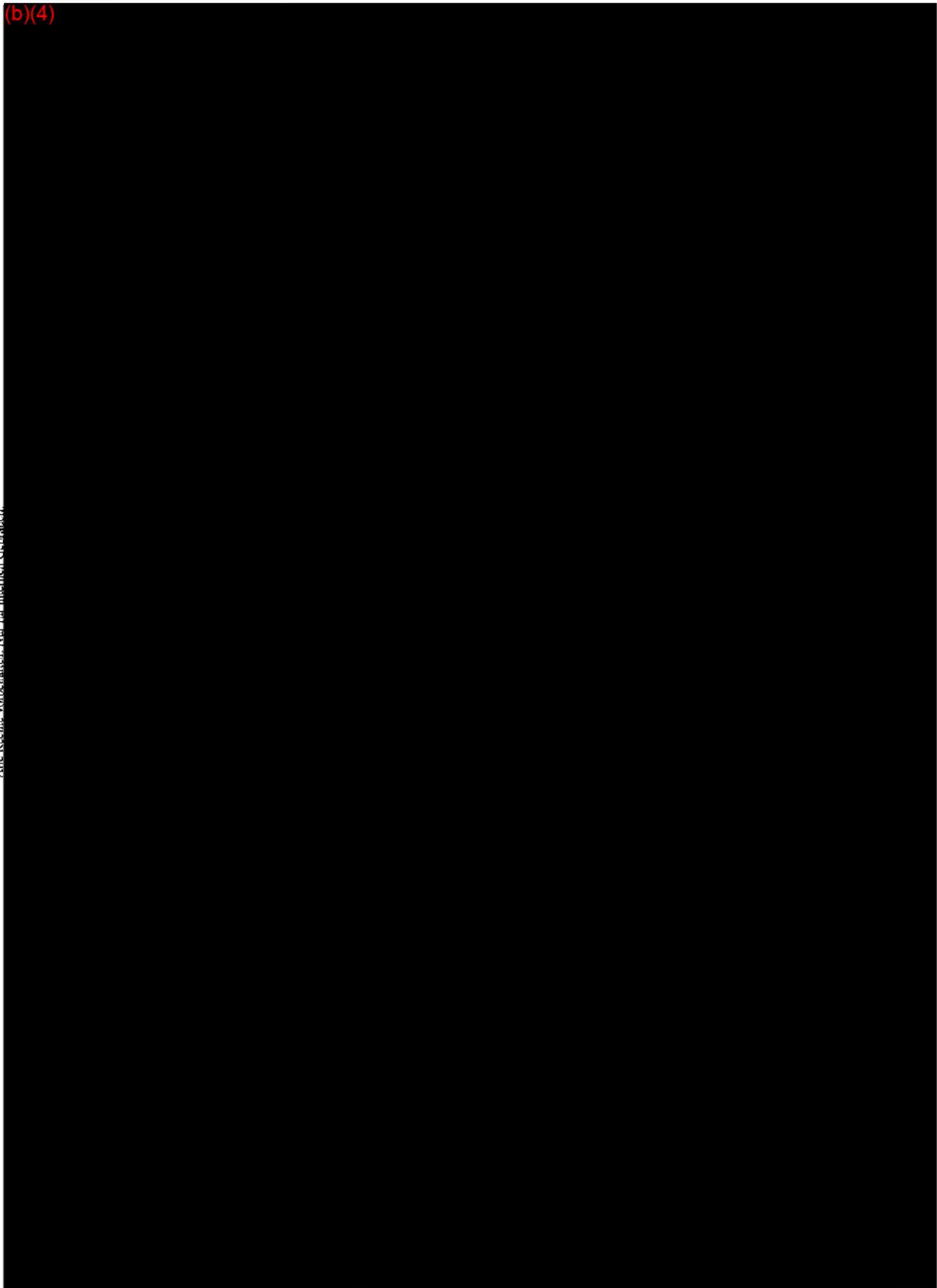
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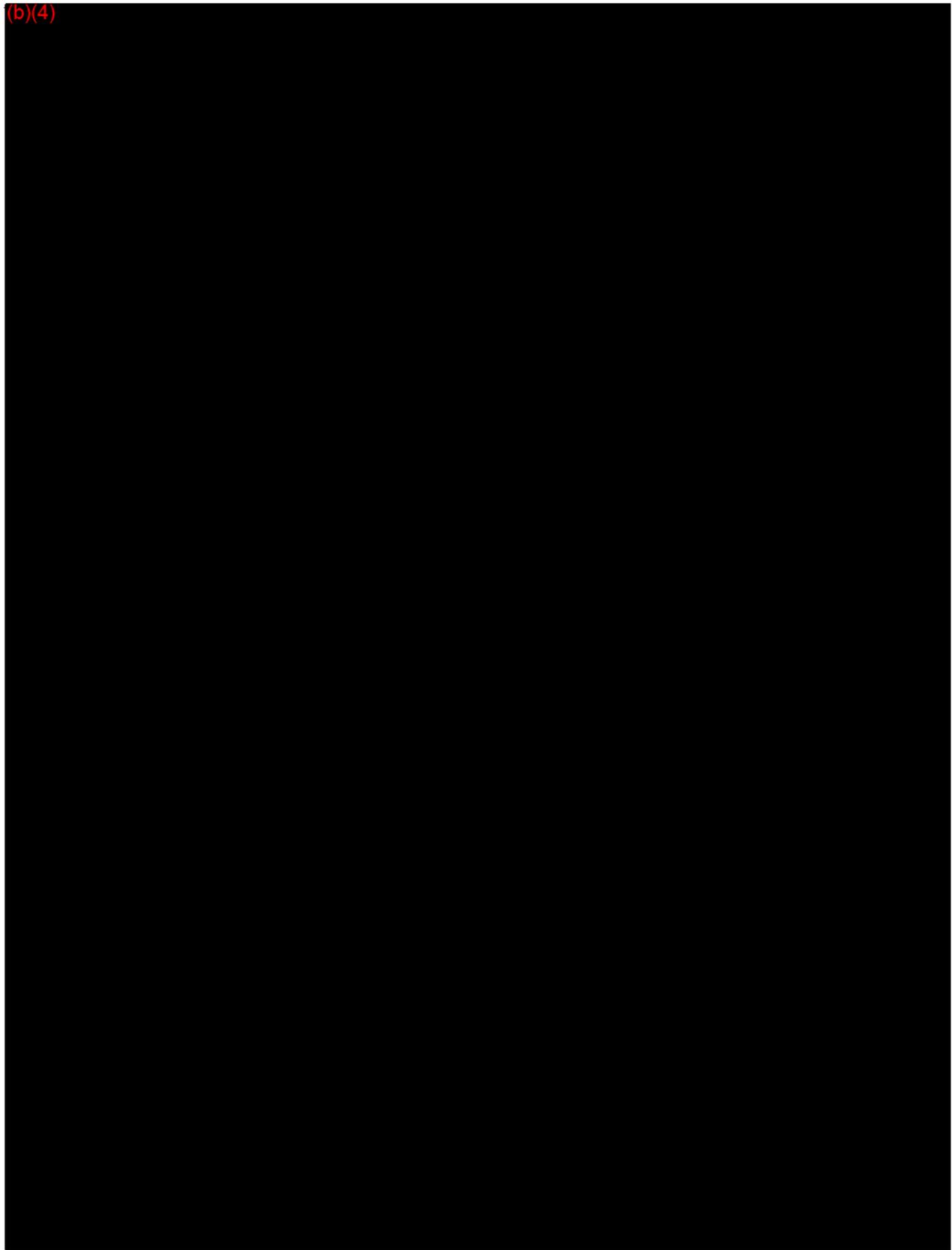
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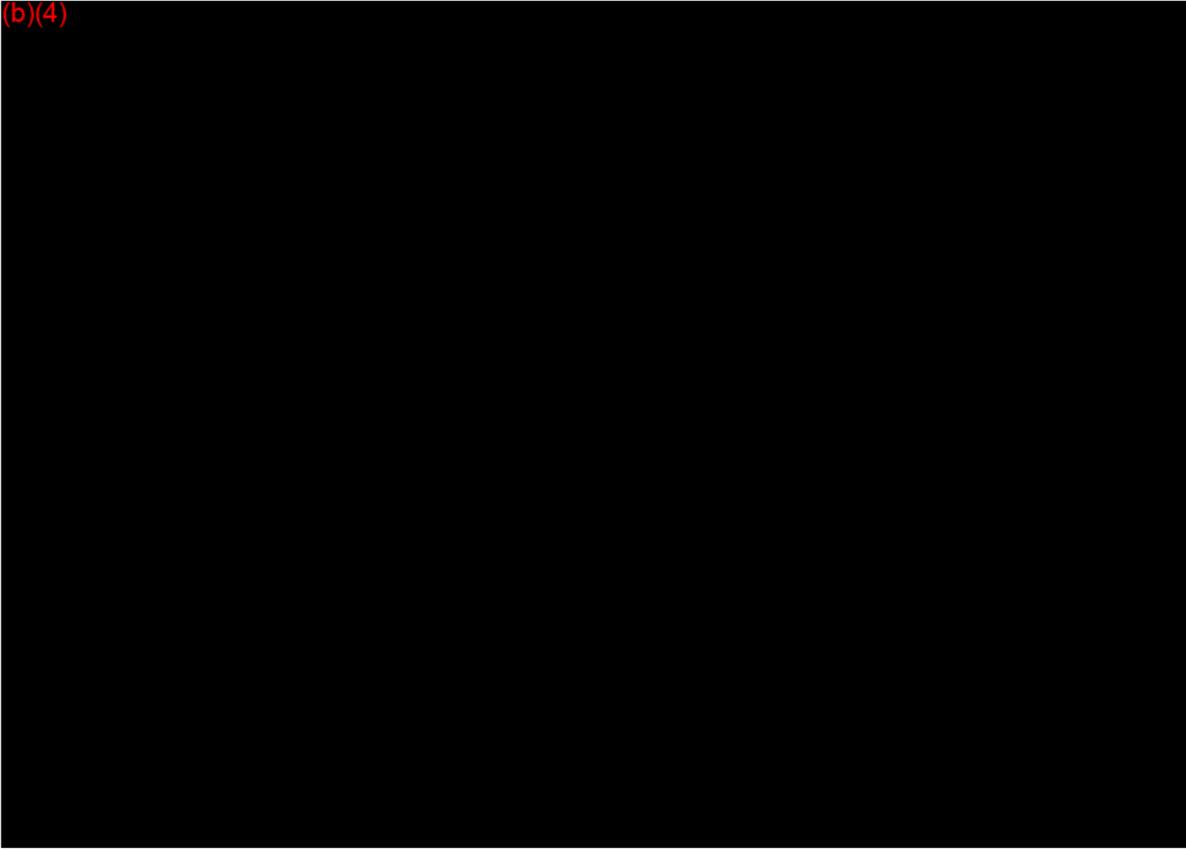
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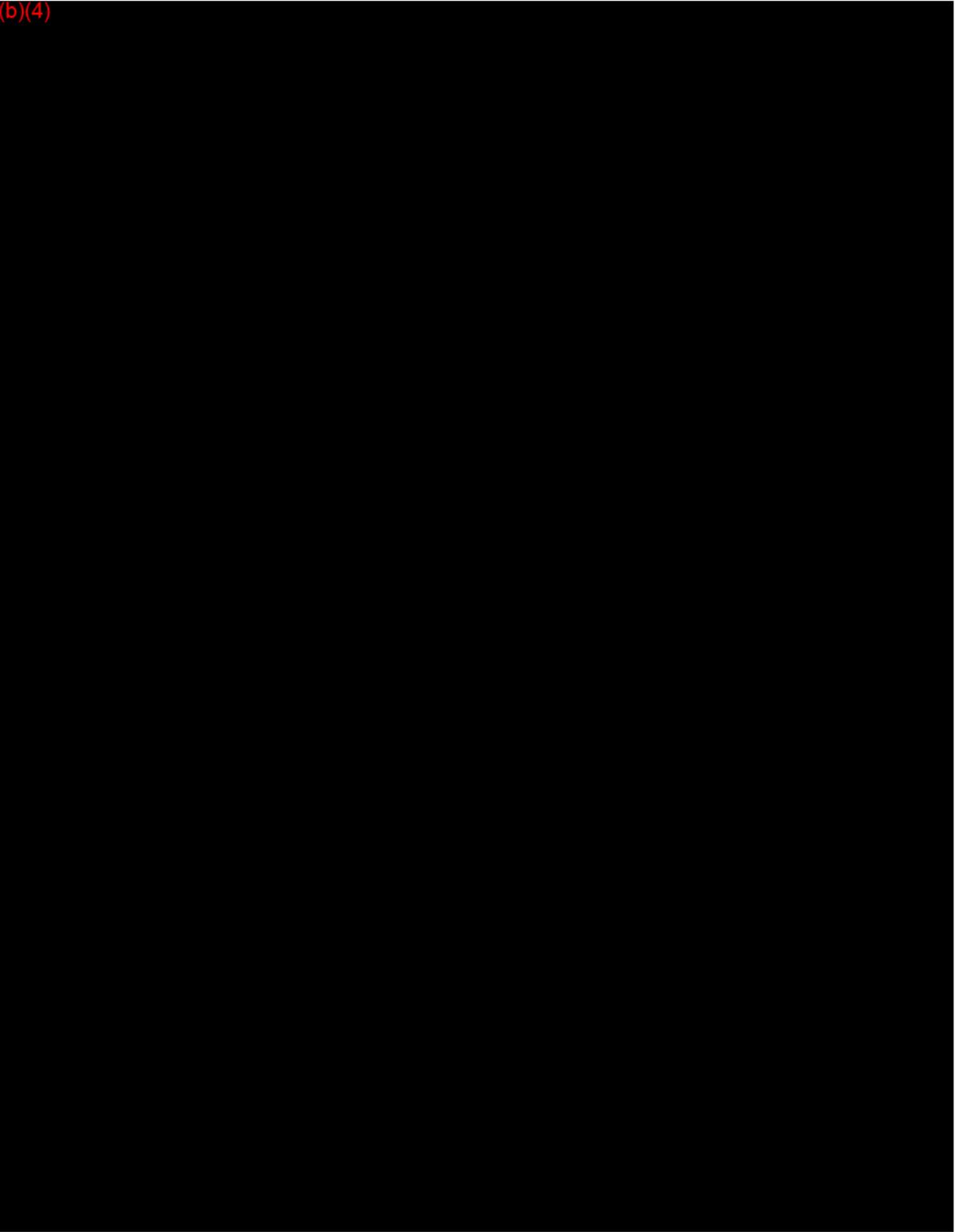
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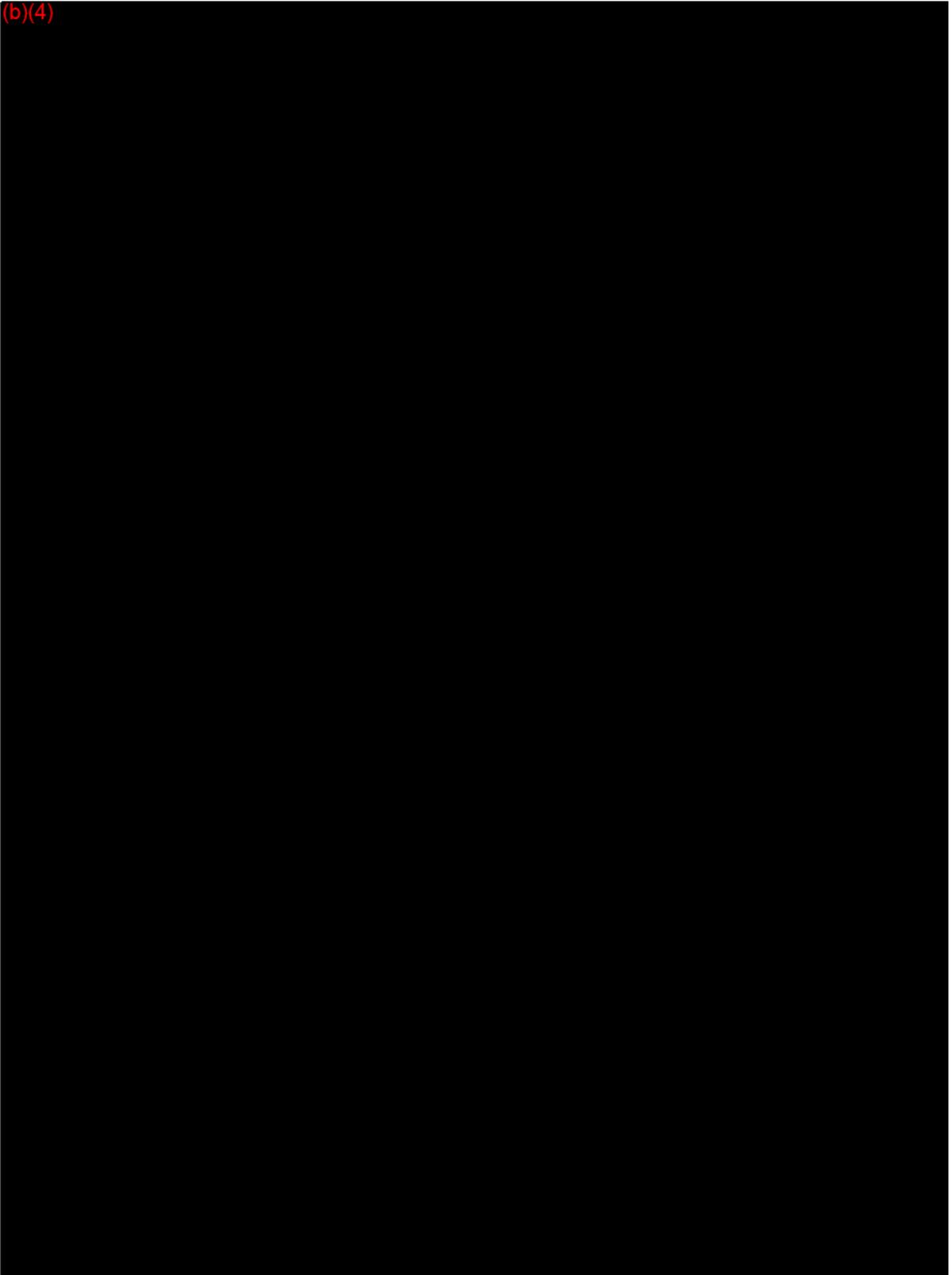
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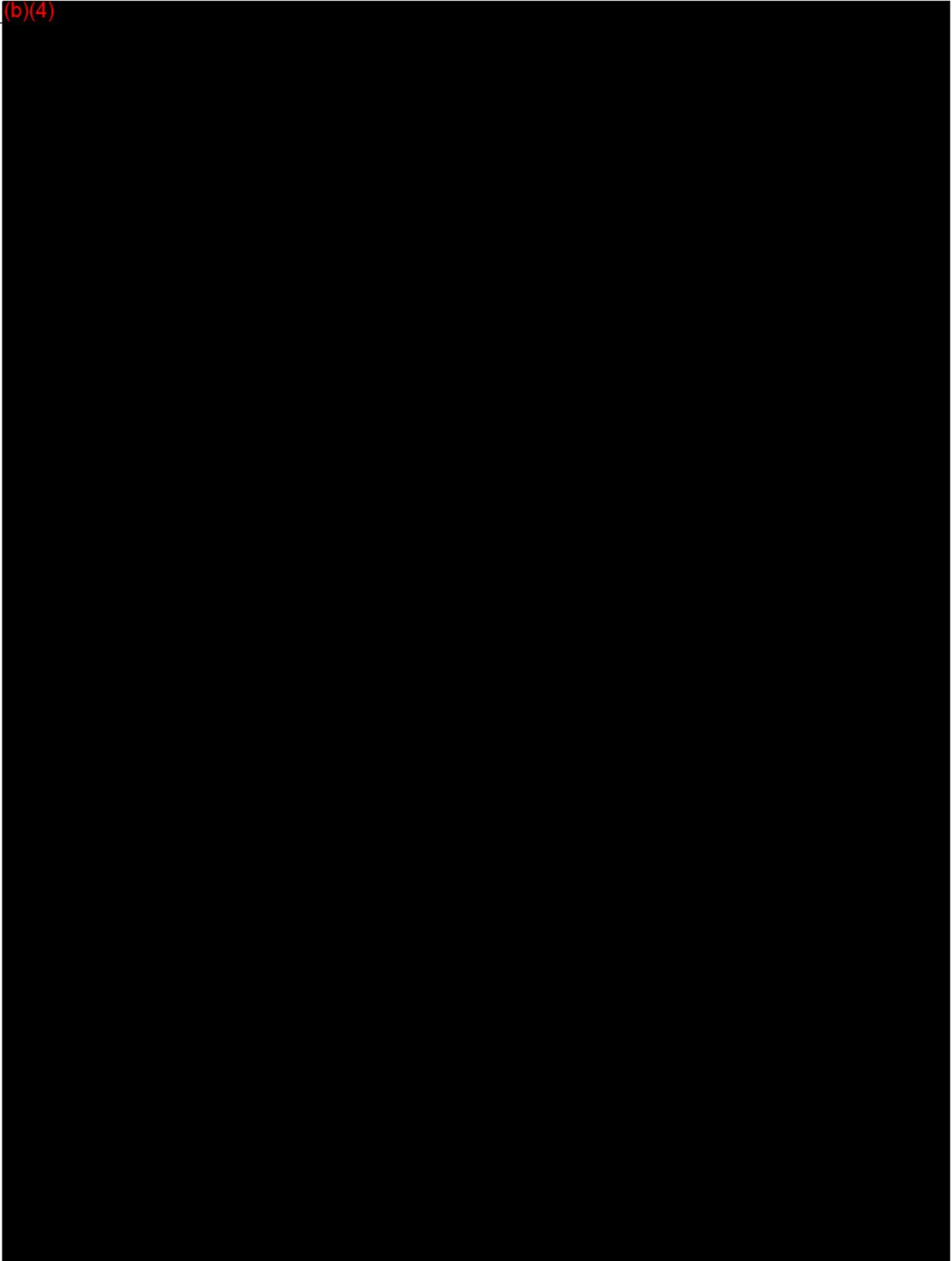


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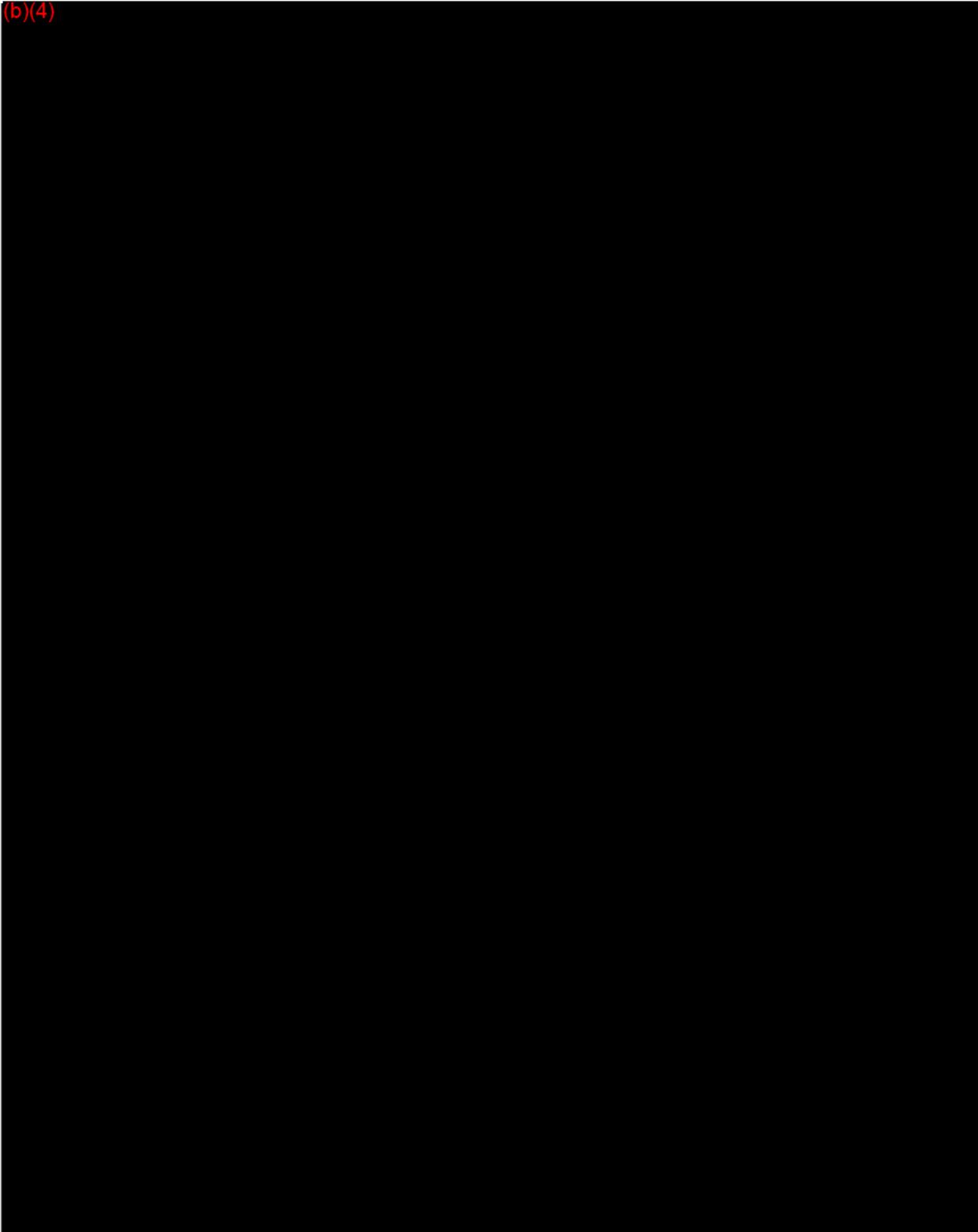
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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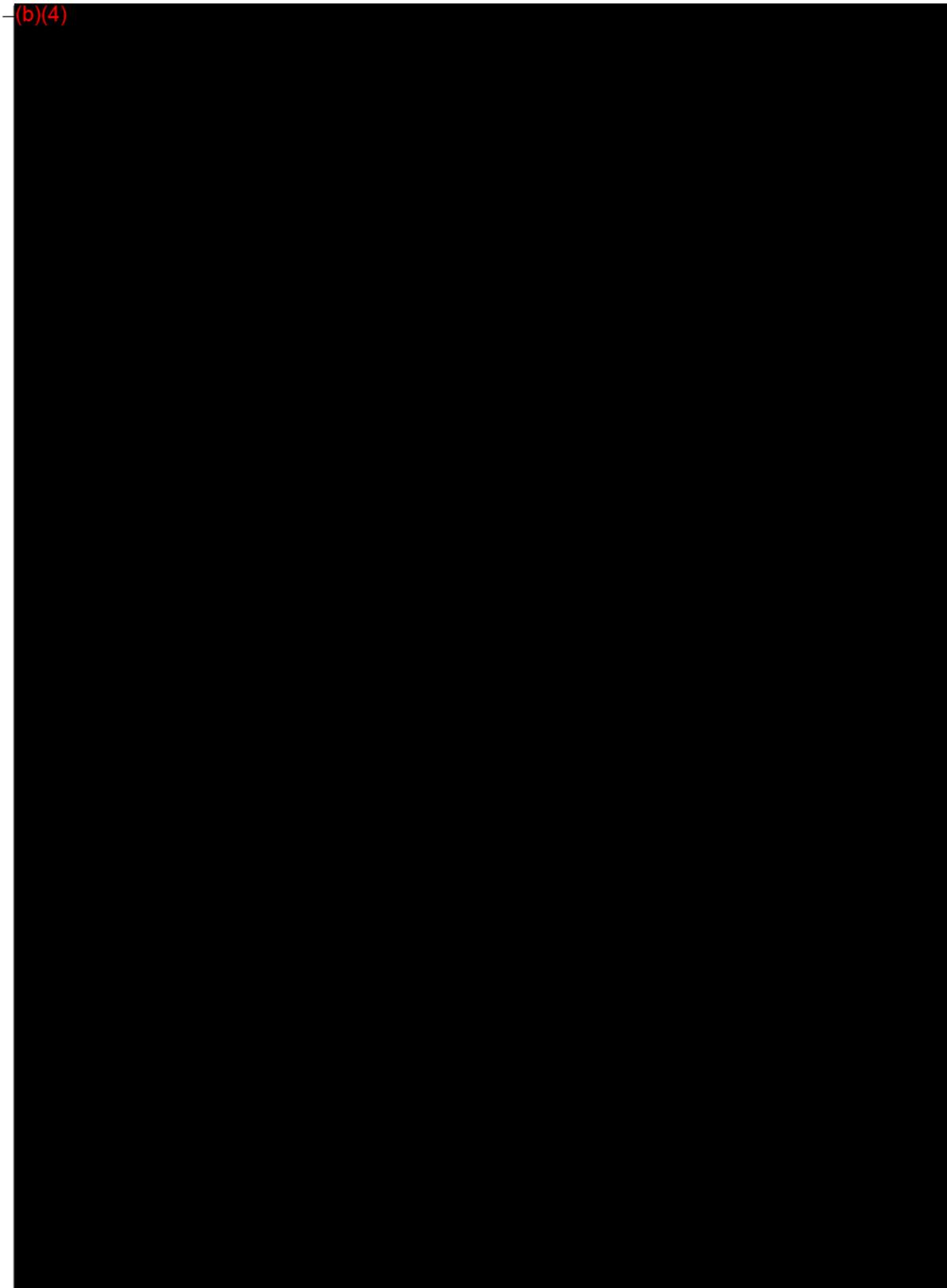
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## 6 Future Issues

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## 7 Open Issues

none

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## 2 Risk Management

### 2.1 Risk Management Plan / Scope

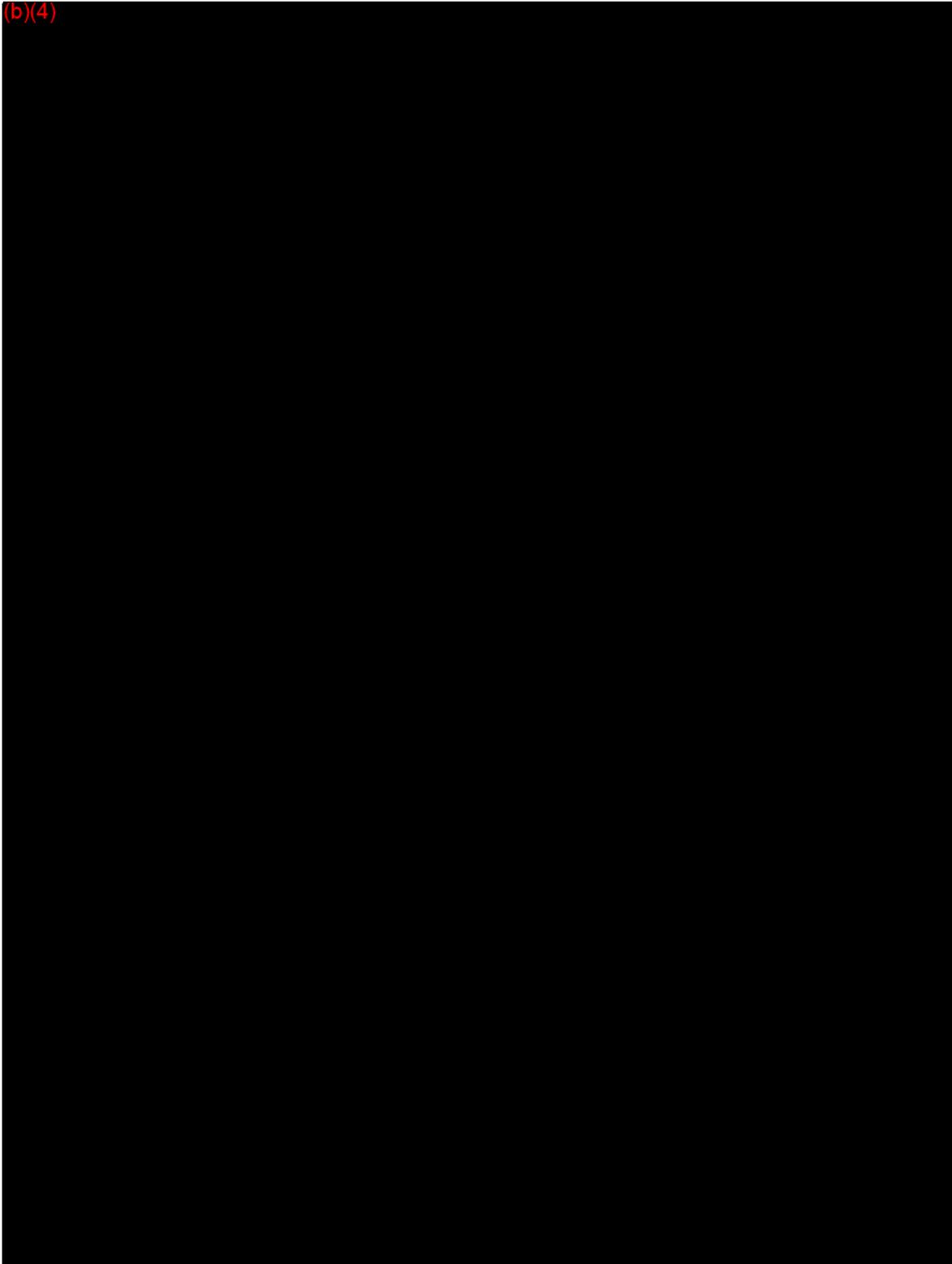
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#### 2.1.1 Responsibilities / Risk Management Team

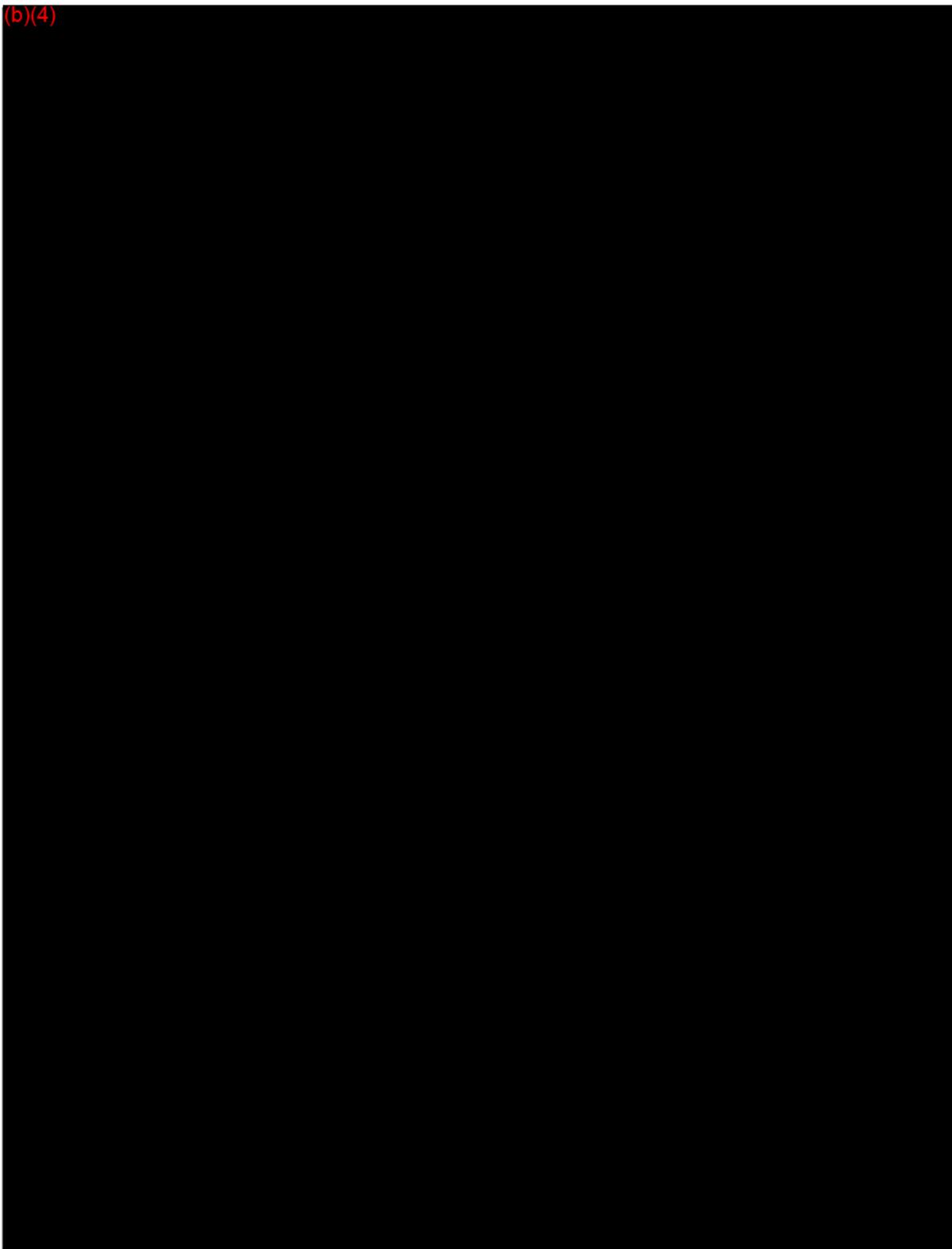
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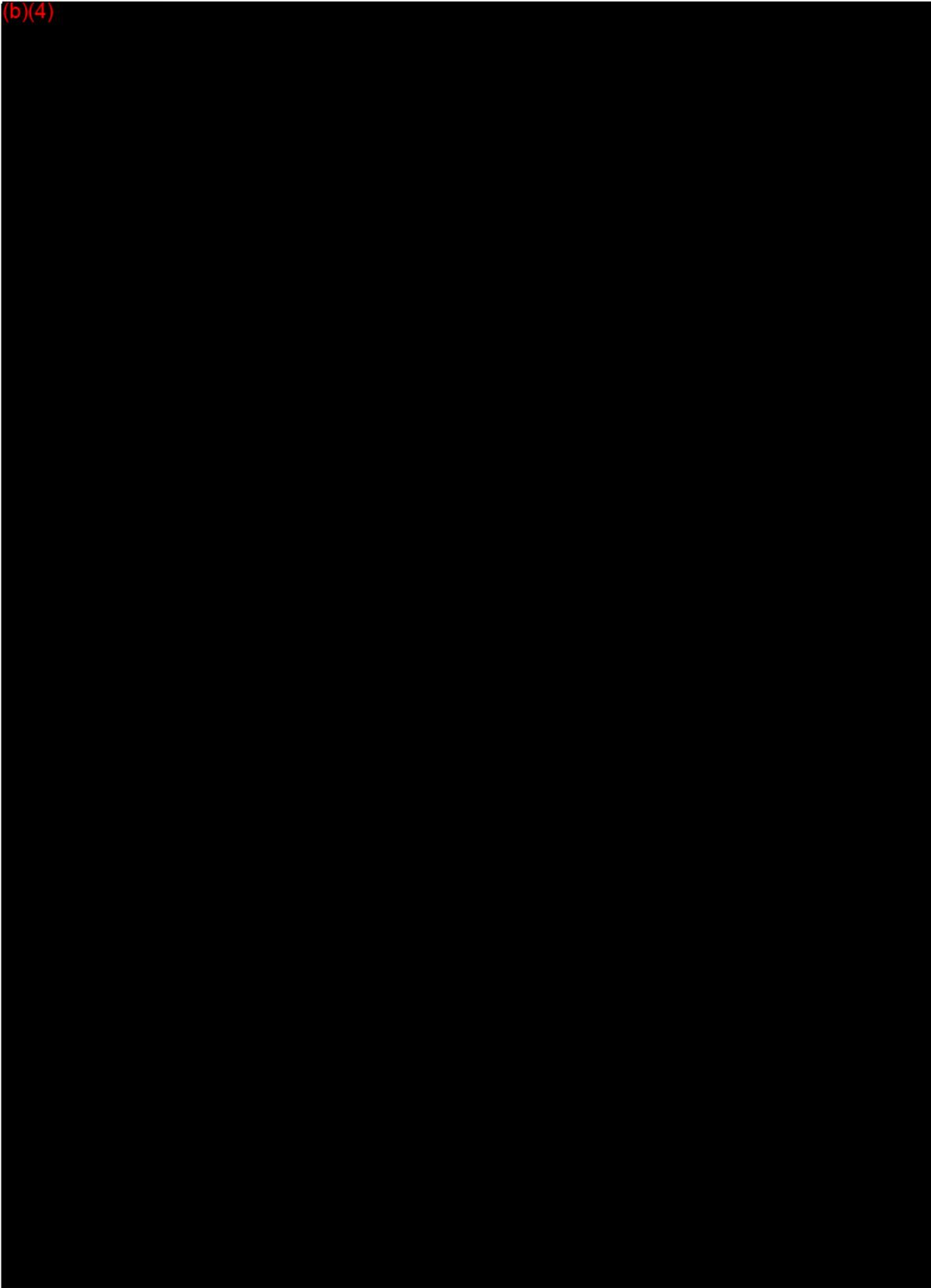
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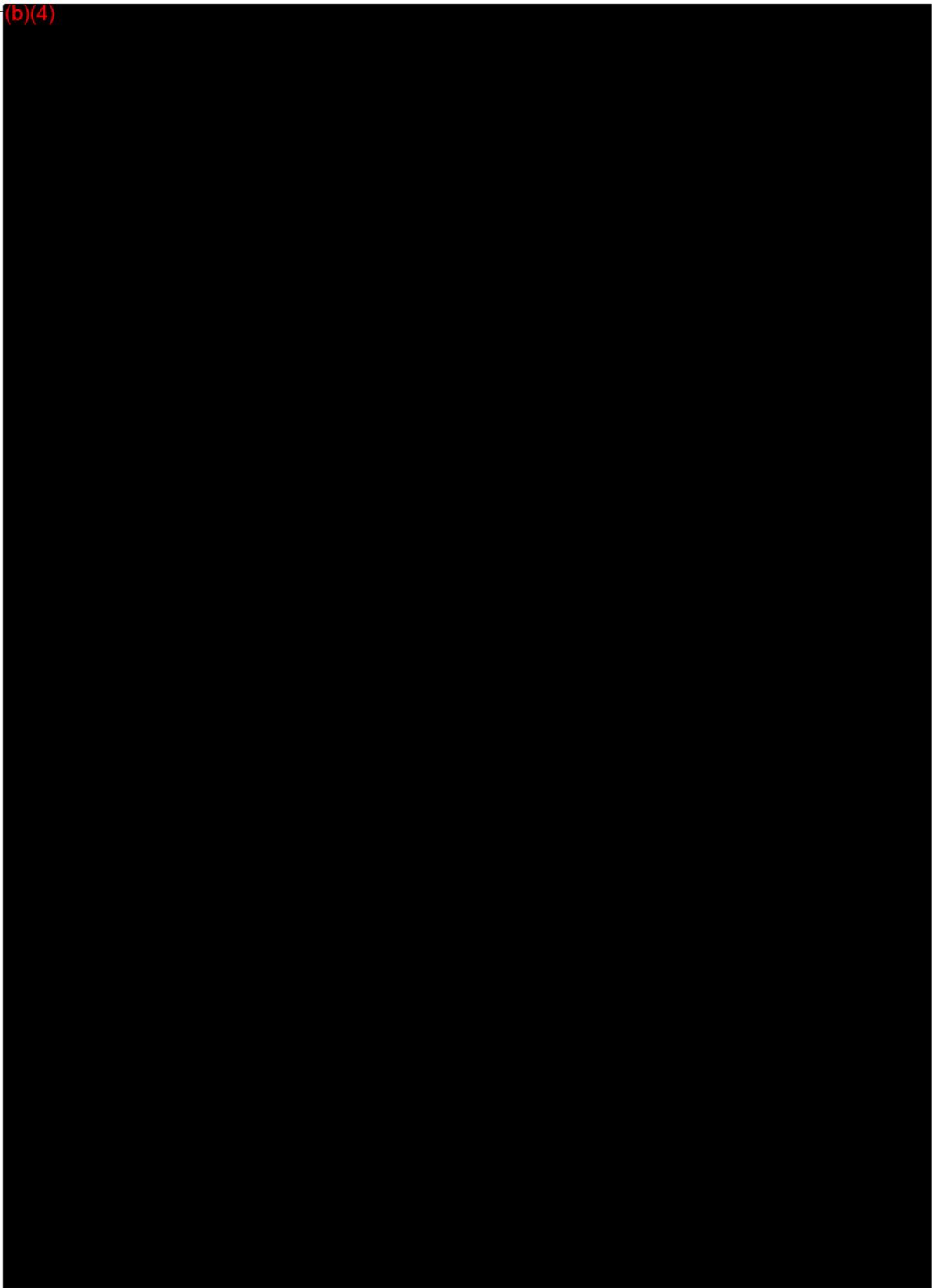
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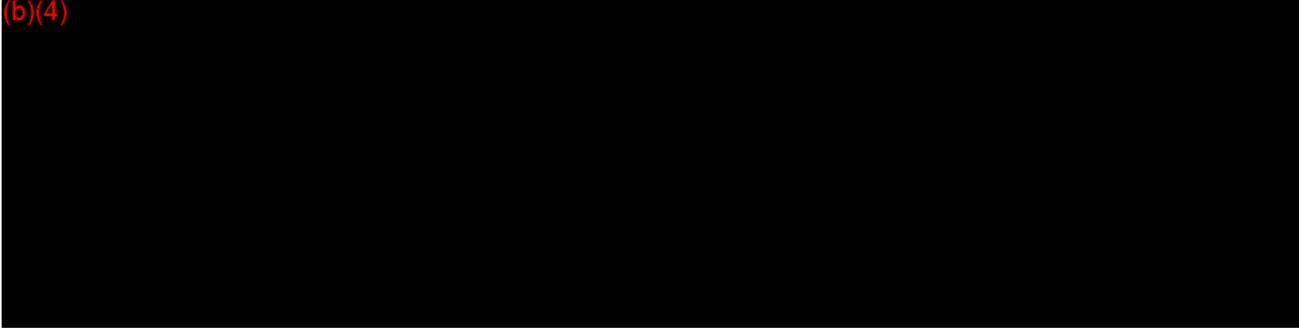
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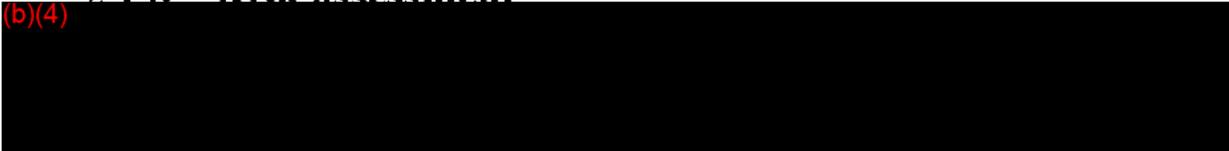
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## 2.1.8 Risk assessment

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**Test Specification**  
**(contains safety relevant test cases)**

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| [Redacted]        | [Redacted] | [Redacted] | [Redacted]         | [Redacted]  | [Redacted] |
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# History

## Document History

| Version    | Date of Issue | Author | Change & Reason of Change/<br>Change Request/CHARM  |
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| V (b)<br>b | 27-Jan-2003   | (b)(6) | Incorporation of review comments<br>Review Participants :<br>(b)(6) (b)(4)<br>(b)(6) (b)(4)<br>(b)(6) (b)(4) (b)<br>Released for (b)(4) b<br>and following versions |
| V (b)      | 21-Feb-2003   | (b)(6) | (b)(4)<br>(b)(4)<br>(b)(4)<br>(b)(4)  |
| V (b)      | 25-Feb-2003   | (b)(6) | Incorporation of review comments<br>Review Participants :<br>(b)(6) (b)(4)<br>(b)(6) (b)(4)<br>Released for (b)(4)<br>and following versions                        |

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## History of released Versions

| Version | Release Date | Product Version |
|---------|--------------|-----------------|
| V (b)   | 27-Jan-2003  | (b)(4)          |
| V (b)   | 25-Feb-2003  | (b)(4)          |

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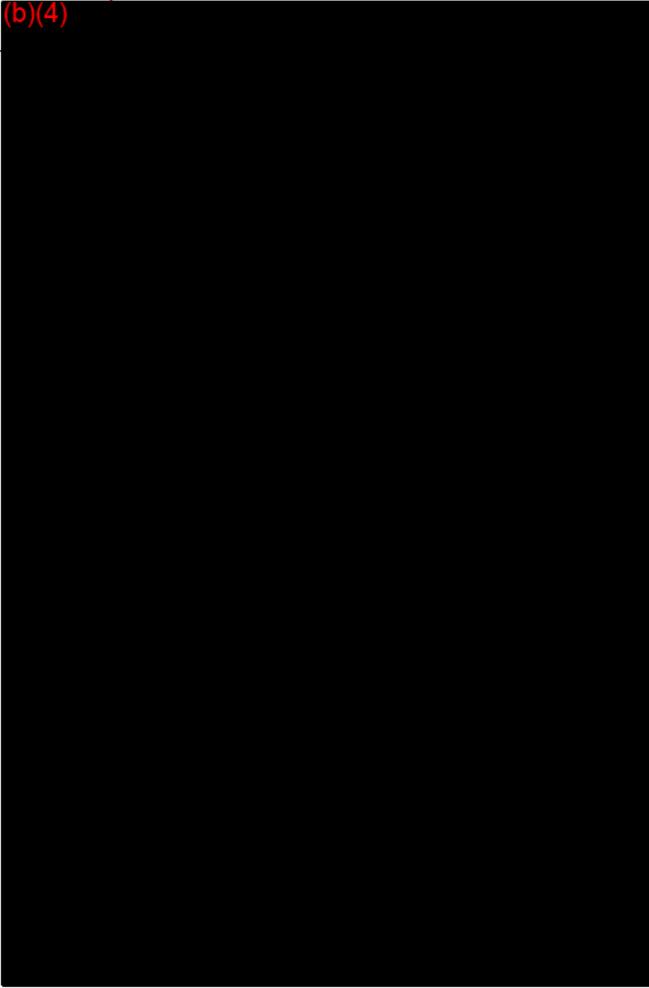
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# 1 Introduction

## 1.1 Purpose

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## 1.2 Scope

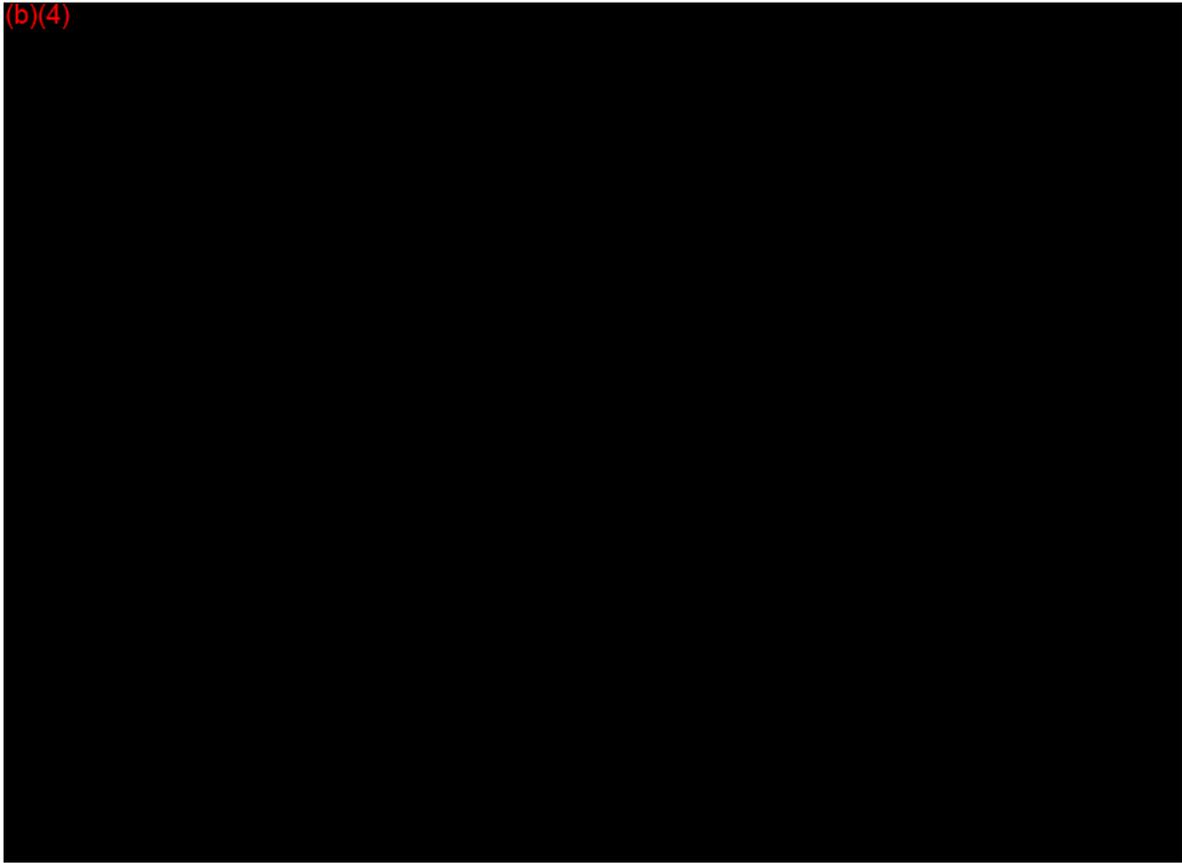
(b)(4)

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## 1.3 Definitions, Acronyms and Abbreviations

### 1.3.1 Acronyms and Abbreviations

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## 1.4 References



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## 2 Test Description

### 2.1 Overview

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### 2.2 Tester Qualification

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### 2.3 Test Environment

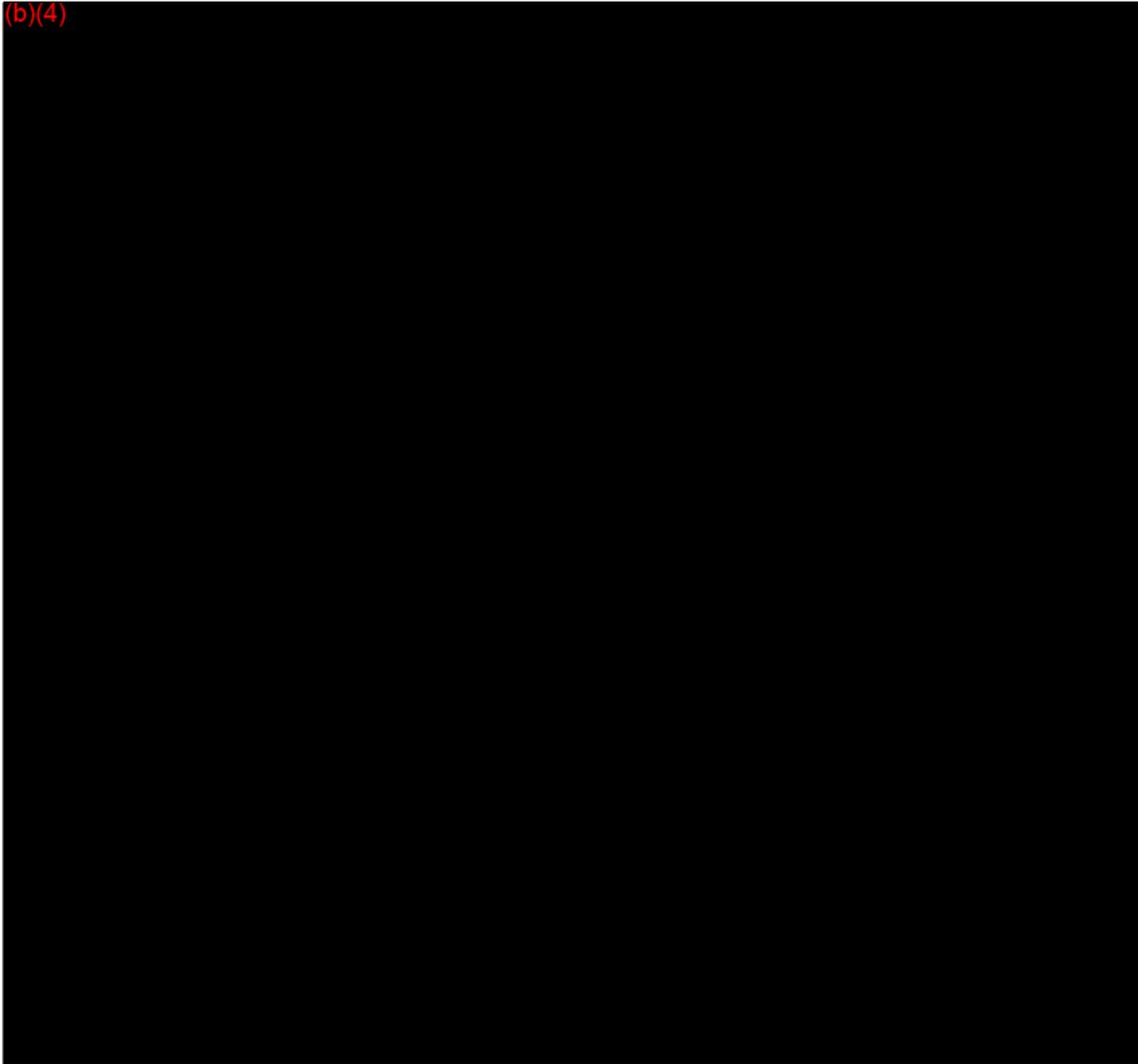
(b)(4)

### 2.4 Test Tools

(b)(4)

(b)(4)

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# A [Appendices]

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(b)(4) (b)(4) Test Specification

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**(b)(4)** Test Specification / Protocol: Summary

**(b)(4)**

Test Concept for **(b)(4)**

Based upon specification: **(b)(4)**

**(b)(4)**

**(b)(4)**

**(b)(4)**  
Last Change: 23-Feb-2003

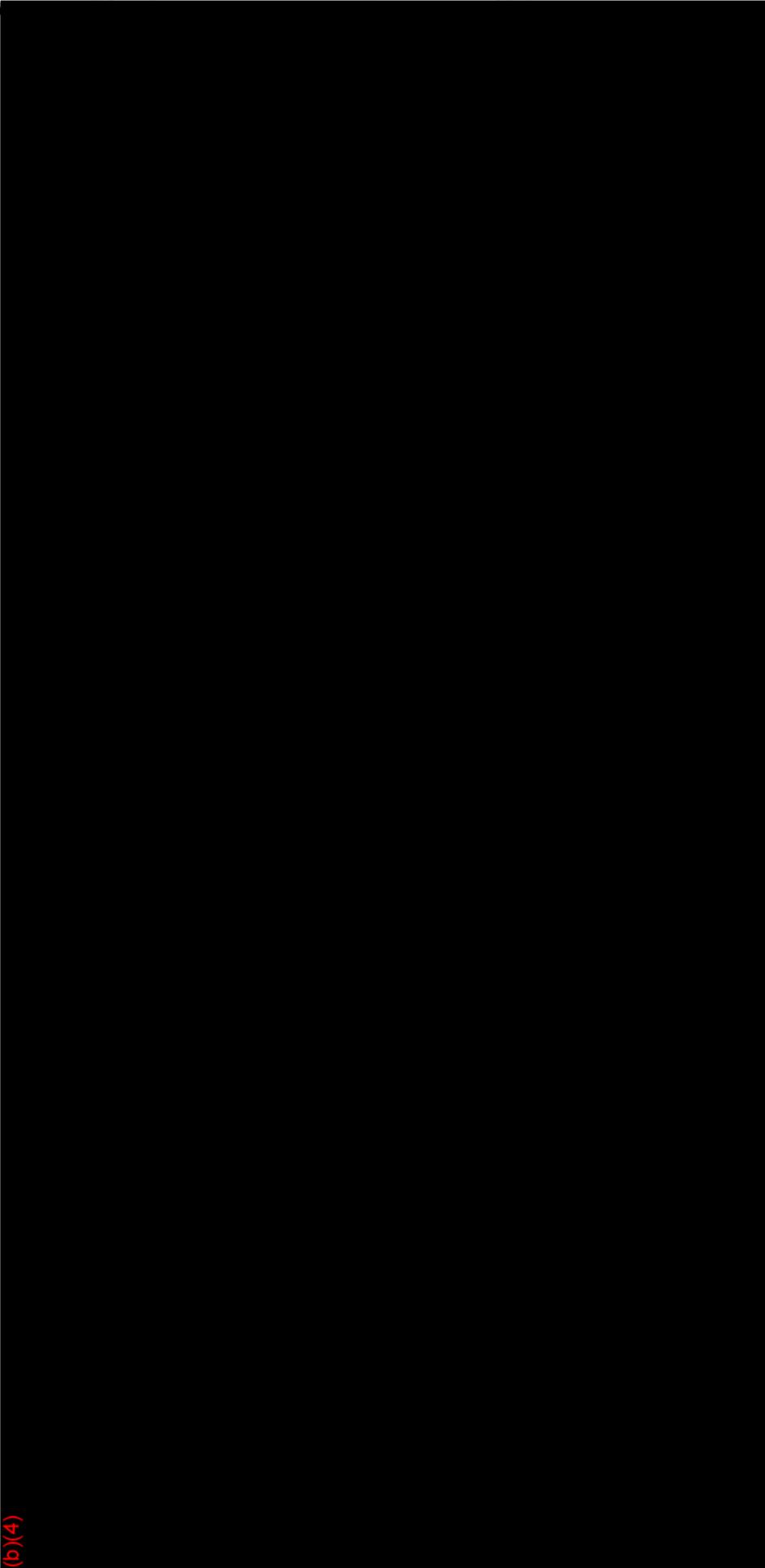
**(b)(4)**

Siemens AG Medical Solutions  
Index: 8.11.4.17

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Records process

Note: The versions of (b) (4) [Redacted] are shown via the <Options - Versions> entry in the main menu.



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(b)(4)

Test Specification / Protocol

(b)(4)

(b)(4)

UT: Test site, date, signature not required.

Test site: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Siemens AG Medical Solutions  
Index: 8.11.4.17

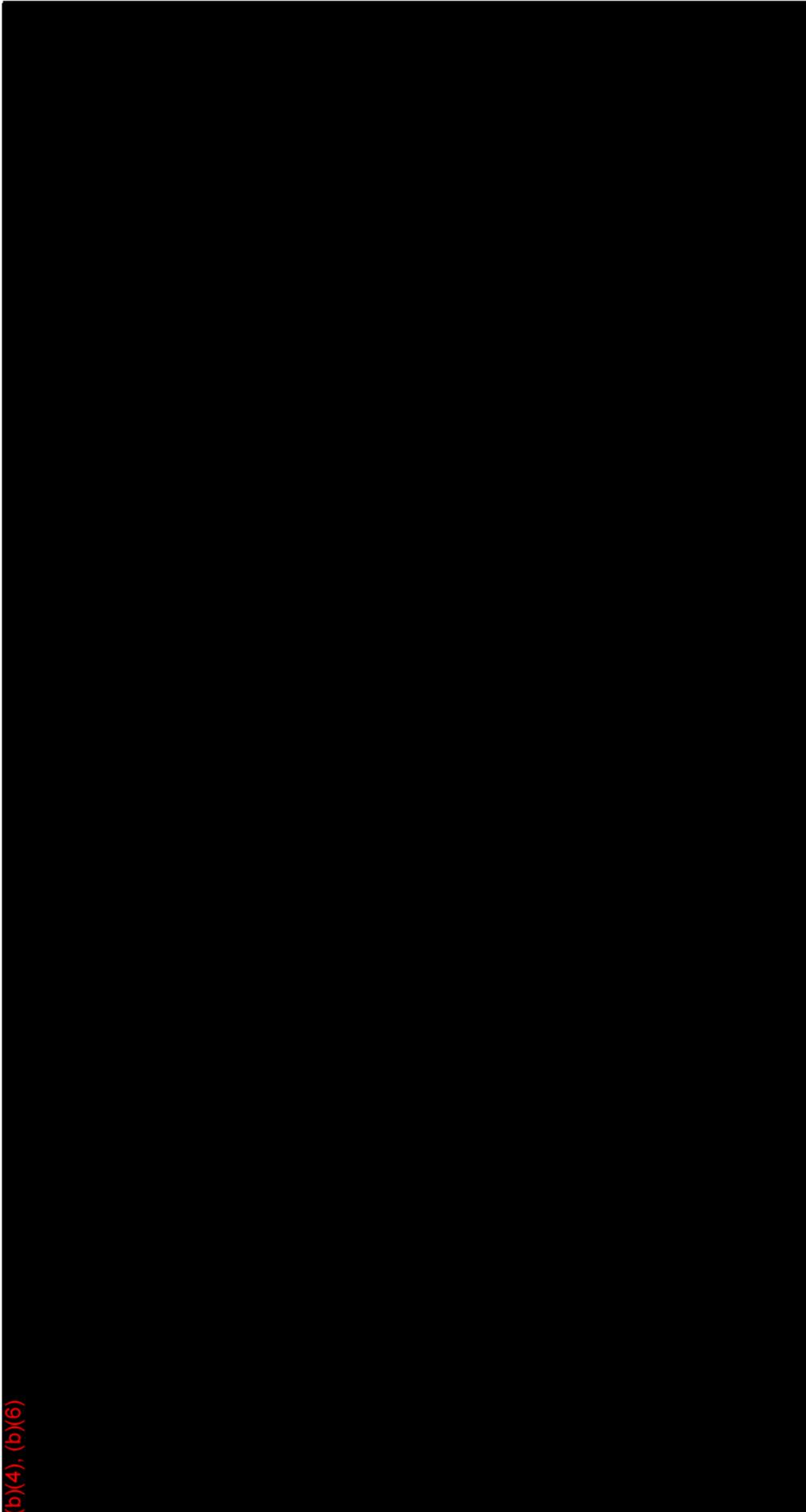
(b)(4)

Last Change: 25-Feb-2003

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(b)(4) **Test Specification / Protocol** (b)(4)

(b)(4)



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

UT: Test site, date, signature not required. **Test site:** \_\_\_\_\_ **Date:** \_\_\_\_\_ **Signature:** \_\_\_\_\_

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Index: 8.11.4.17  
Last Change: 25-Feb-2003

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

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(b)(4) Test Specification / Protocol (b)(4)

(b)(4)

Re [REDACTED]

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10-21-2015

UT: Test site, date, signature not required. Test site: \_\_\_\_\_ Date: \_\_\_\_\_ Signature: \_\_\_\_\_

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Siemens AG Medical Solutions Last Change: 2003-02-20  
Index: 8.11.4.17

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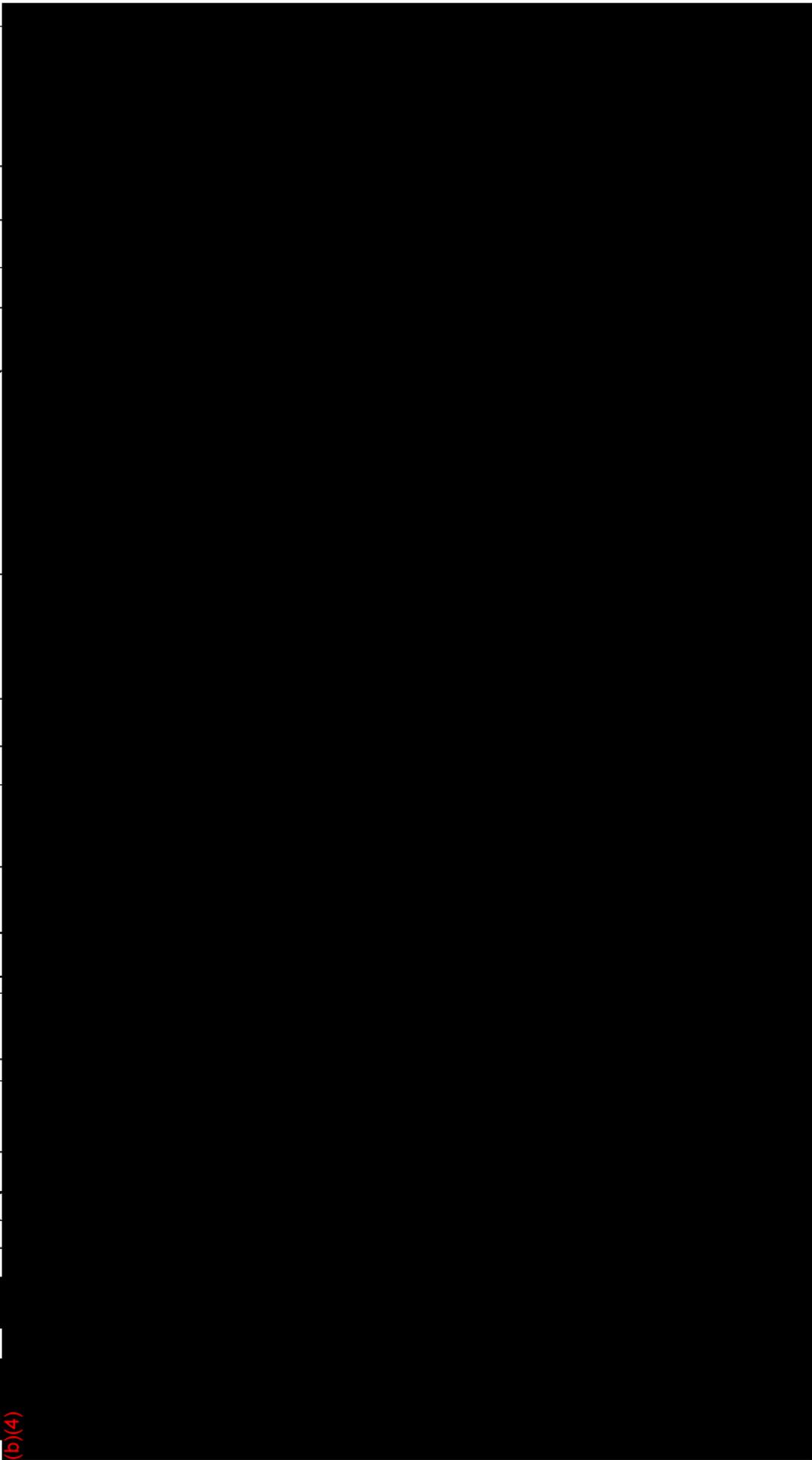




(b)(4)

(b)(4) Test:  
(b)(4) appendix 1  
K1500 8.4.4.5

(b)(4) Test (b)(4) Summary



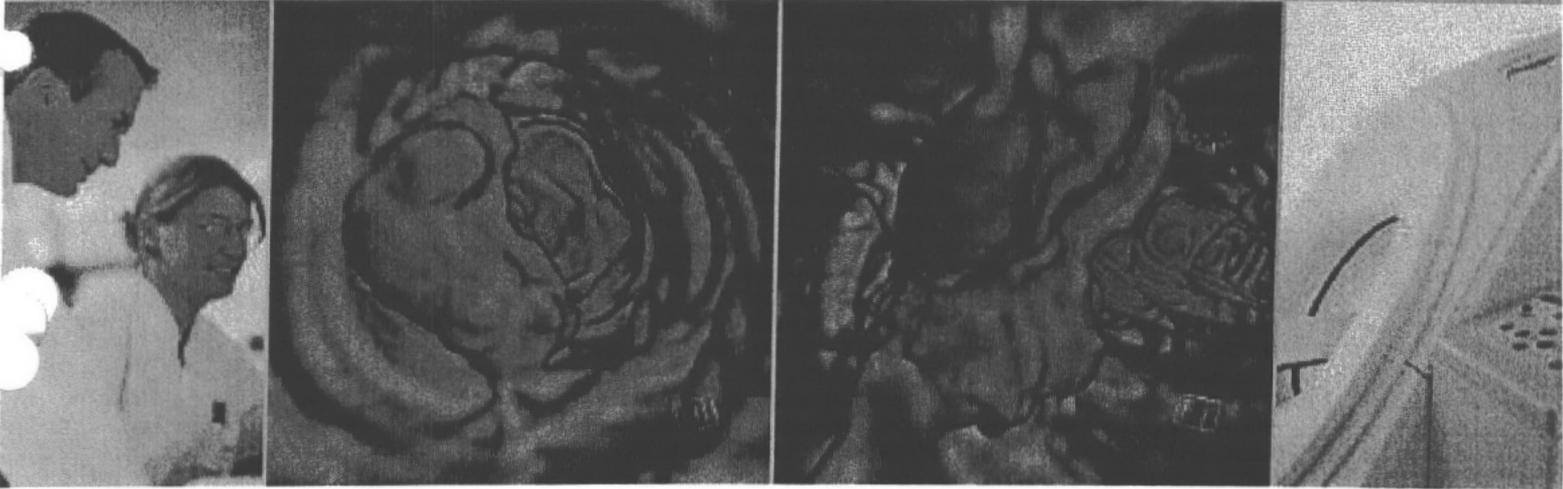
6-8118

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**Attachment 6**  
**Scientific Information supporting CT colonography**

The following pages demonstrate the clinical use of the Siemens (b)(4)

(b)(4)



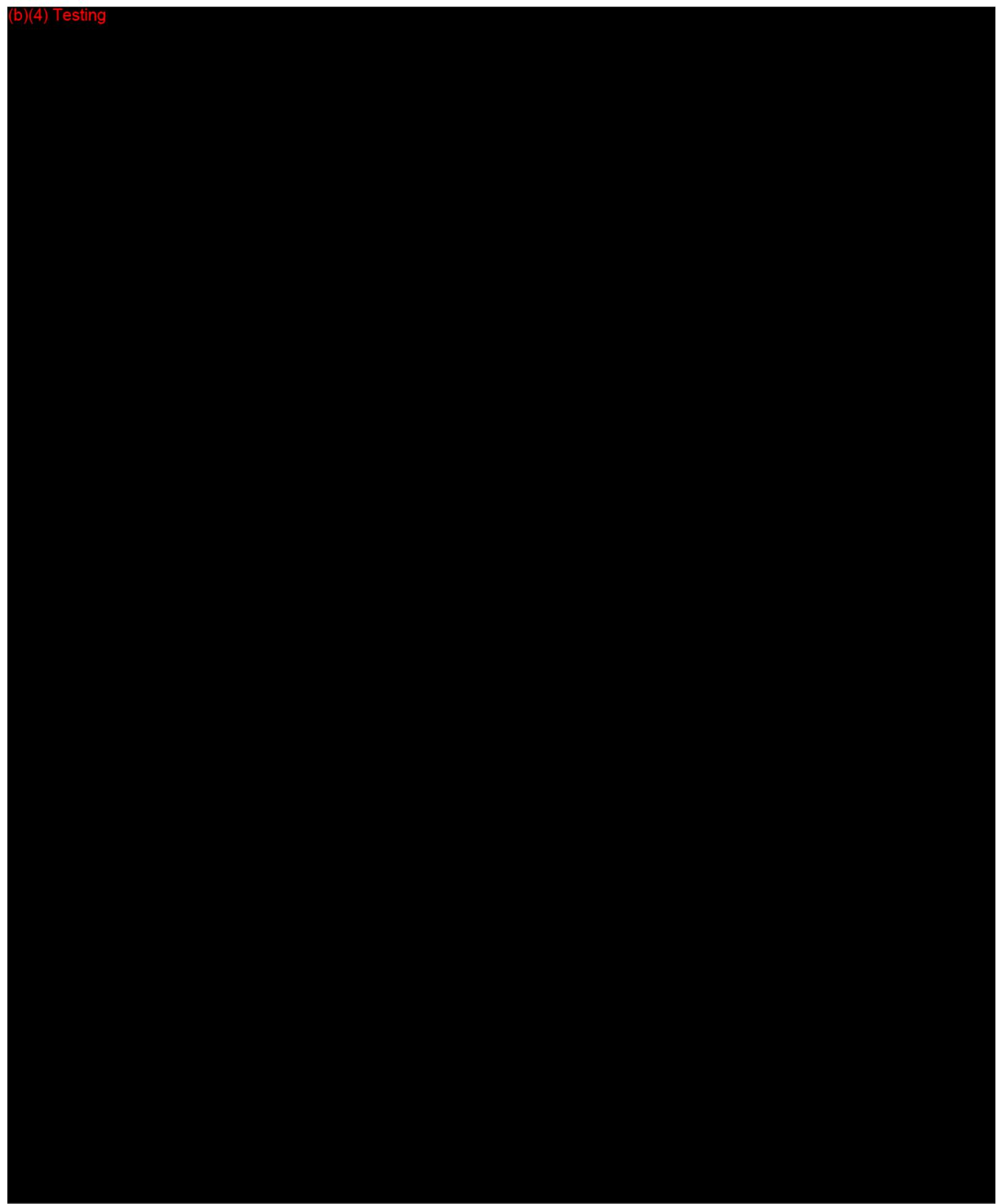
(b)(4)

(b)(4)

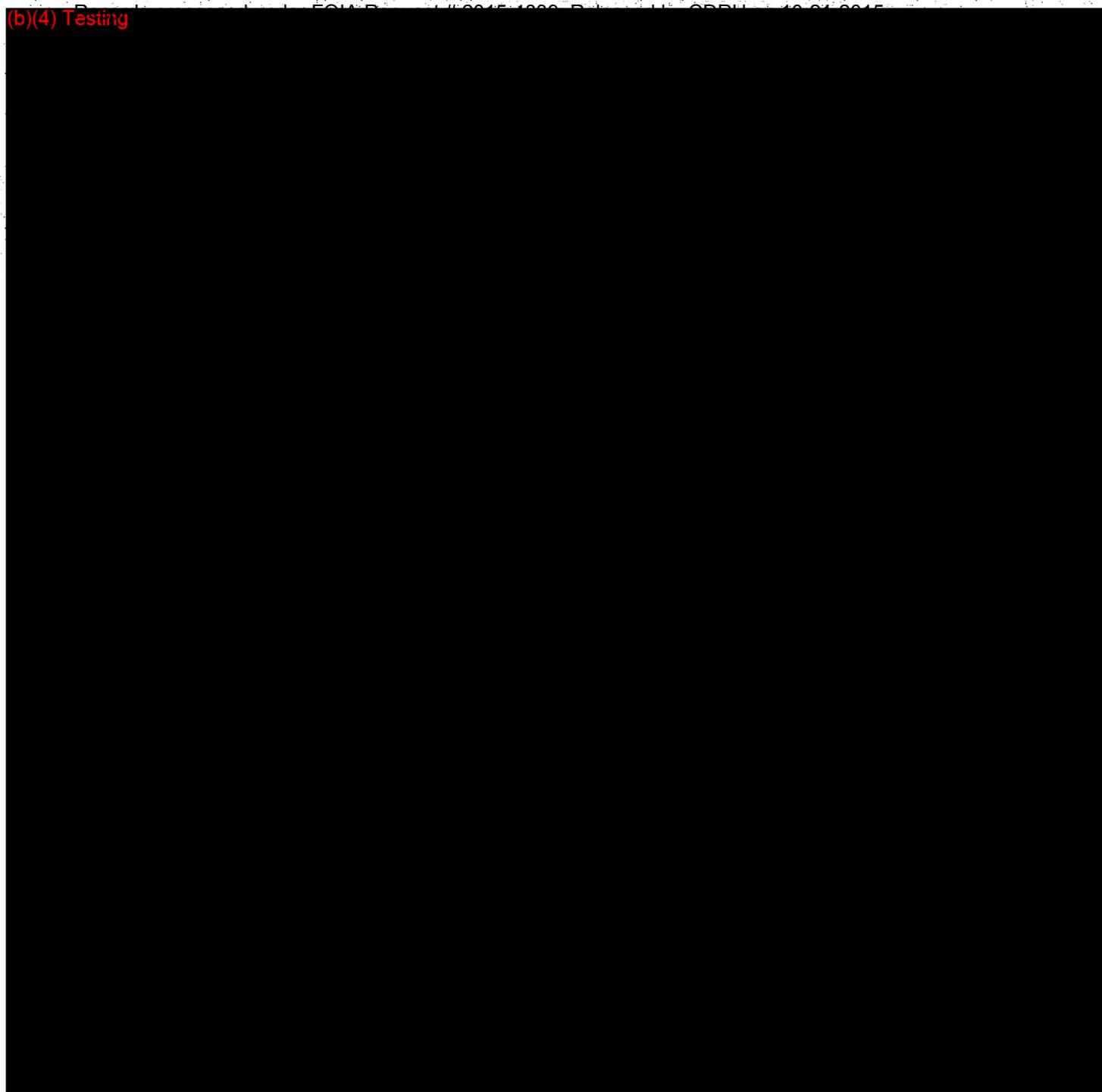
**SIEMENS**

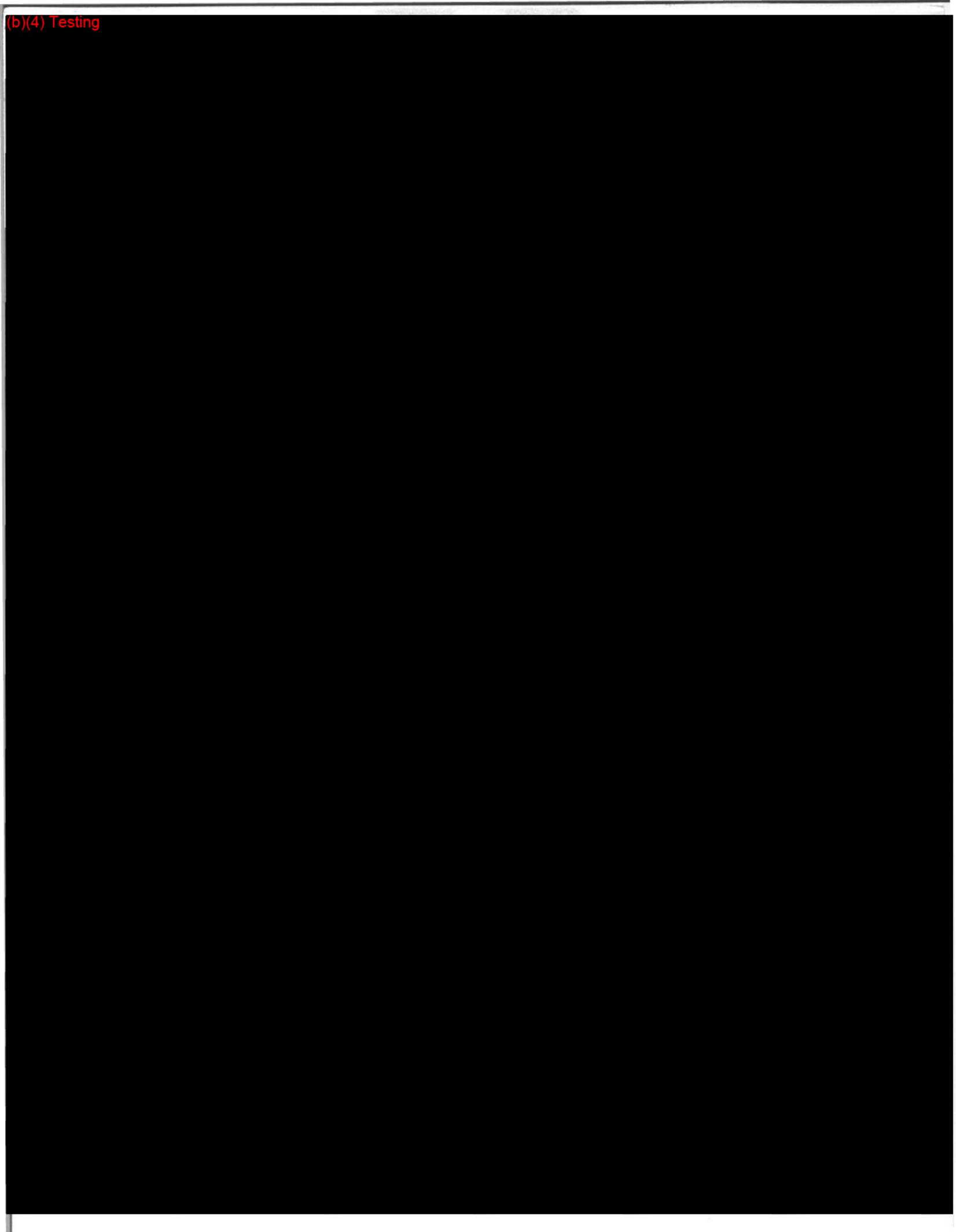
medical

(b)(4) Testing



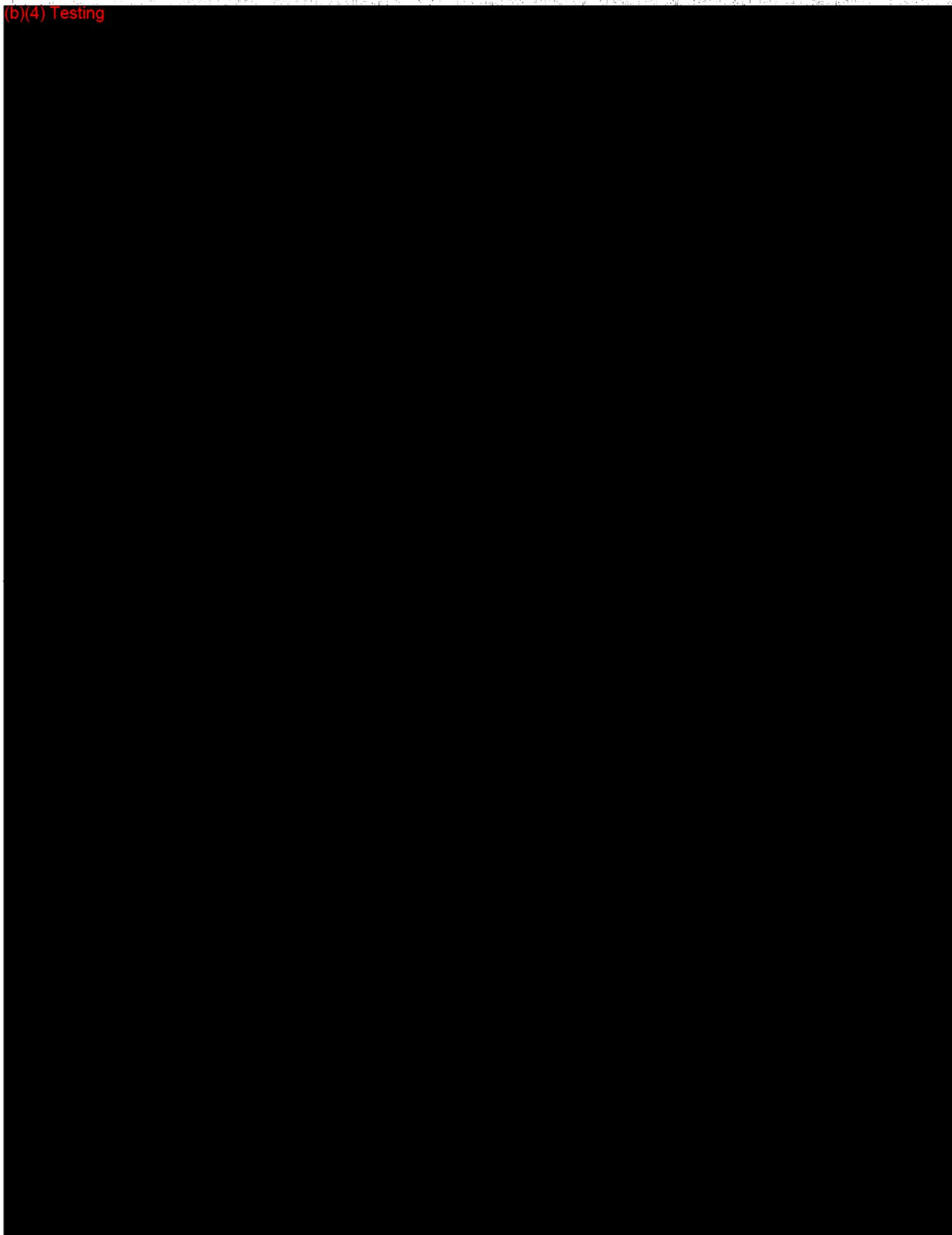
(b)(4) Testing





(b)(4) Testing

(b)(4) Testing



Author:

(b)(6)  
(b)(4)  
[Redacted]  
A

The information in this document contains general descriptions of the technical options available, which do not always have to be present in individual cases. The required features should therefore be specified in each individual case at the time of closing the contract.

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# CT-Colonography Using Multi-Slice Computed Tomography

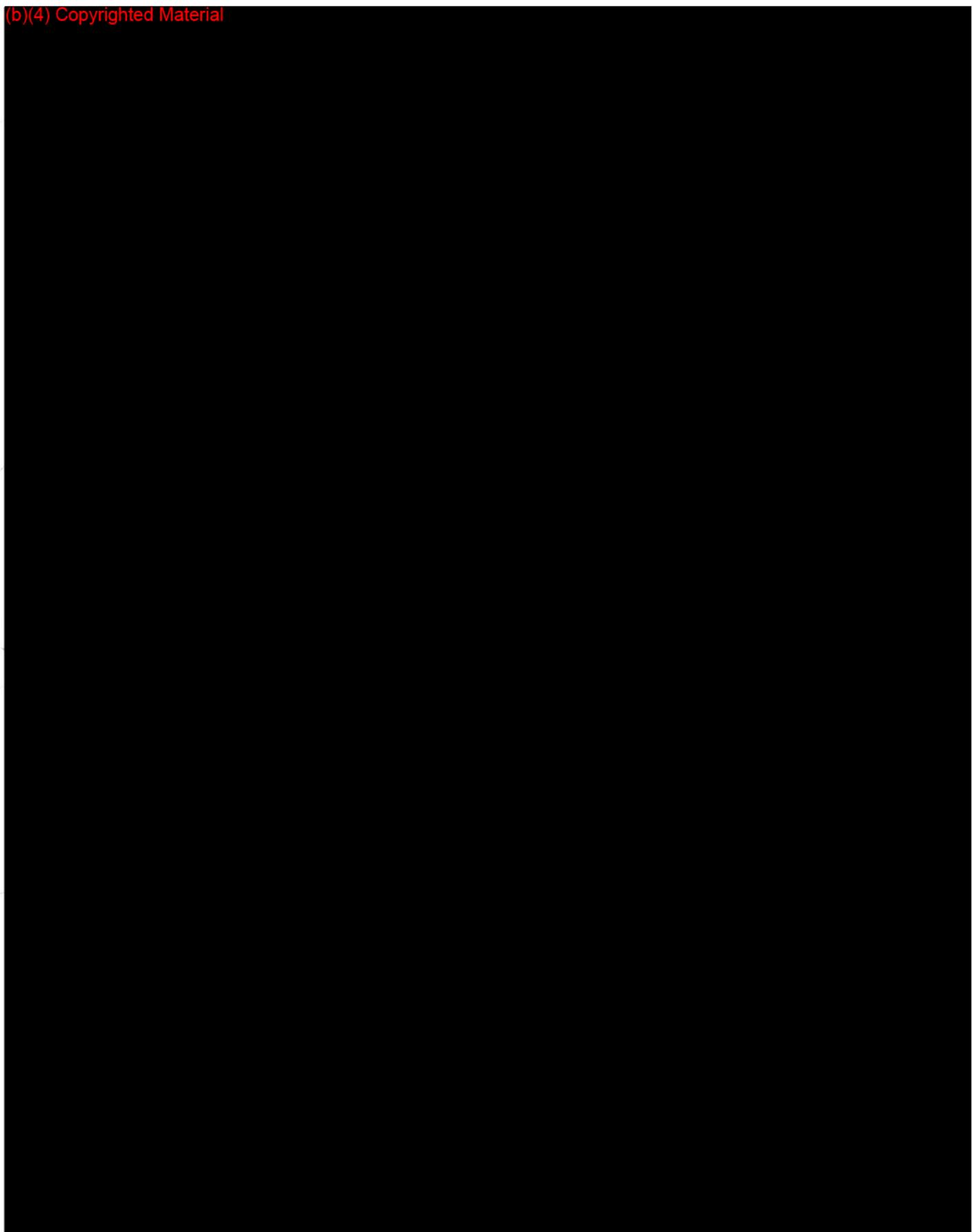
R. Fischbach, J. Wessling

*Department of Clinical Radiology, University of Muenster, Germany*

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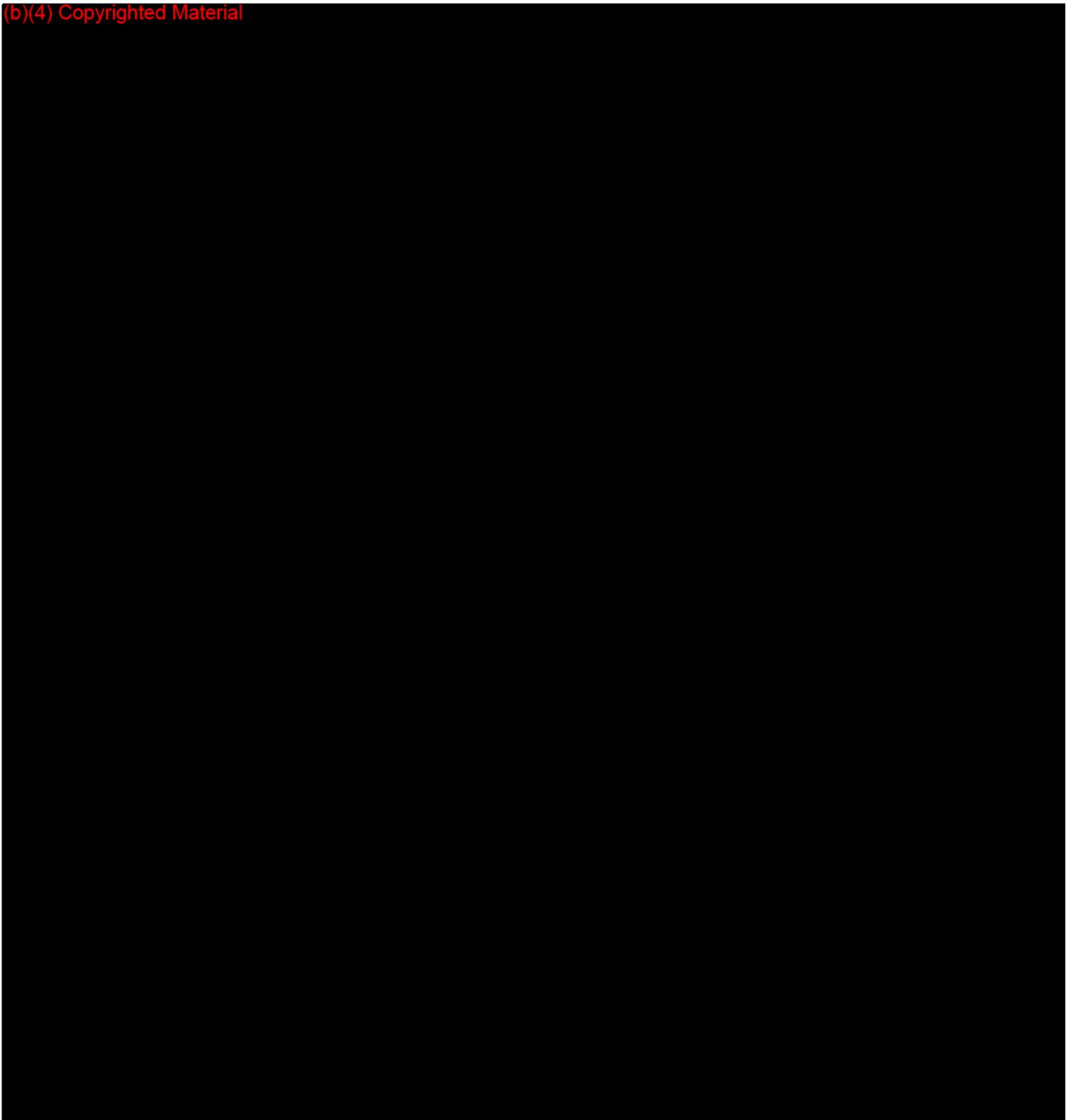


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e-mail: rfisch@uni-muenster.de

**Attachment 7**  
**Substantial Equivalence Information**

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We believe that within the meaning of the Safe Medical Device Act of 1990, the Siemens Syngo Colonography software package is substantially equivalent to the following medical devices in commercial distribution:

| <i>Predicate Device Name</i>                             | <i>FDA Clearance Number</i> | <i>FDA Clearance Date</i> |
|--|-----------------------------|---------------------------|
| GE CT Colonography/Navigator 2 Workstation               | K012313                     | 08/07/01                  |
| Siemens Fly Through                                      | K971717                     | 09/03/97                  |
| Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso) | K973010                     | 11/10/97                  |

The following matrix compares the functionality of Syngo Colonography to the predicate devices. In instances where the Syngo Colonography feature is adopted from an existing Siemens product, workstation or system, the predicate device and 510(k) number are referenced in a footnote.

In addition, many of the image processing, display and evaluation components of syngo Colonography are currently available on software options like the Volume Rendering Technique option, K923524/S2, cleared on May 17<sup>th</sup> 1994 and workstations like the syngo Multimodality Workstation, K010938 cleared on 26<sup>th</sup> June 2001 wherein the Fly Thorough software algorithms were transferred over to the syngo software platform. syngo Colonography packages these image processing and image display components in an optimized workflow palette.

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|                      | Siemens Colonography Software Package  | Syngo Software Package   | Siemens Fly Through Software Package  | Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso)  | GE Colonography/Navigator 2 Package | CT |
|----------------------|--|--|---|---|-------------------------------------|----|
| Image Data Supported | CT/MR  | CT/MR  | CT/MR   | CT/MR   | CT/MR                               |    |
| Intended Use         | <p>to provide 3D Multiplanar Reconstruction, Maximum Intensity Projection, Rendering Technique, Surface Shaded Display and interactive endoscopic views of colonic lesions using Computed Tomography (CT) or MR (Magnetic Resonance) datasets, as specified by the user (radiologists /clinicians/ referring physicians)</p> | <p>Fly Through allows the user to visualize representation of Computed Tomography (CT) or Magnetic Resonance (MR) image reconstructions from positions within the image volume. Using the segmentation processes offered by the program, the user is able to create a 3-dimensional computer model representing anatomic objects. The user can move a viewing point within the computer model and from that point visualize representations of the 3D models and the internal cut planes in real time.</p> | <p>The Siemens Realtime 3D application is intended to provide the physician with additional diagnostic information through displaying the tomographic dataset in 3D space which can show the spatial relationship among different anatomical structures. It can also be used for pre-surgical and post-surgical evaluation by surgeons. Due to its real time performance, Realtime 3D provides the user with fast case-turnaround time which leads to improved patient care and cost savings.</p> | <p>to provide 3D Multiplanar Reconstruction, Maximum Intensity Projection, Volume Rendering Technique, Surface Shaded Display and interactive endoscopic views of colonic lesions using Computed Tomography (CT) or MR (Magnetic Resonance) datasets, as specified by the user (radiologists /clinicians/ referring physicians)</p> |                                     |    |
| Indications for Use  | <p>syngo Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package</p>  | <p>From user specified sets of CT or MR images, Fly Through can be used for</p> <ul style="list-style-type: none"> <li>• 3D presentation of segmented anatomic models</li> </ul>   | <p>From user specified sets of CT or MR images, Fly Through can be used for</p> <ul style="list-style-type: none"> <li>• 3D presentation of complete anatomic structures</li> </ul>   | <p>CT Colonography allows the user to study the inside, wall and the outside of the colon. It provides the user with an ability to view datasets from</p>   |                                     |    |

| Siemens Colonography Software Package  | Syngo  | Siemens Fly Through Software Package   | Siemens RealTime Diagnostic Workstation (3D Virtuoso)   | GE Colonography/Navigator 2 Package | CT |
|--|--|--|---|-------------------------------------|----|
| <p>can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-luminal view), the wall and the outside (extra-luminal view) of the colon. With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the</p> | <p>(e.g., tracheas, bones, vessels, colon, etc.);</p> <ul style="list-style-type: none"> <li>• navigating interactively through 3D segmented models that represent body cavities (e.g., vessels, colon, spine, lung, etc.);</li> <li>• for viewing the inner surface of organ models (vessels, colon, etc.). Fly Through offers advantages over real endoscopy. For example, Fly Through can be performed within models of organs or blood vessels inaccessible to a real endoscope;</li> <li>• a training tool for surgeons to practice endoscopic procedures;</li> <li>• surgical planning;</li> <li>• feasibility study of an actual endoscopic procedure; and</li> <li>• a 3D positioning and orientation tool for Multiplanar reconstruction, thus assisting diagnosis from Multi-Planar-Reconstructions (MPRs): the</li> </ul> | <p>(e.g. head, chest, abdomen etc.); covered by the original CT or MR images for diagnosis and use in treatment planning</p> <ul style="list-style-type: none"> <li>• diagnosing as well as treatment planning from realtime MPR; the realtime 3D tool can help the user to position and visualize the 3D location of MPR within the 3D volume by using interactive clip planes in realtime</li> <li>• CTA and MRA displaying enhanced vessels</li> <li>• Measurement of anatomical structures in the 3D volume. Important for quantitative measurement of geometry and length of anatomy indices;</li> <li>• Displaying the position of anatomical structures in relationship to one another; Navigating interactively through anatomical structures (e.g. vessels, colon, spine, lung, etc) or inside the 3D volume</li> </ul> | <p>both, prone and supine positions, facilitating detection of colonic lesions. In comparison to colonoscopy, this tool has an advantage of non-invasive depth penetration due to its 3D presentation capability.</p> |                                     |    |

|  | Siemens Colonography Software Package   | Syngo Software   | Siemens Fly Through Software Package   | Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso)   | GE Colonography/Navigator 2 Package   | CT |
|--|---|--|--|--|---|----|
|  | physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.<br>Due to all these capabilities the syngo Colonography software has the advantage of non-invasive evaluation of colonic lesions as compared to conventional colonoscopy. |  | Fly Through tool can help the user to position and visualize the 3-dimensional location of the MPR within the segmented dataset. | <ul style="list-style-type: none"> <li>Depth perception using stereo display option to visualize overlaying and underlaying vessels</li> <li>for viewing the inner surfaces of the organs (vessels, colon etc.)</li> </ul> |   |    |
| Workstation on Operating Software Platform | Windows NT 4.0/2000 (Syngo)   | Windows NT 4.0/2000 (Syngo)  | Windows NT 4.0/2000 (Syngo)  | Unix   | Sun Sparc   |    |
| Lesion Marking                             | <ul style="list-style-type: none"> <li>Semi-automated, user needs to indicate area of interest</li> <li>Bookmarking Tool to mark lesion</li> <li>Linear Measurements</li> </ul>   |  | <ul style="list-style-type: none"> <li>not available</li> </ul>  | <ul style="list-style-type: none"> <li>not available</li> </ul>  | <ul style="list-style-type: none"> <li>Semi-automated</li> <li>Bookmarking tool to mark lesion location</li> <li>Linear measurements</li> </ul> |    |
| Image Processing                           | <ul style="list-style-type: none"> <li>Intelligent Workflow Palette</li> </ul>  | <ul style="list-style-type: none"> <li>Intelligent Workflow Palette</li> </ul> | <ul style="list-style-type: none"> <li>Intelligent Workflow Palette</li> </ul>   | <ul style="list-style-type: none"> <li>Intelligent Workflow Palette</li> </ul>   | <ul style="list-style-type: none"> <li>Workflow palette</li> </ul>  |    |

<sup>1</sup> Based on MIP described in the Volume Rendering Technique premarket notification, K923524 cleared on May 17<sup>th</sup> 1994.

<sup>2</sup> Based on MPR described in Siemens Somatom Plus 4 with Volume Zoom option CT System, K941546, cleared on September 20<sup>th</sup> 1994

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|                | Siemens Syngo Colonography Software Package  | Siemens Fly Through Software Package   | Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso)   | GE Colonography/Navigator 2 Package  | CT |
|----------------|--|--|--|--|----|
| and Evaluation | <ul style="list-style-type: none"> <li>Targeted Presets</li> <li>Saved Lesion Location</li> <li>Multi-tissue opacity control</li> <li>Window Level</li> <li>Zoom/Pan control</li> <li>Maximum Intensity Projection(MIP)<sup>1</sup></li> <li>Multi Planar Reconstruction(MPR)<sup>2</sup></li> <li>Shaded Surface Display(SSD)<sup>3</sup></li> <li>Volume Rendering Technique(orthogonal perspective)<sup>4</sup></li> <li>Automatic Segmentation<sup>5</sup></li> <li>Volumetric Estimation<sup>5</sup> using consistent standardized measurement protocol.</li> </ul> | <ul style="list-style-type: none"> <li>Targeted Presets</li> <li>Window Level</li> <li>Zoom/Pan control</li> <li>Maximum Intensity Projection(MIP)<sup>6</sup></li> <li>Multi Planar Reconstruction(MPR)<sup>7</sup></li> <li>Shaded Surface Display(SSD)<sup>8</sup></li> </ul> | <ul style="list-style-type: none"> <li>Targeted Presets</li> <li>Window Level</li> <li>Zoom/Pan control</li> <li>Maximum Intensity Projection(MIP)<sup>9</sup></li> <li>Multi Planar Reconstruction(MPR)<sup>10</sup></li> <li>Shaded Surface Display(SSD)<sup>11</sup></li> </ul> | <ul style="list-style-type: none"> <li>Multiple 2D and 3D views, with 2D reading integrated with analysis by 3D and virtual dissection</li> <li>MIP</li> <li>MPR</li> <li>SSD</li> <li>Volumetric Assessment using consistent standardized measurement protocol.</li> <li>Comparator Tool to allow synchronized comparison of nodule/lesion over time</li> </ul> |    |

<sup>3</sup> Based on SSD described in Siemens Realtime 3D Diagnostic Workstation (3D Virtuoso), K973010 cleared on November 10<sup>th</sup> 1997.  
<sup>4</sup> Described in Volume Rendering Technique premarket notification, K923524, cleared on May 17<sup>th</sup> 1994.  
<sup>5</sup> Described in Siemens Calcium Scoring Software Package premarket notification, K990426, cleared on April 30<sup>th</sup> 1999.  
<sup>6</sup> Based on MIP described in the Volume Rendering Technique premarket notification, K923524 cleared on May 17<sup>th</sup> 1994.  
<sup>7</sup> Based on MPR described in Siemens Somatom Plus 4 with Volume Zoom option CT System, K941546, cleared on September 20<sup>th</sup> 1994  
<sup>8</sup> Based on SSD described in Siemens Realtime 3D Diagnostic Workstation (3D Virtuoso), K973010 cleared on November 10<sup>th</sup> 1997.  
<sup>9</sup> Based on MIP described in the Volume Rendering Technique premarket notification, K923524 cleared on May 17<sup>th</sup> 1994.  
<sup>10</sup> Based on MPR described in Siemens Somatom Plus 4 with Volume Zoom option CT System, K941546, cleared on September 20<sup>th</sup> 1994  
<sup>11</sup> Based on SSD described in Siemens Realtime 3D Diagnostic Workstation (3D Virtuoso), K973010 cleared on November 10<sup>th</sup> 1997.

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|                            | Siemens Syngo Colonography Software Package   | Siemens Fly Through Software Package                  | Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso) | GE Colonography/Navigator 2 Package            | CT |
|----------------------------|---|---|--|--|----|
|                            | <ul style="list-style-type: none"> <li>• Comparator tool for lesion (eg.Polyp) matching by synchronization of two datasets</li> <li>• Classification of lesions (eg. Polyp) using configurable descriptors</li> </ul> |   |  |  |    |
| User Interface             | GUI-based   | GUI-based   | GUI-based  | GUI-based                                      |    |
| Archiving/Storing Hardware | MOD, CD-R, film in the future DVD<br>PC with Windows NT or Windows 2000   | MOD, CD-R, film<br>PC with Windows NT or Windows 2000 | MOD, CD-R, film<br>Silicon Graphics with Unix            | Information not available<br>Sun U80 with Unix |    |
| Communication              | DICOM compatible  | DICOM compatible                                      | DICOM compatible   | DICOM compatible                               |    |

**Attachment 8**  
**Predicate Device Literature**



AUG - 7 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

General Electric Medical Systems  
% Mr. Reiner Krumme  
Manager, Medical Division  
TUV Rheinland of North America  
12 Commerce Road  
NEWTON CT 06470

Re: K012313  
CT Colonography/Navigator 2 (CT Navigation software package)  
Dated: July 18, 2001  
Received: July 23, 2001  
Regulatory Class: II  
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

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

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

Sincerely yours,

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known):

Device Name: CT Colonography

Indications for Use

CT Colonography/Navigator2 is an image analysis software package that contains CT Colonography and Navigator2.

CT Colonography allows the user to study the inside, wall and outside of the colon. It provides the user with an ability to view datasets from both, prone and supine positions, facilitating detection of colonic lesions. In comparison to colonoscopy, this tool has an advantage of non-invasive depth penetration due to its 3D presentation capability.

Navigator2 provides endoluminal views of anatomical structures. Navigator2 is designed to enhance and modify current image quality, tools, speed and user interface of Navigator for improved productivity. Navigator2 provides a visualization tool to investigate structures (such as polyps, tumors, stones, calcification etc.) within anatomy, airways and organs. Thus, its viewing capability of the inner and outer surfaces of organs as well as within their walls provides additional supplemental information, complementing endoscopy/colonoscopy, to support interpretation and treatment planning. Navigator2 is applicable to X-ray as well as CT/MR.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801-109)

OR Over-The-Counter Use \_\_\_\_\_

Nancy C. Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K012313

AUG - 7 2001



**GE Medical Systems**  
General Electric Company  
P O Box 414 Milwaukee, WI 53201

K012313

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

**Submitter** Larry A. Kroger, Ph.D.  
Senior Regulatory Program Manager  
Telephone: (262) 544-3894, FAX: (262) 544-3863  
Date Prepared: June 12, 2001

**PRODUCT IDENTIFICATION**

**Name:** CT Colonography/Navigator2

**Classification Name:** Accessory to Computed Tomography System

**Manufacturer :** General Electric Medical Systems  
283, rue de la Miniere  
78533 Buc Cedex, FRANCE

**Distributor:** General Electric Medical Systems, Milwaukee, WI

**Marketed Devices** The CT Colonography/Navigator2 is substantially equivalent to the device listed below:

**Model:** Navigator  
**Manufacturer:** General Electric Medical Systems, Milwaukee, WI  
**510(k) #:** K954355

**Device Description:**

CT Colonography/Navigator2 (CTC/Nav2) is an image analysis software package that allows the user to study the inside, wall, and outside of the colon using CT-acquired helical images. The tool is laid out to facilitate the detection of colonic lesions. CT Colonography requires Navigator2 for its operation however, Navigator2 can also be utilized as a stand-alone option. Navigator2 is an advanced visualization software option that provides endoluminal views of anatomical structures. The flexibility of this software allows the user to move interactively from air paths to inner vessels visualization and thus, it is not limited to inner navigation of structures as lungs and sinuses. Volume Analysis (includes both, CT/MR Windows Workstation, K913770 and 3D & Dentascan for Windows K923077) provides the base for CTC/Nav2 and Nav2 alone, which allows an increase in the ease of use and productivity. CTC/Nav2 and Nav2 alone, also use some options of Volume Rendering (AW Volume Render Option

Records processed under FOIA Request # 2015-4839; Released by CDRH on 10-21-2015  
K972399), which allows the user to quickly isolate structure of interest and render volumetric data in three dimensions.

**Indications for Use :**

CT Colonography/Navigator2 is an image analysis software package that contains CT Colonography and Navigator2.

CT Colonography allows the user to study the inside, wall and outside of the colon. It provides the user with an ability to view datasets from both, prone and supine positions, facilitating detection of colonic lesions. In comparison to colonoscopy, this tool has an advantage of non-invasive depth penetration due to its 3D presentation capability.

Navigator2 provides endoluminal views of anatomical structures. Navigator2 is designed to enhance and modify current image quality, tools, speed and user interface of Navigator for improved productivity. Navigator2 provides a visualization tool to investigate structures (such as polyps, tumors, stones, calcification etc.) within anatomy, airways and organs. Thus, its viewing capability of the inner and outer surfaces of organs as well as within their walls provides additional supplemental information, complementing endoscopy/colonoscopy, to support interpretation and treatment planning. Navigation2 is applicable to X-ray as well as CT/MR.

**Comparison with Predicate:**

CT Colonography/Navigator2 is an image analysis software built on Navigator 2 features that allows the user to study the inside, wall, and outside of the colon using CT acquired helical images. The tool is laid out to facilitate the detection of colonic lesions. Navigator 2 is a new version of the current GE Navigator, it has improved performance and usability. The functional features of this package are substantially equivalent to that of the following device:

| Device Name                                 | FDA Clearance Number |
|---|----------------------|
| Advantage Windows 3D with Navigator Option* | K 954355             |
|   |                      |

*\*referred as Navigator in this application*

**Adverse Effects on Health :**

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

**Conclusions:**

The CT Colonography/Navigator2 does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the CT Colonography/Navigator2 to be equivalent to those of Navigator (K954355).



**GE Medical Systems**

## COMPUTED TOMOGRAPHY

### Advanced CT Applications

#### CT Colonography



With the new **CT Colonography Applications Package** from GE Medical Systems, patients can have quick, accurate, non-invasive colon exams. This new application will benefit a large segment of the population who physically can't or won't have a traditional colon exam.

(Click on images to view sample cases)



#### Benefits of GE CT Colonography

- Colon Surface Evaluation
- Deep Colon and Abdominal assesment
- Multiple 2D and 3D views, with 2D reading integrated with analysis by 3D and virtual dissection
- Robust polyp assessment tools
- Superior patient comfort and recovery
- Lower procedure Expense
- Enables colon and extra-colonic patient assessment

#### More Information

- [Clinical Development Team](#)
- [Patient Review Screen](#)
- [Patient Analyze Screen](#)

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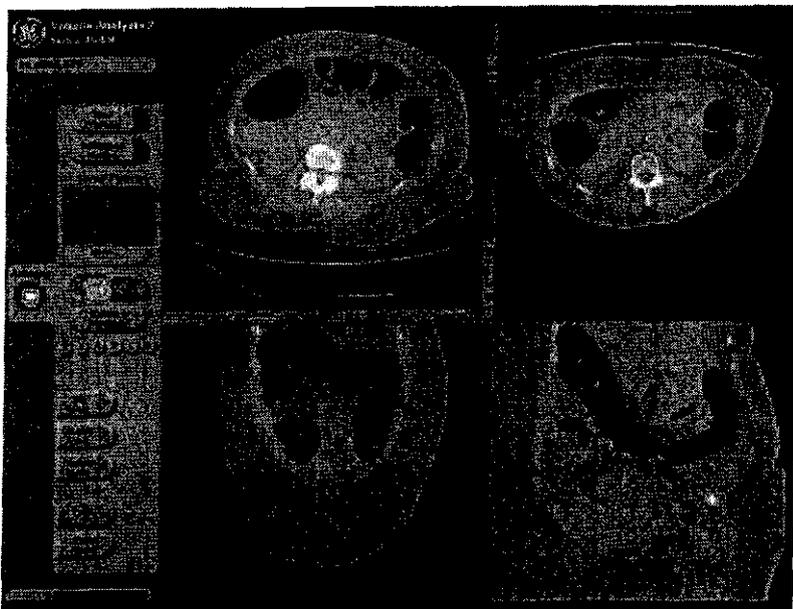


**GE Medical Systems**

# COMPUTED TOMOGRAPHY

## Advanced CT Applications

### CT Colonography



- Prone and Supine views displayed and synchronized together
- Coronal views displayed
- Bookmarking tools available to mark polyp location
- Review controller to page through images, measurements, annotation

[click to enlarge](#)

Printed from <http://www.gemedicalsystems.com/rad/ct/applications/colon/review.html>

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**GE Medical Systems**

# COMPUTED TOMOGRAPHY

## Advanced CT Applications

### CT Colonography



3 oblique images and endoluminal view  
Navigator tools to "fly" around polyp  
"Lock Tools" for easy navigation - navigator will stay "locked" on polyp and stay within the colon at all times

[click to enlarge](#)

Printed from <http://www.gemedicalsystems.com/rad/ct/applications/colon/analyze.html>

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SIEMENS

# 3DVirtuoso

## CT, MR and Angio Workstation

### The Power To See It All



# 3DVirtuoso

# The power to see it all

**Siemens 3DVirtuoso— the advanced postprocessing workstation for CT, MR and Angio— your all-in-one system for diagnostic and therapeutic image evaluation**

**Develop new opportunities**

**Processing features help improve diagnostic capabilities using powerful high-quality visualization perspectives such as 3-D Volume Rendering, Maximum Intensity Projection, Fly Through and Image Fusion**

**Reduce patient turn-around time to minutes— faster diagnoses using realtime 3-D viewing**

**Improve communication between radiologists and clients using interactive visualization and stereo viewing**

**Reduce costs— exploit the wide range of conventional and future-oriented 3-D tools**

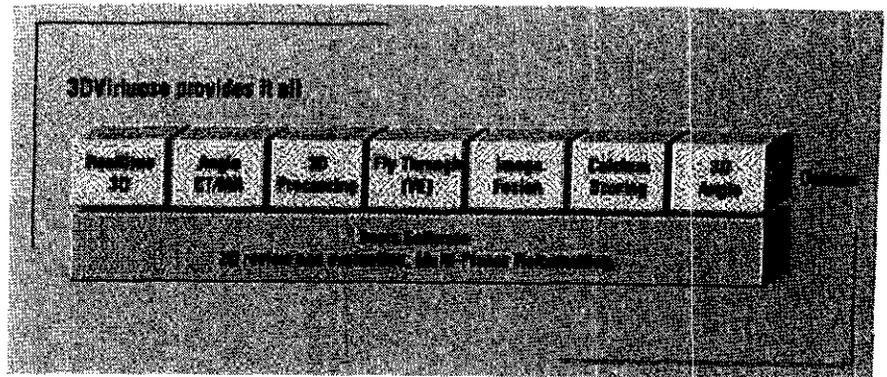
**As a professional, 3DVirtuoso will assist you in your daily work**

**Visualize image details to aid in Interventional Procedures, Orthopedics and Surgical Planning**

**High-quality images for CT and MR Angiography that can be used for surgical pre- and post-evaluation**

**Quality images assists in the diagnosis of many illnesses especially important for oncology and interventional radiology**

**Excellent display of spatial relationships to aid evaluation of transplant donors and recipients**



**The complete functionality for diagnosis, surgical planning and interventional procedures**

**Fully modular packaging**

*The Basis Software can be extended by adding optional software packages depending on your requirements. See last page for packaging and availability.*

**3DVirtuoso**

# Basis Software

**All the functionality you need for 2-D viewing of images, including very comprehensive MPR, network communication (DICOM), filming, archiving.**

## Patient Management

Patient database with patient, study, series and image level selection

Sort by name, date, load order

Copy patient, study, series

Merge two image series

## Interfacing

Interface to CT/MR scanners through DICOM 3.0 protocol (Service Class User and Service Class Provider)

- Send/Receive
- Query/Retrieve

## Archiving

Magneto-optical disc (MOD) [optional]

Background archiving

Selective archiving of multiple exams by study or series

## Filming / Color printing / Video

Filming either through a digital interface or using DICOM Basic Print communication standard

Filming from applications at any time (not Image Fusion)

Free placement of individual images on film

Customizable film layouts (up to 20 on 1)

Automated filming of entire series

Video output PAL/NTSC

## 2-D image review and analysis

Multiple synchronized **Cine** viewing

Interactive Cine review controlled by mouse

Image **manipulation**: Zoom, pan, flip, rotate, mirror—applicable to all images, series, or current image

Measurements and **statistical** analysis, including HU, distance, irregular ROIs

Side-by-side comparison of multiple studies

Cross-reference between series within the same study

User-defined layouts (up to 8x8)

Window width and level (separate controls), convenient, modality-specific presets

Text annotation

## Multi-Planar Reformating (MPR)

Interactive **orthogonal** reformats (axial, sagittal and coronal)

**Curved** and **oblique** reformats

Multiple-cut MPR with variable number, spacing, thickness, and field of view

Multiple-cut ranges

Ability to save all reformatted cuts into patient folder

MPR orientation correction, twist slice stack to compensate for patient placement

## Laser imagers supported

- 3M 952 Imager
- 3M 963 HQ
- 3M 969
- Kodak Ektascan 100 XLP
- Kodak Ektascan 2180
- Kprince EL21
- Agfa MCL/MG 3000
- Polaroid Helios 810

Requires Analogic DASM/CAM Laser Camera Digital Interface ANC 201 000 104 SW version 1.2 or greater

## DICOM Basic Print devices supported

- Agfa Dvystar 2000
- Agfa MG 3000
- Imation DryView 8300
- Imation DryView 5700
- Kodak MLP 190
- Codonics NR 1800M Color Printer

The film sheet can also be saved as an image file in the following formats.

## Film to disk file Supported formats

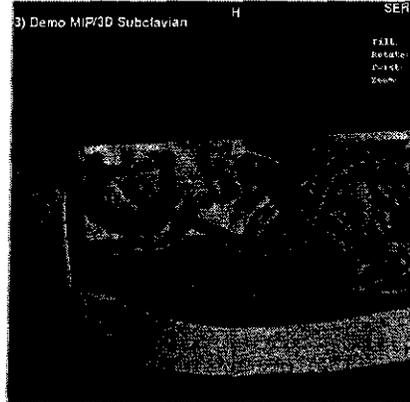
- PPM
- TIFF
- JPEG
- PCX
- BMP
- PICT
- Encapsulated Postscript

# Angio CT/MR Option

# 3D Processing Option

Conventional Angio package offers automatic filming and secondary capture output ranges from MIP images. Image editing using either thresholds, objects (such as bone), or irregular regions of interest (ROI).

Comprehensive set of 3-D segmentation facilities based on region-growing techniques. Includes a 3-D toolset for model editing and measurement. Segmented anatomy is visualized as multi-color shaded surface displays (SSD).



### 3-D Surface Rendering

- Interactive rotation of 3-D objects
- Concurrent display of multiple objects in different colors
- Zoom and pan
- Adjustable depth shading
- Translucent viewing
- Tissue removal to expose interior
- Greyscale mapping on exposed interior surfaces

### Maximum Intensity Projection

- Interactive MIP views with high-resolution rendering
- Simultaneous display of 3 orthogonal MIP images for improved spatial interpretation
- Dynamic range clipping to remove unwanted background and reduce processing time
- 3-D volume targeting with an arbitrary 3-D object
- Freehand drawing include and exclude clipping regions
- Interactive rotation of MIP images along any axis
- Interactive zoom, pan, and windowing of MIP images

### 3-D Segmentation

- Fast segmentation using threshold in tri-planar mode
- Guided segmentation using threshold and seeded regions of interests on a multiple-slice basis
- ROI definition tools include seeding, cutting, adding, and lasso
- Removal of 3-D object parts that are not connected to the selected volume (disarticulation)
- Automatic and manual separation of connected objects
- 3-D objects and ROI definition can be saved and later re-used or edited

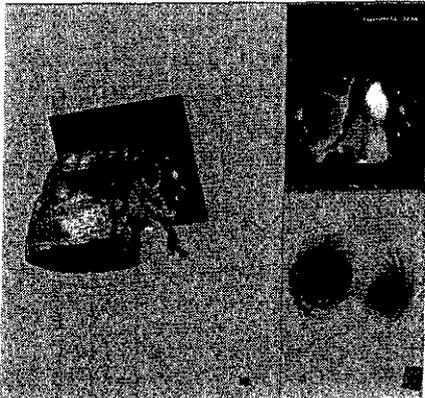
### 3-D Morphometric Measurement

- Volume, surface area, angle and linear distance
- Cross-reference of points between 3-D objects and original 2-D images in MPR mode
- SSD images can be selectively cut away to reveal internal anatomy, and can be correlated with superimposed orthogonal MPRs.

FOIA STATUS

## Fly Through Option

SSD/Volume Rendered virtual endoscopy showing external, internal and correlated oblique MPR views, plus a collision detection feature to help determine whether real endoscopy is likely to be viable. Fully automatic path planning makes navigation simple.



### Display Layouts

**Global view.** Showing external perspective of 3-D models with endoscope and superimposed MPR view

**Endoscope view.** Showing internal perspective from virtual endoscope

**Correlation view.** Showing the corresponding 2-D slice perpendicular or parallel to the endoscope position

SSD, Volume Rendered or composite display

3-D navigation of endoscope using mouse or keyboard

Automatic path definition within the 3-D model between selected starting and target points

Automatic selectable collision detection to prevent virtual endoscope from breaking through walls

Endoscope size and field of view adjustable

Composite/individual filming of global, endoscope and correlation view

Stereo viewing mode with optional stereo kit

## Image Fusion Option

CT / MR image registration by easy-to-use manual or point-based techniques. Output orthogonal MPR fusion images in monochrome or color provide an adjustable balance between the two superimposed data sets.

### Display Layouts

MPR display of both studies

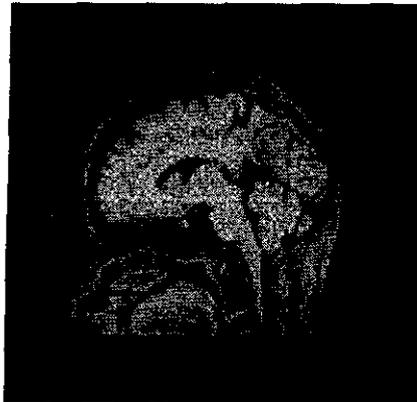
Superimposition display\* of both studies with adjustable intensity

Semiautomatic registration using anatomical landmarks. Fully manual registration also available

Selection of reference study

Definition, editing and deleting of anatomical markers available

\*Filming and Secondary Capture Image storage are not supported



## Calcium Scoring Option

This dedicated application estimates the amount of detected calcium in ECG-triggered imagery obtained on SOMATOM Plus 4 scanners equipped with Subsecond CardioCT. It calculates the Agatston score for calcium within user-defined regions for up to four coronary arteries.

### Detection of Calcium

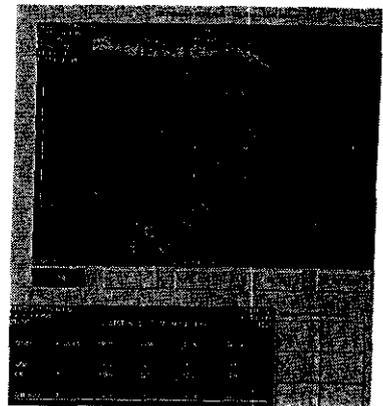
Slice-by-slice user-defined regions-- ellipses, freehand-draw, or semi-automatic seeded outlining

Region editing and selection/ deselection from contributing to calcium score

Regions user-allocated to one of four arteries (LM, LAD, CX, RCA) or noise

Region definitions storable in patient database and archivable to MOD

Image annotation



### Reporting Calcium Score

Detailed report printout of score table on film sheet or Postscript compatible printer (optional)

Filming of individual images

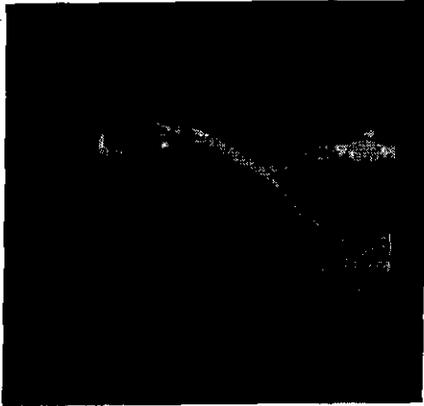
### Display Layouts

Selectable layouts for high-detail display or axial slice plus MIP and MPR views

Tabular display of Agatston score in up to four coronary arteries updated automatically

# Realtime 3D Option

**Advanced interactive 3-D working environment using real-time Volume Rendering, Maximum Intensity Projection, Shading and Multi-Planar Reformatted displays. Includes 3-D measurements, Stereo visualization and Virtual Endoscopy with Fly-Around.**



### Interactive 3-D Visualization

- Display of anatomy as 3-D volume, Real-time manipulation
- Visualization in monochrome or color to aid tissue determination
- Shading with adjustable light source
- Volume-rendered display
- Maximum Intensity Projection
- Multi-Planar Reformating
- Perspective Viewing

### Interactive 3-D Volume Rendering

- Real-time visualization of volume-rendered 3-D dataset
- Real-time adjustment of rendering parameters including opacity
- Color Tissue Classifier

### Interactive 3-D Angio

- Real-time display of 3-D dataset using Maximum Intensity Projection
- Interactive viewing from any angle

### Interactive Multi-Planar Reformating (MPR)

- Real-time placement of up to 6 oblique MPR cutplanes
- Display of 3 orthogonal MPRs with correlated 3-D dataset
- MPR displayed using VRT or MIP

### Volume-Rendered Virtual Endoscopy and Fly-Around

- Positioning of viewpoint anywhere inside the 3-D volume
- No prior preprocessing of images necessary
- Volume-rendered display
- Real-time performance
- Additional external orientation view

### Interactive 3-D Tools

- Interactive editing using up to 6 freely positioned clip planes
- Near and far clip-plane editing in endoscopic modes (thin slice)
- 3-D Distance and Angle measurements
- Global visualization presets available for all patient cases
- Case-dependent and modality-dependent visualization presets
- 3-D Pan and Zoom

### Display Layouts

- Single, dual and quad 3-D volume views
- MPR view giving 3 orthogonal MPRs plus a correlated 3-D volume view. Each view can be displayed using a different visualization technique
- Fly View with 3-D endoscopic and external orientation view

### Stereo

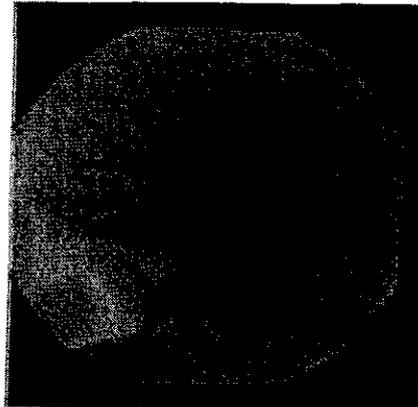
- Stereo display function for visualization of spatial relationships – requires stereo glasses

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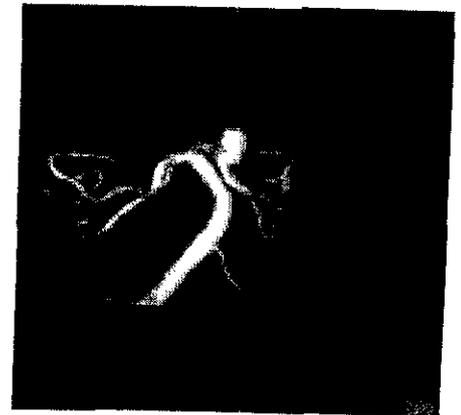
# 3D Angio Option

**A new development in 3-D visualization is the reconstruction of 3-D views from angiographic images, providing a powerful diagnosis and intervention tool for neuroradiologists and radiologists.**

At a C-arm system, a rotational angiographic examination DYNAVISON is performed over an angle of 200° with a speed up to 40°/s and with up to 80 projections. These images are transferred to 3DVirtuoso for generation of 2-D slices from the projections. The 2-D slices are then used to generate 3-D views of contrast-filled vessels to show aneurysms, arterio venous malformations AVM, stenoses, and also coils, glue, stents, and OR clips. The calculation time is short enough that the patient can remain on the table until the decision on further treatment is made.



*Selection of VOI in the angiographic image for slice selection*



*Aneurysm with wide neck*

## **Workflow**

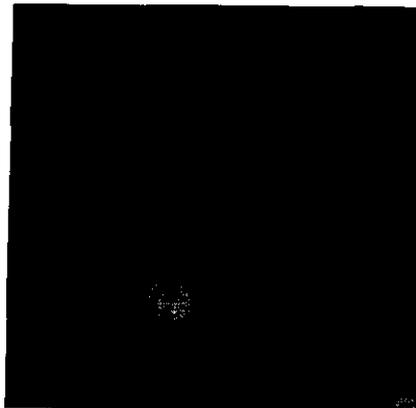
Rotational angiographic projection images are sent via fast, dedicated Ethernet interface to 3DVirtuoso

Image correction for geometrical inaccuracy and distortion from image intensifier

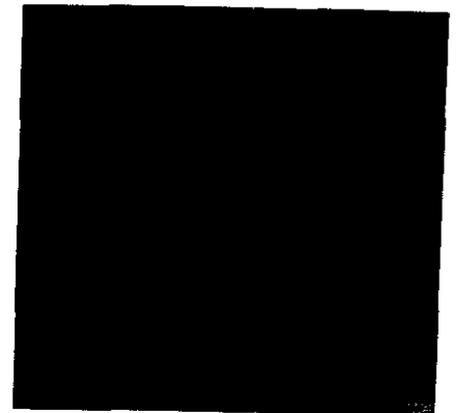
User-selectable VOI defined for slice generation

2-D slices calculated using a cone beam algorithm

The "CT-like" slices stored in patient data base for 3-D reconstruction and visualization



*Aneurysm at MCA filled with coils*



*Aneurysm without coils to see remaining space*

## **Specification**

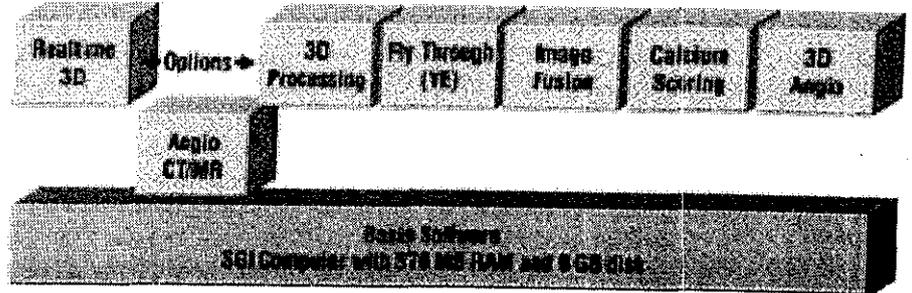
Slice resolution 128 × 128, 256 × 256 or 512 × 512

User-selectable High Speed or High Quality Reconstruction methods

Unsubtracted (DA) or subtracted (DSA) images can be used for 3-D reconstruction

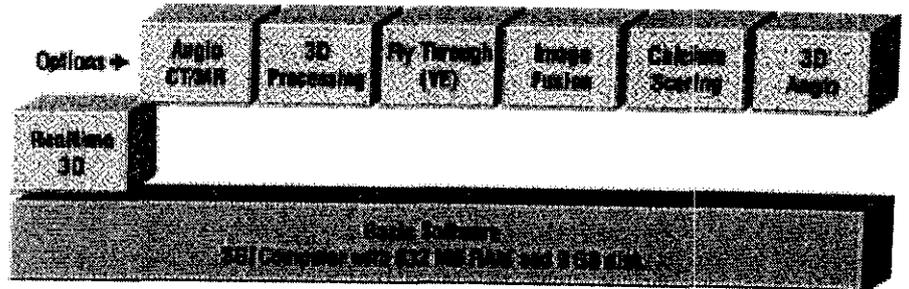
**3DVirtuoso P1 Modular**

3DVirtuoso P1 Modular includes the Basis Software plus the **Angio CT/MR** option and the SGI computer. Realtime 3D, 3D Processing, Fly Through, Image Fusion, Calcium Scoring and 3D Angio can be purchased as options.



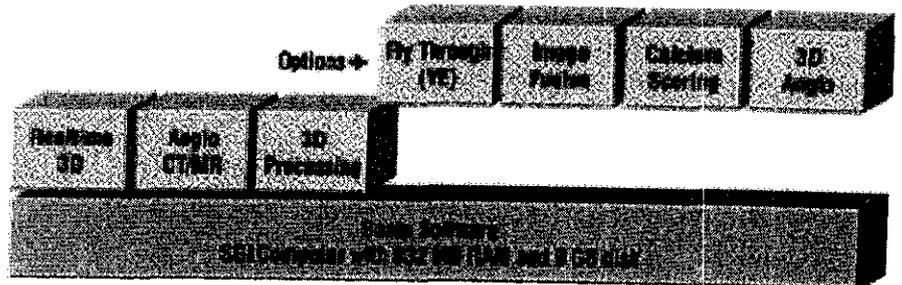
**3DVirtuoso P2 Realtime**

3DVirtuoso P2 Realtime includes the Basis software plus the **Realtime 3D** option, the SGI computer and two pairs of stereo glasses. Angio, 3D Processing, Fly Through, Image Fusion, Calcium Scoring and 3D Angio can be purchased as options.



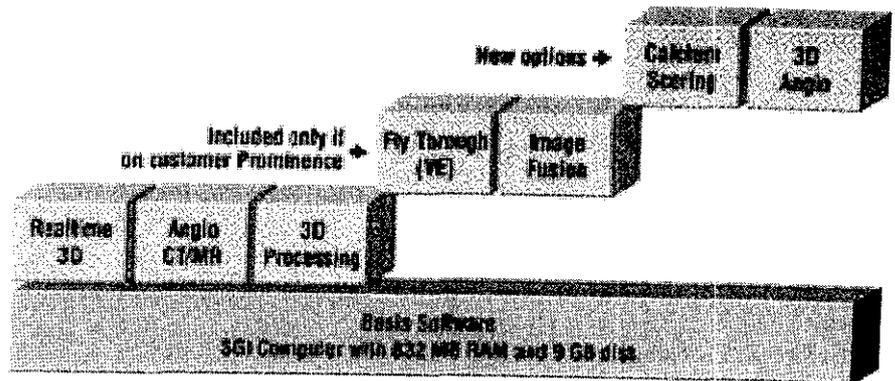
**3DVirtuoso P3 All-in-One**

3DVirtuoso P3 All-in-One includes the Basis software with the **Real-time 3D, Angio** and **3D Processing** software plus the SGI computer and two pairs of stereo glasses. Fly Through, Image Fusion, Calcium Scoring and 3D Angio can be purchased as options.



**3DVirtuoso Upgrade**

3DVirtuoso Upgrade converts an existing customer Prominence to a 3DVirtuoso All-in-One. The upgrade includes the Basis software, SGI computer, two pairs of stereo glasses and the Realtime 3D option, plus all software options that the customer already owns on the Prominence. The Prominence host ID must be provided with the order. The Prominence system is removed when the upgrade is installed.



3DVirtuoso

# Hardware Specifications

## SiliconGraphics (SGI) Computer

| Ordering Information    |         |         |           |
|-------------------------|---------|---------|-----------|
| Systems & Upgrades      | CT      | MR      | AX        |
| P1 Modular              | 4417718 | 5803213 | -         |
| P2 Realtime             | 4417726 | 5803452 | -         |
| P3 All-in-One           | 4417734 | 5803460 | 44-22-809 |
| Upgrade from Prominence | 4417742 | 5803577 | -         |
| Options                 |         |         |           |
| Realtime 3D             | 4417528 | 5803551 | -         |
| Angio                   | 4417759 | 5803544 | -         |
| 3D Processing           | 4417679 | 5803221 | -         |
| Fly Through             | 4417338 | 5803239 | 44-22-817 |
| Image Fusion            | 4417346 | 5803247 | -         |
| Calcium Scoring         | 4417767 | -       | -         |
| 3D-Angio*               | -       | -       | 44-22-881 |
| CPU Extension           | 4417320 | -       | 44-22-825 |
| Kit Stereo              | 4417536 | 5803569 | -         |

\*3D-Angio requires a system configuration with a 6 GB disk

|                    |               |
|--------------------|---------------|
| SGI computer       | 02            |
| Monitor*           | 21"           |
|                    | 1280 x 1024   |
|                    | 75Hz          |
| RAM                | 576MB (min)   |
| Hard disk Capacity | 9 GB          |
|                    | 8,000 ima-512 |
| MTBF               | ≥ 70,000 h    |

\* 20" monitor supplied until Oct '99

Video output PAL/NTSC

Stereo capable (requires Kit Stereo)

Ethernet connection 10BaseT

CD-ROM drive

**Additional memory (optional).**

For extra RAM storage capacity

|                |         |
|----------------|---------|
| CPU Extension  | 256MB   |
| System maximum | 1024 MB |

## Installation

|                |             |
|----------------|-------------|
| <b>02</b>      |             |
| w/h/d [mm]     | 229×305×267 |
| Weight [kg]    | 10          |
| Power [W]      | 175         |
| <b>Monitor</b> |             |
| w/h/d [mm]     | 498×505×474 |
| Weight [kg]    | 31          |
| Power [W]      | 180         |

## Regulatory Compliance

- IEC 950 CSA/TUV
- CE

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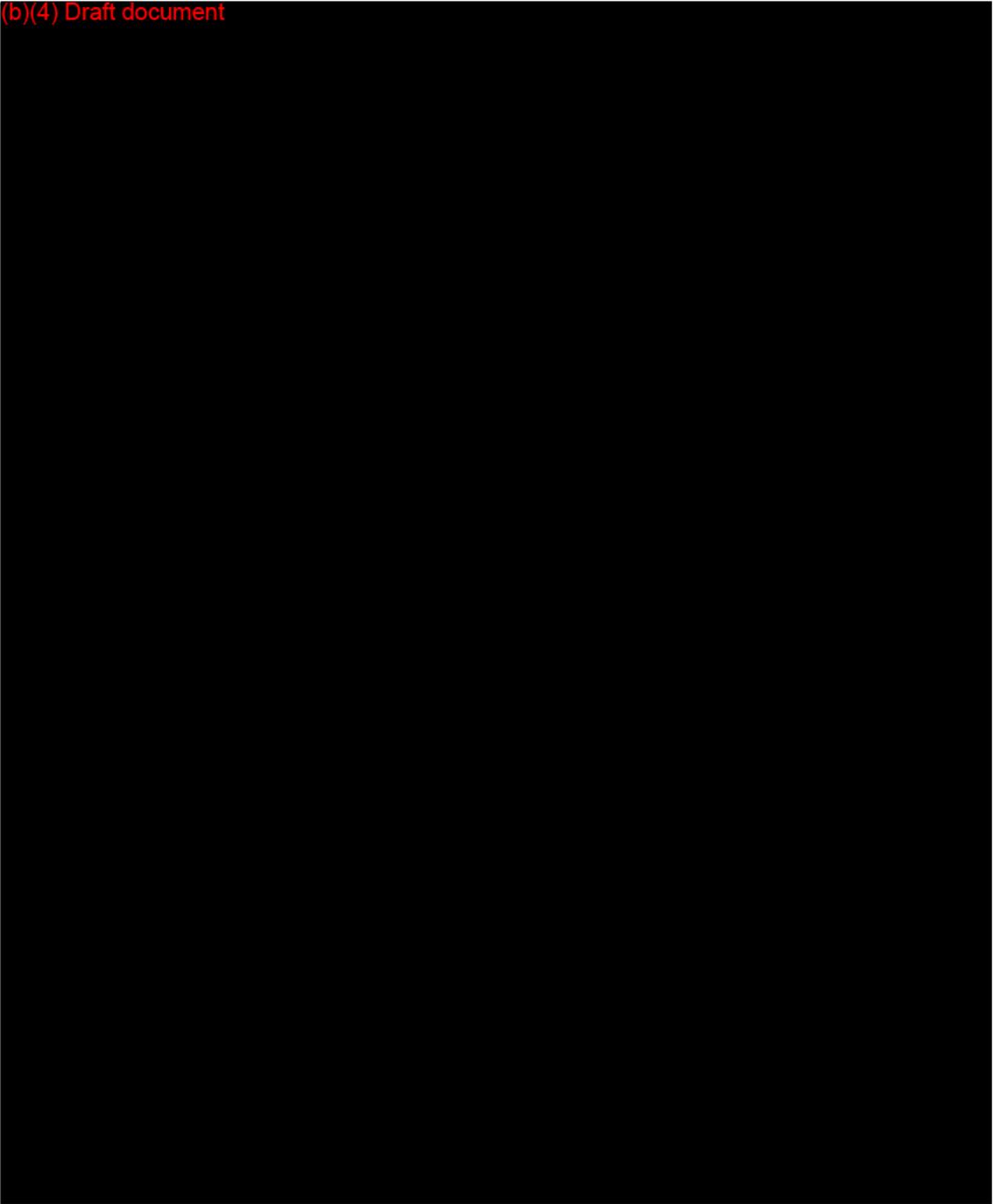
**Attachment 9**  
**Draft Promotional Literature**

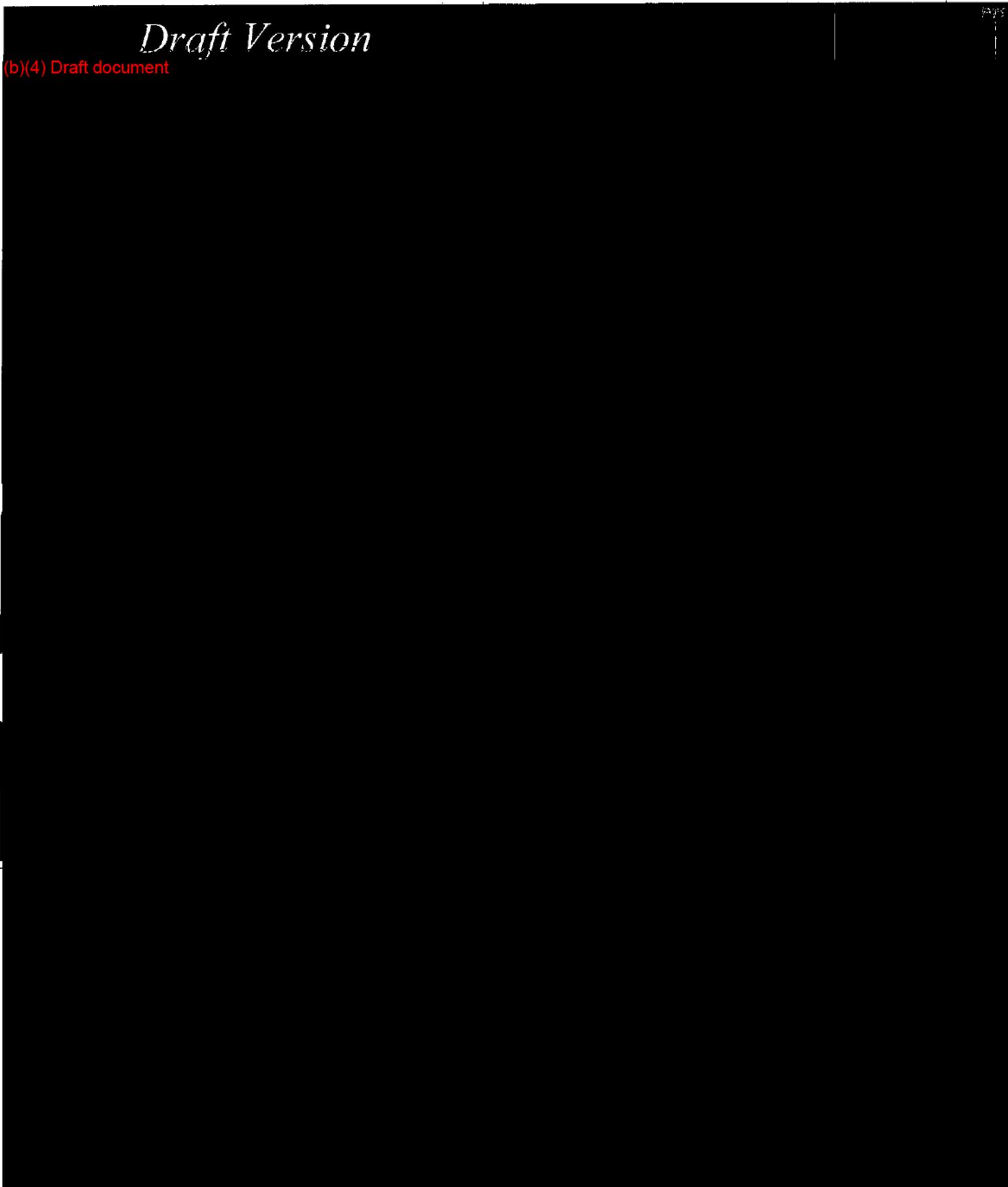
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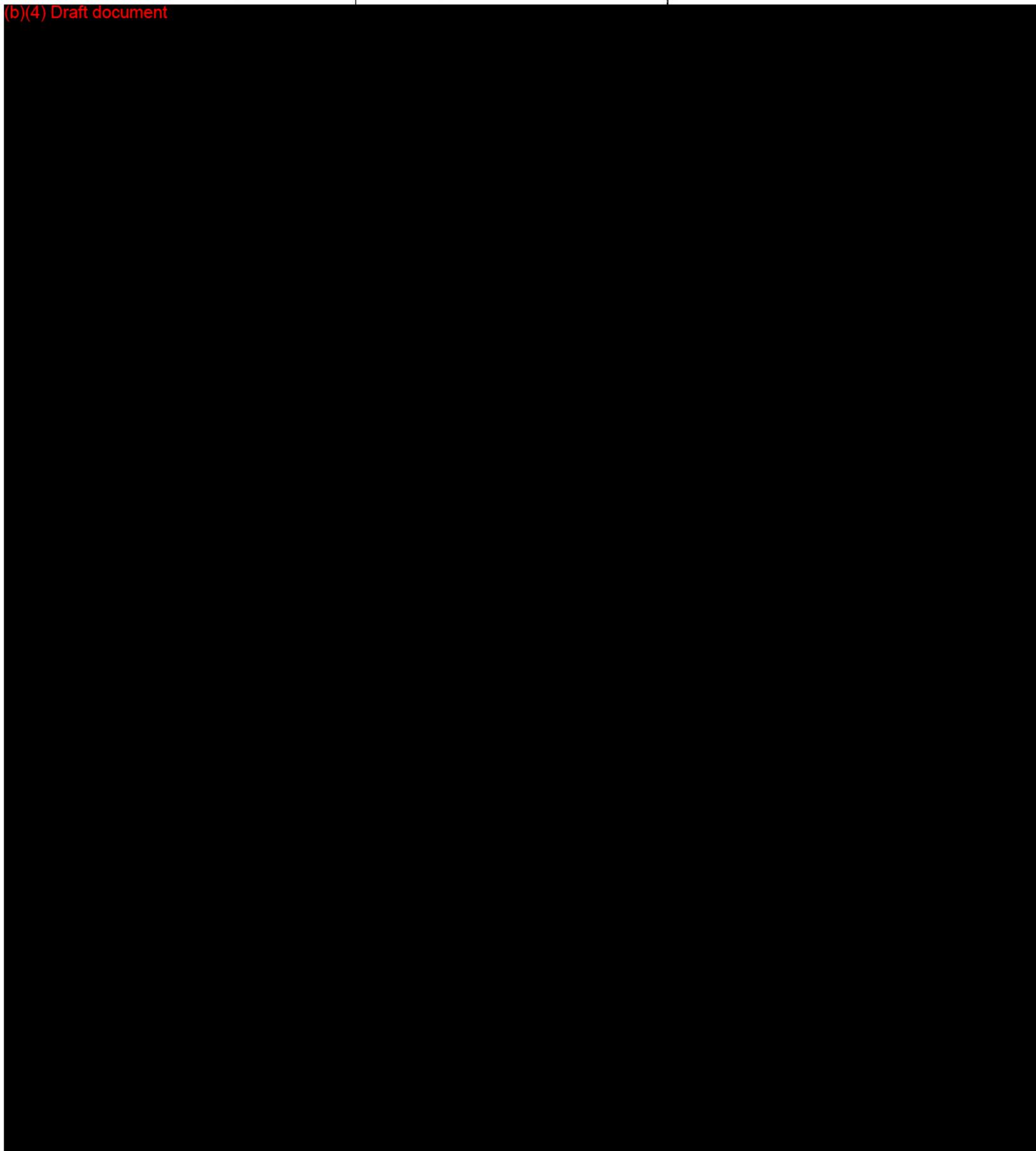
**SIEMENS**

medical

# Draft Version

Records processed under FOIA Request # 2015-4839; Released by CDRH on 10-21-2015

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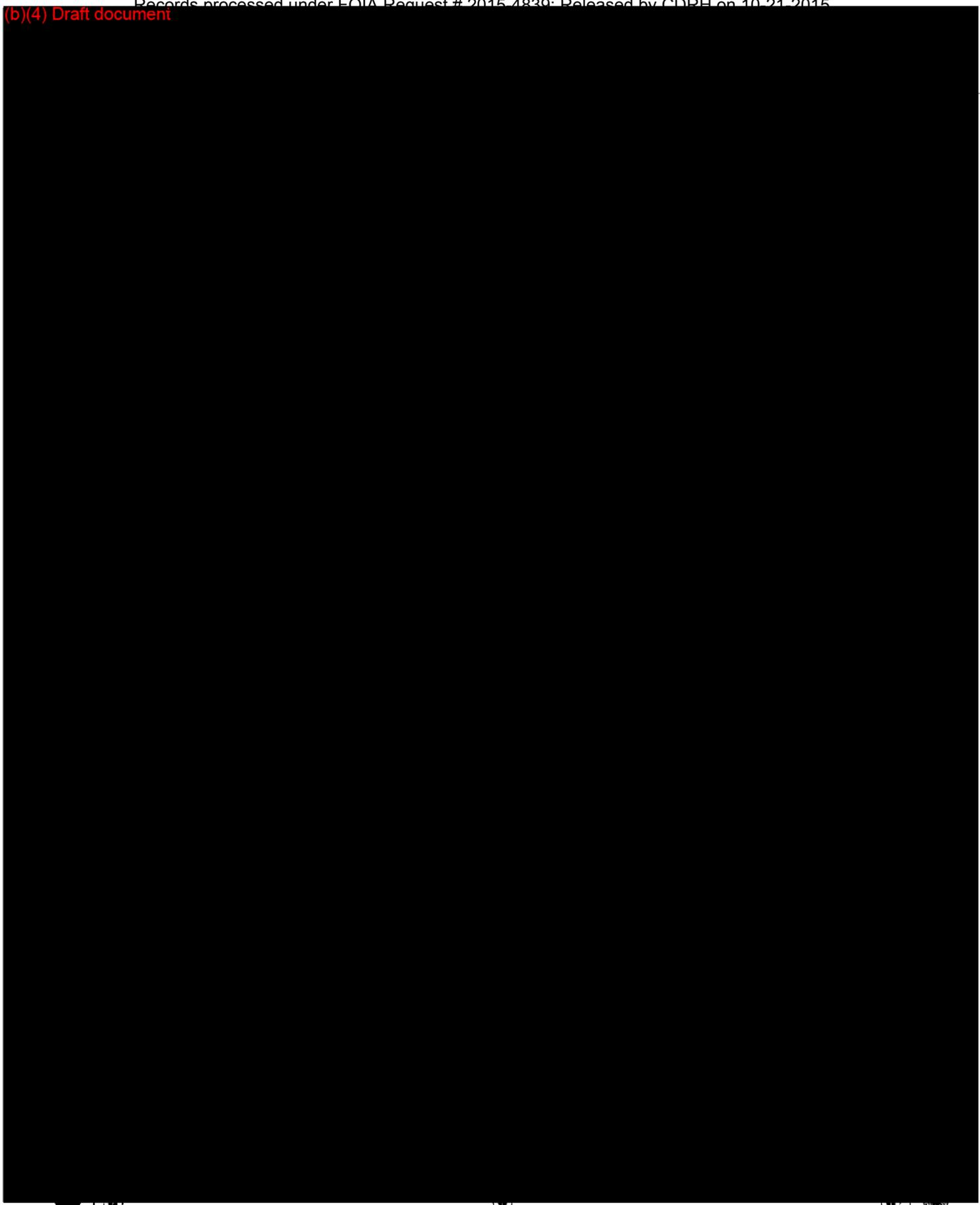
CT-Applications

Siemens Medical  
Solutions that help

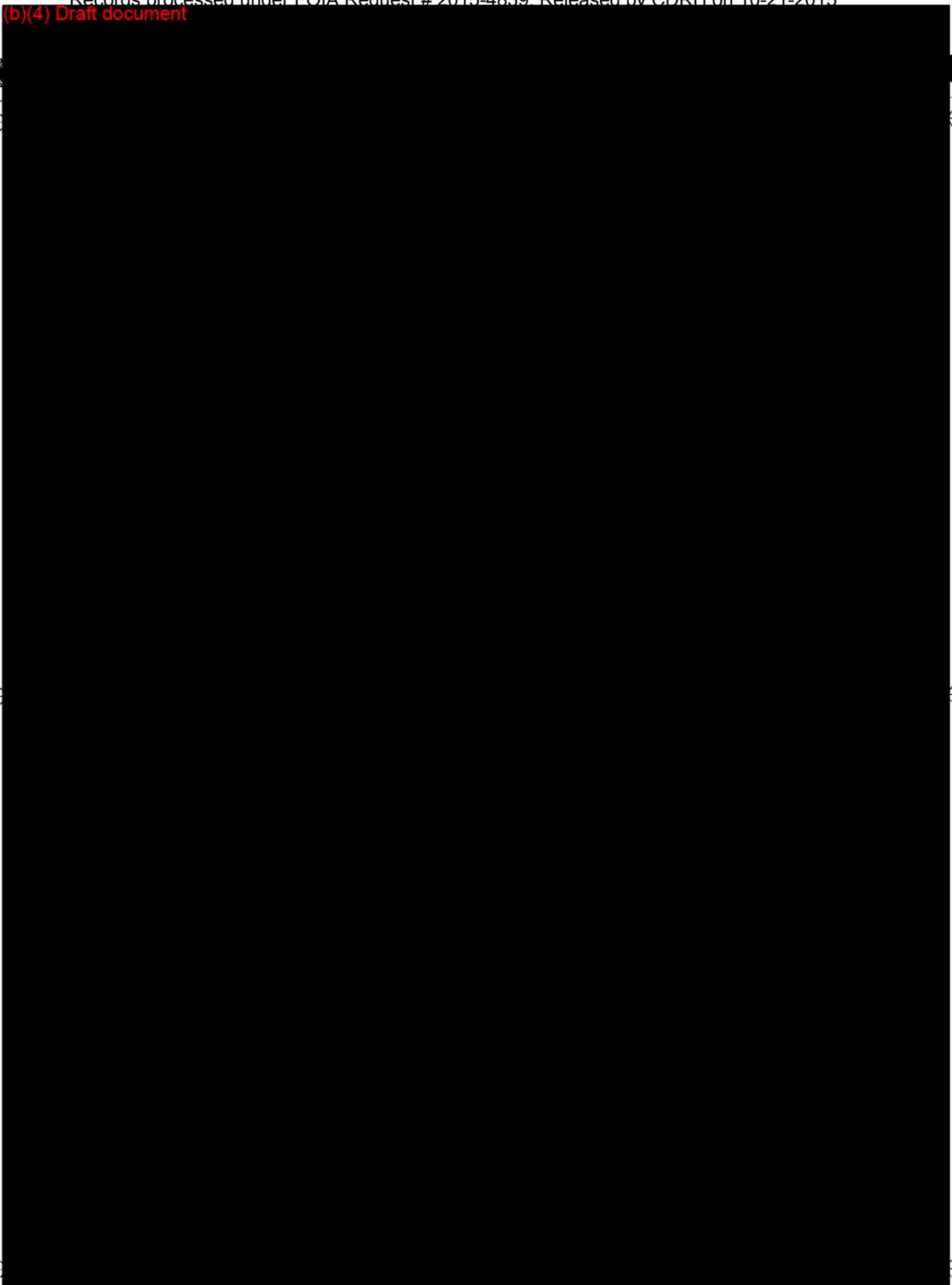
Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

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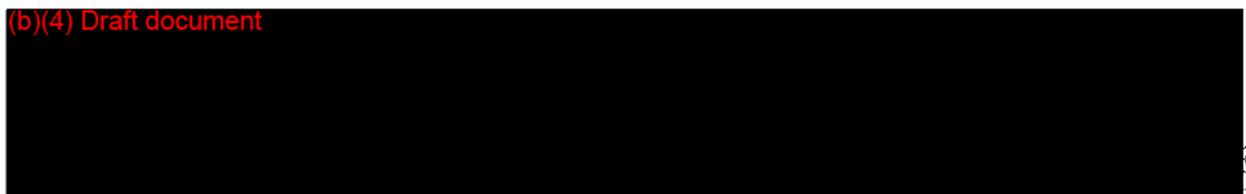
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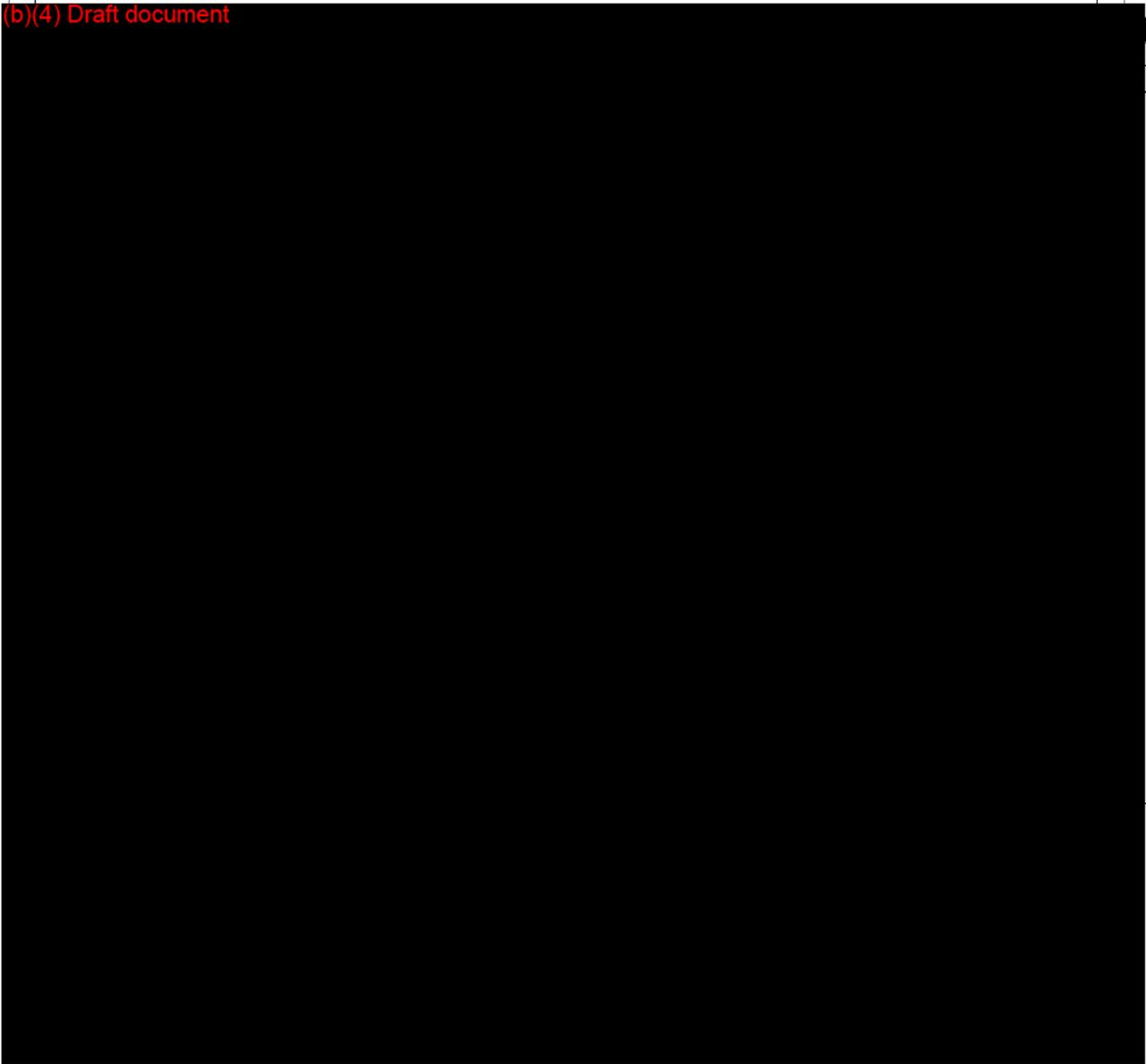
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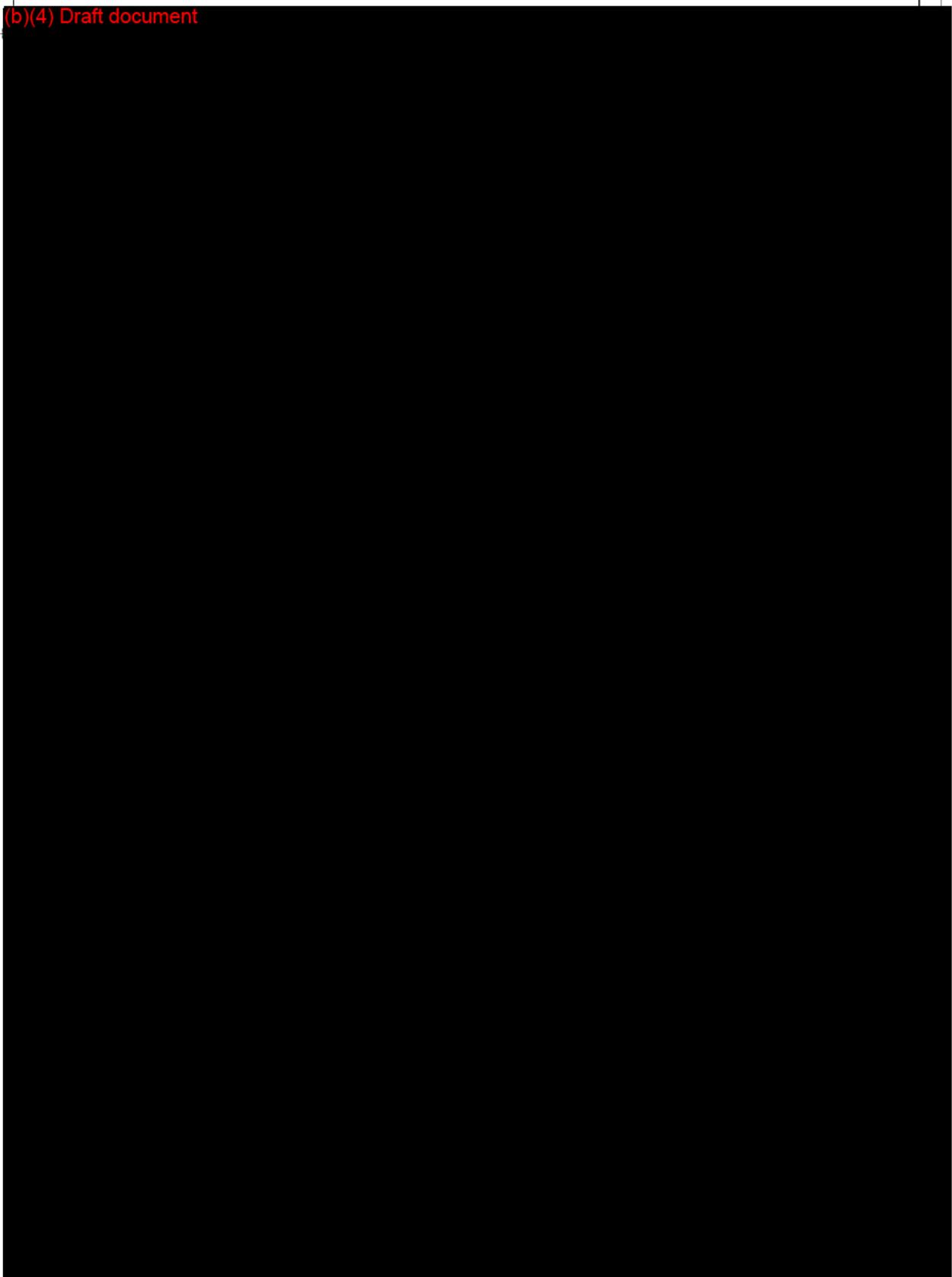
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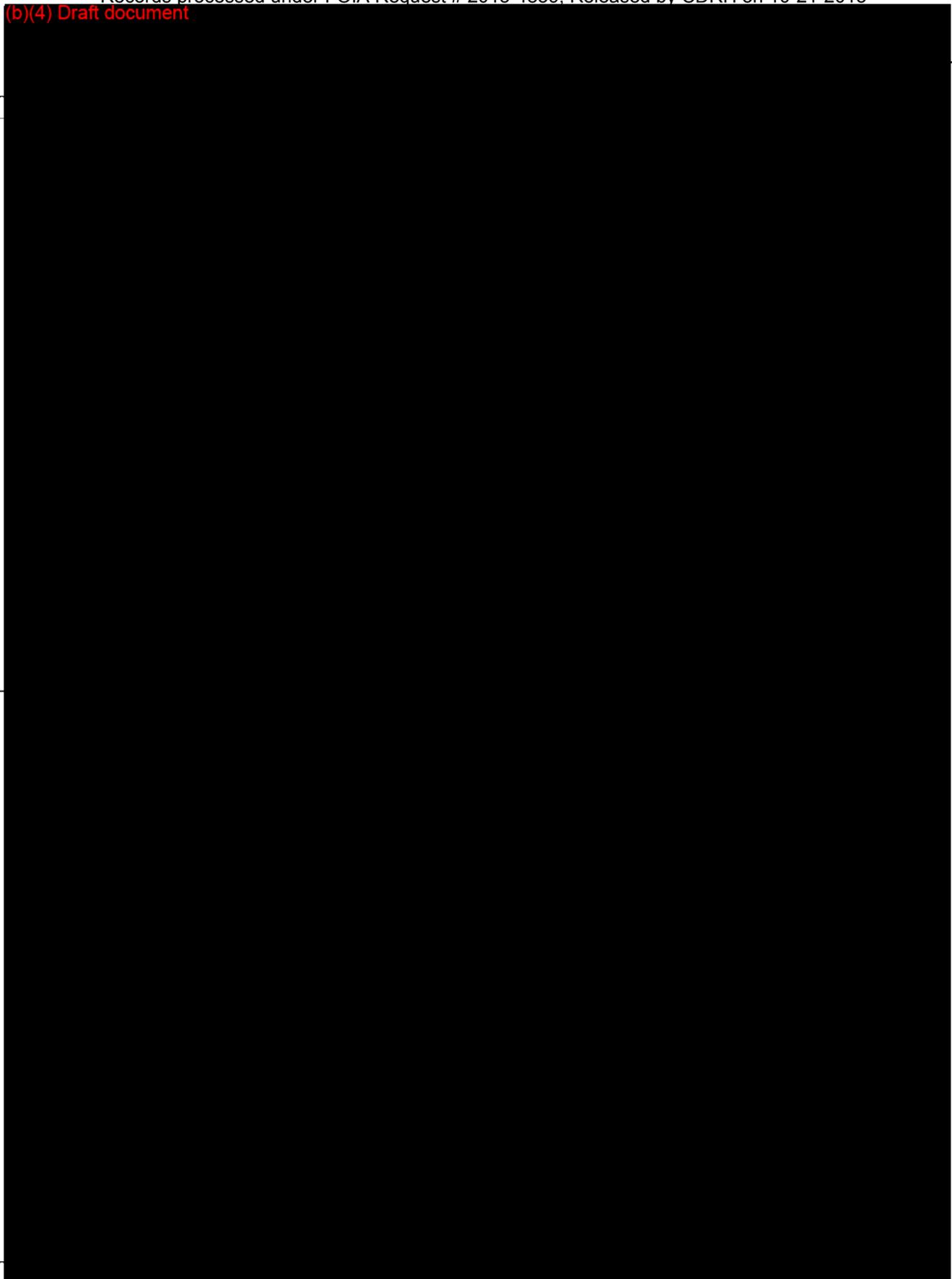
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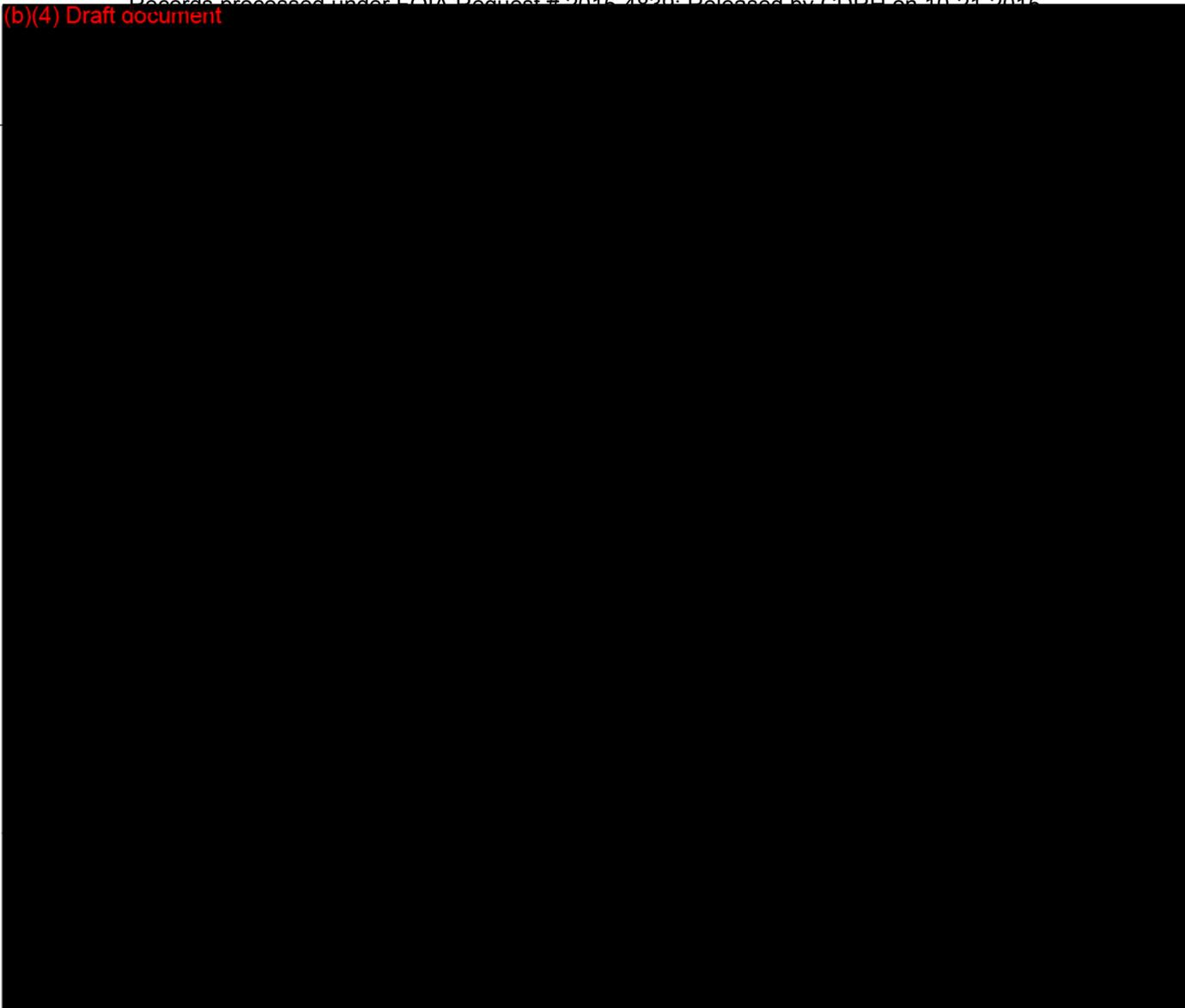
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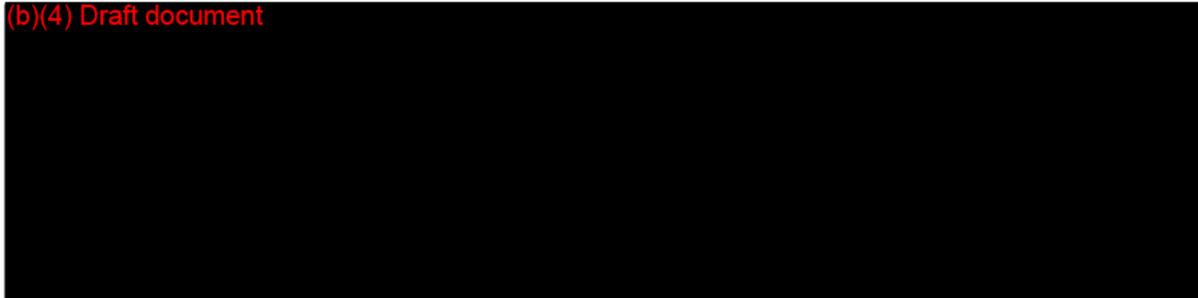
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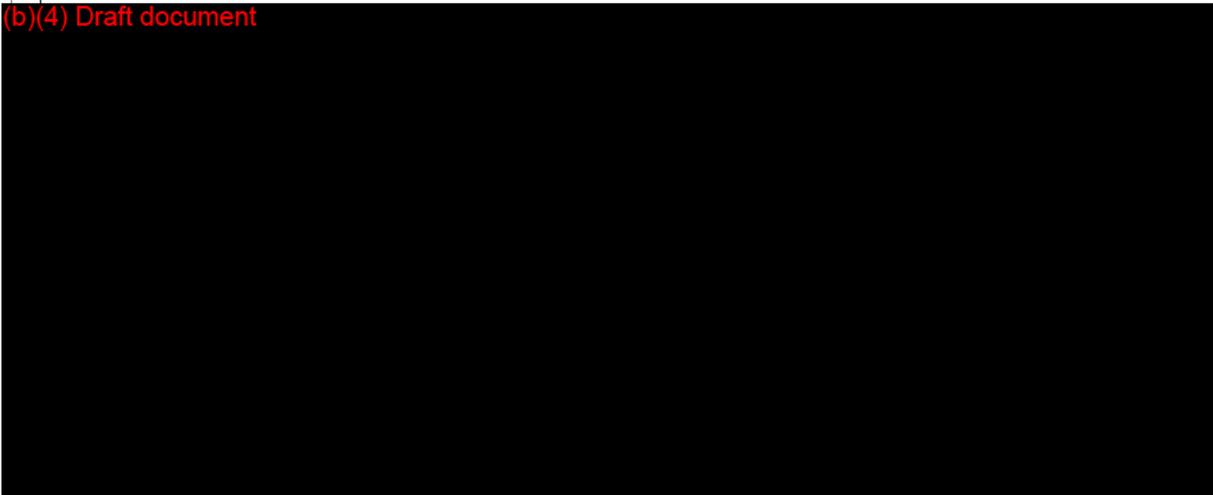
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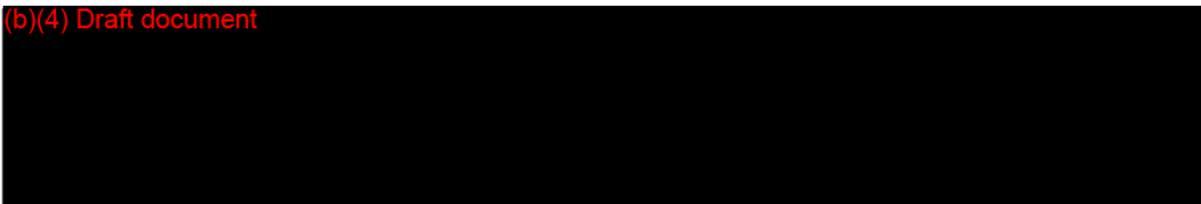
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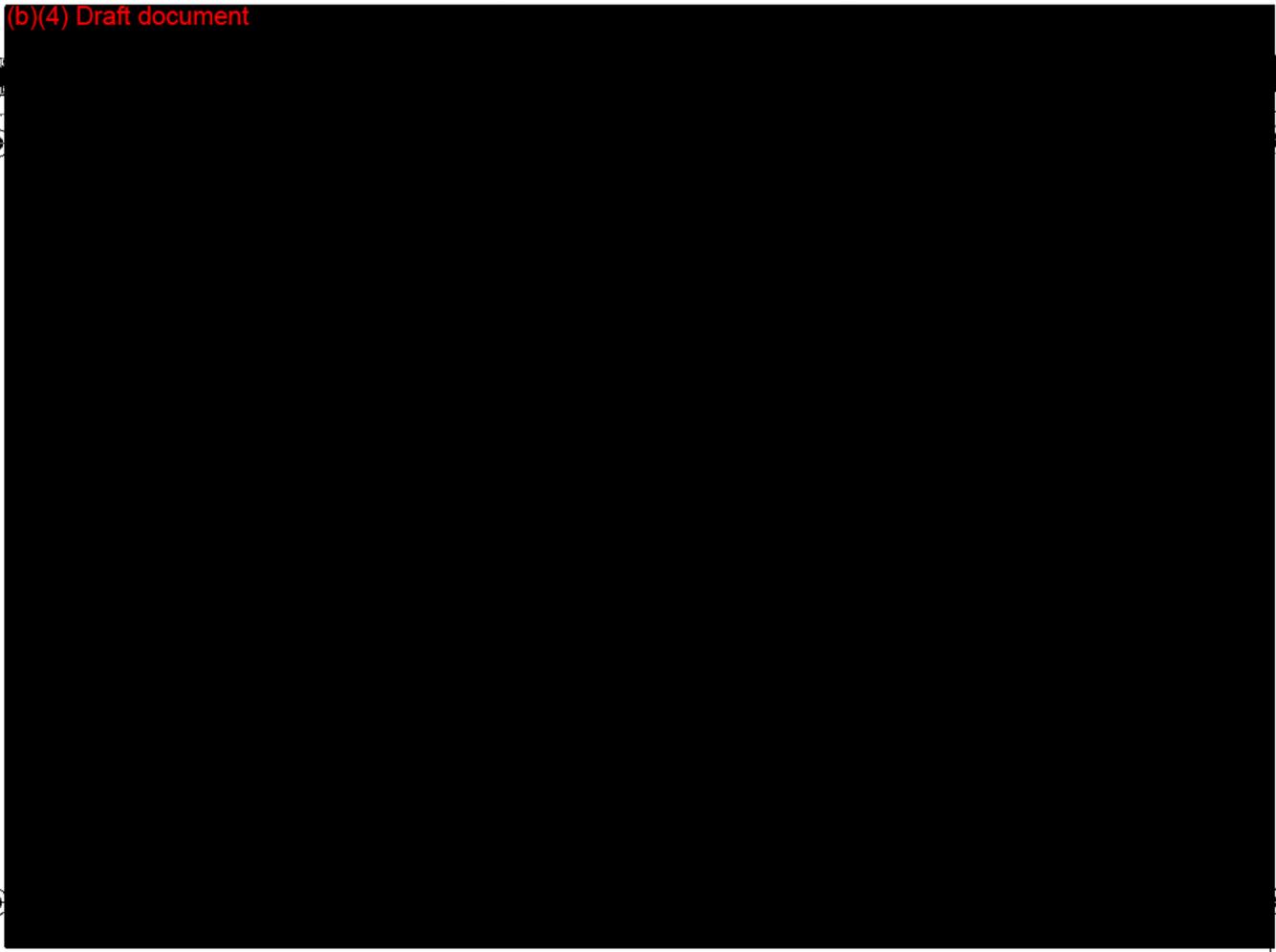
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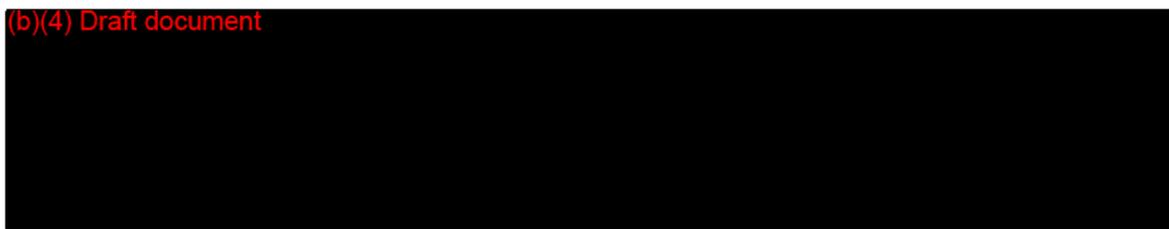
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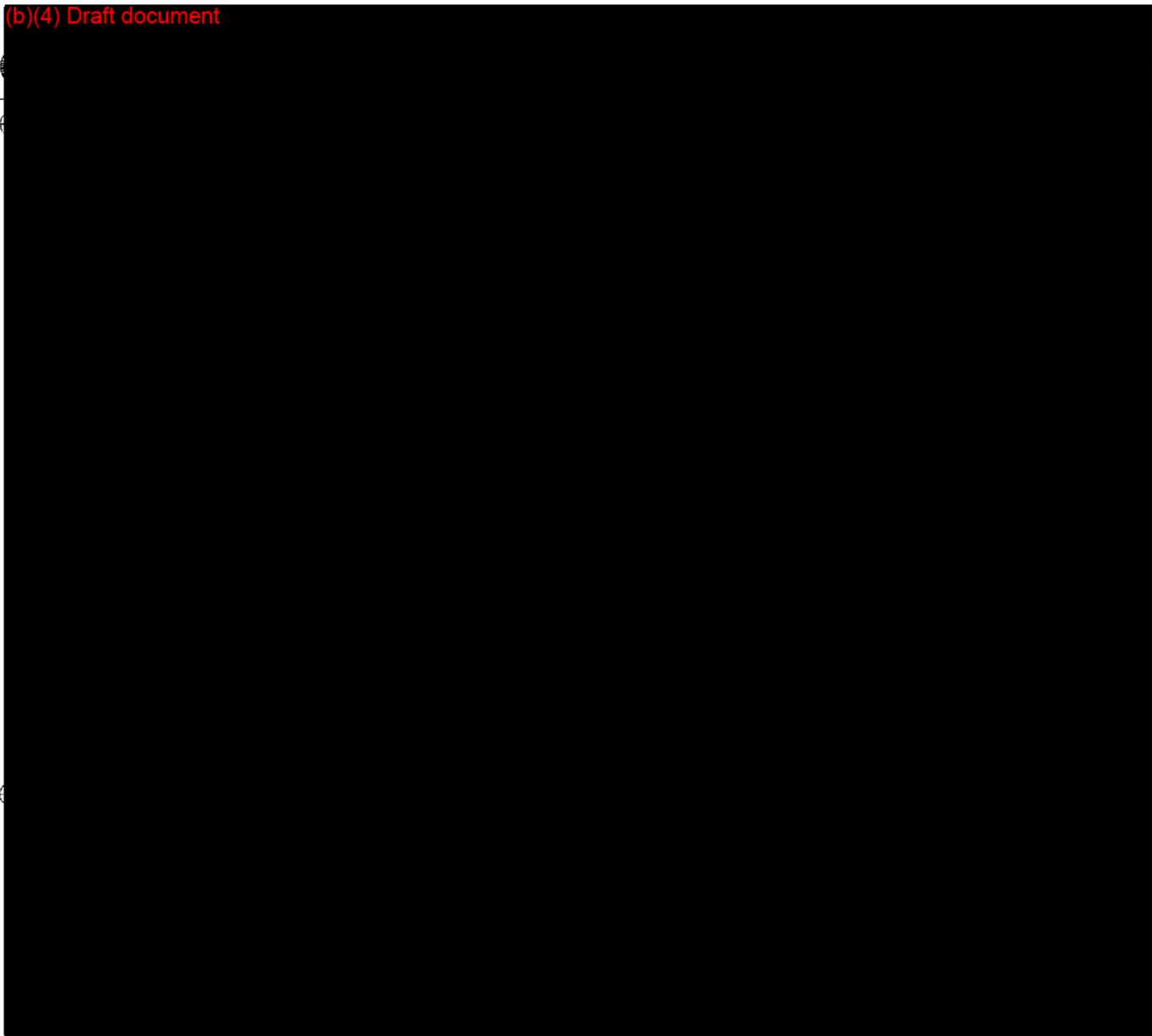
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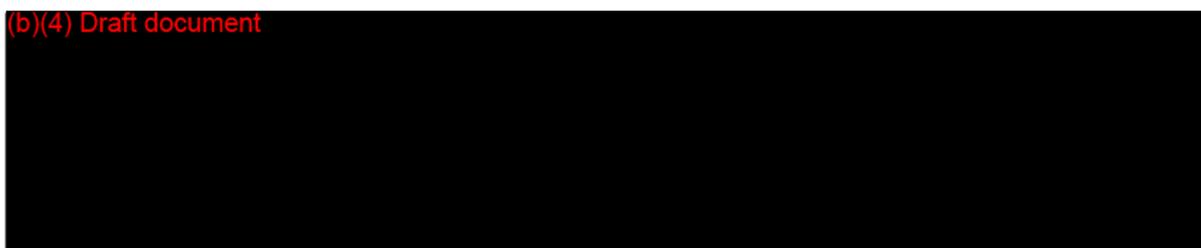
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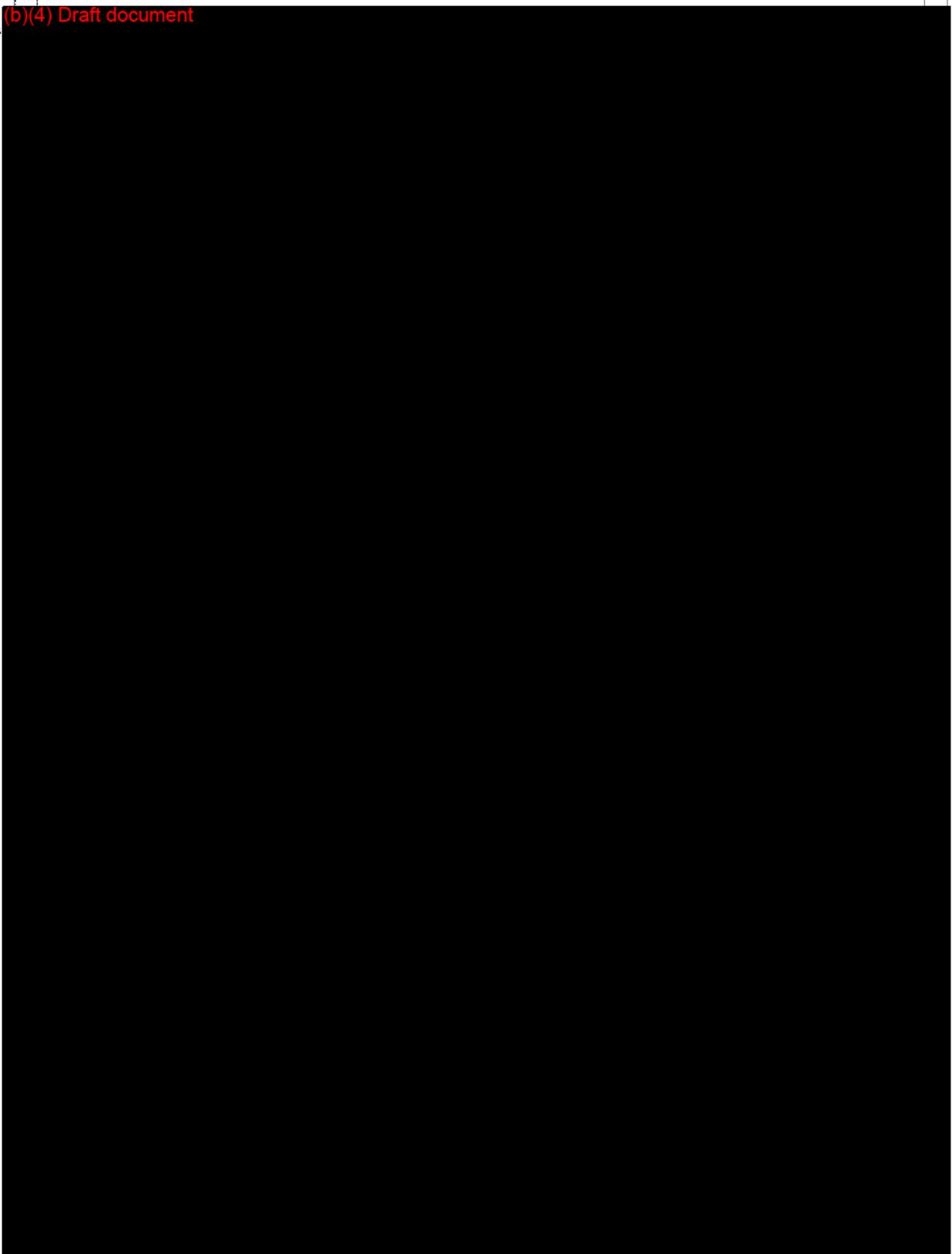
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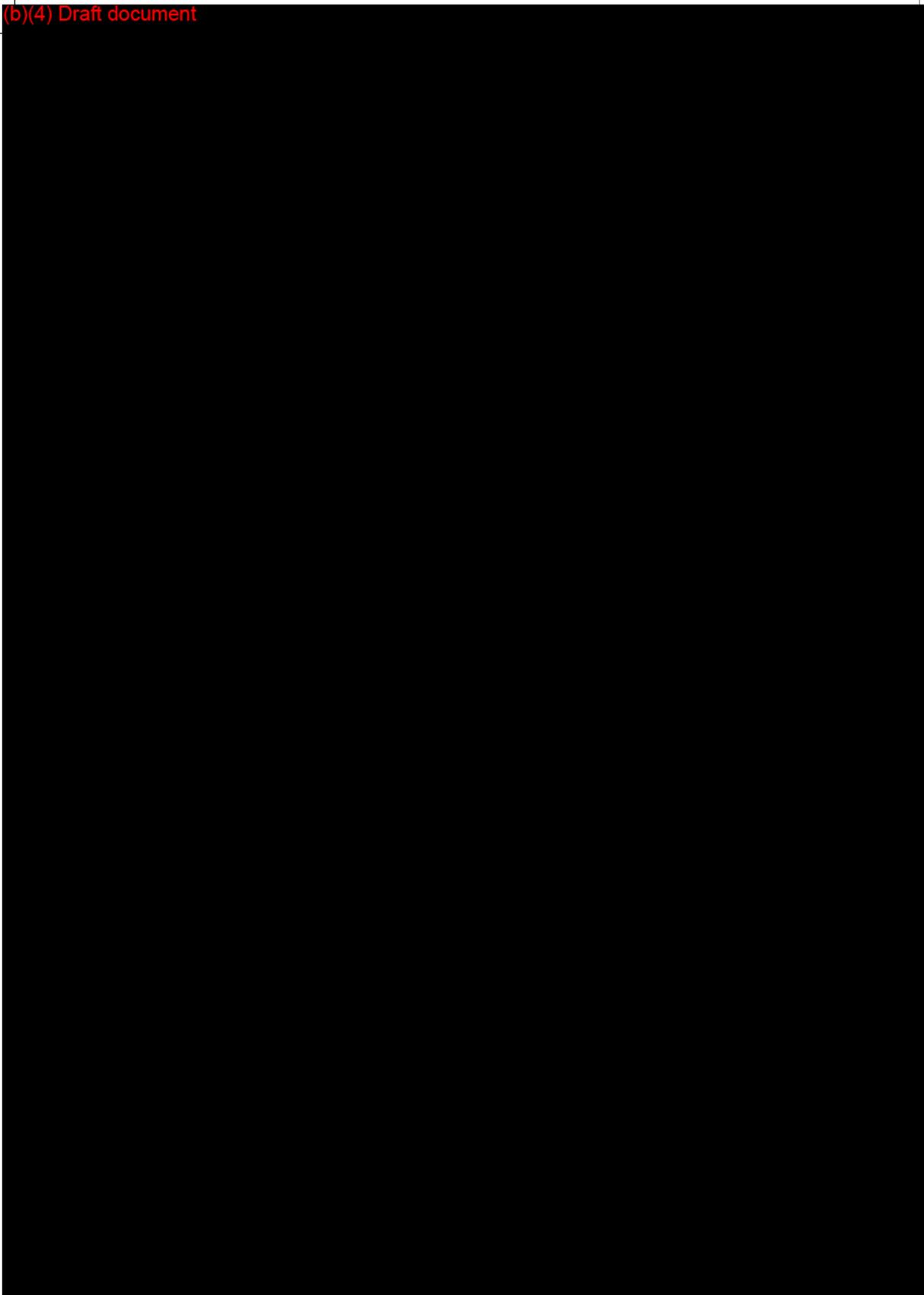
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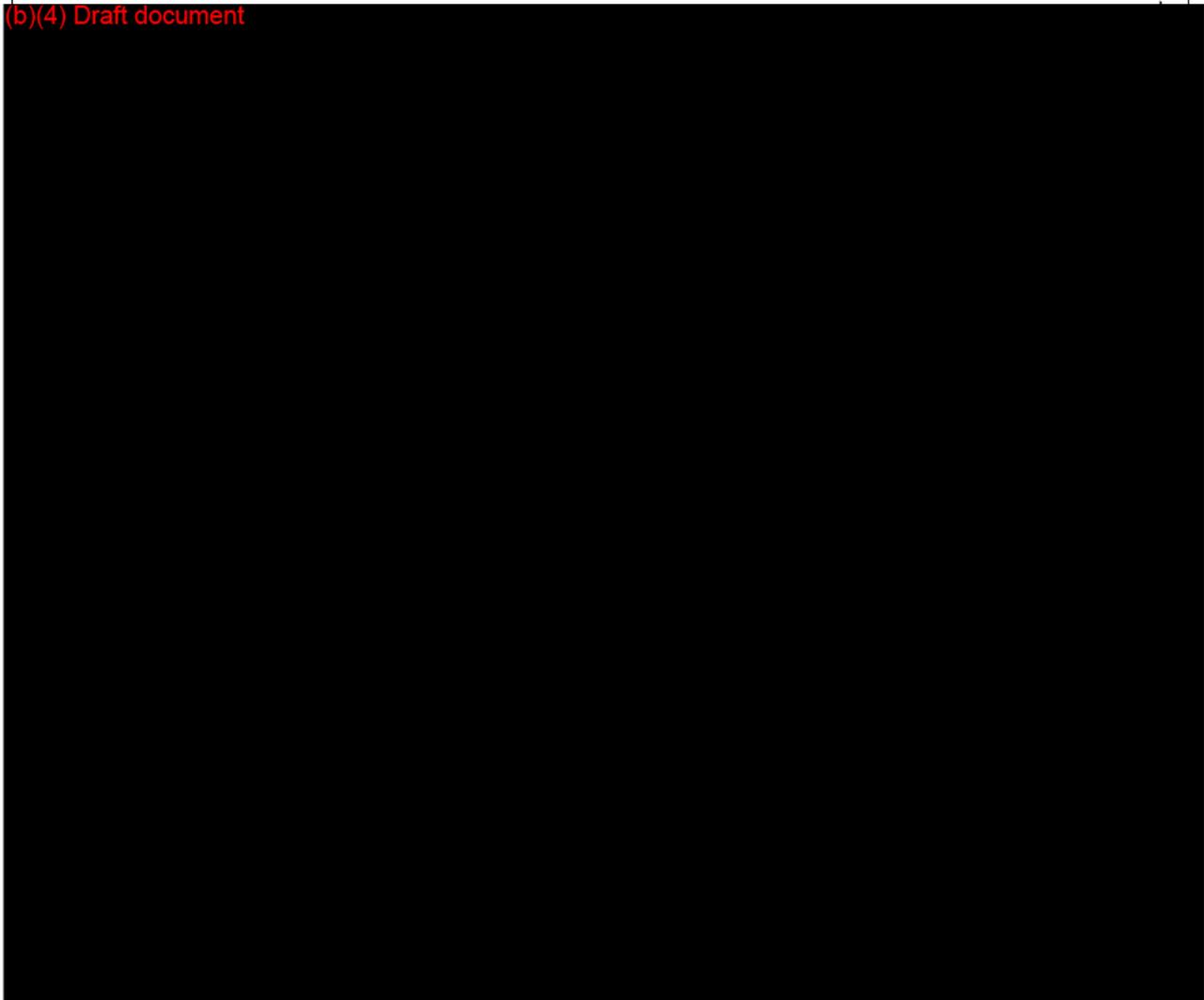
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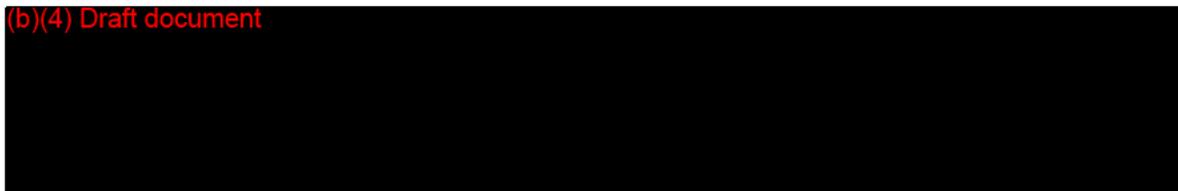
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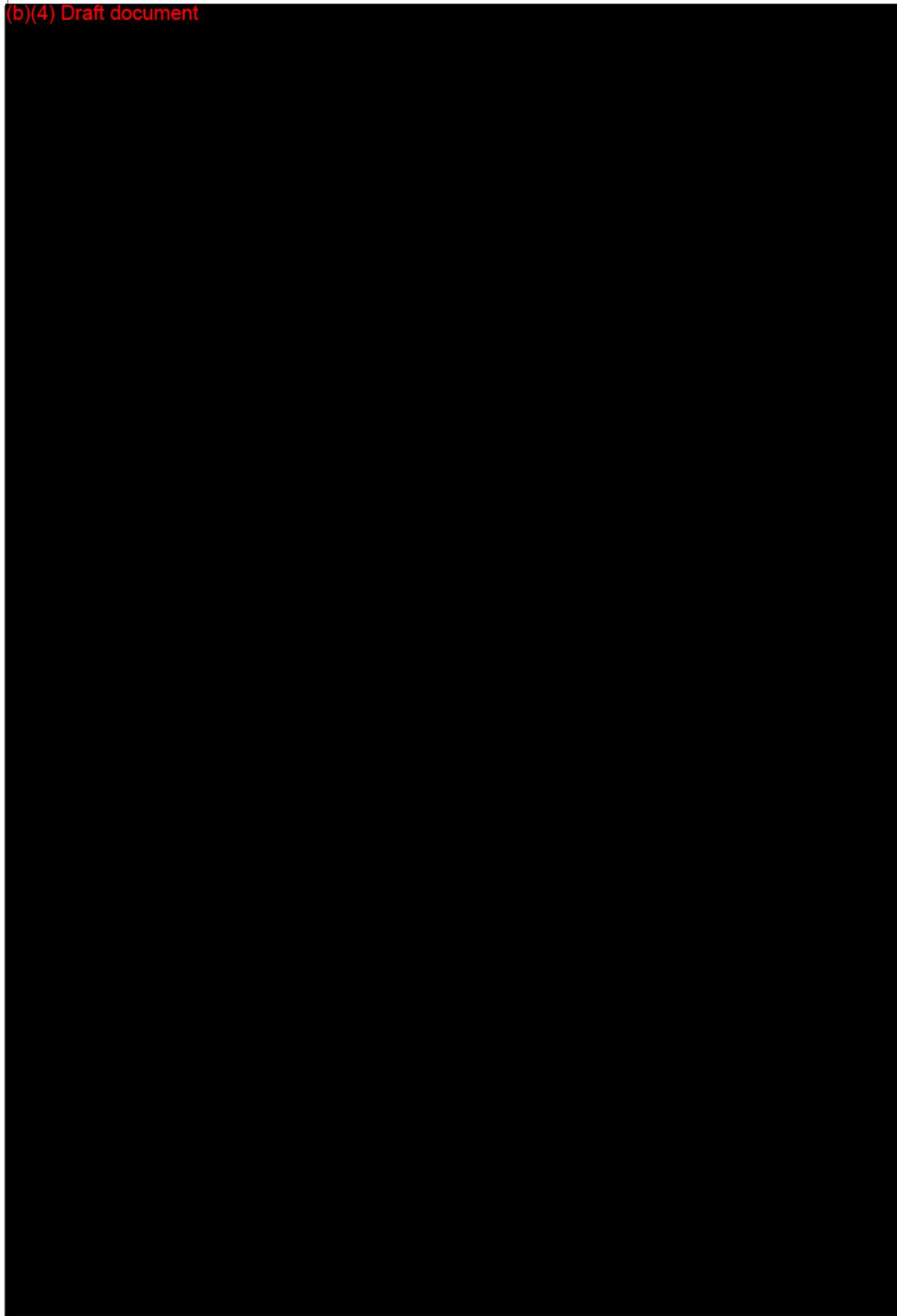
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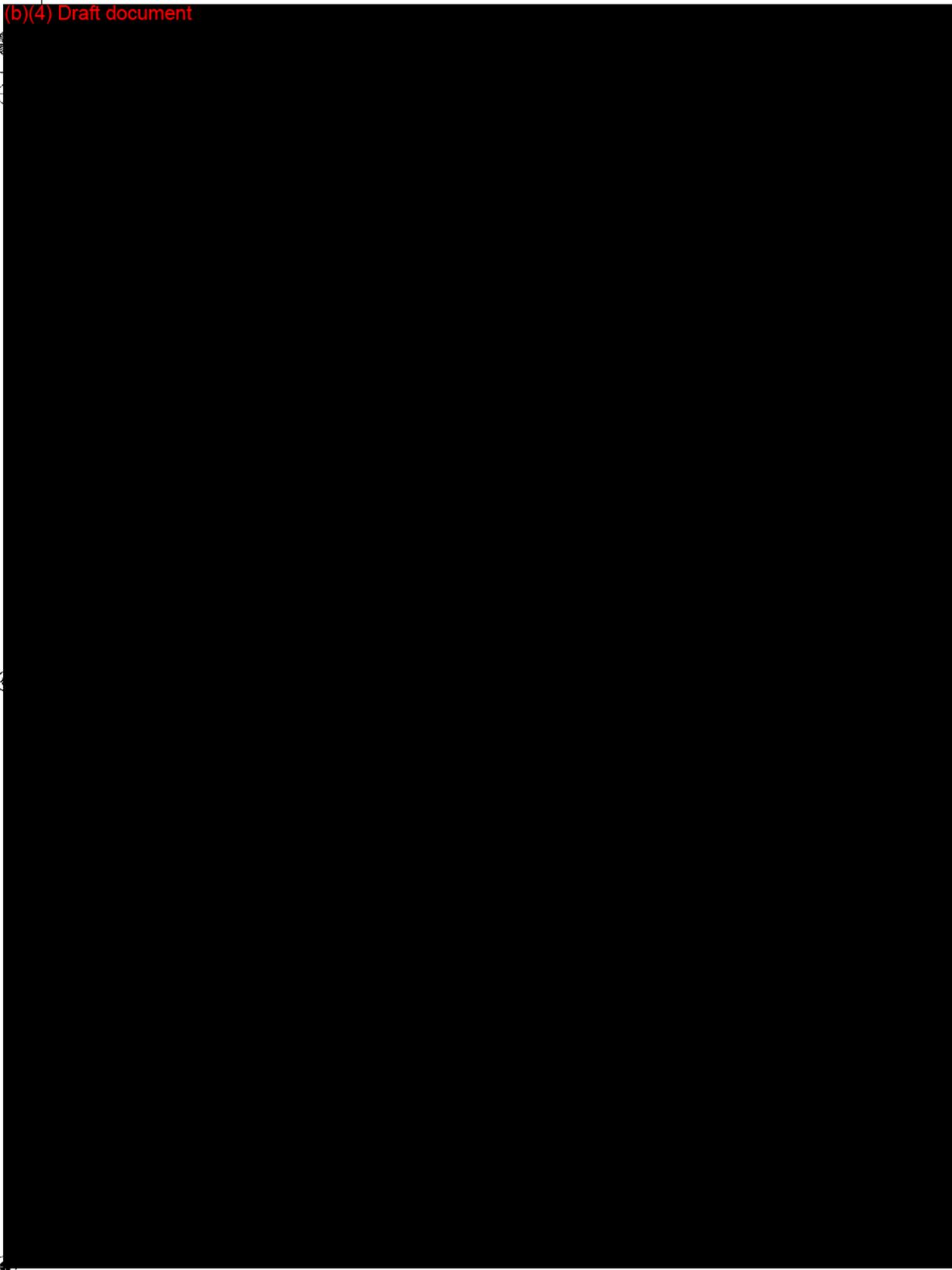
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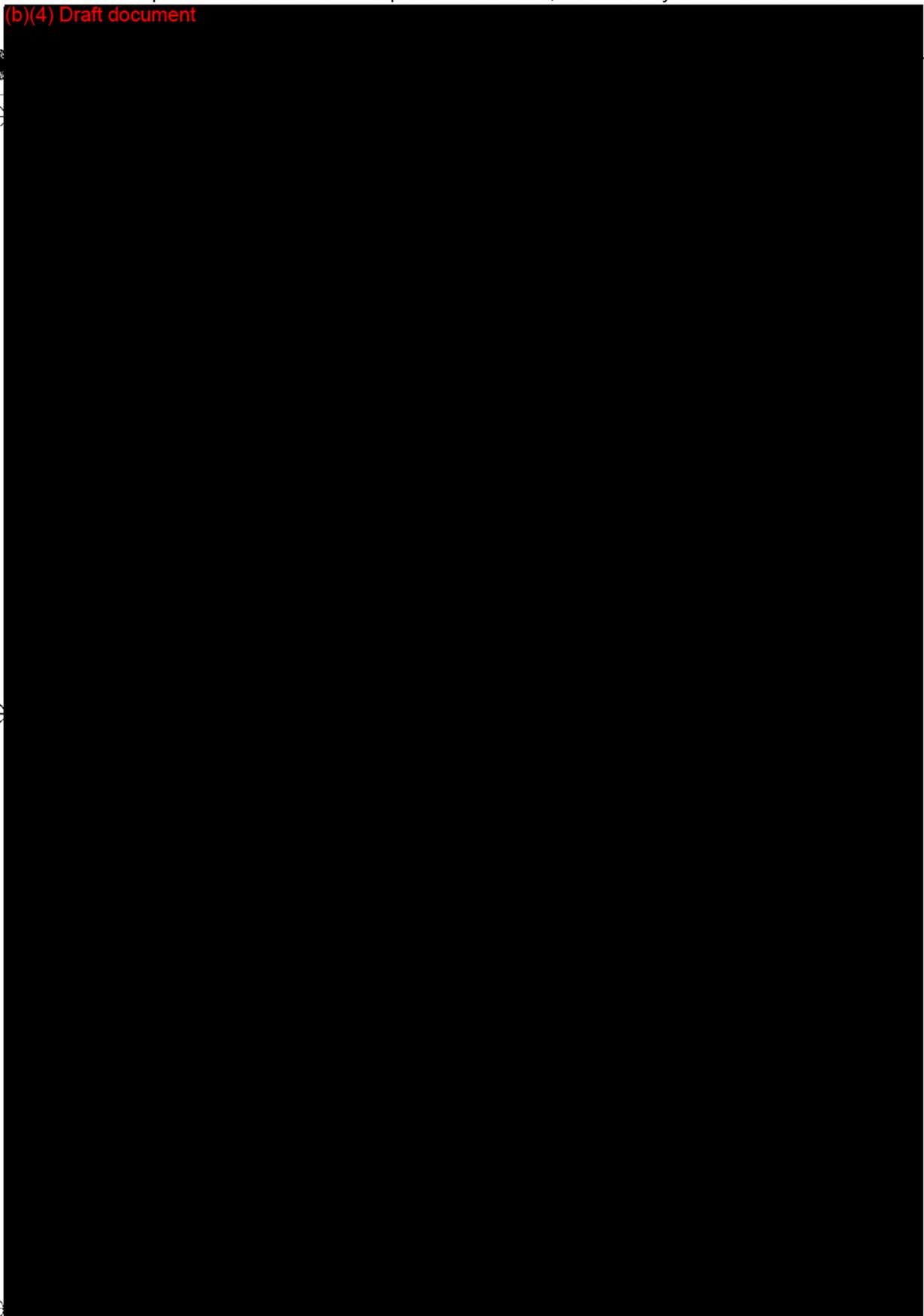
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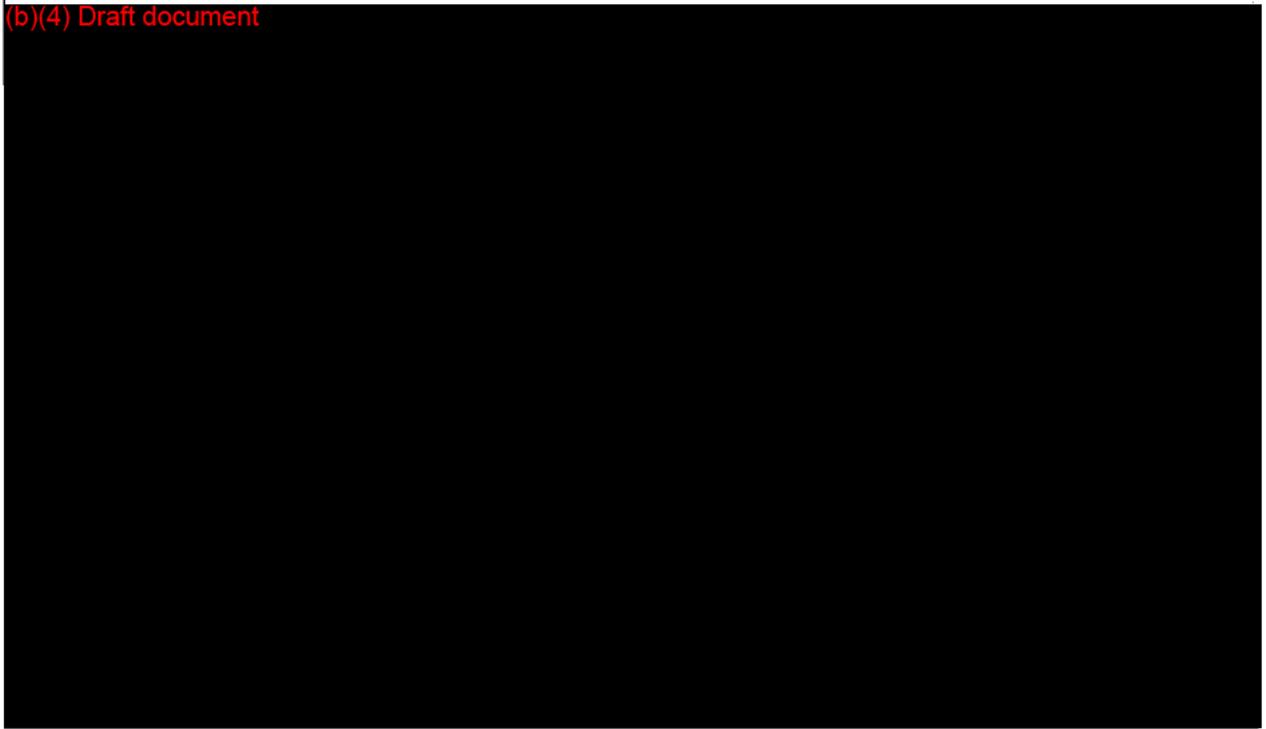
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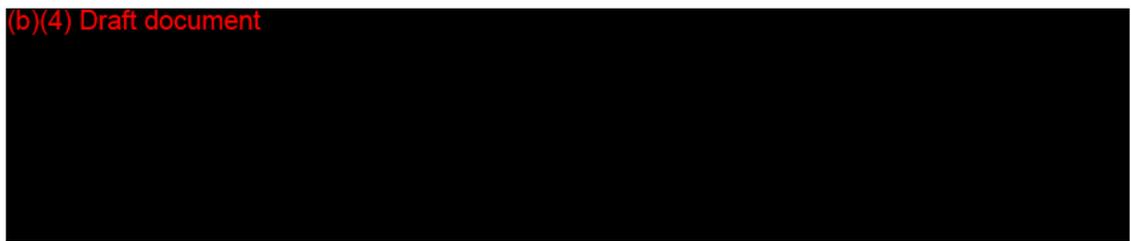
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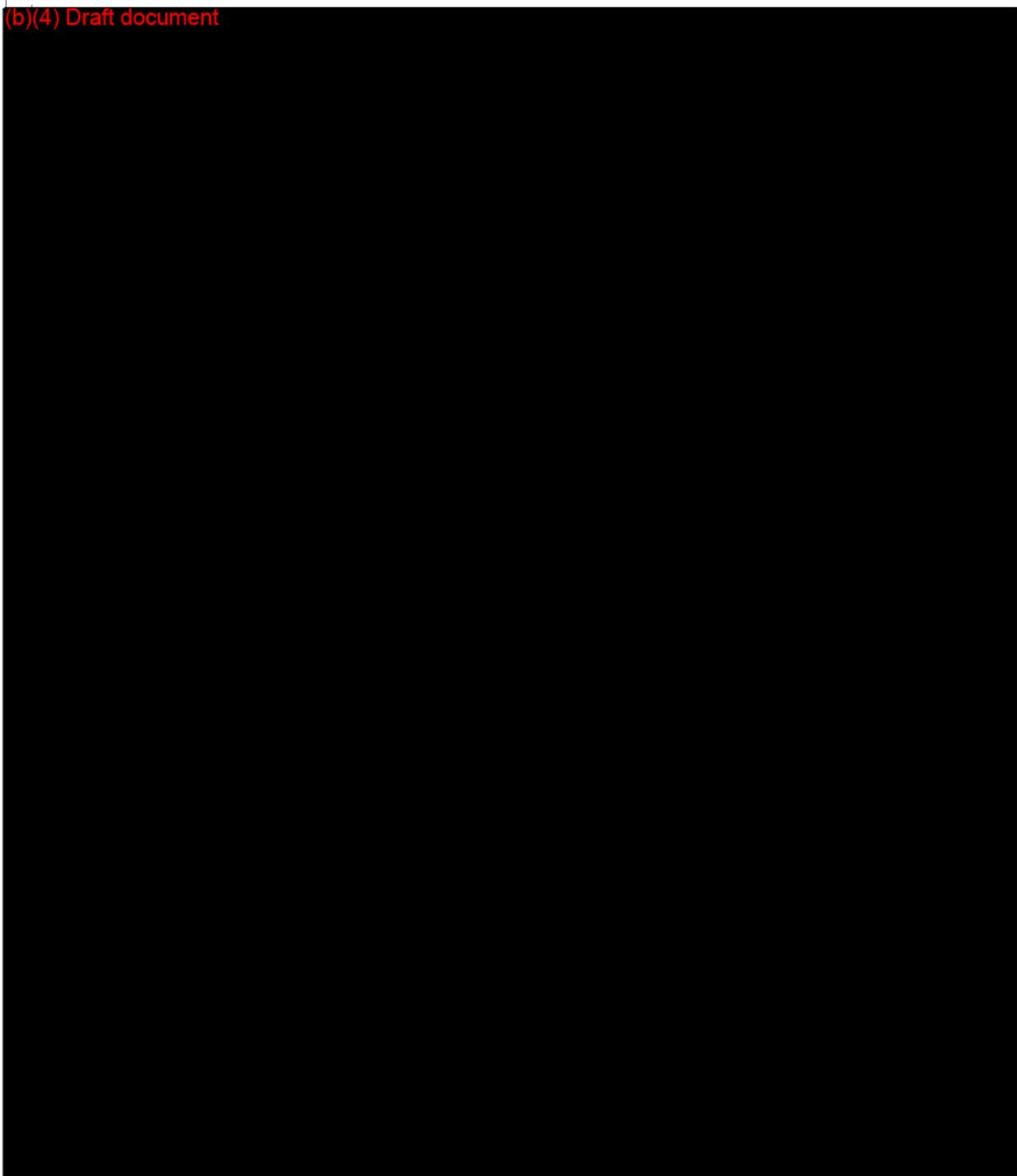
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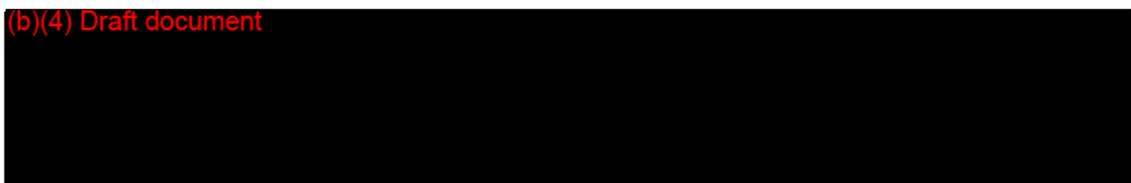
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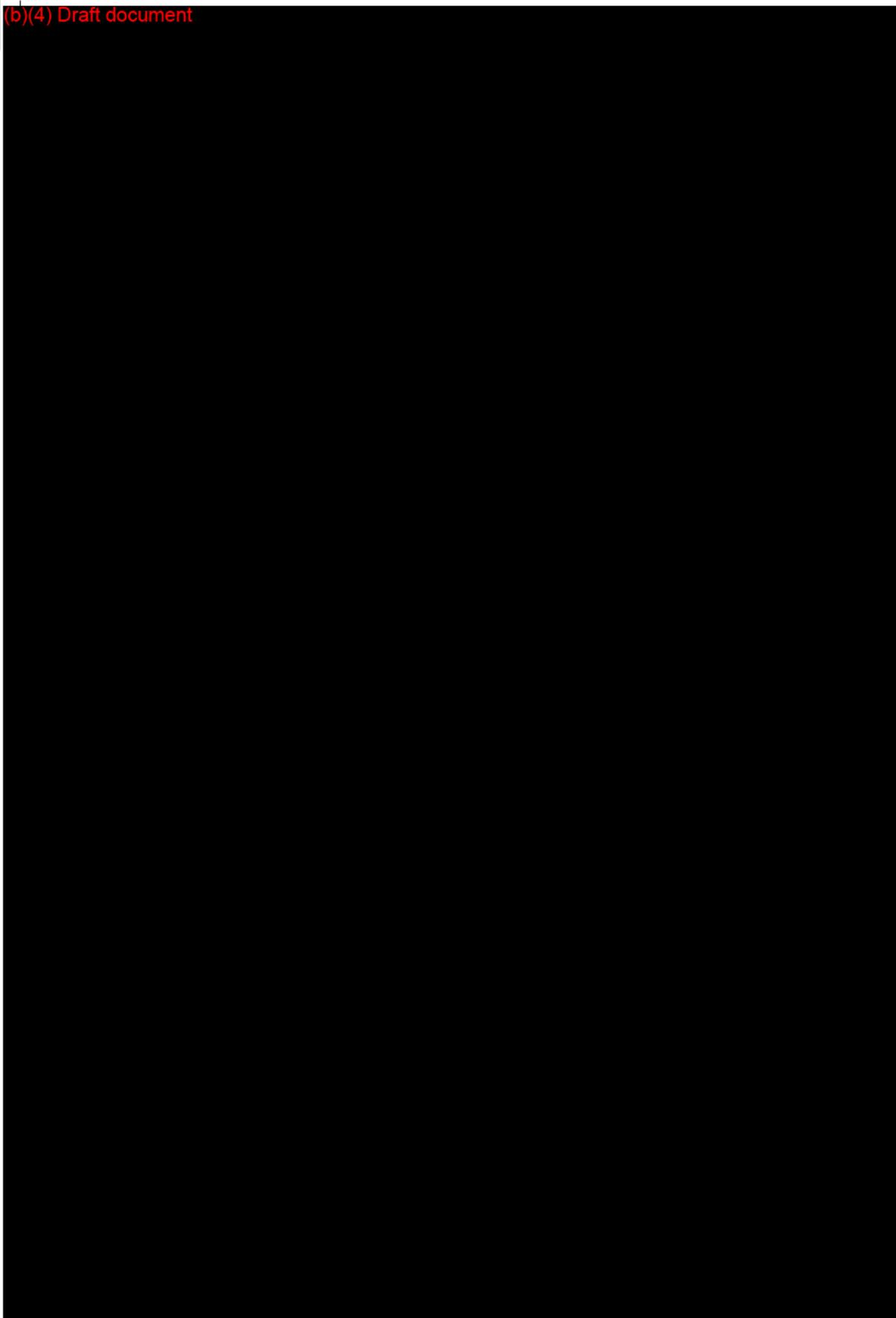
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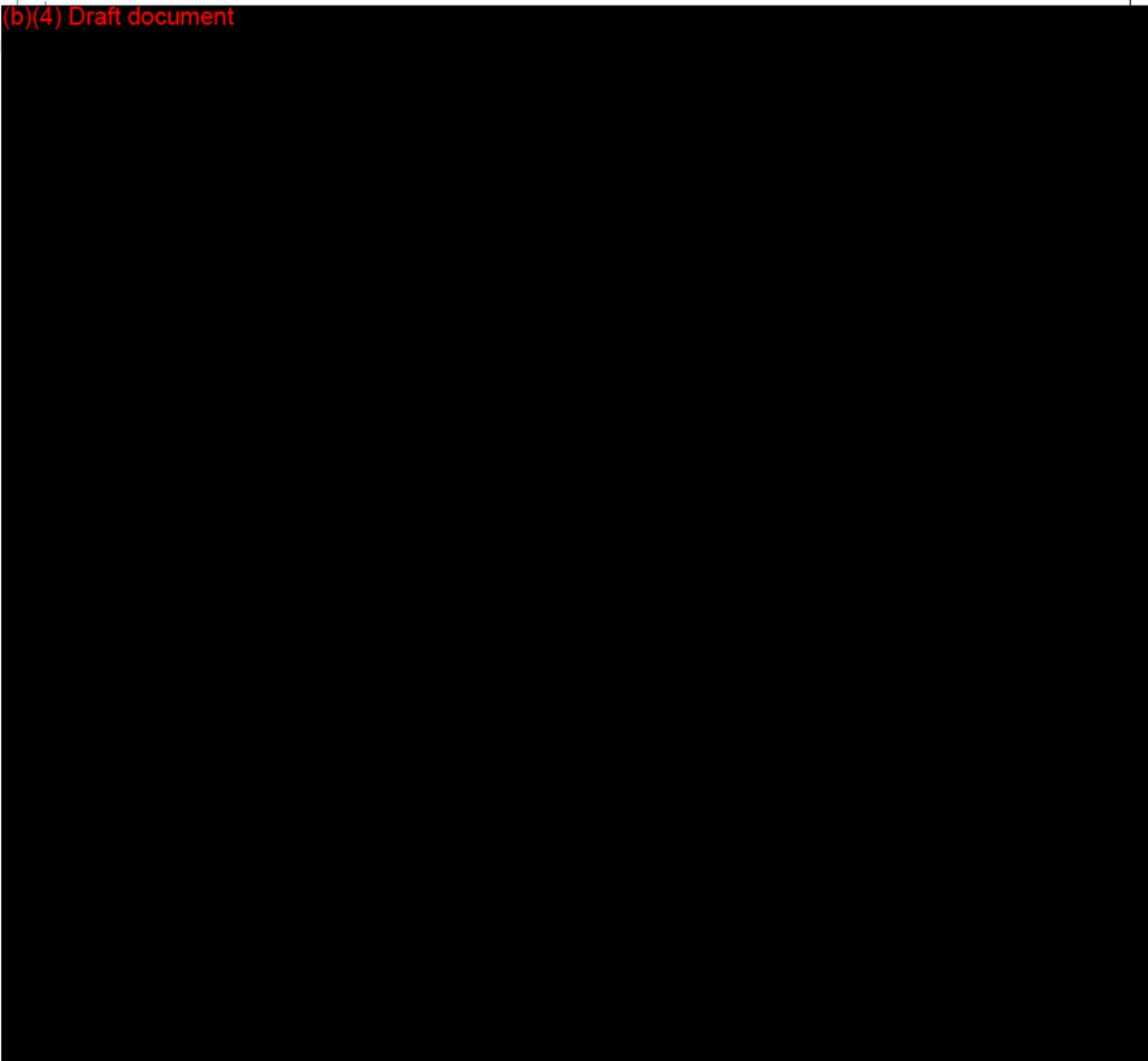
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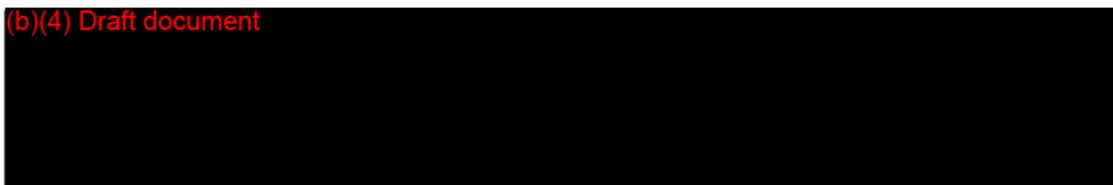
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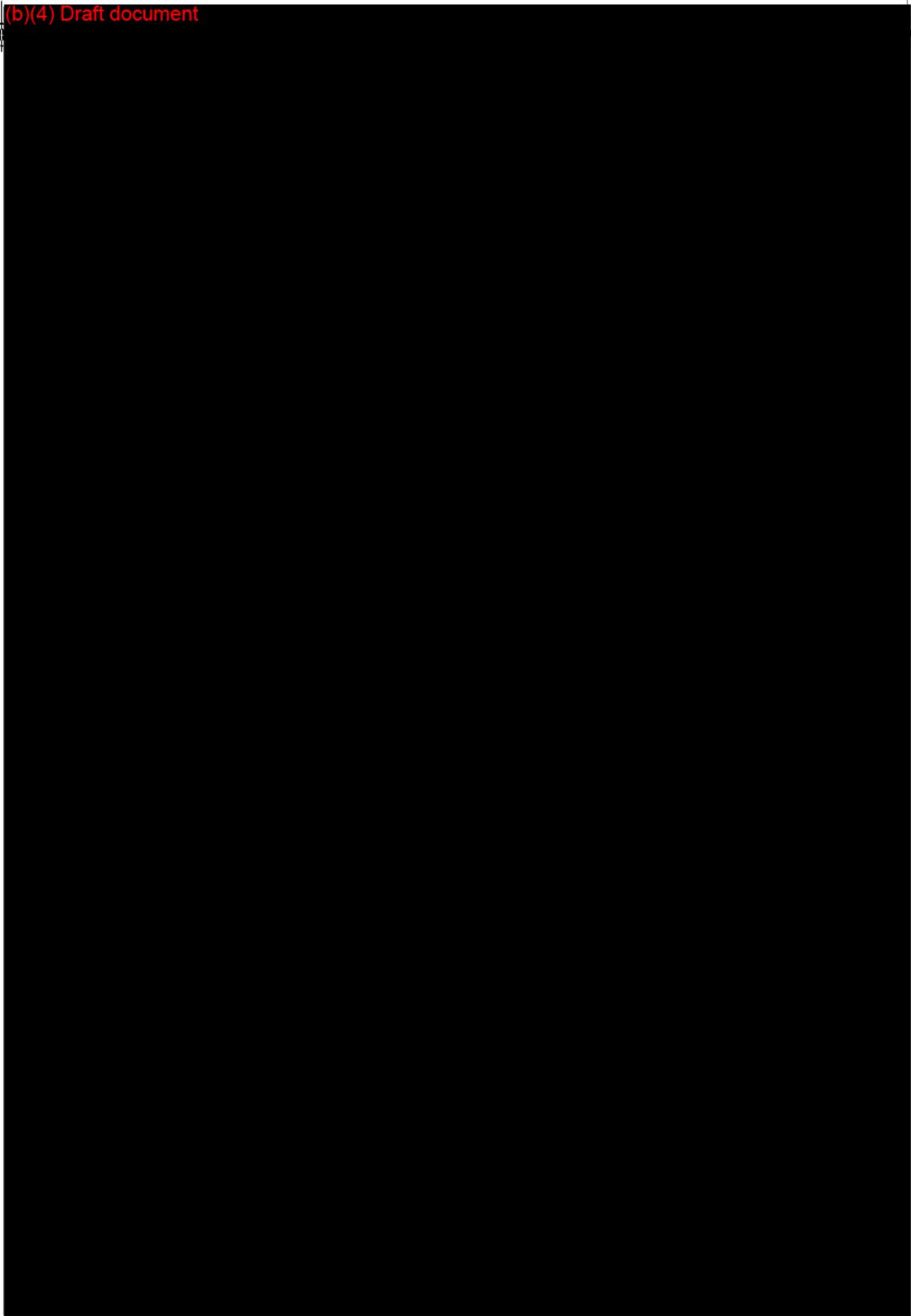
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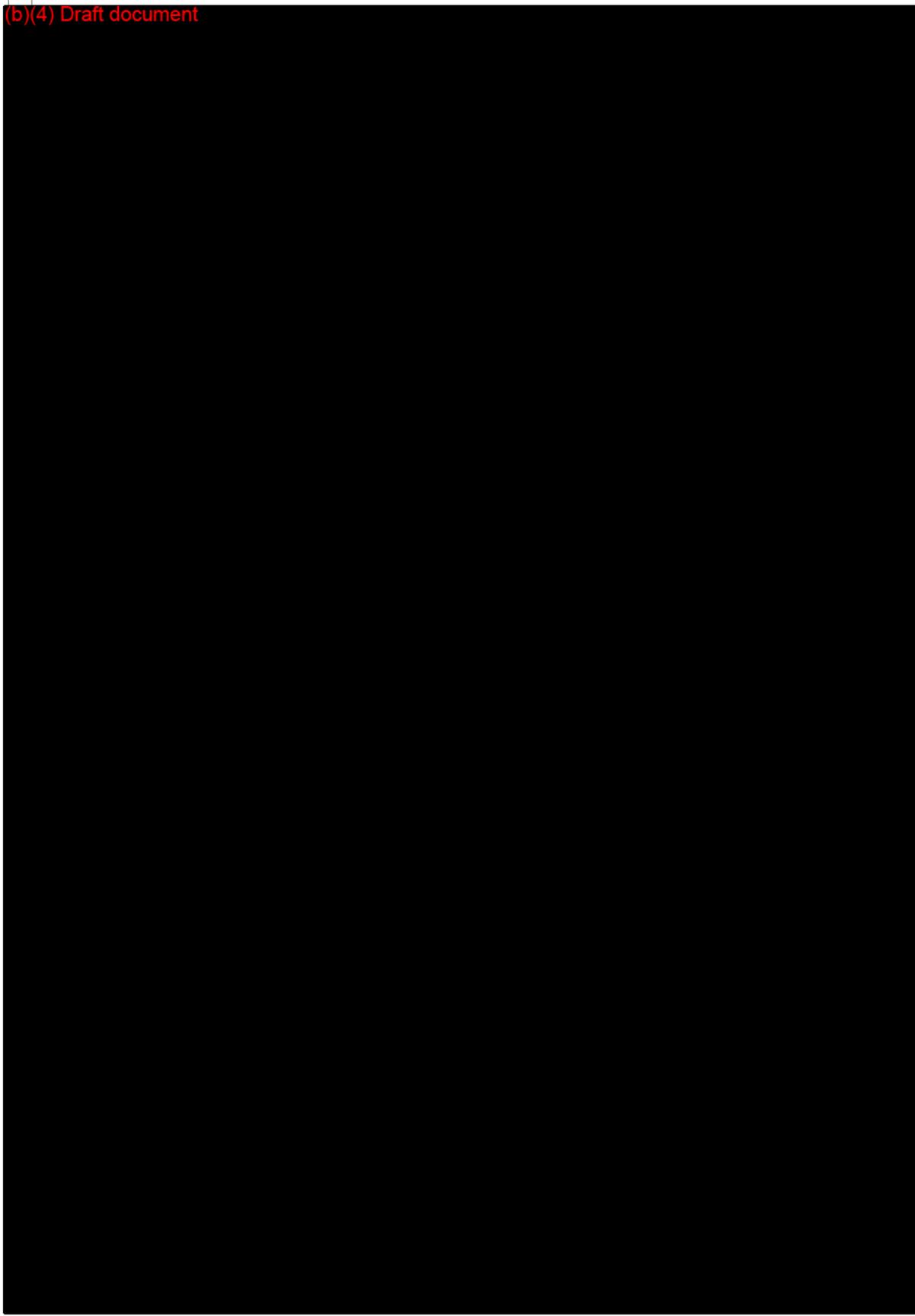
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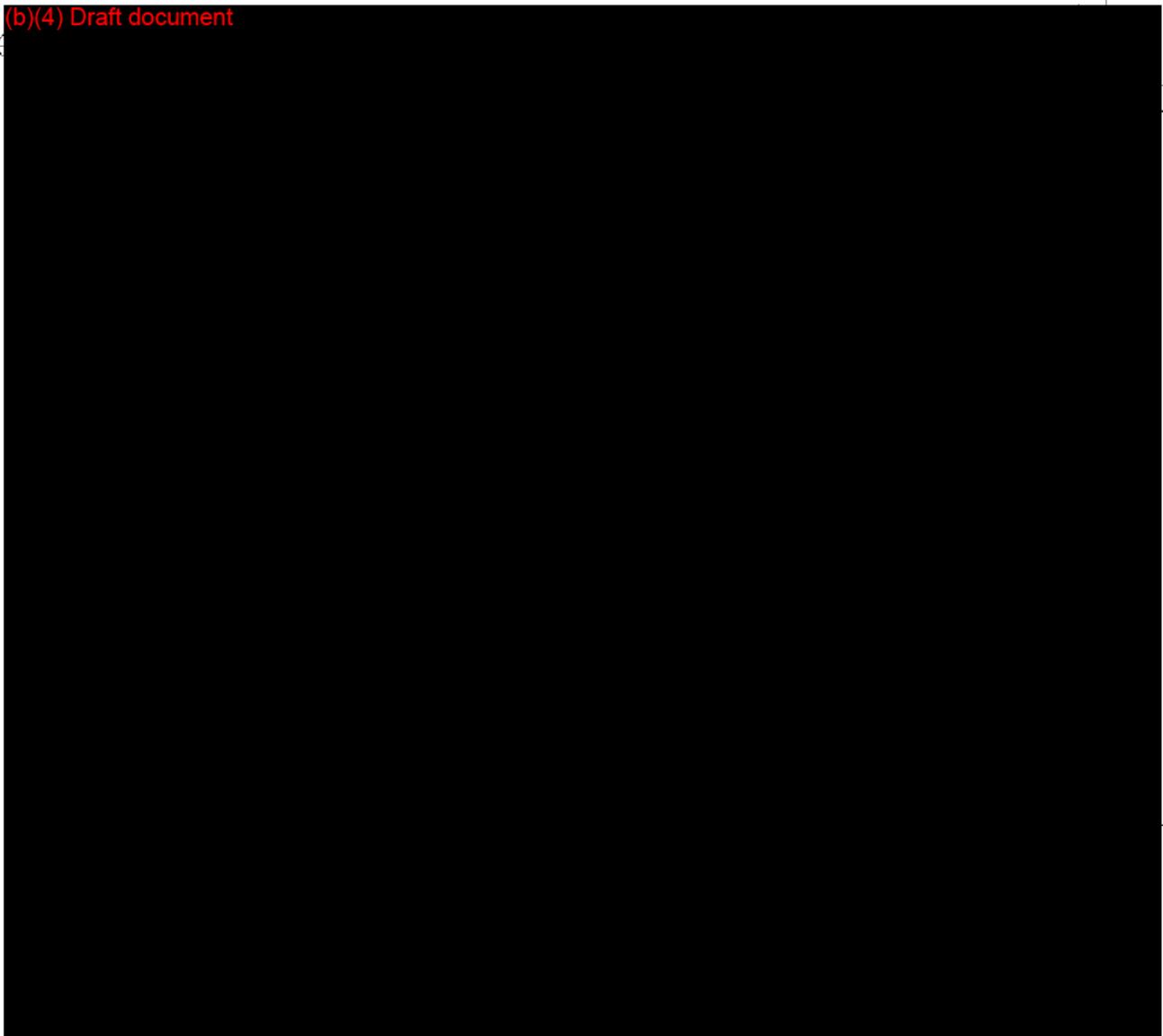
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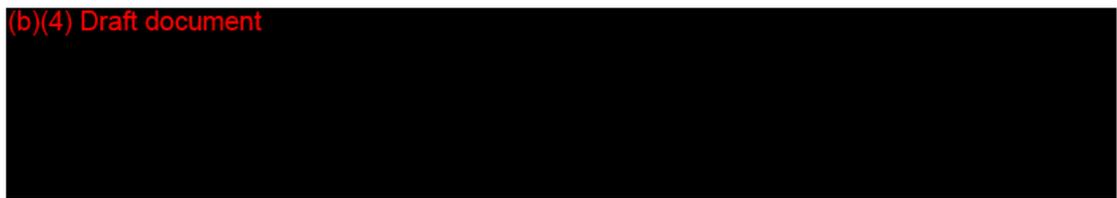
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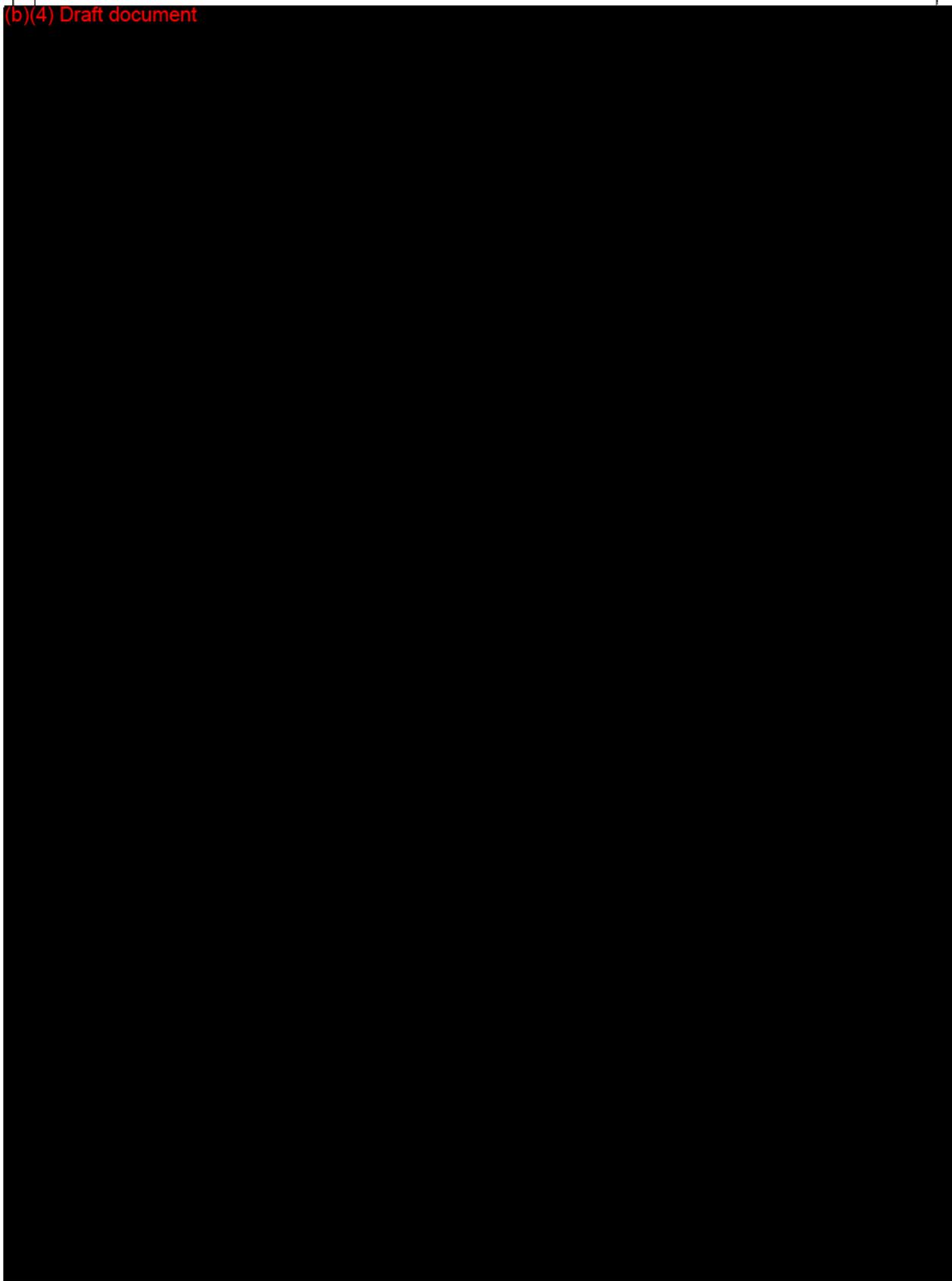
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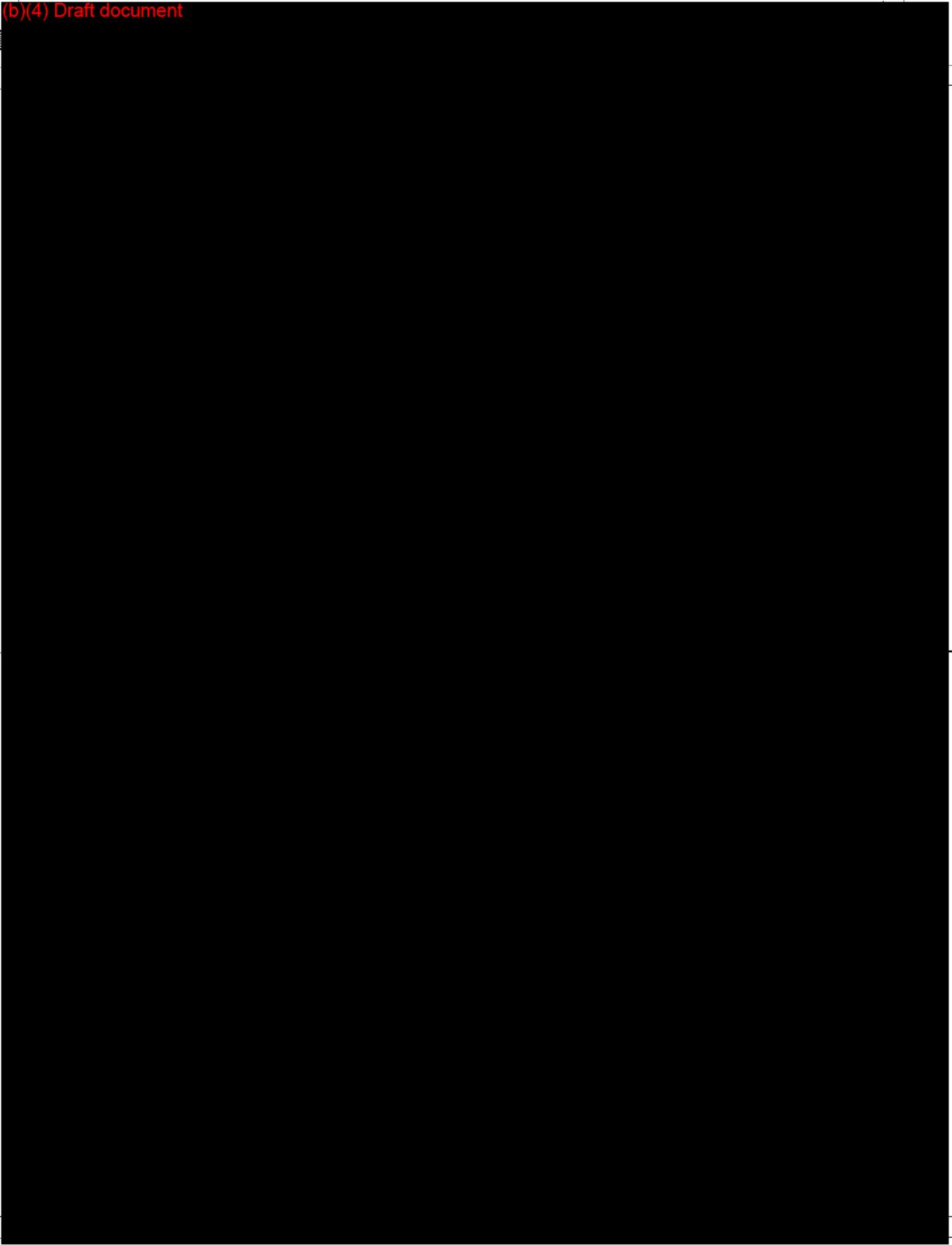
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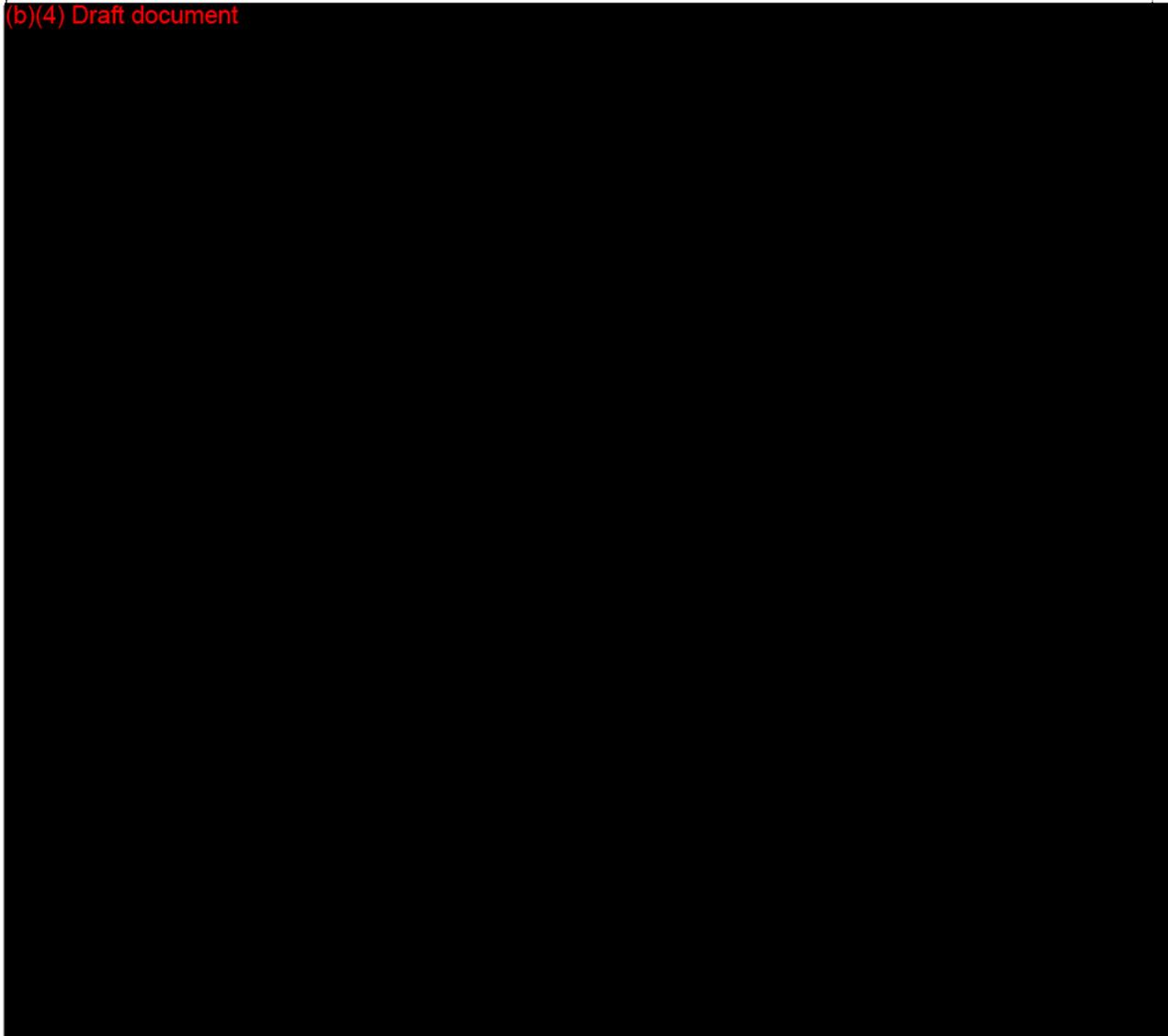
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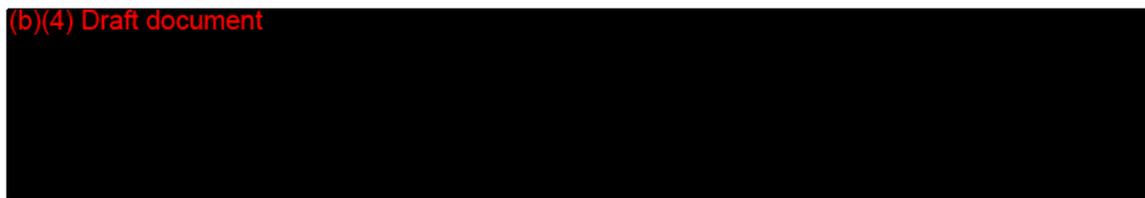
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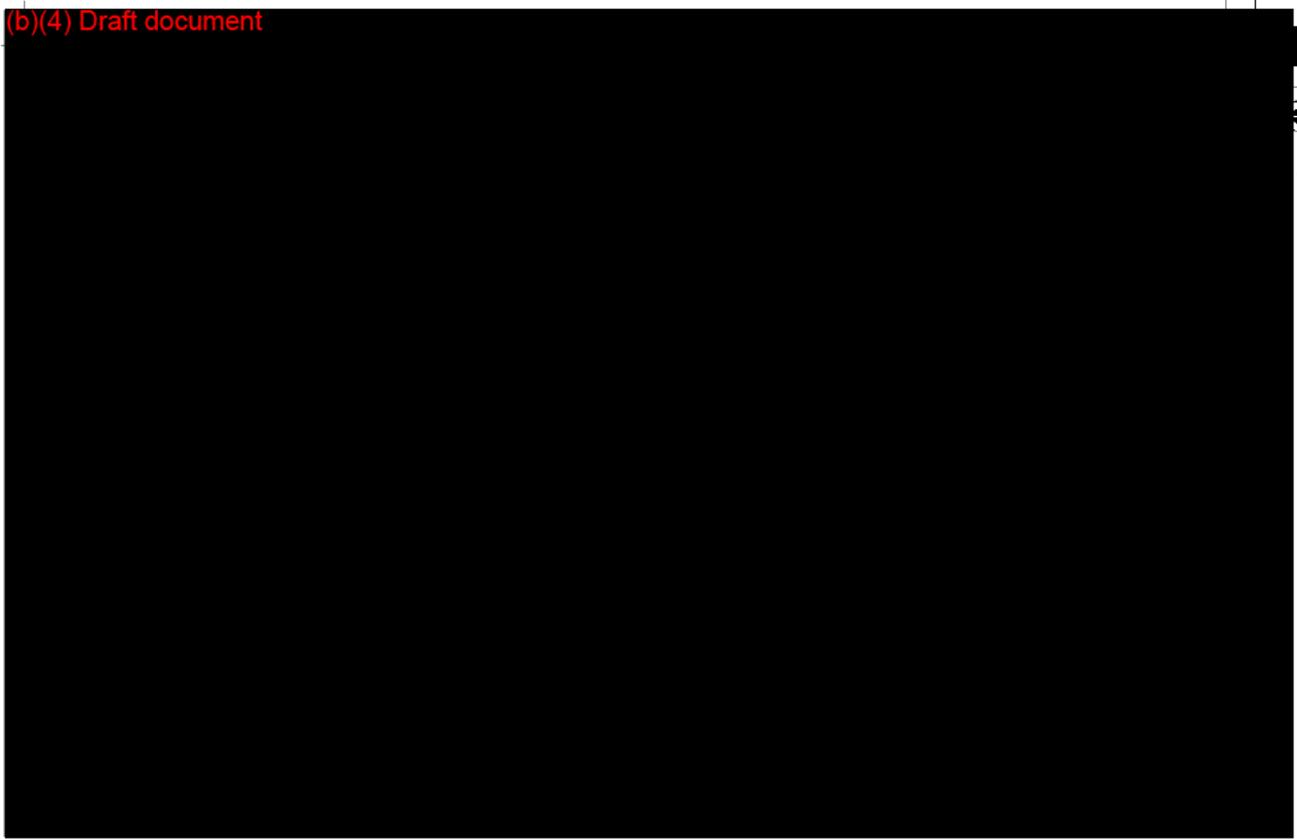
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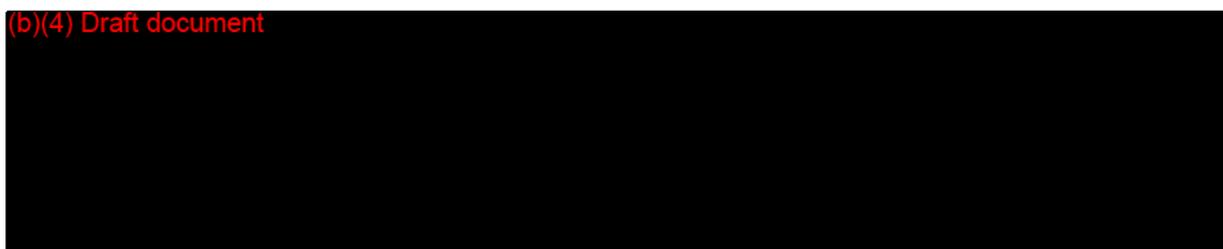
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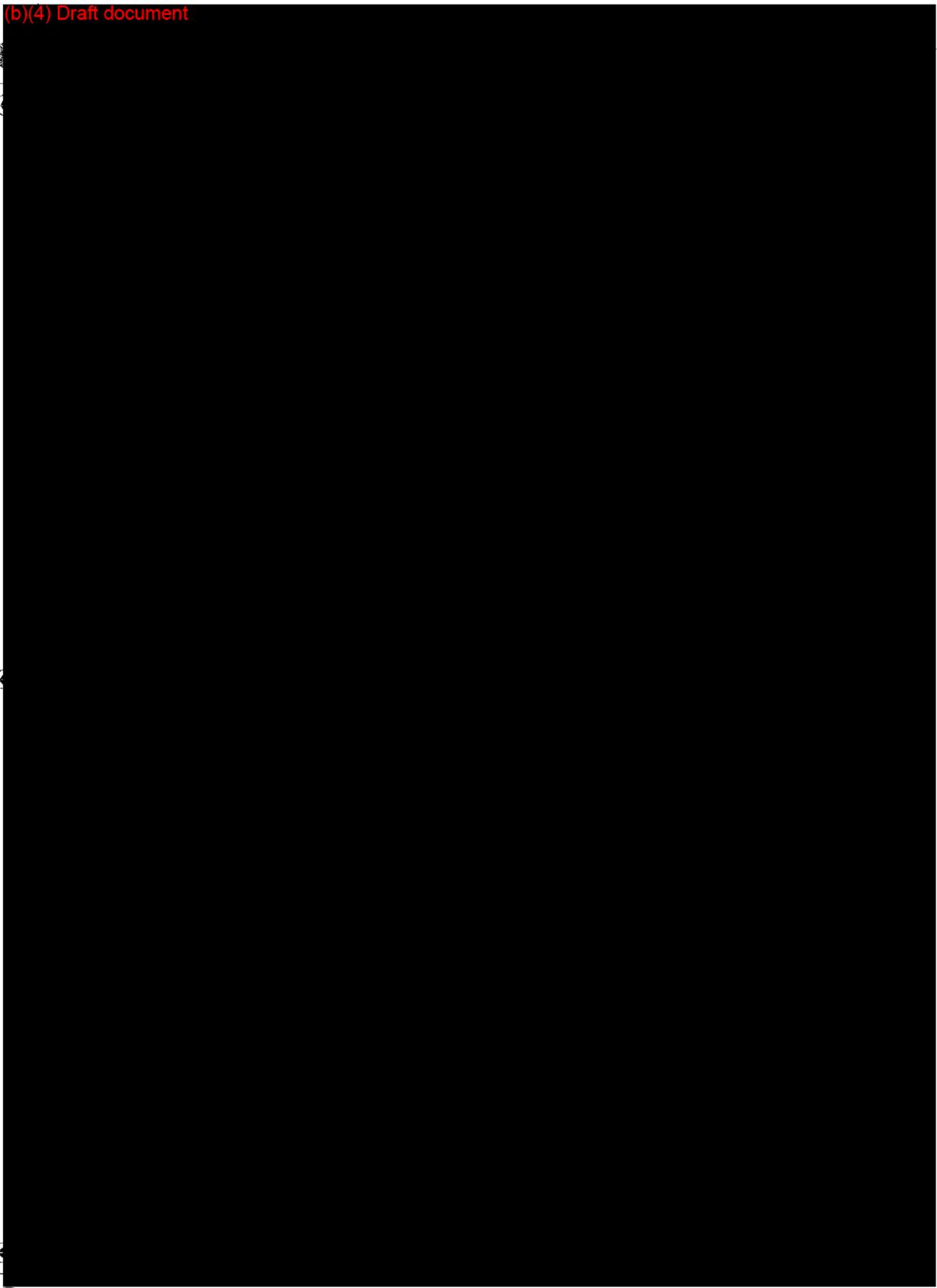
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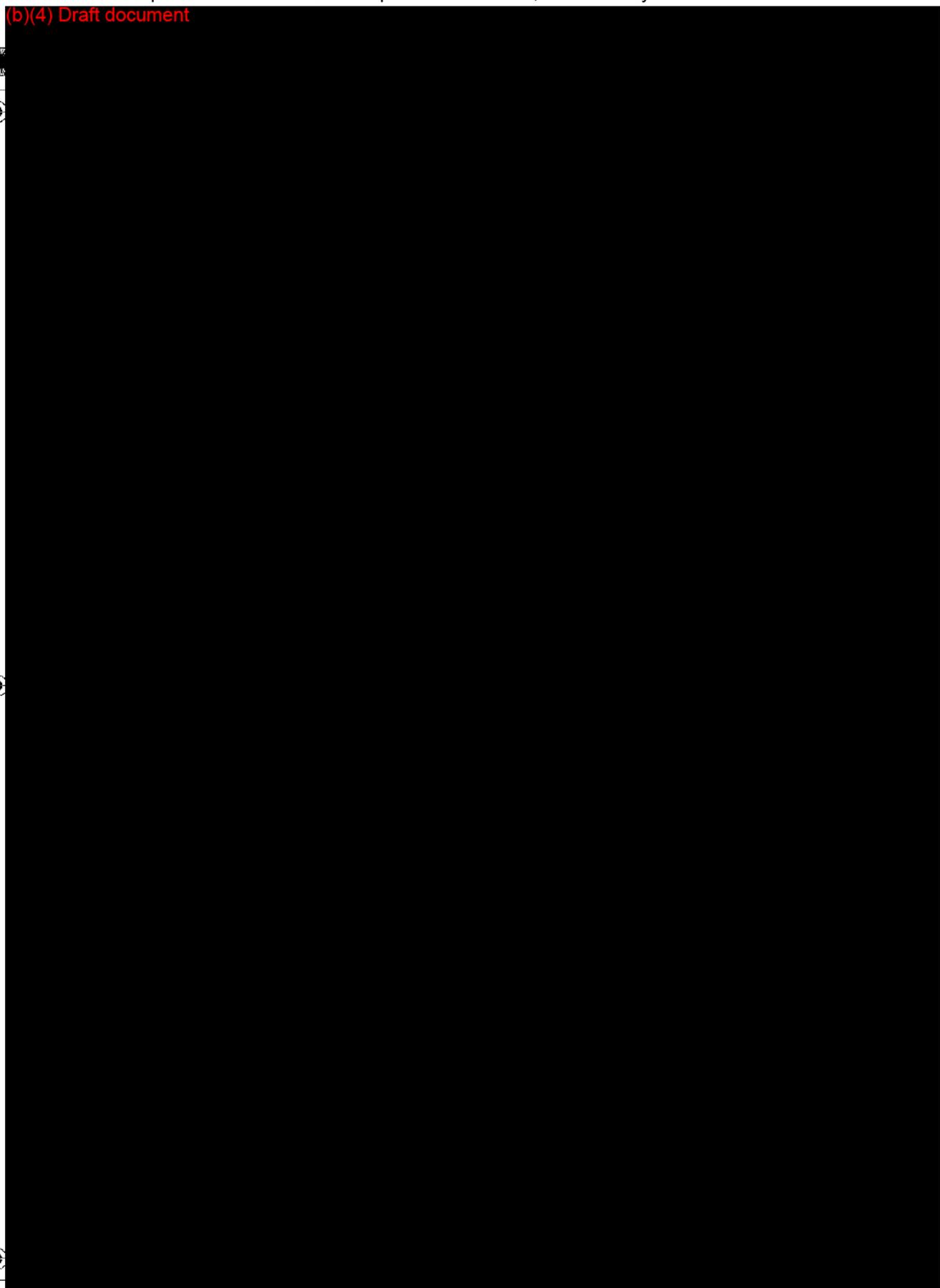
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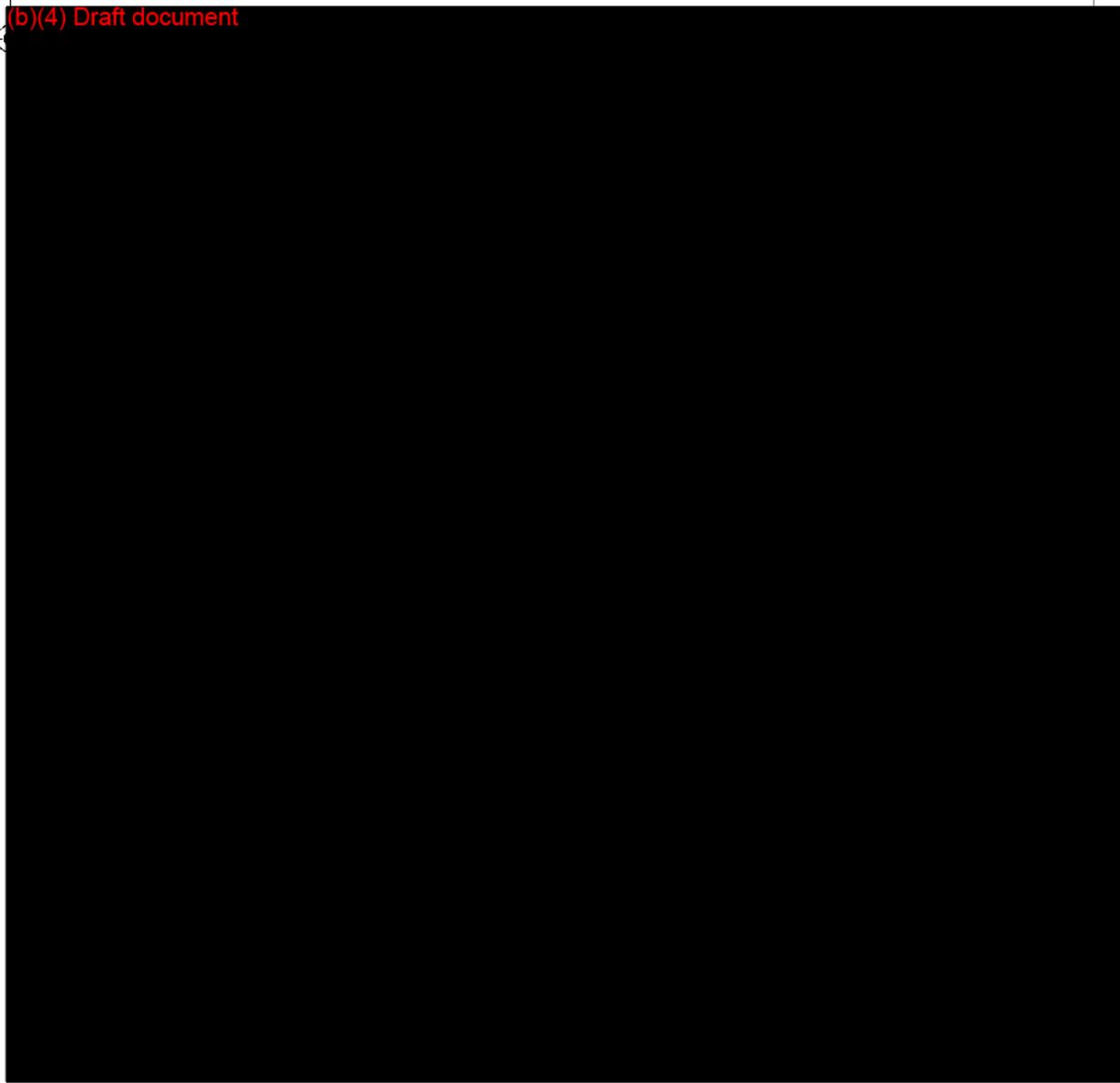
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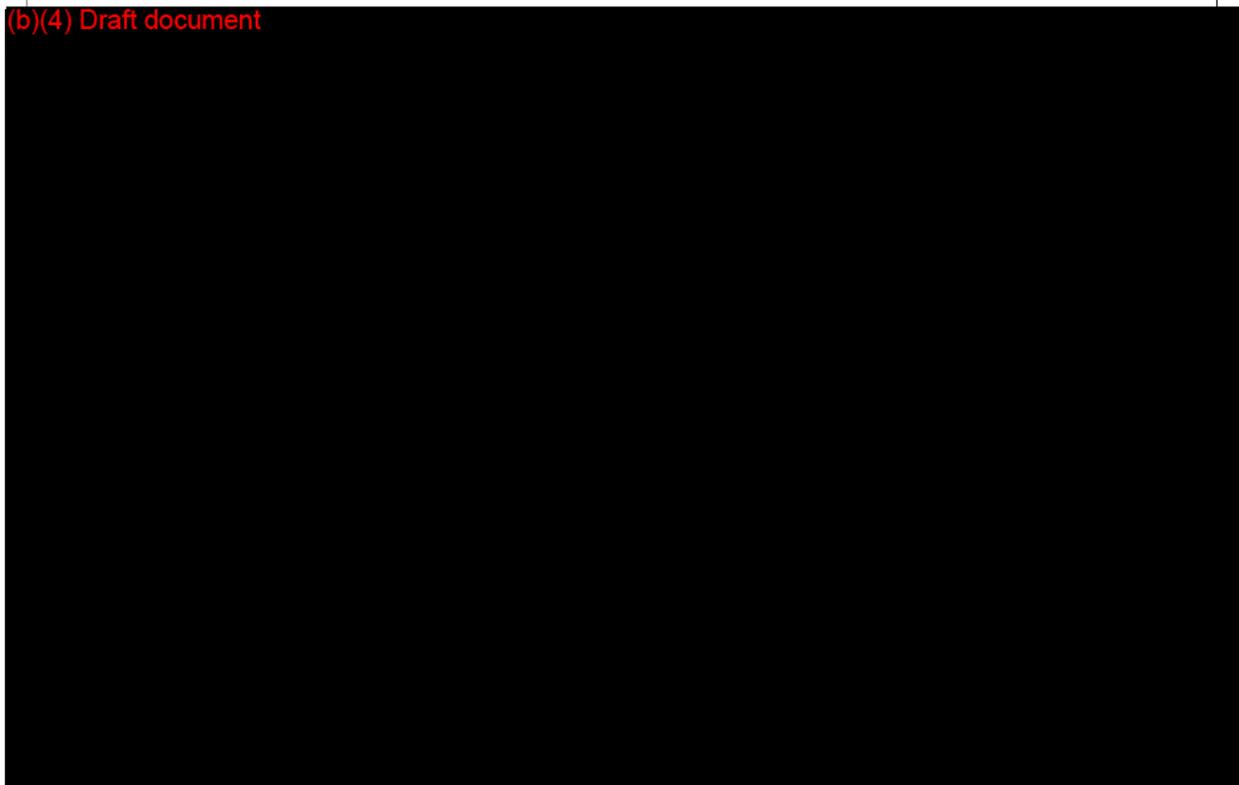
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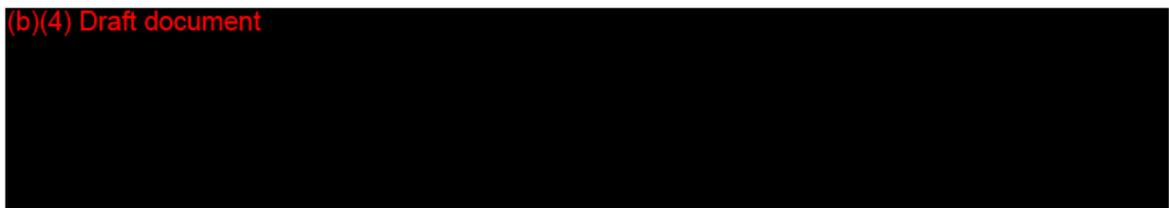
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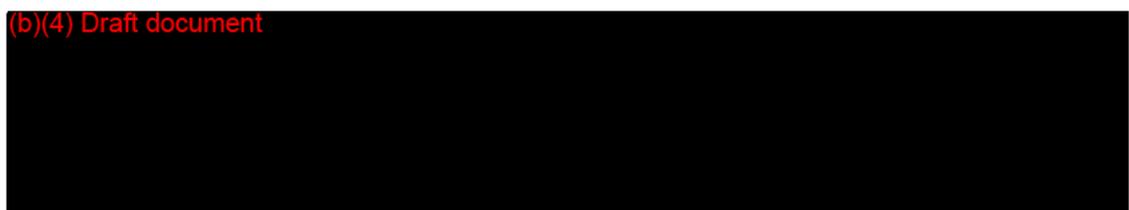
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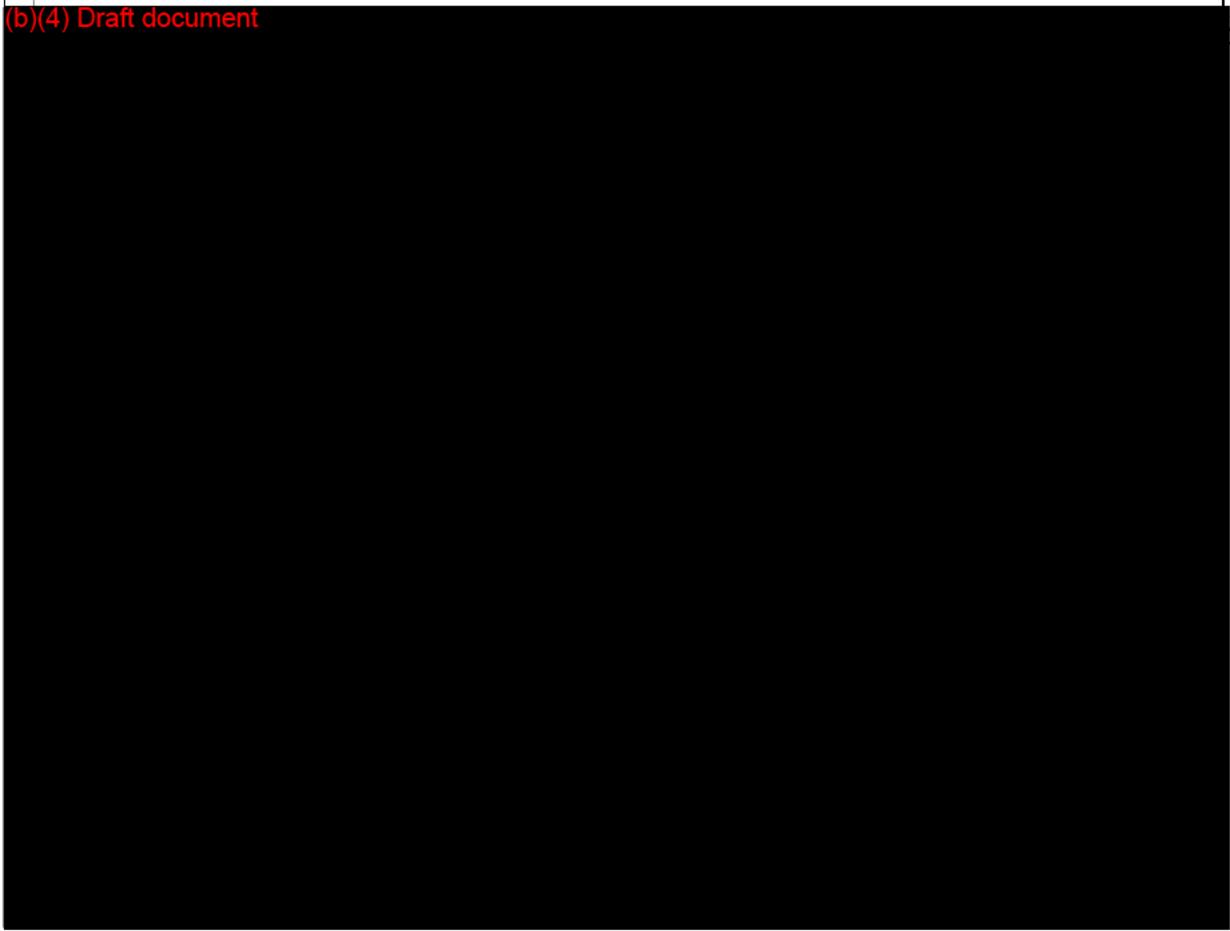
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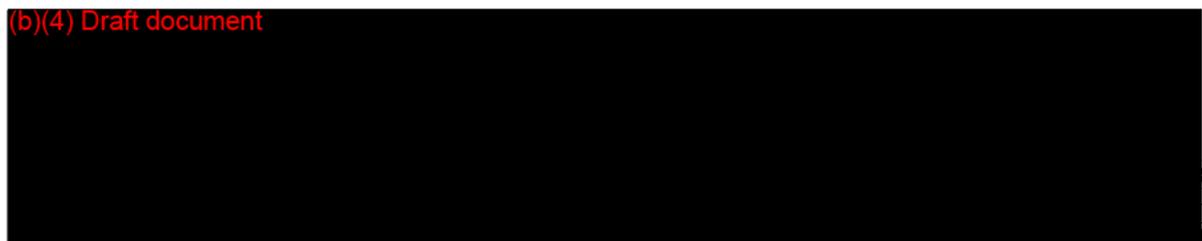
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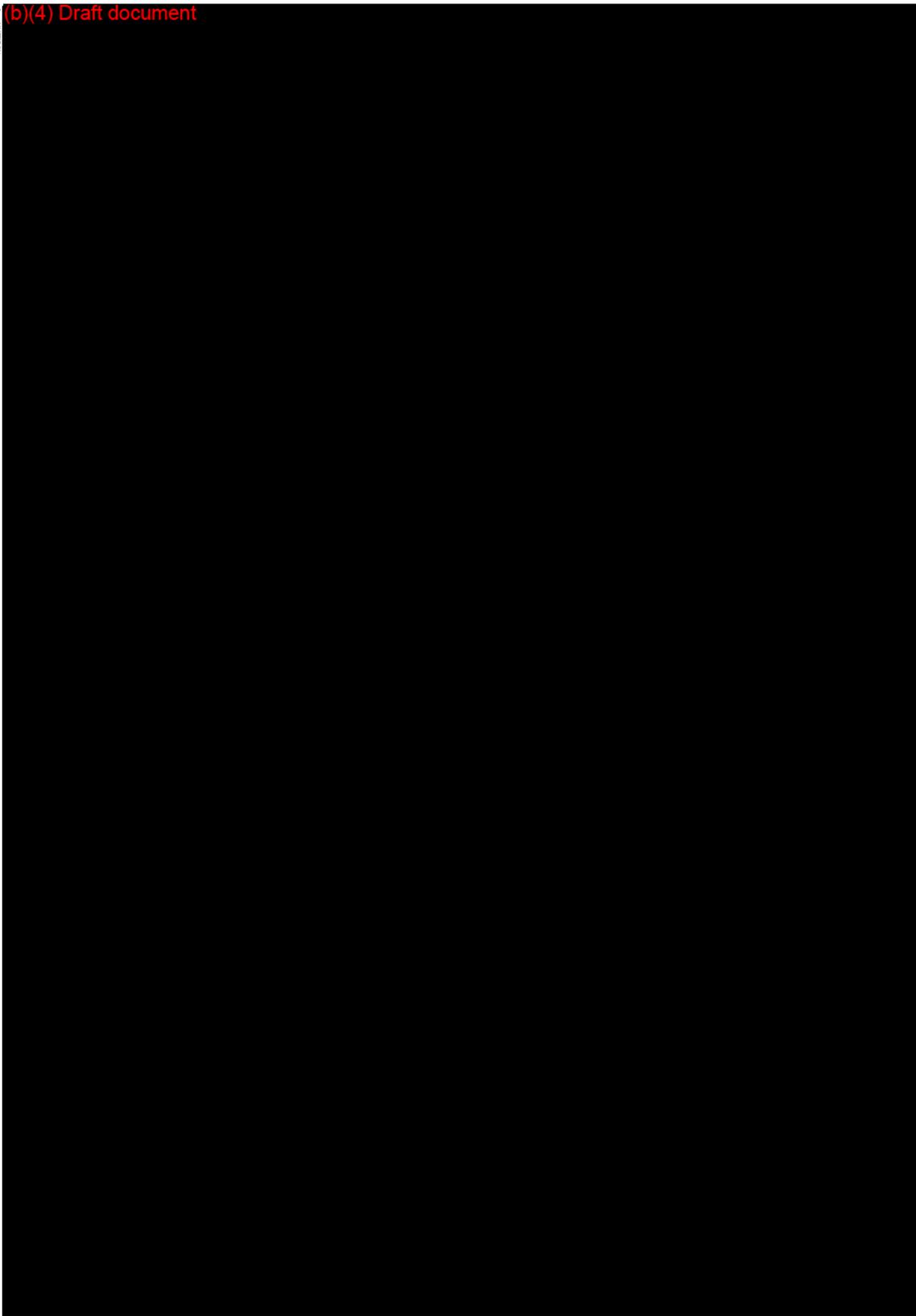
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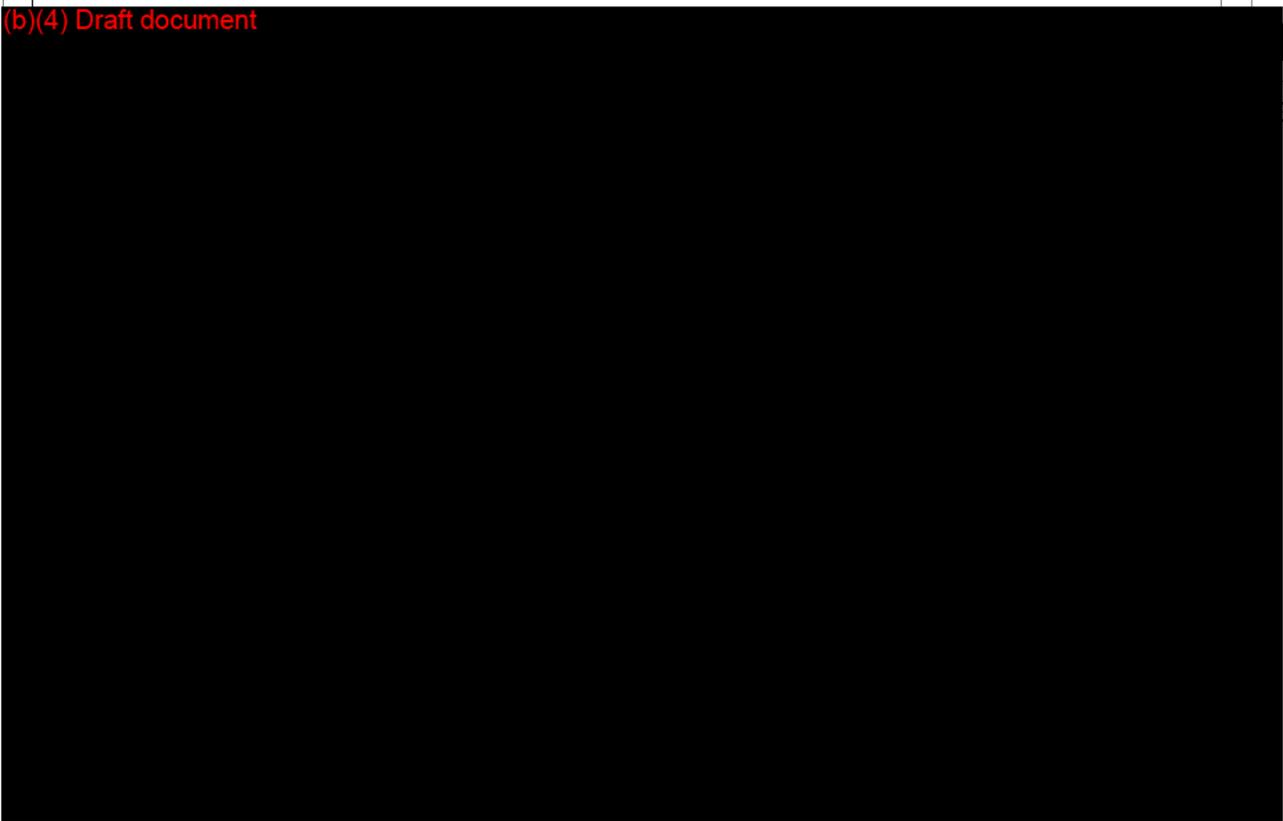
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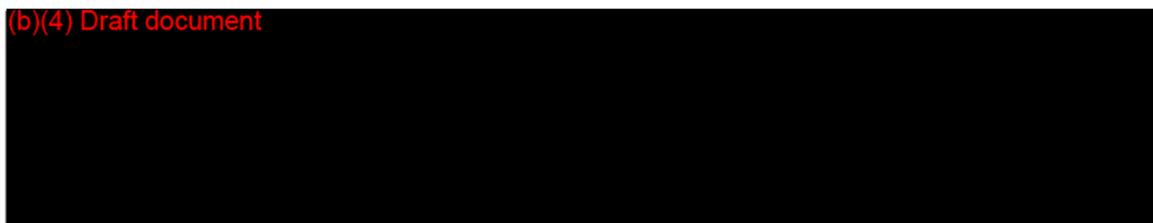
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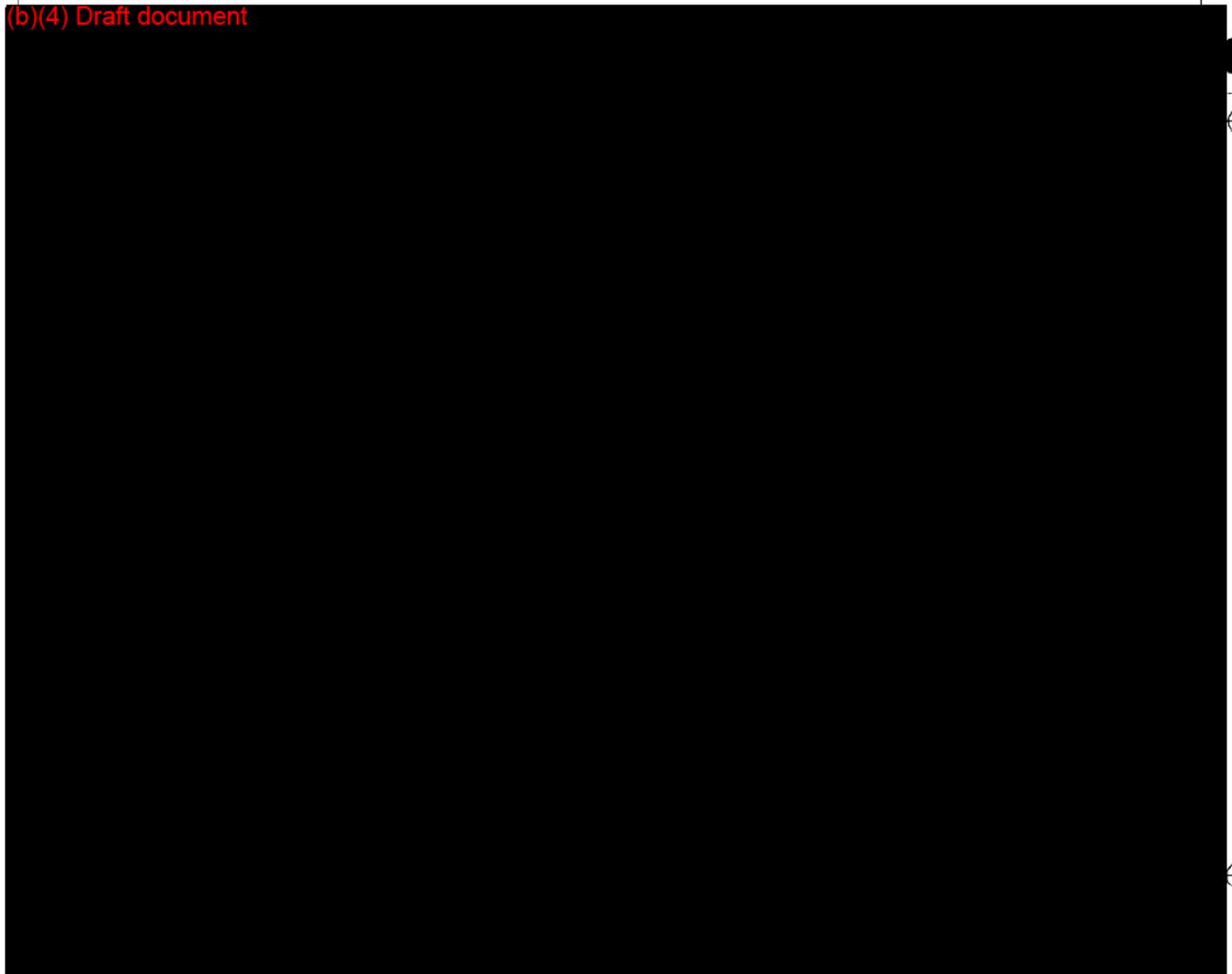
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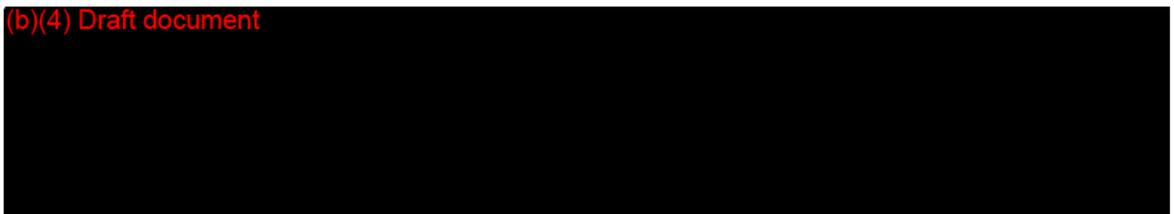
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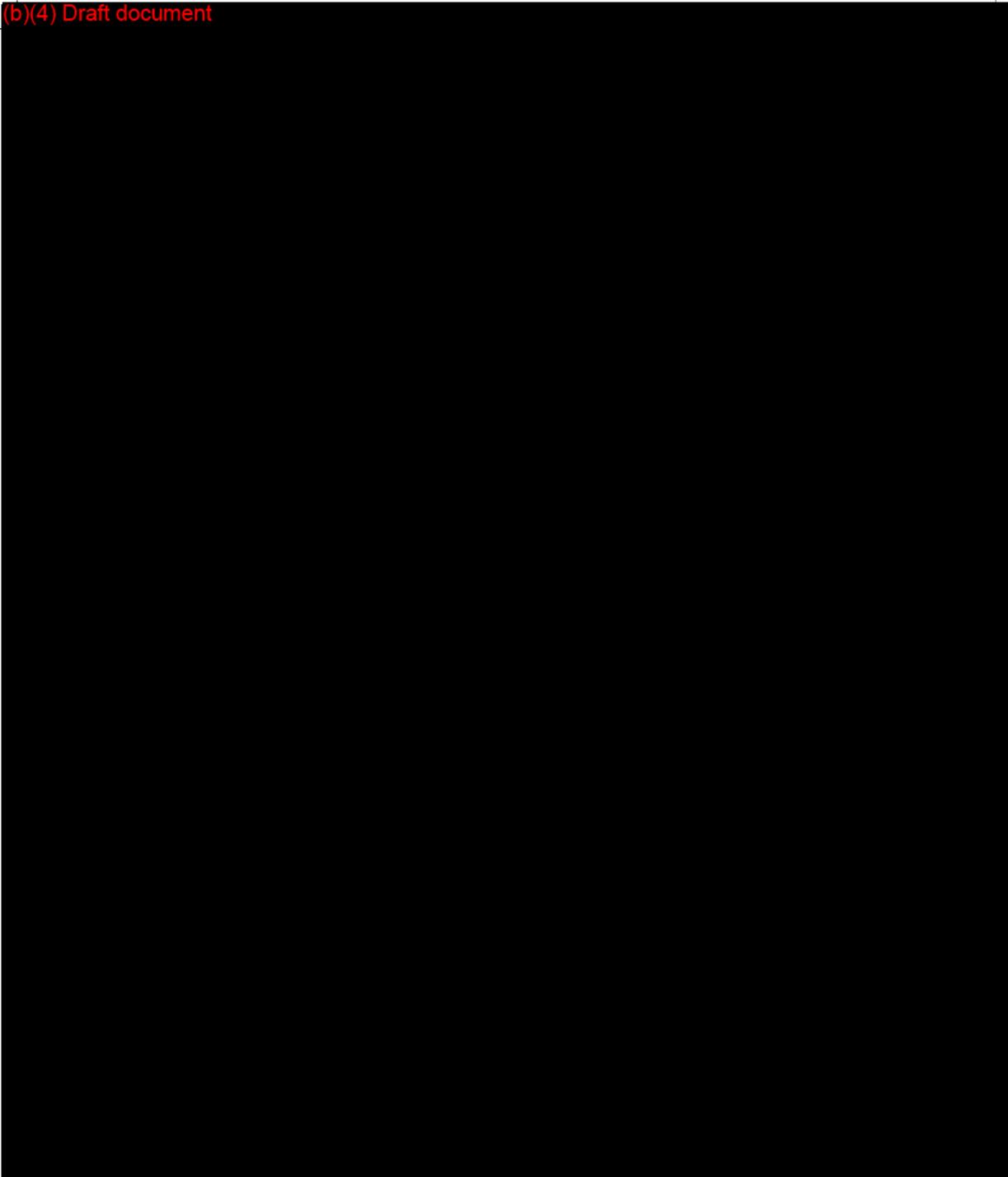
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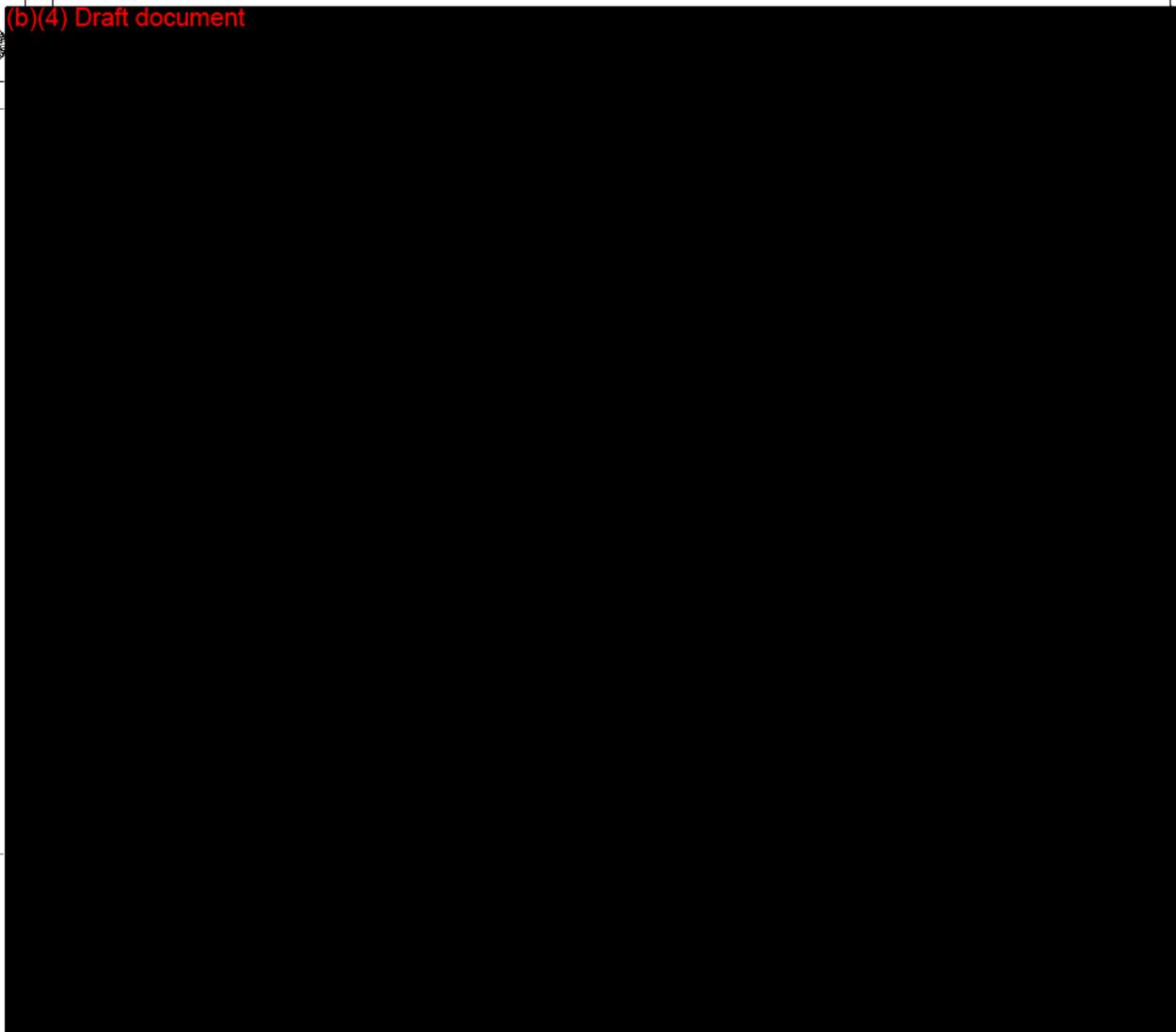
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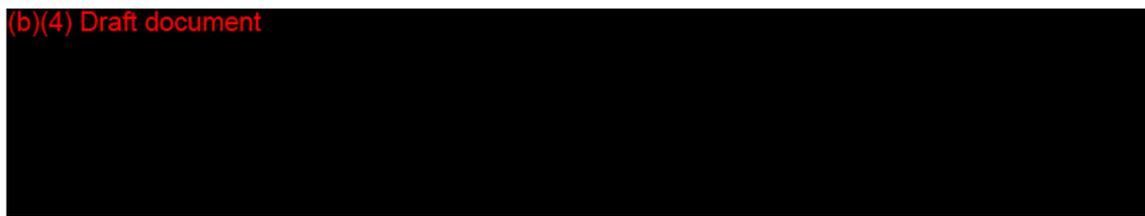
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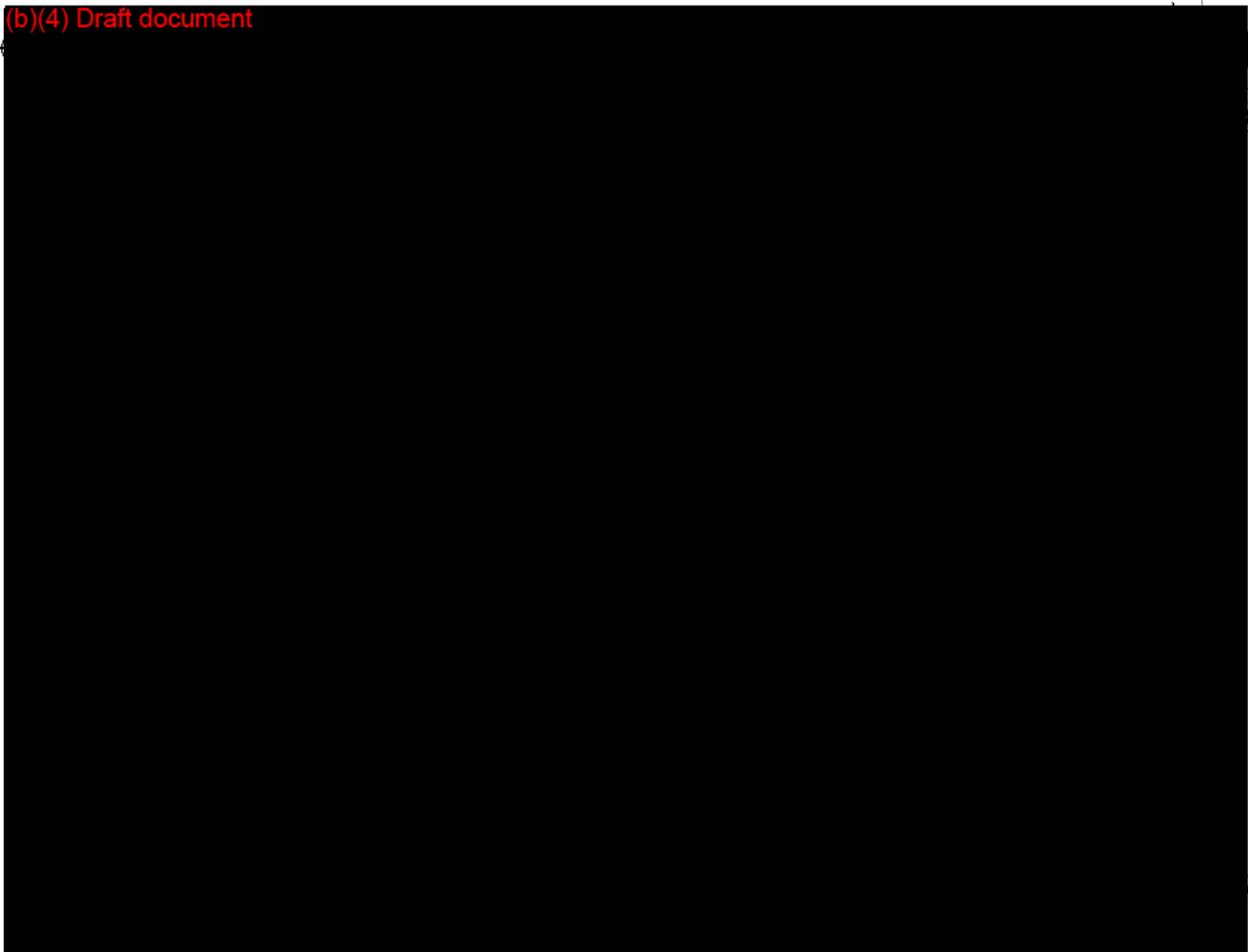
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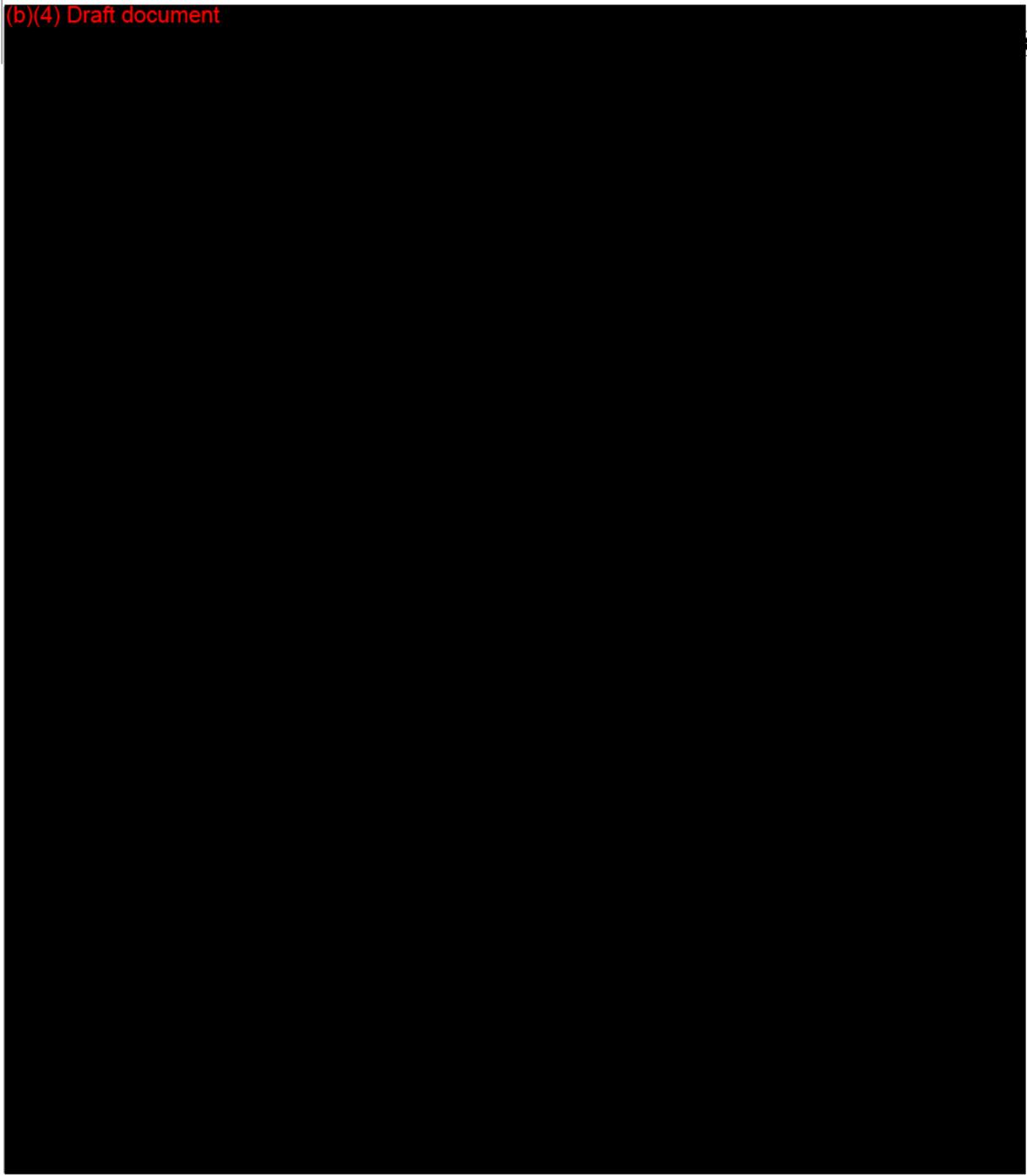
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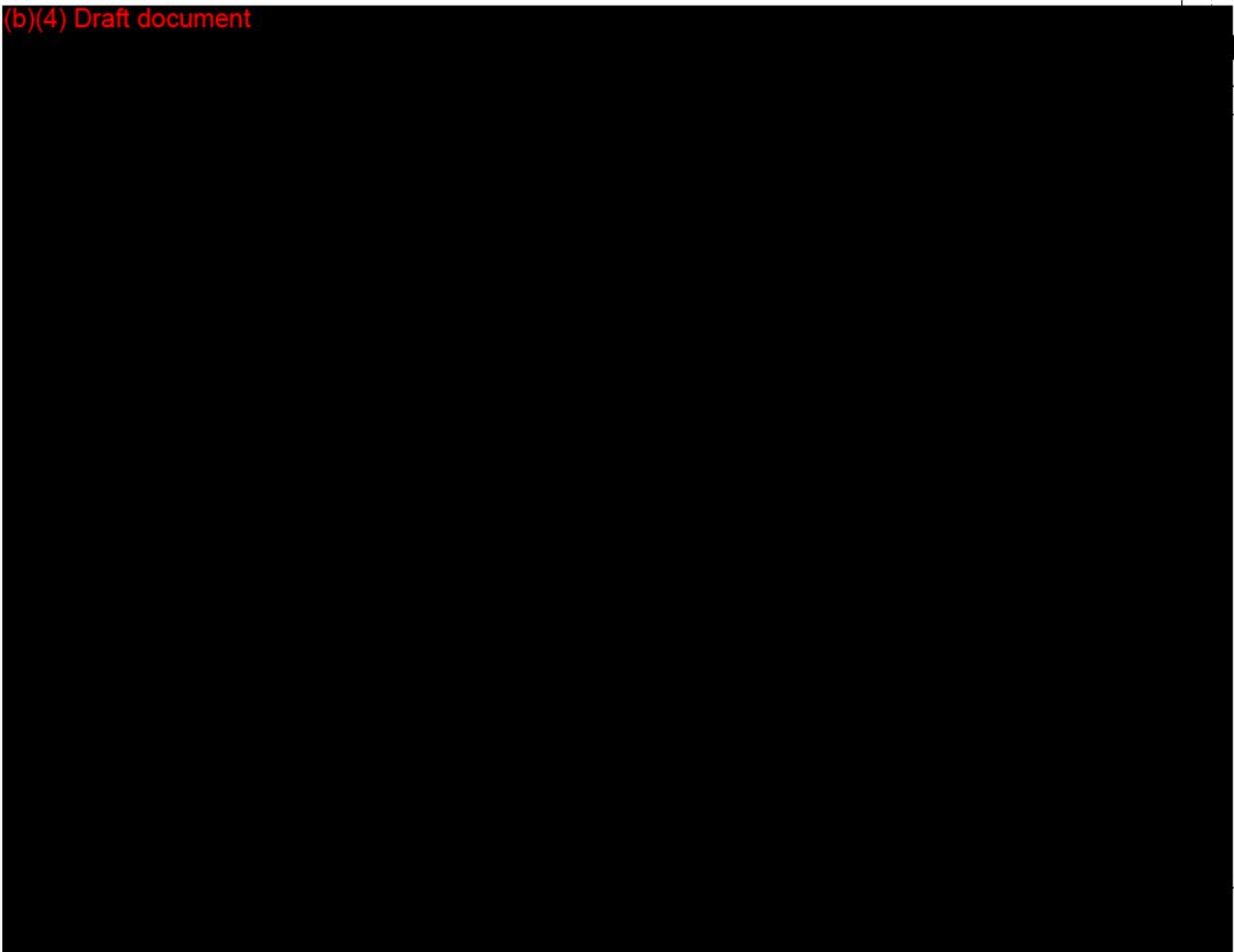
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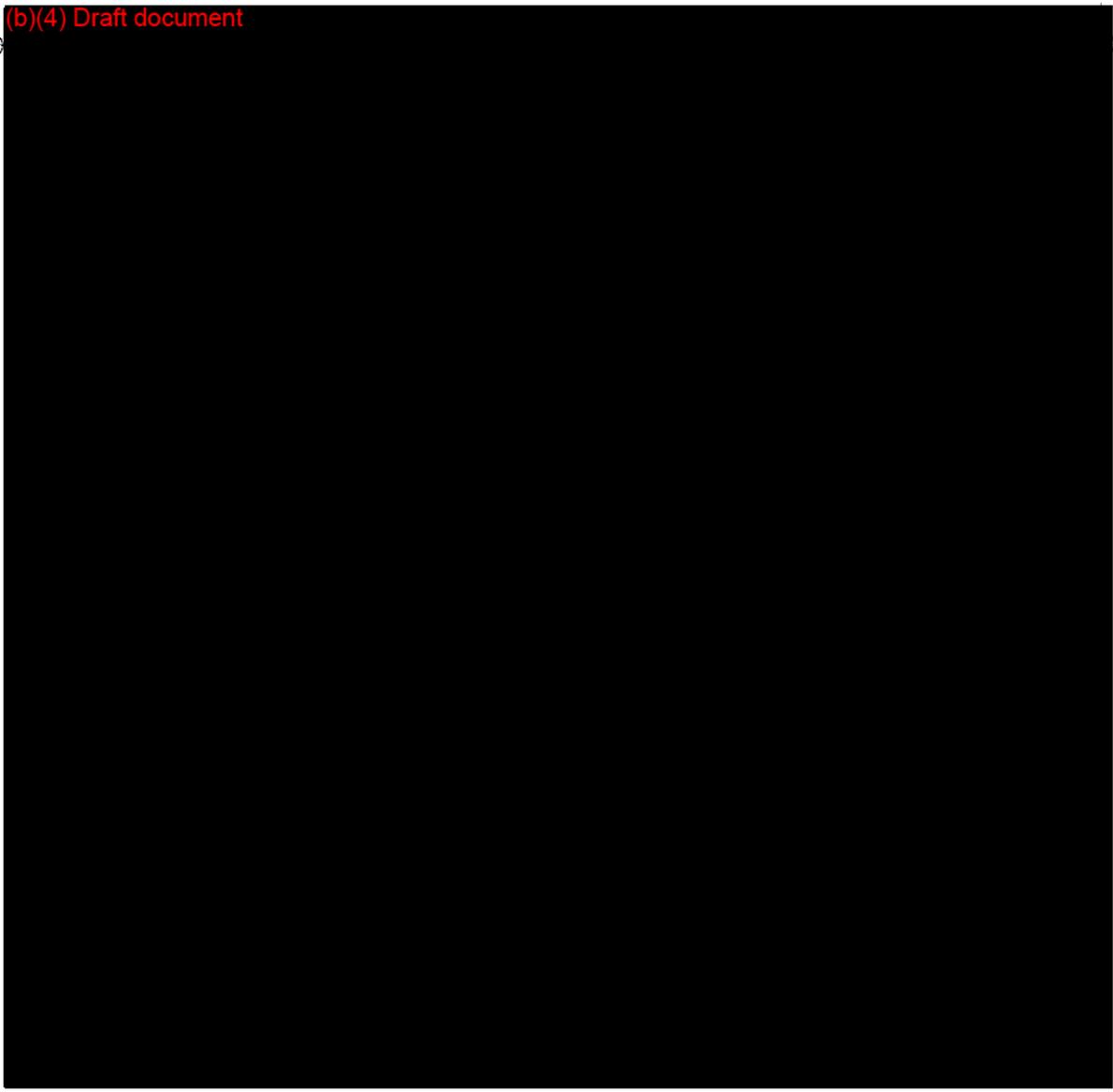
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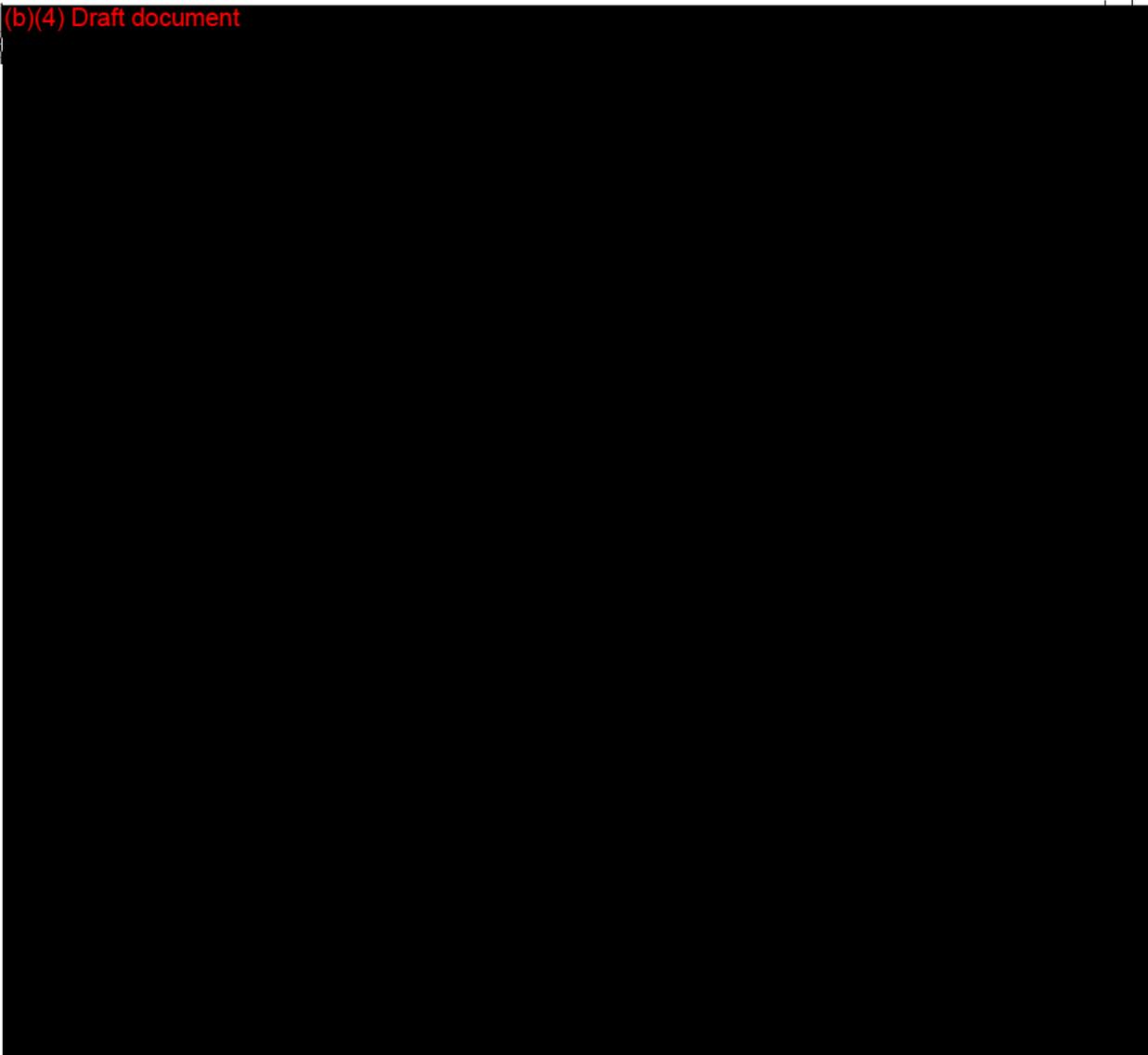
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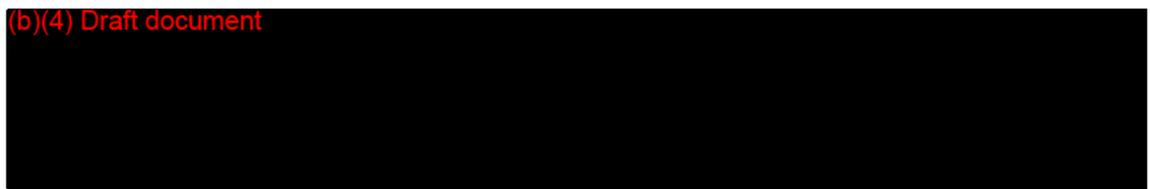
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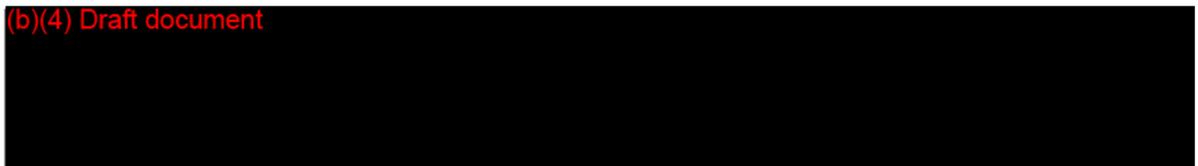
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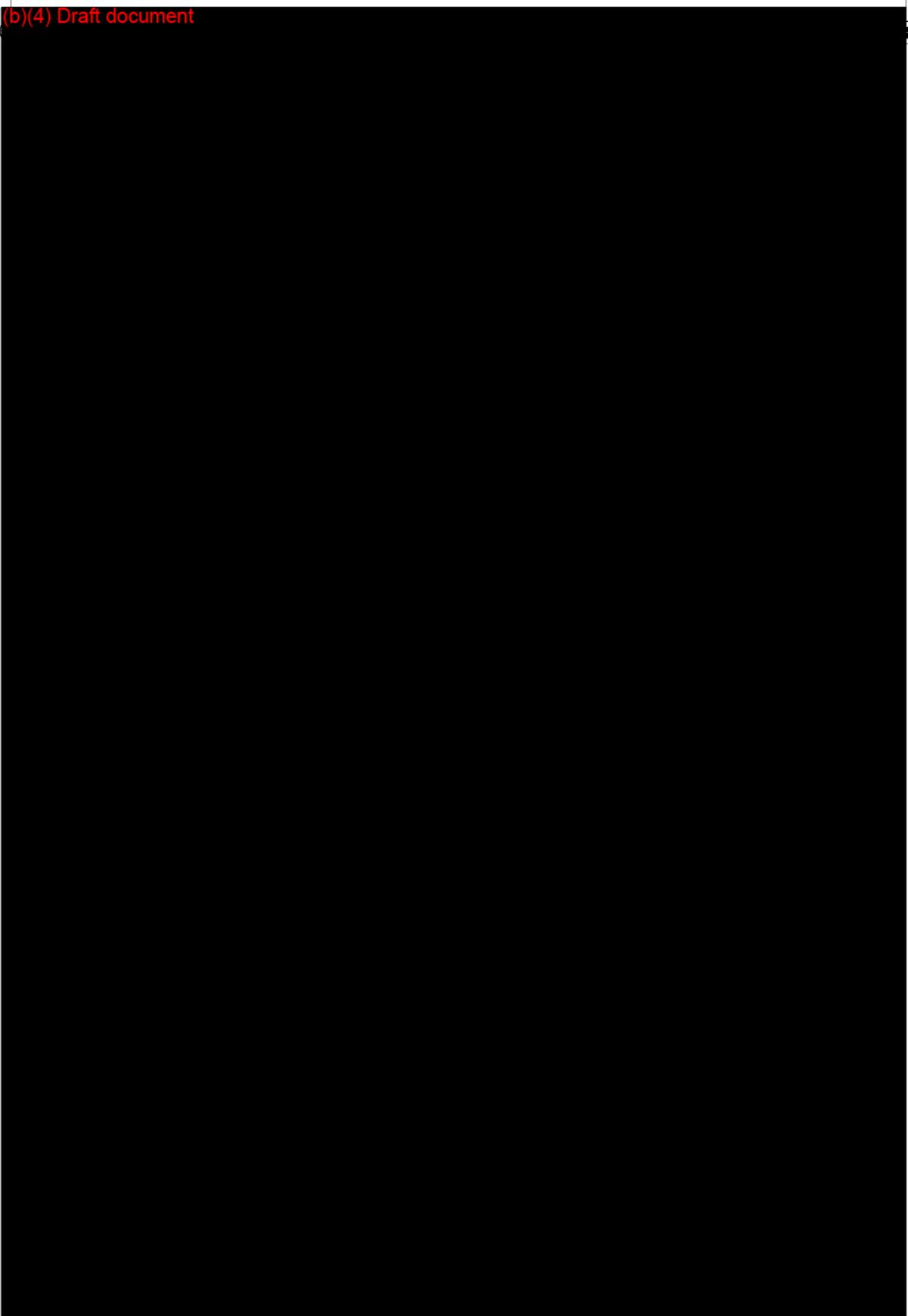
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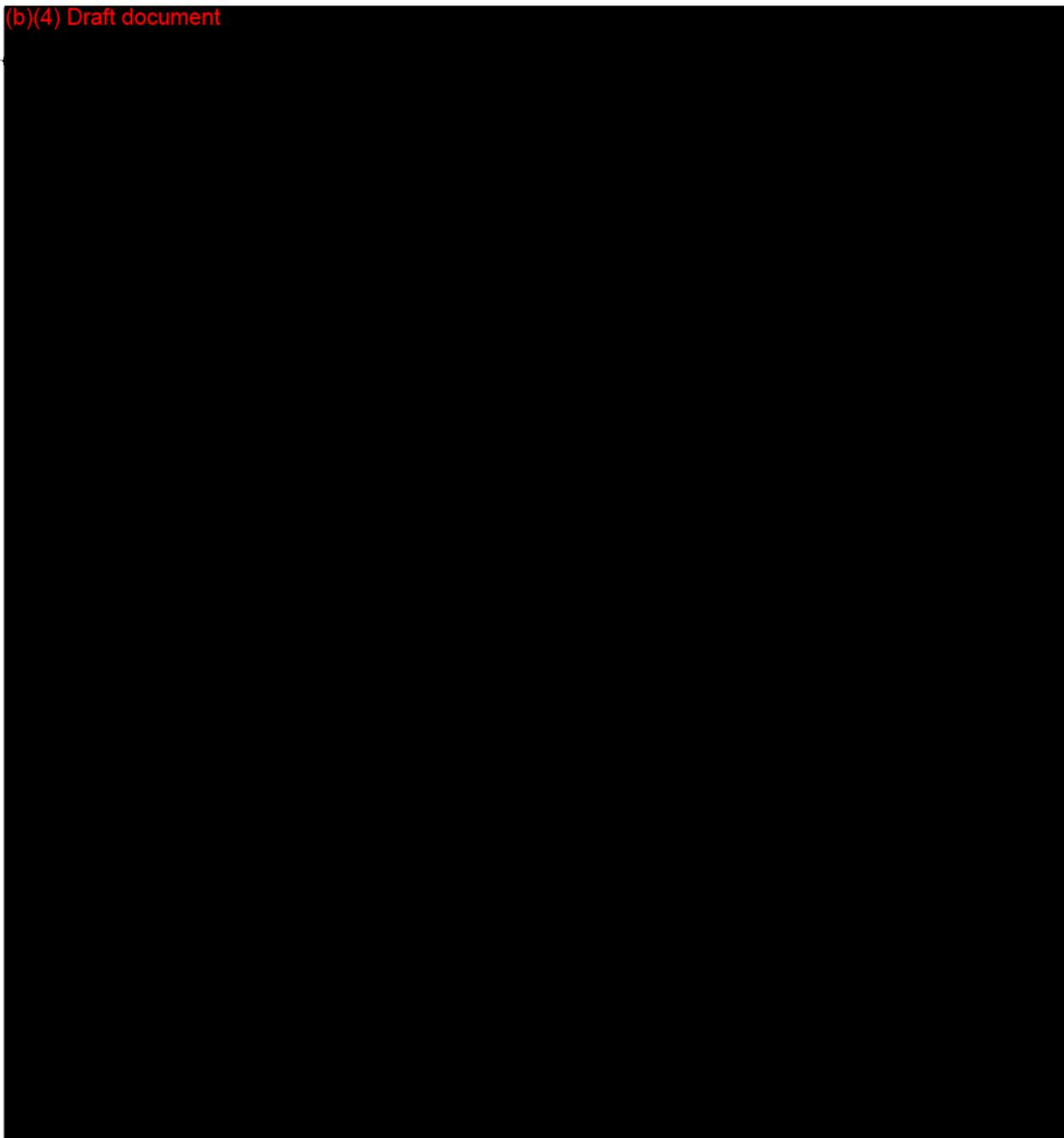
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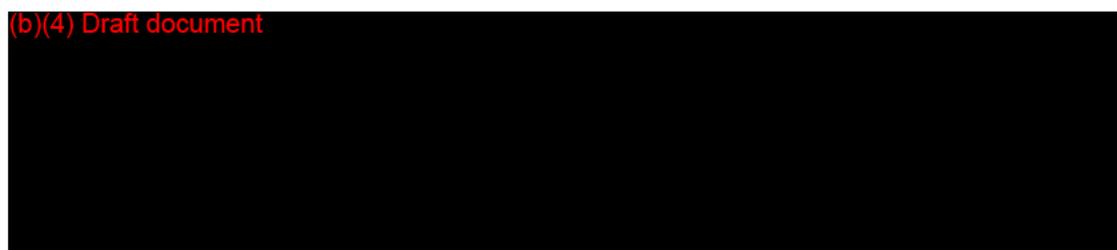
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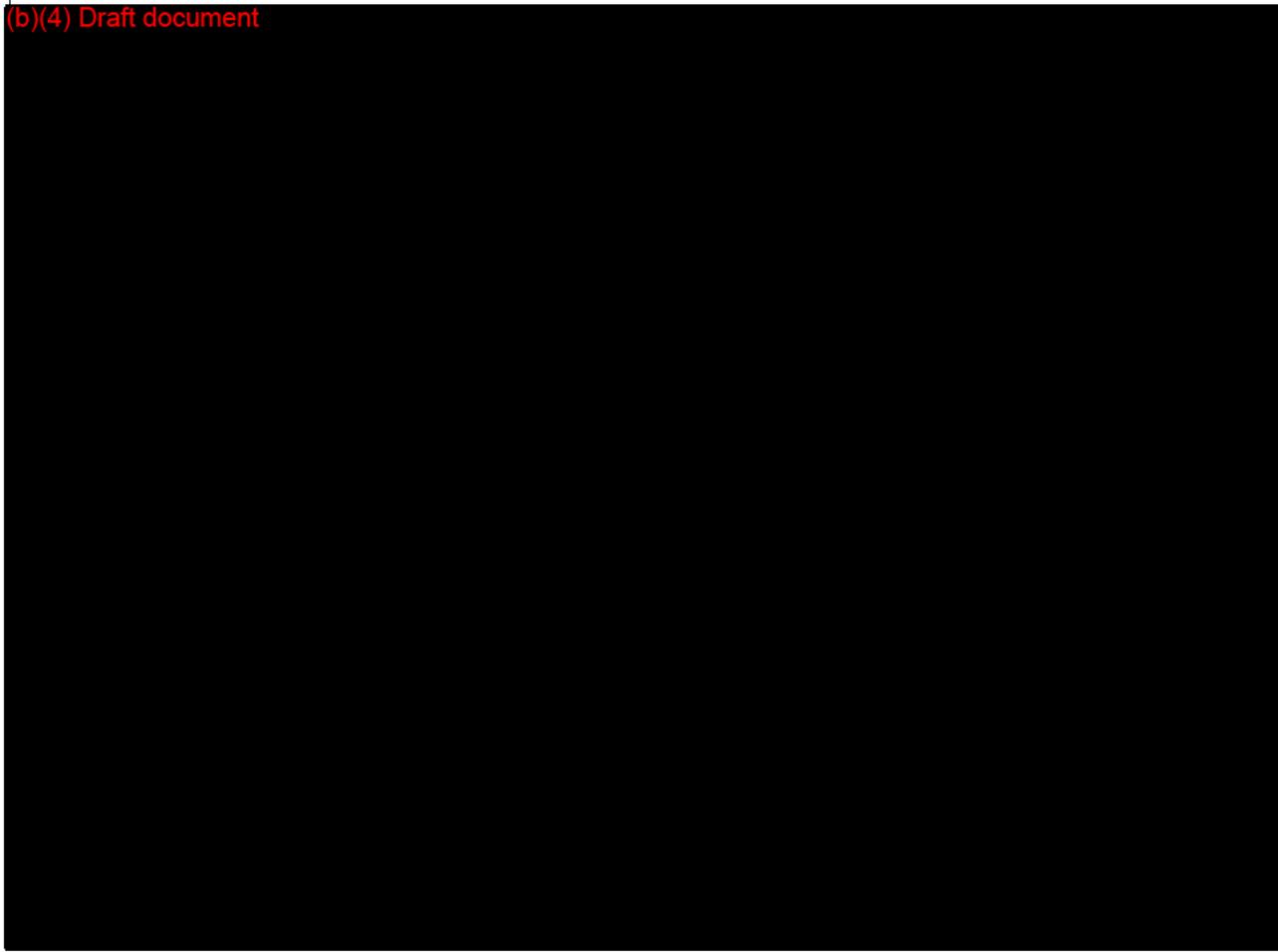
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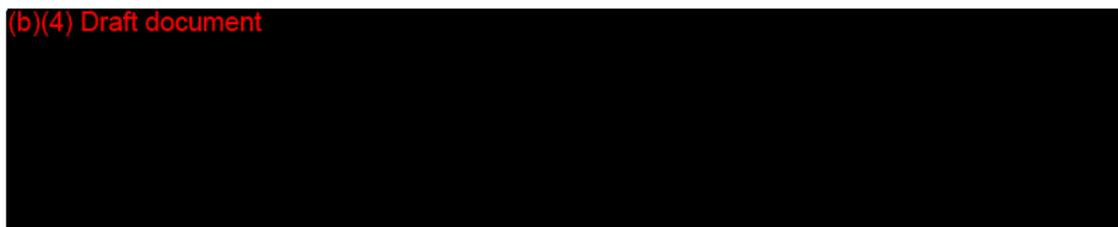
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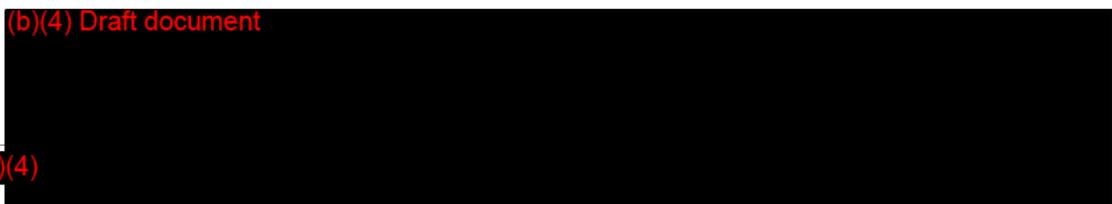
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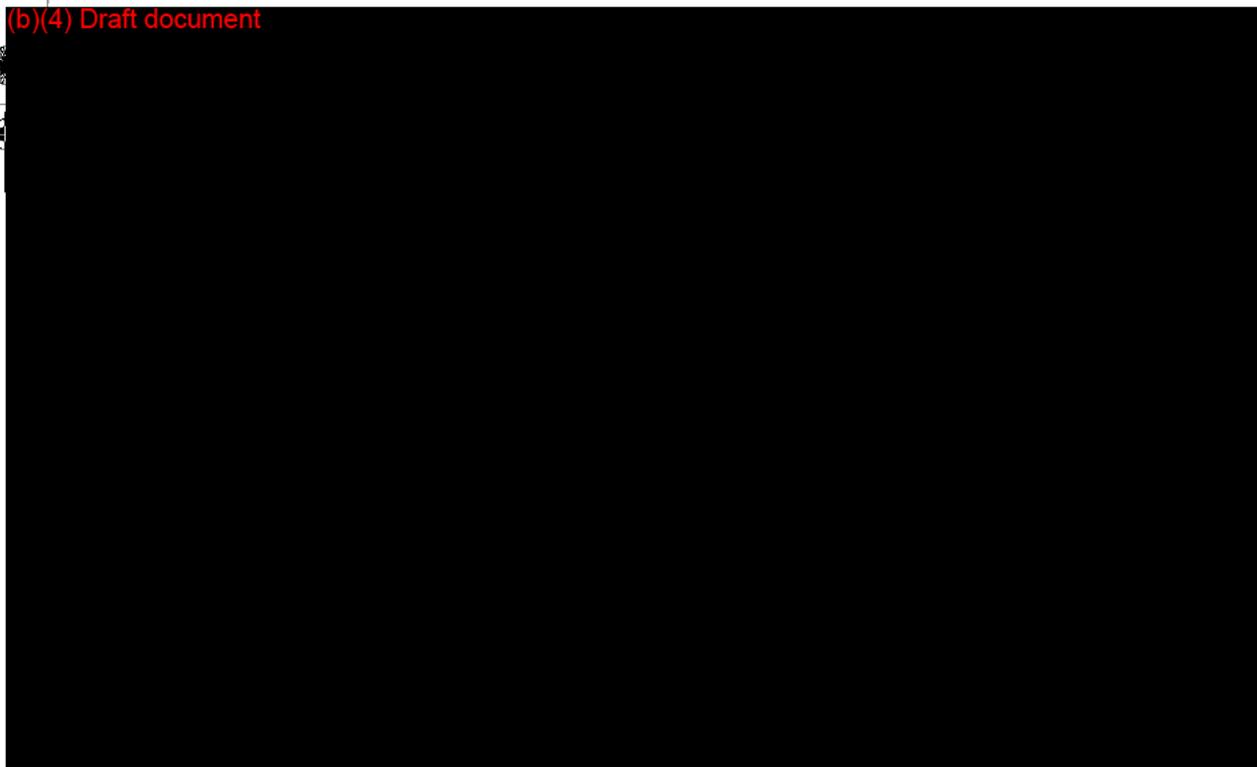
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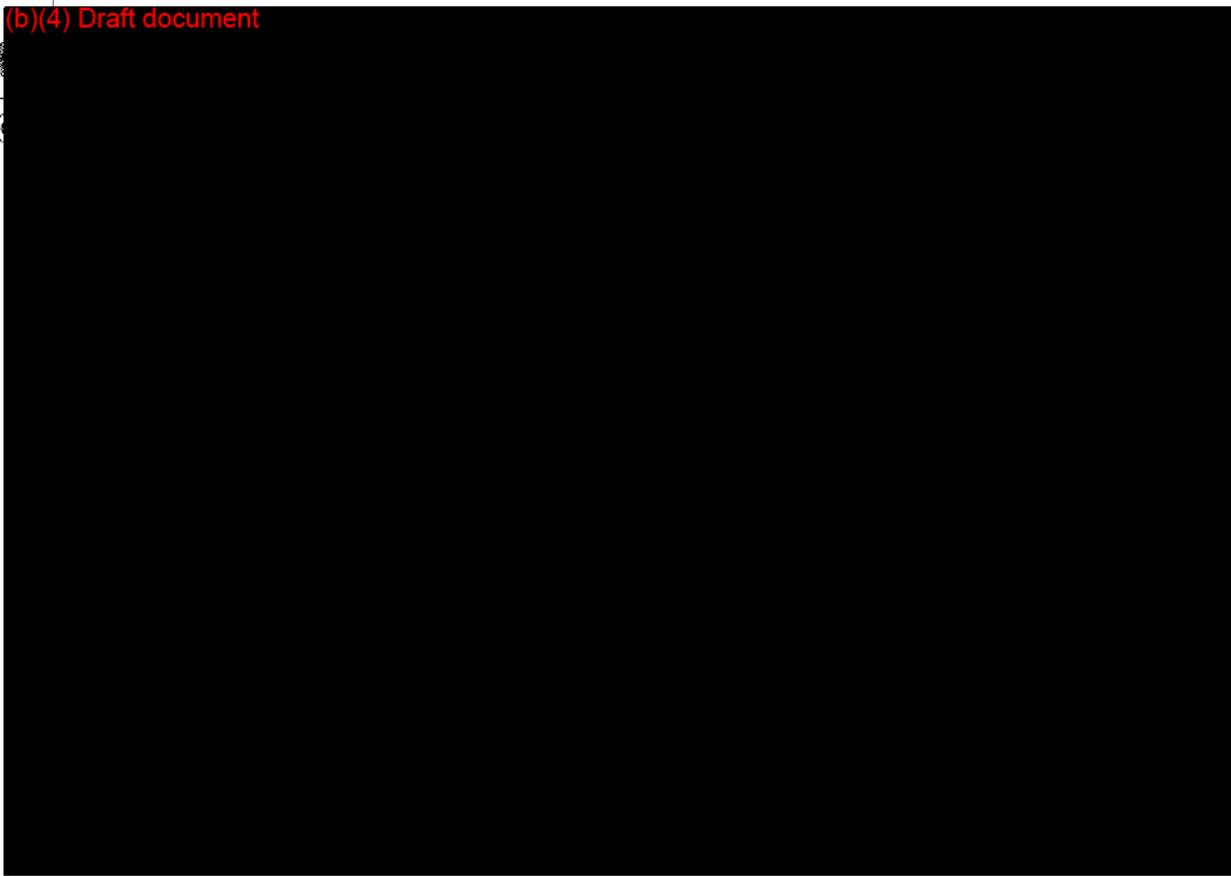
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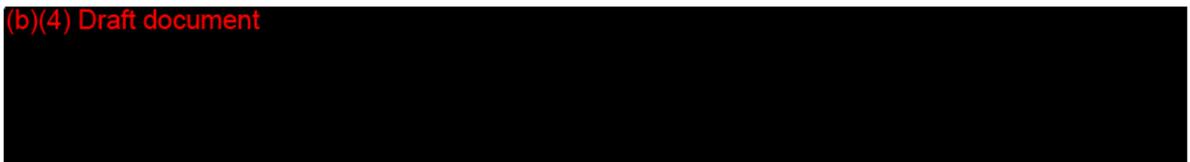
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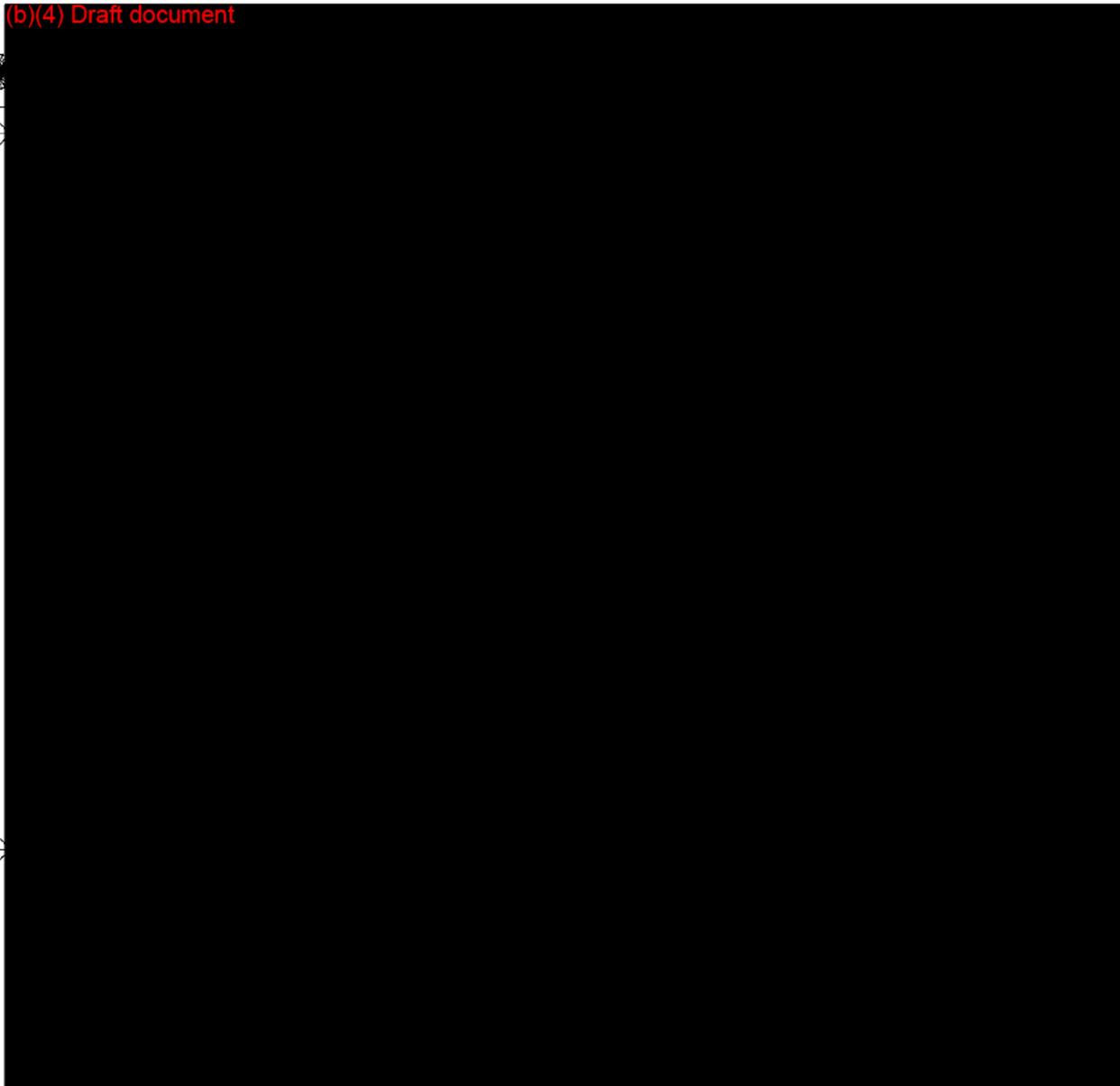
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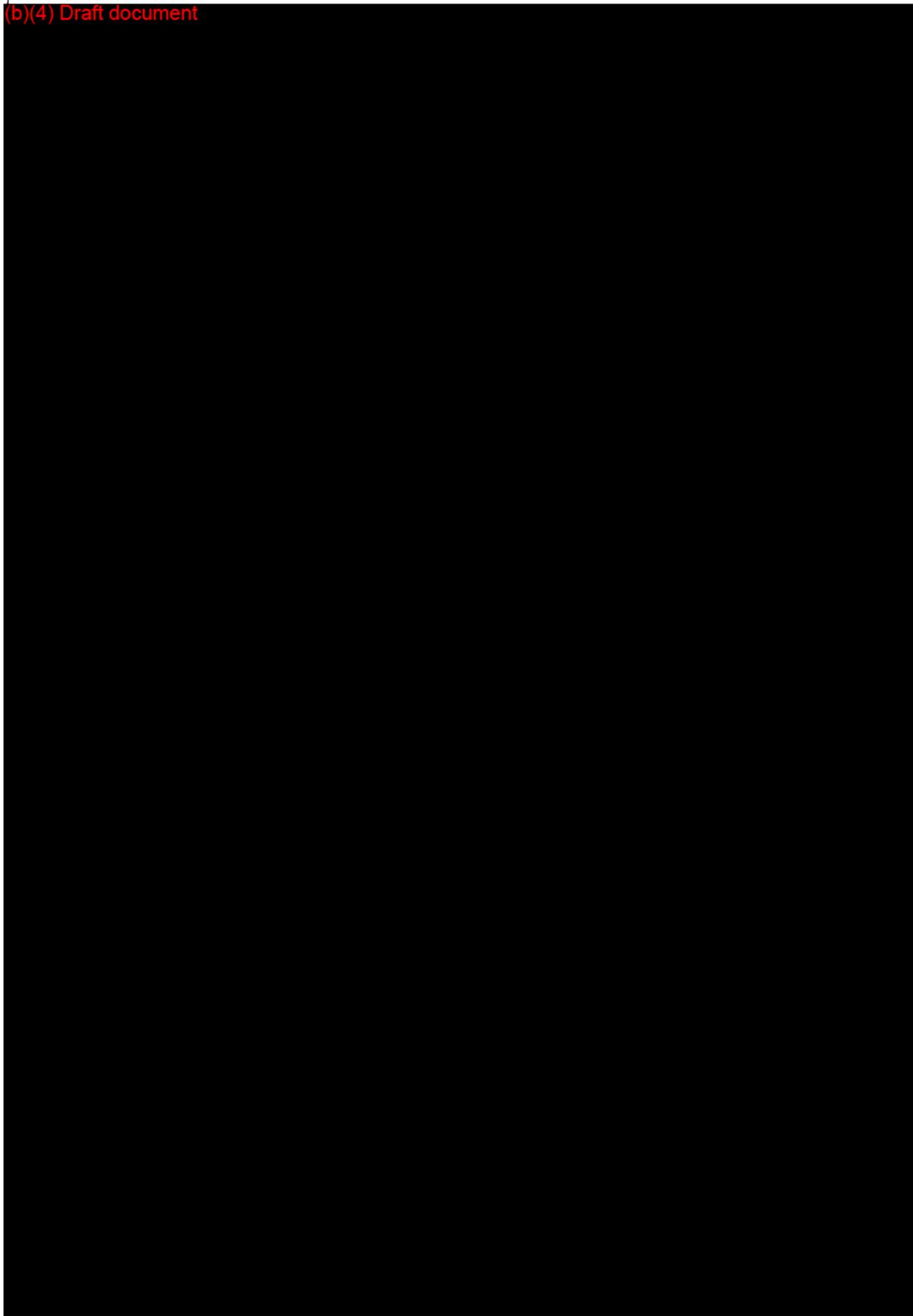
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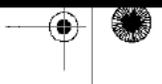
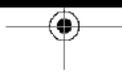
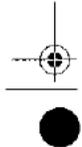
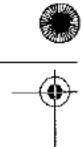
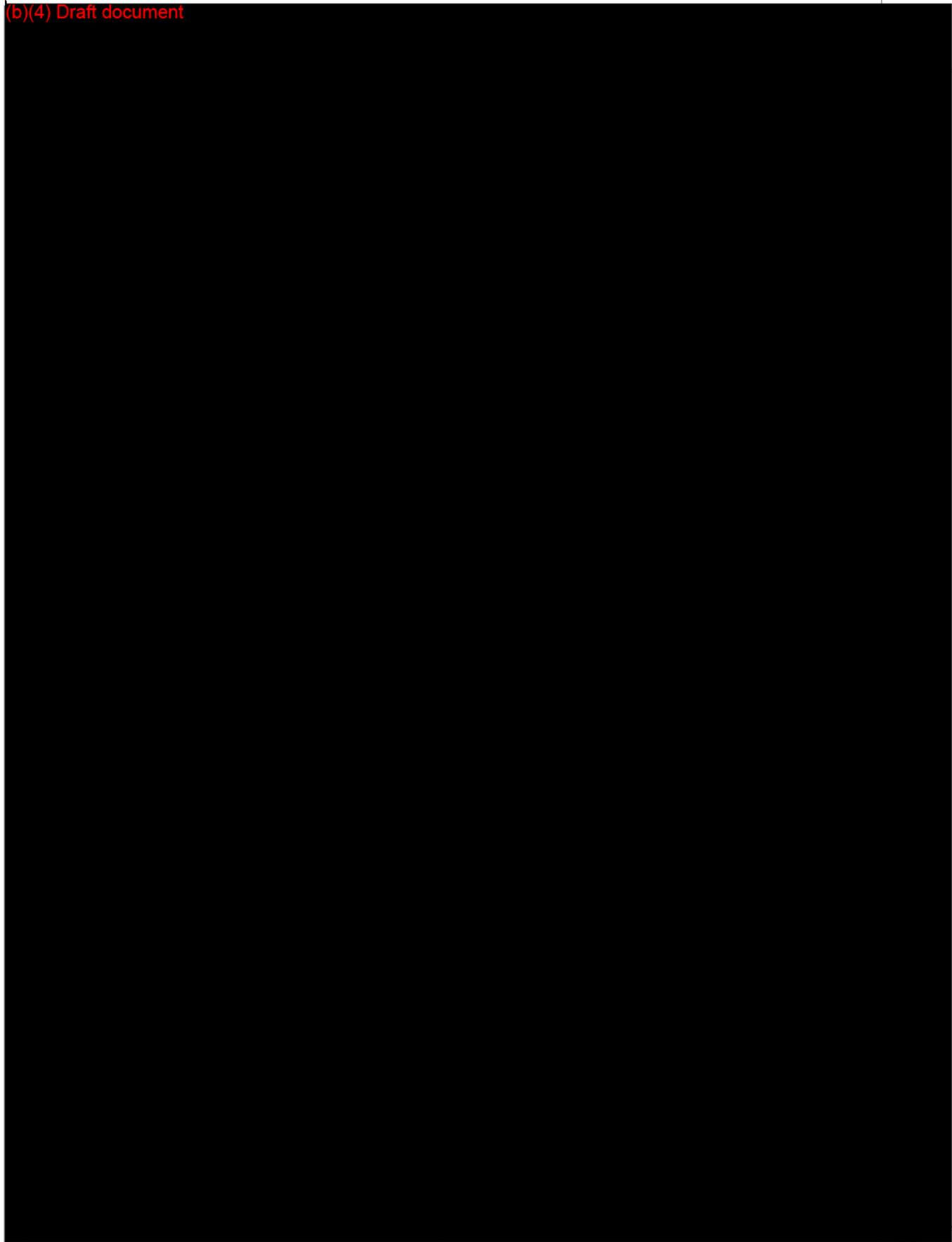
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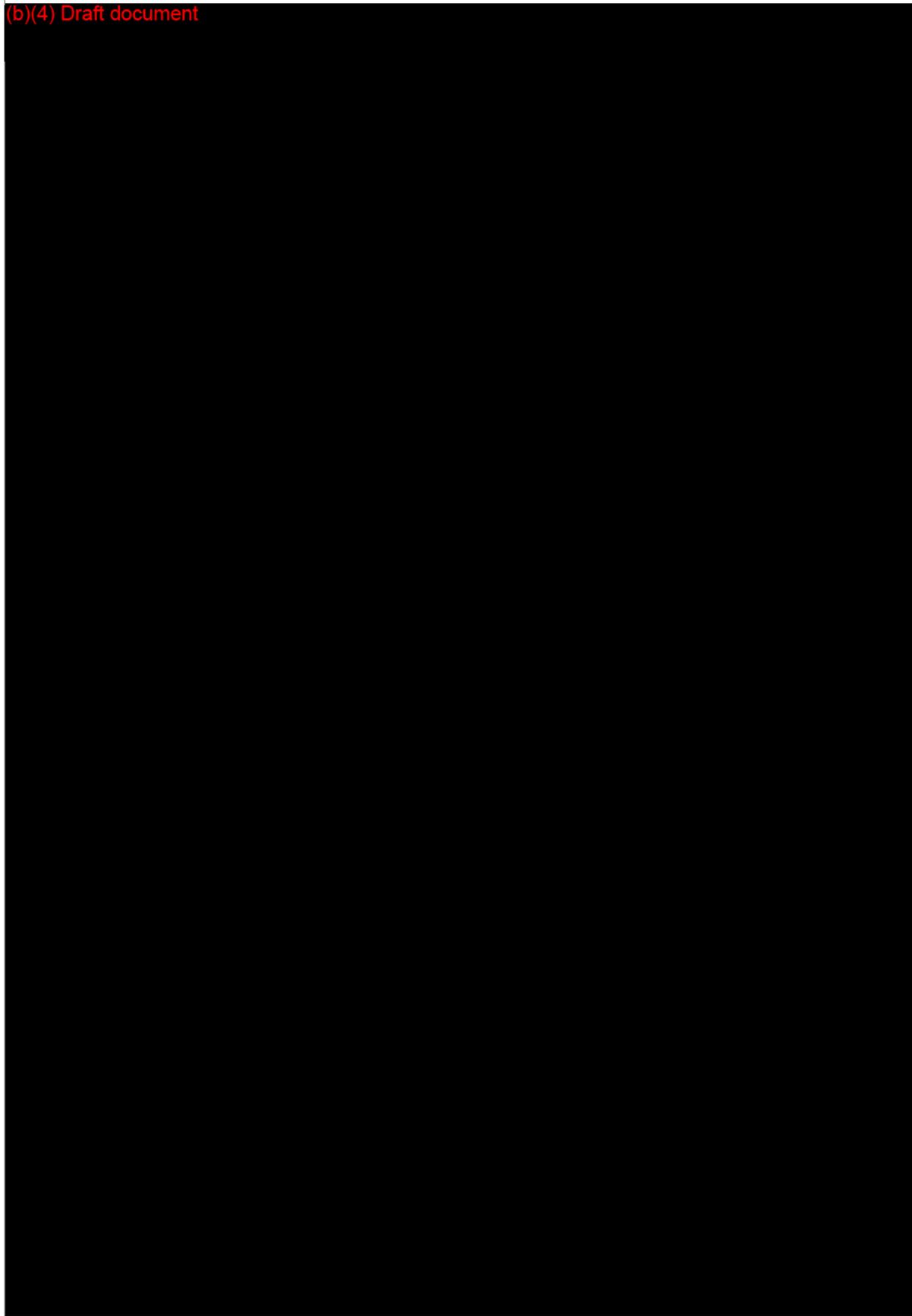
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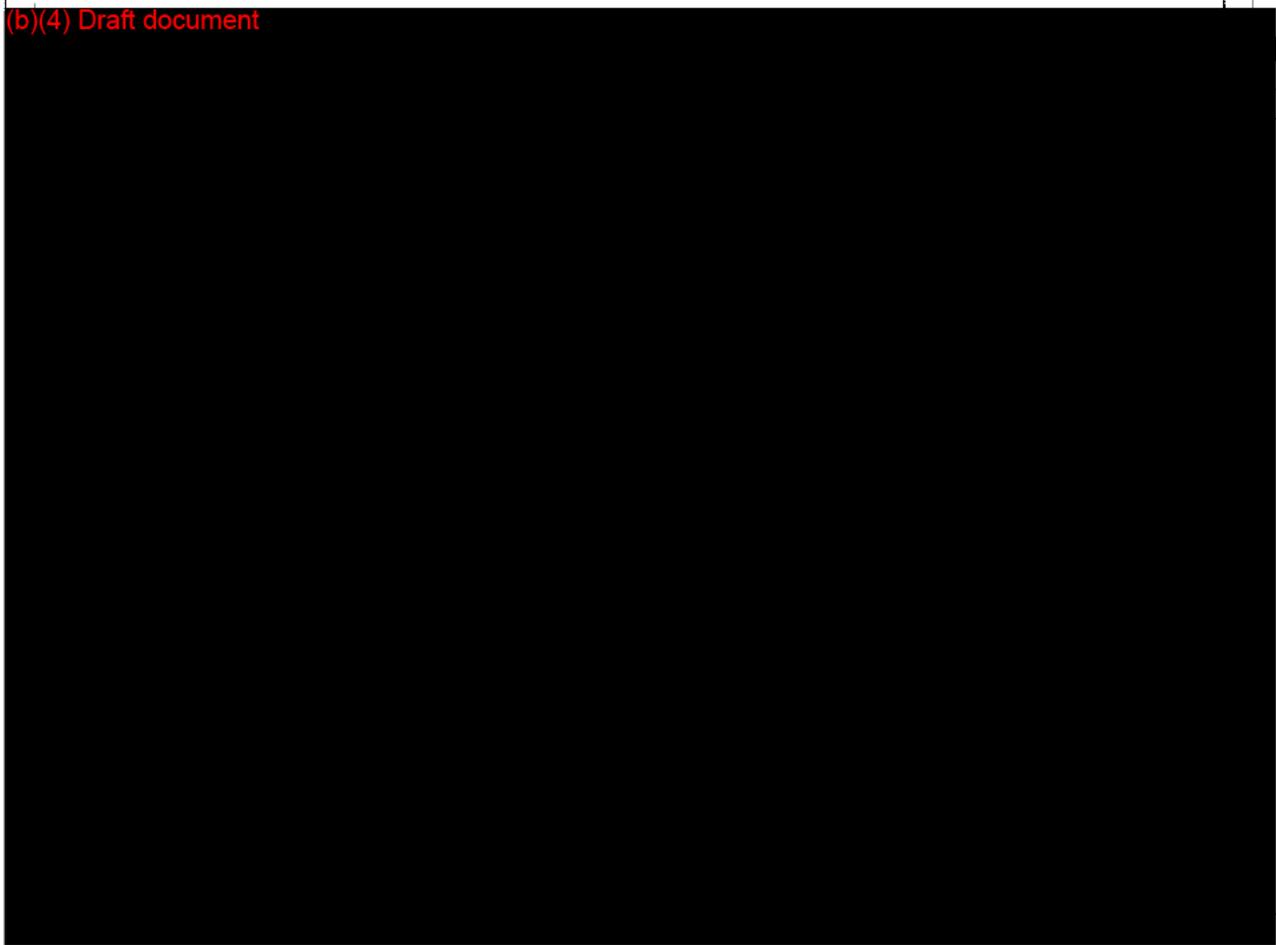
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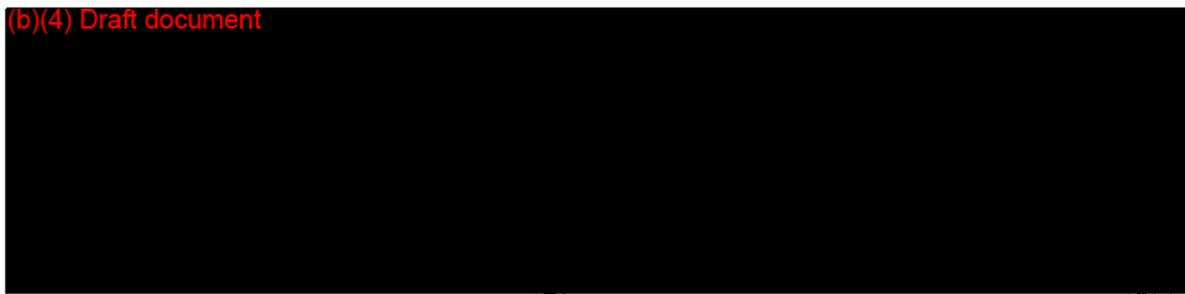
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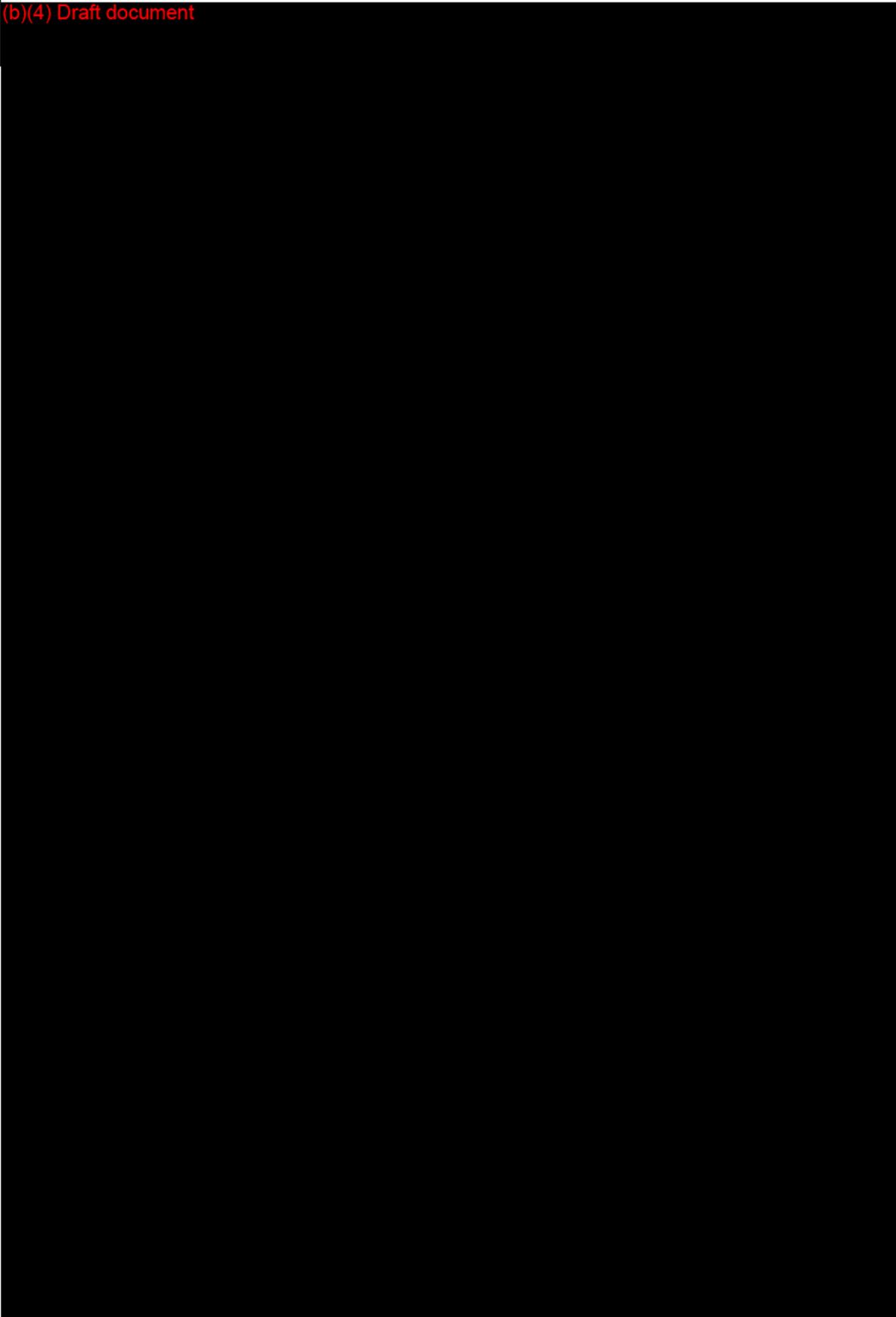
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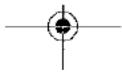
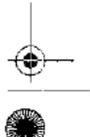
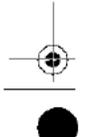
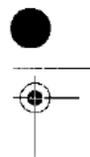
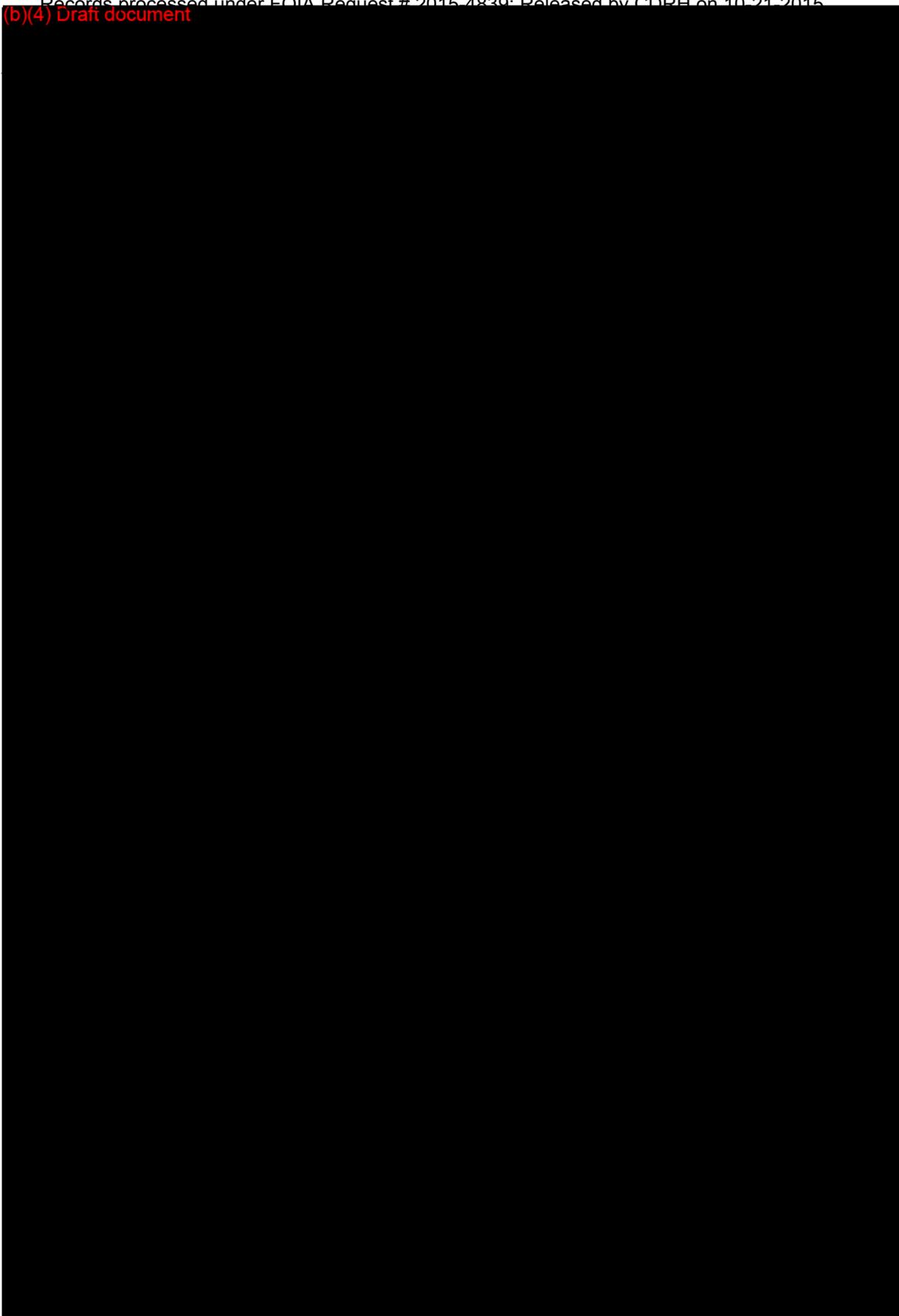
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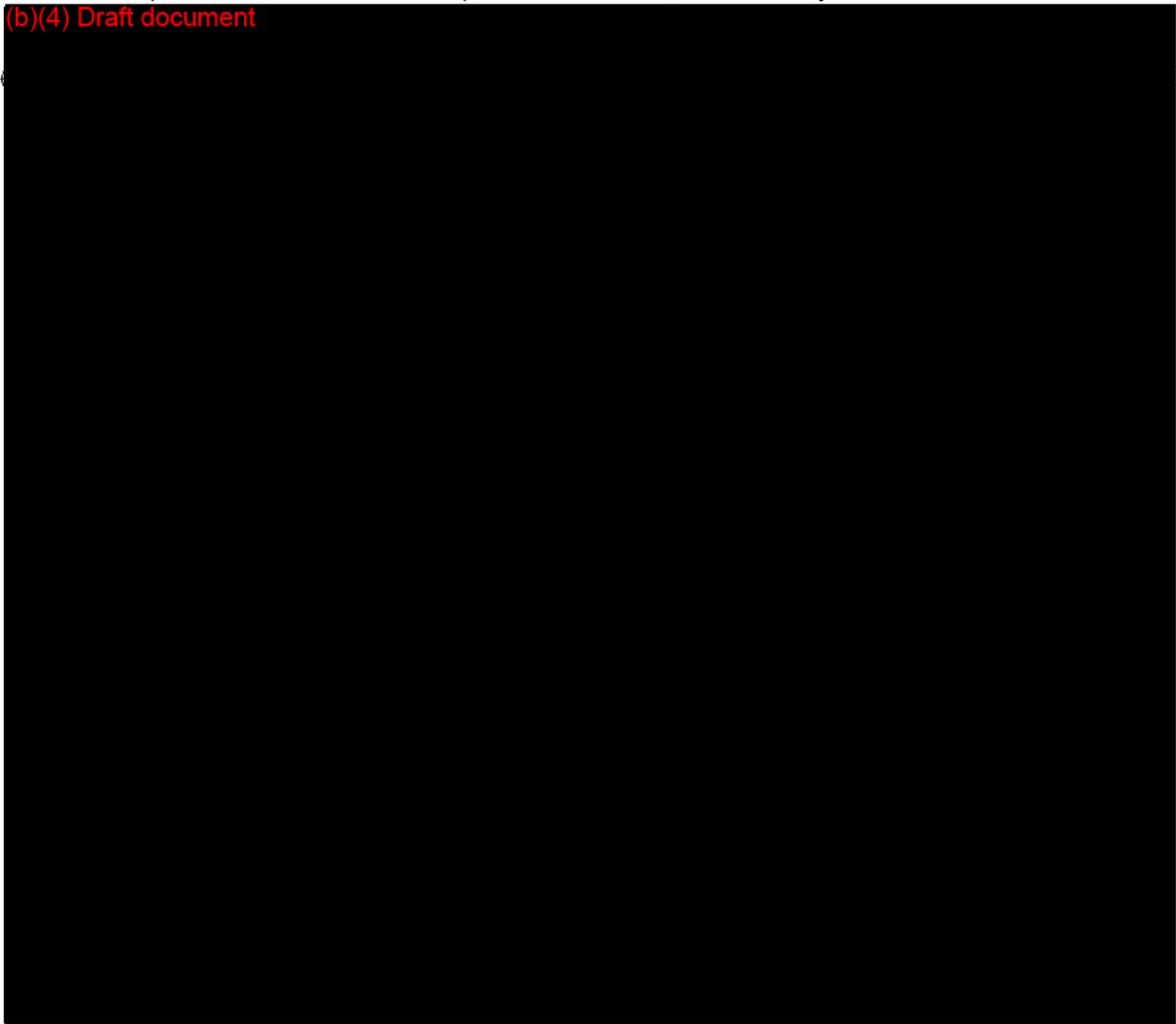
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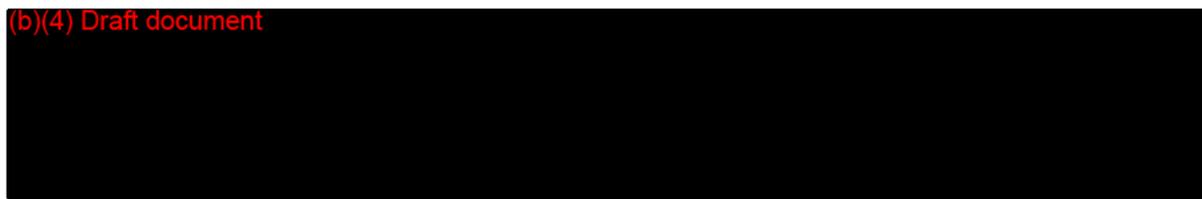
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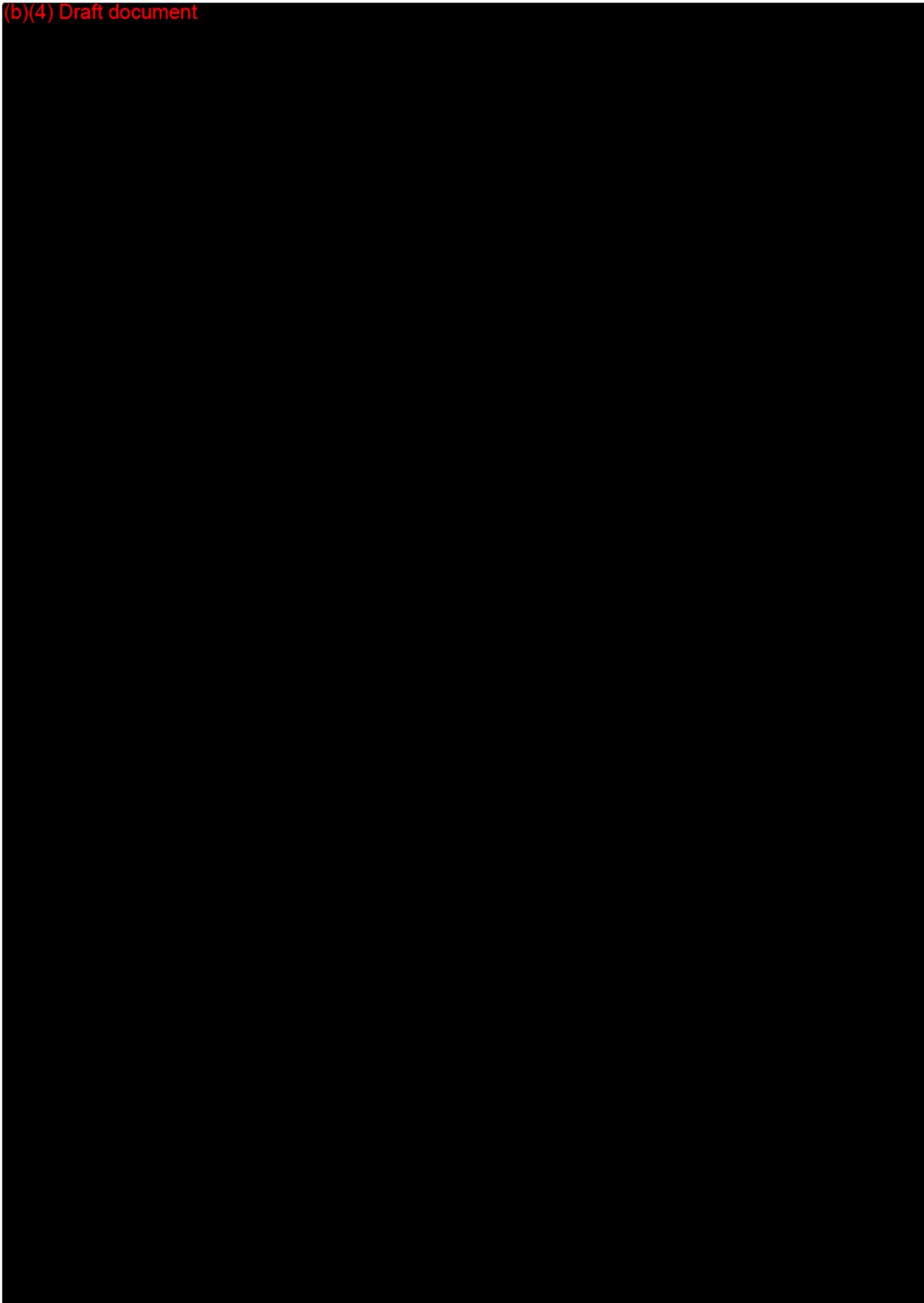
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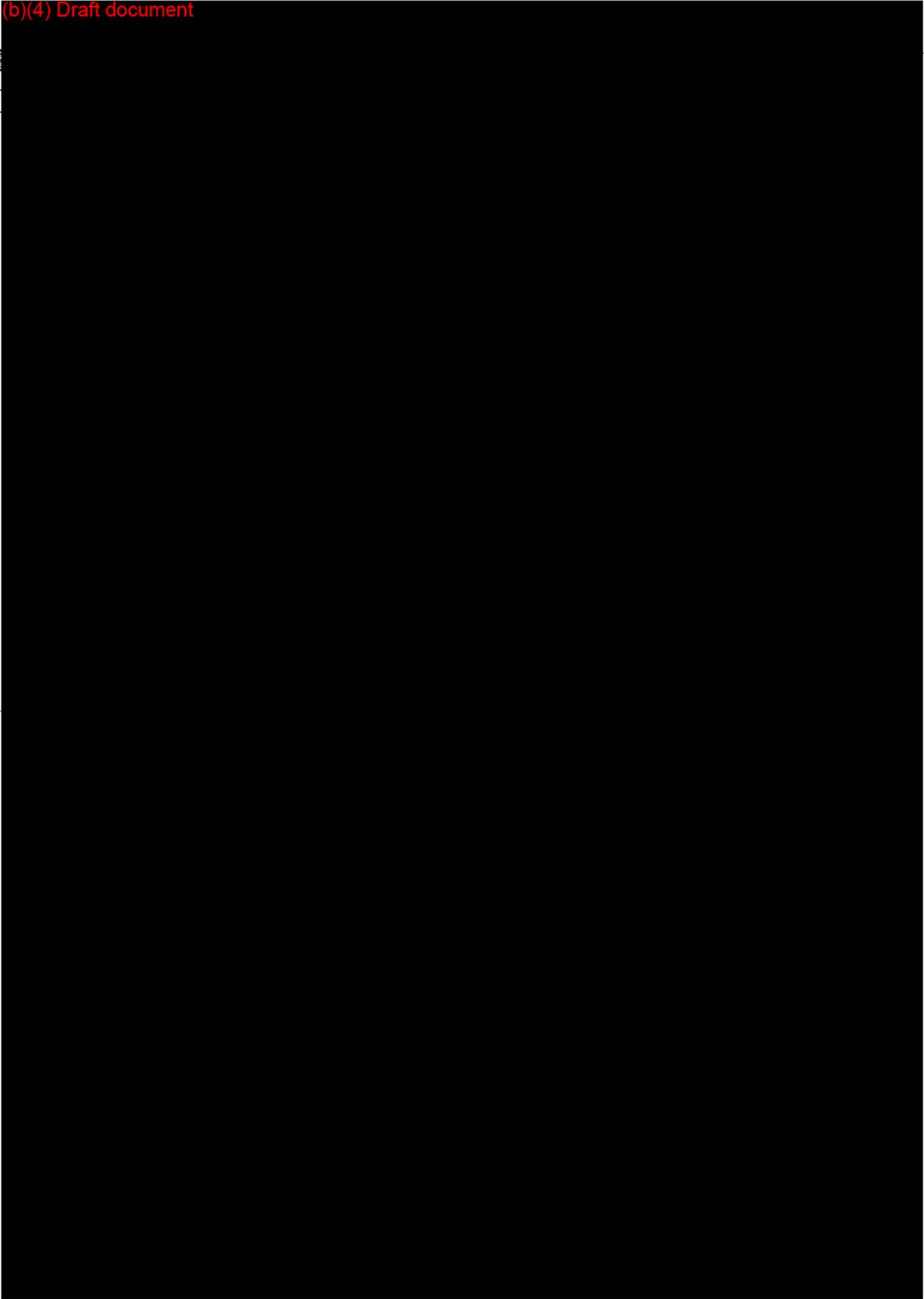
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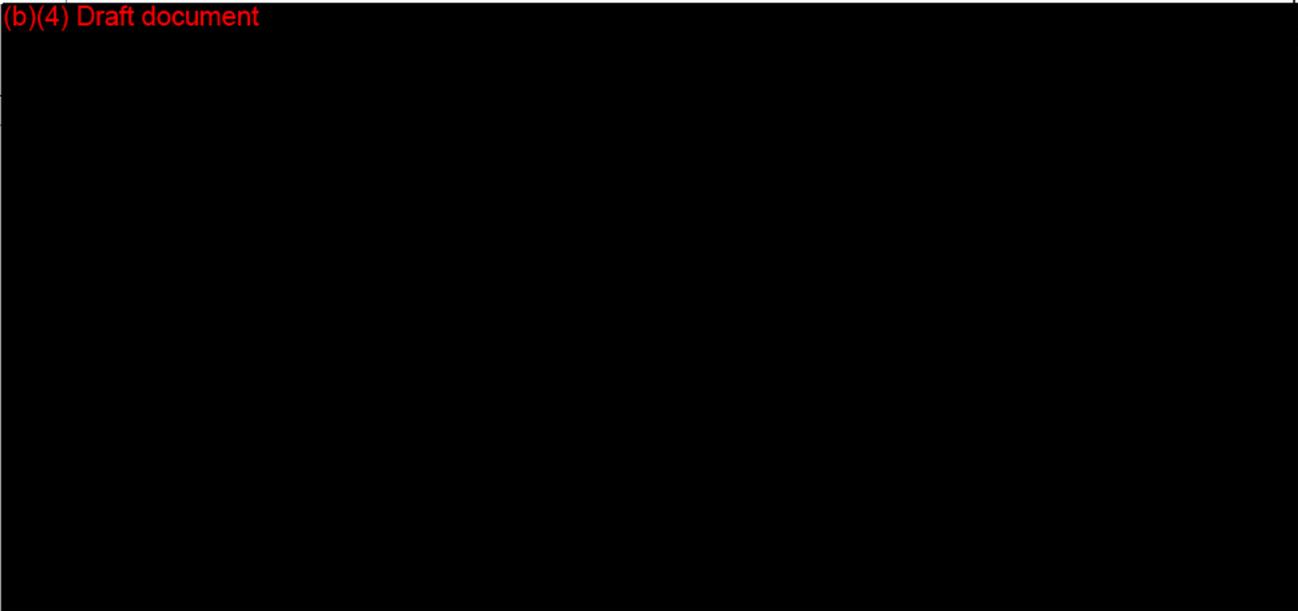
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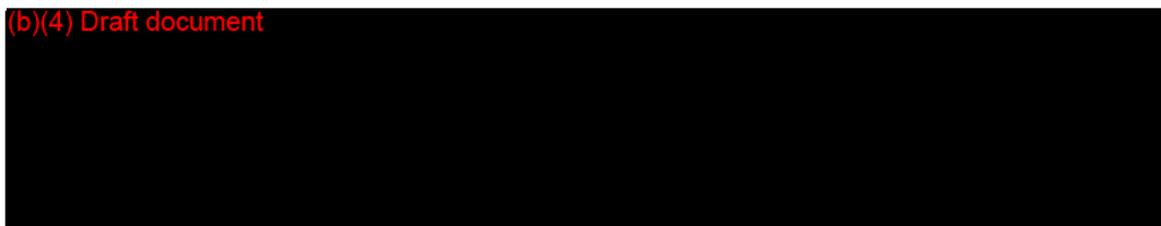
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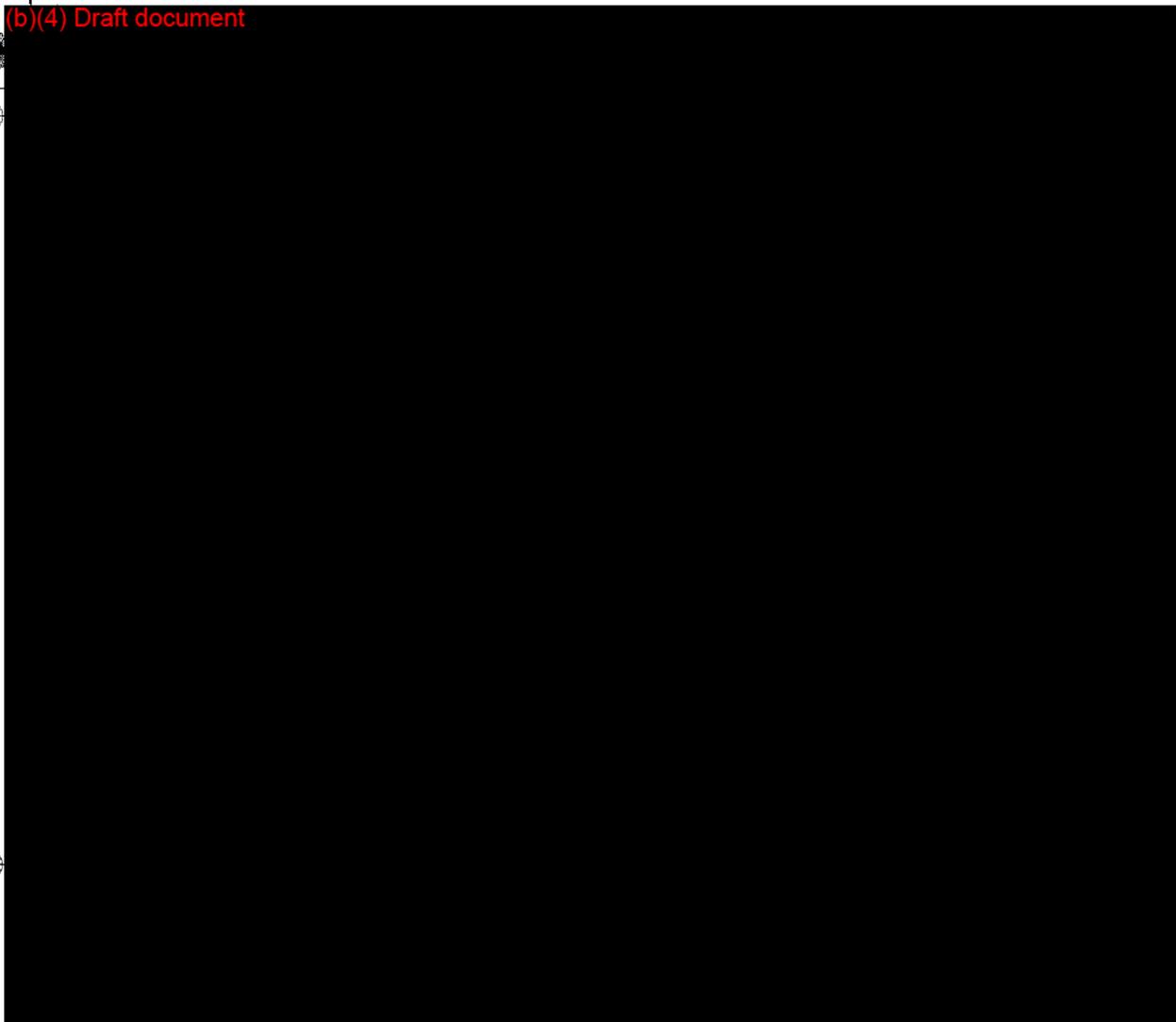
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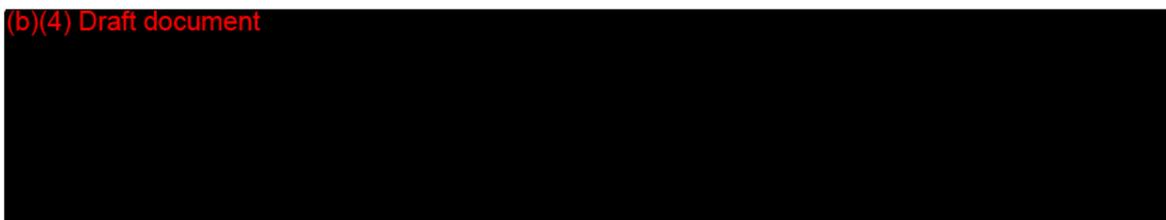
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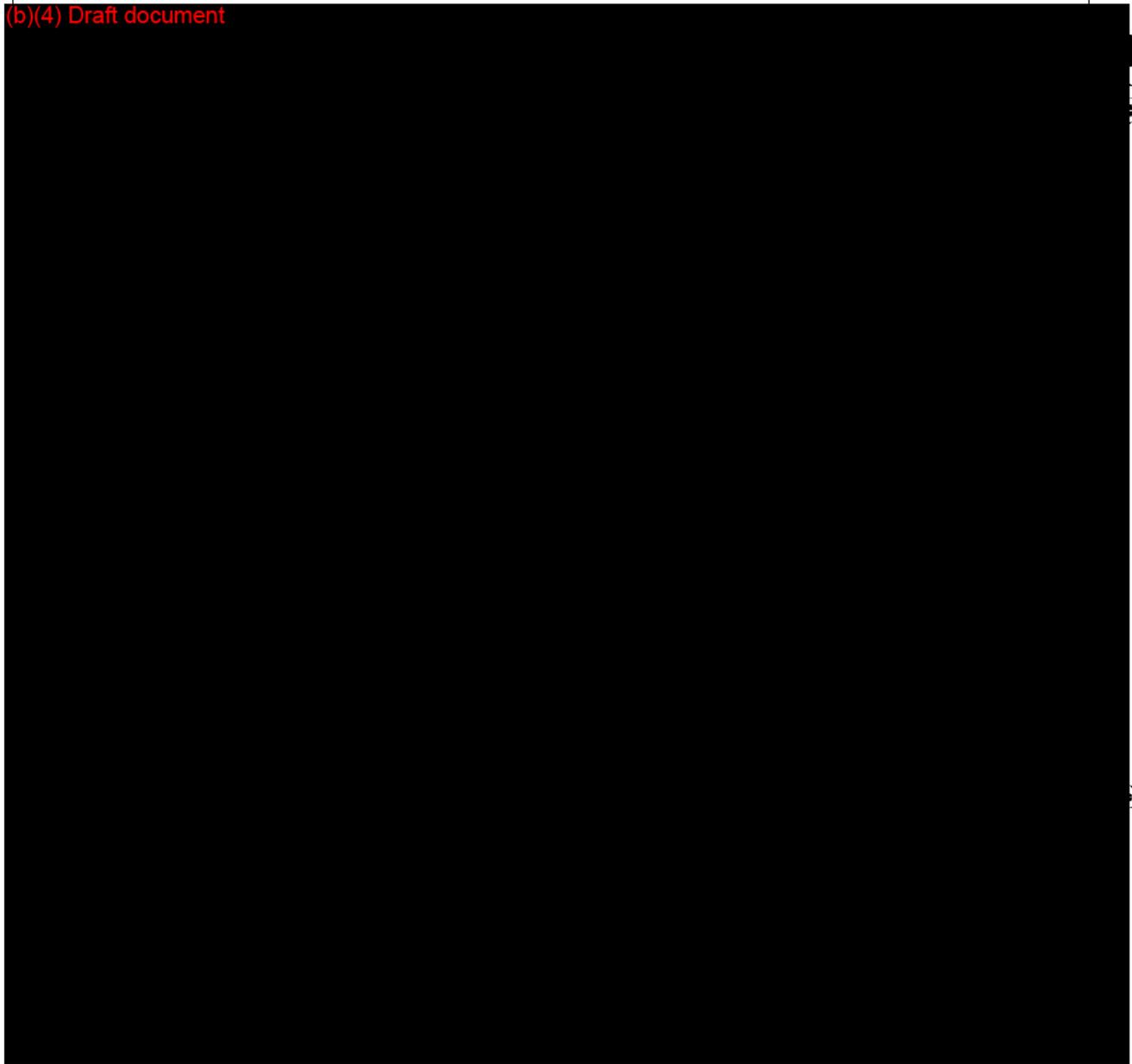
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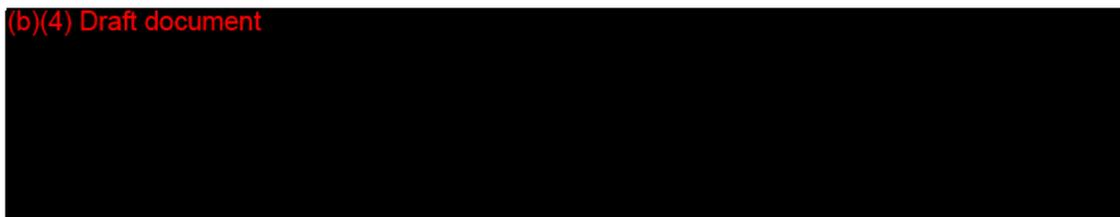
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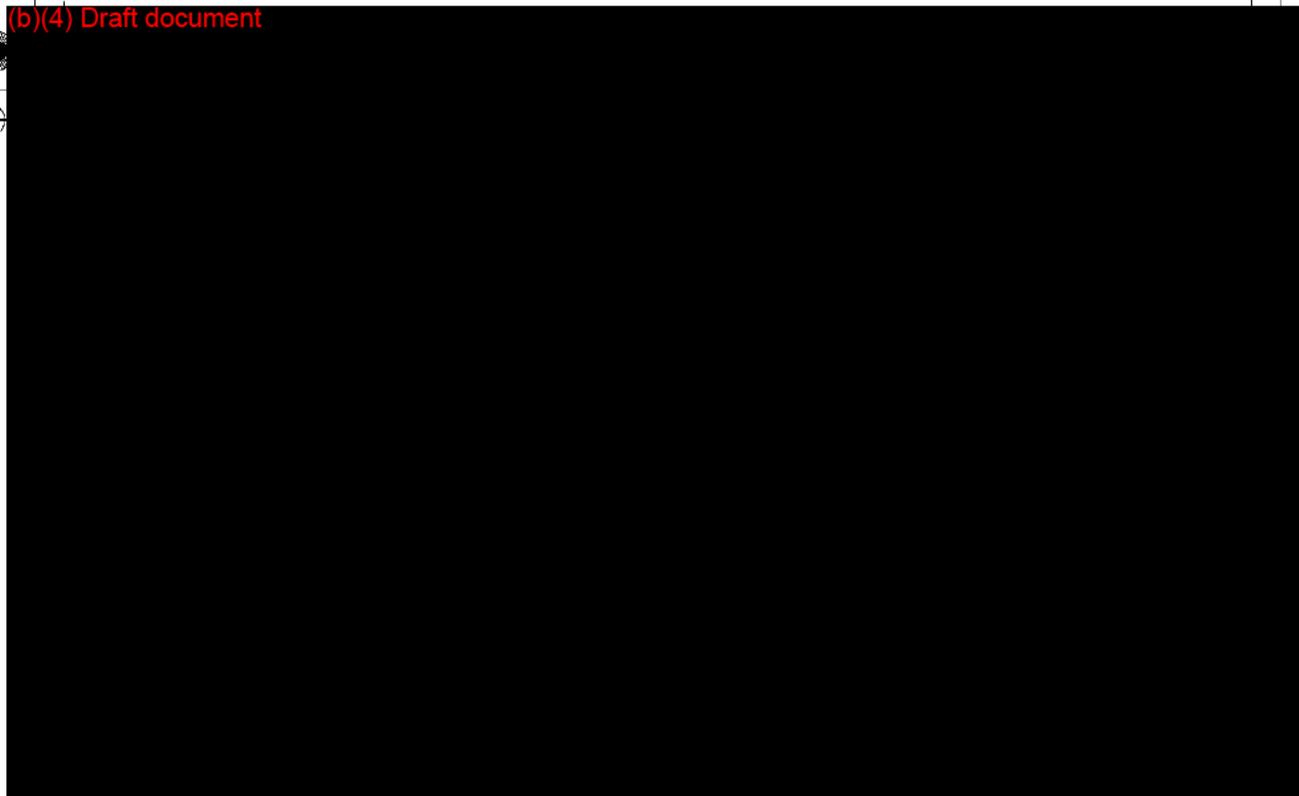
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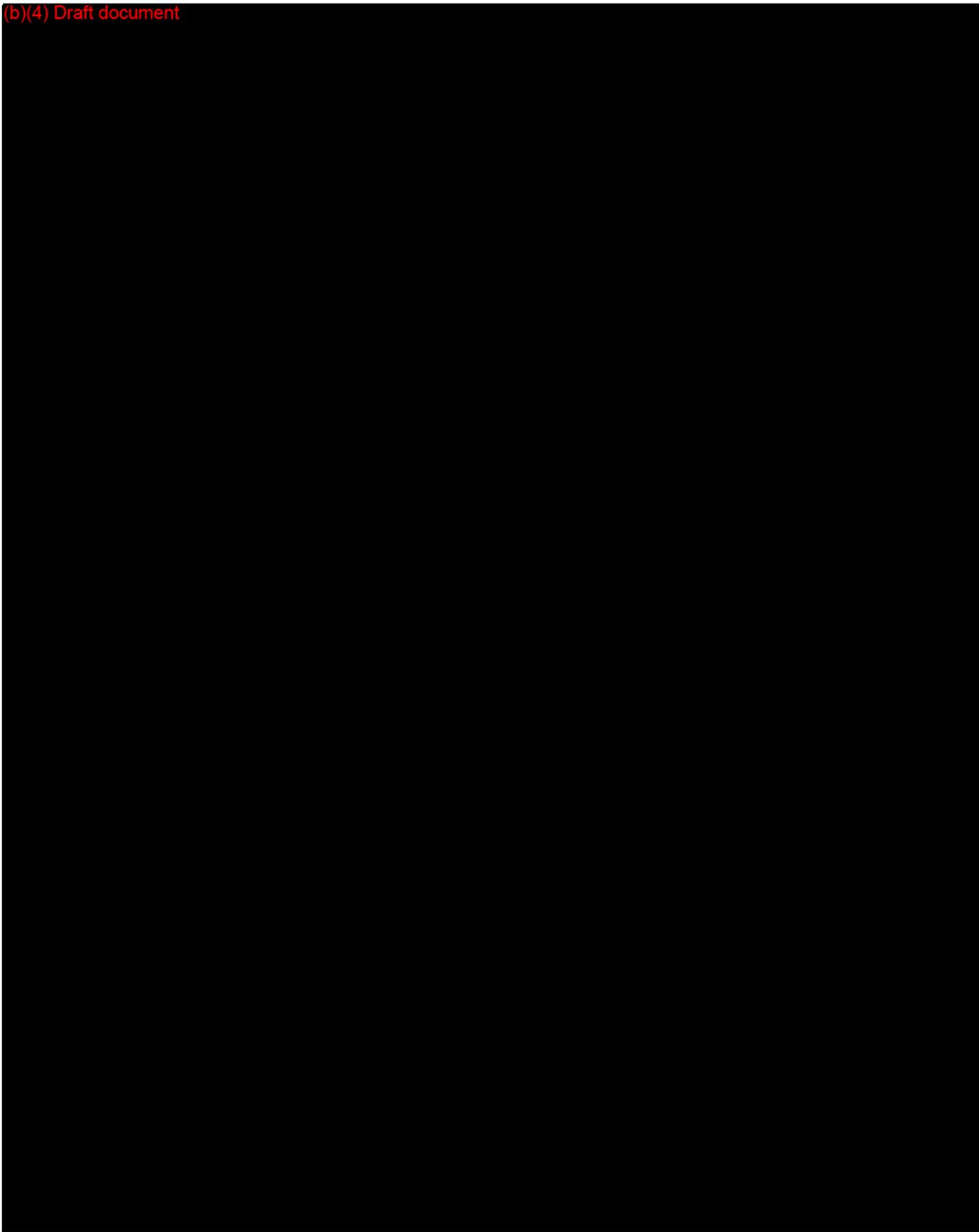


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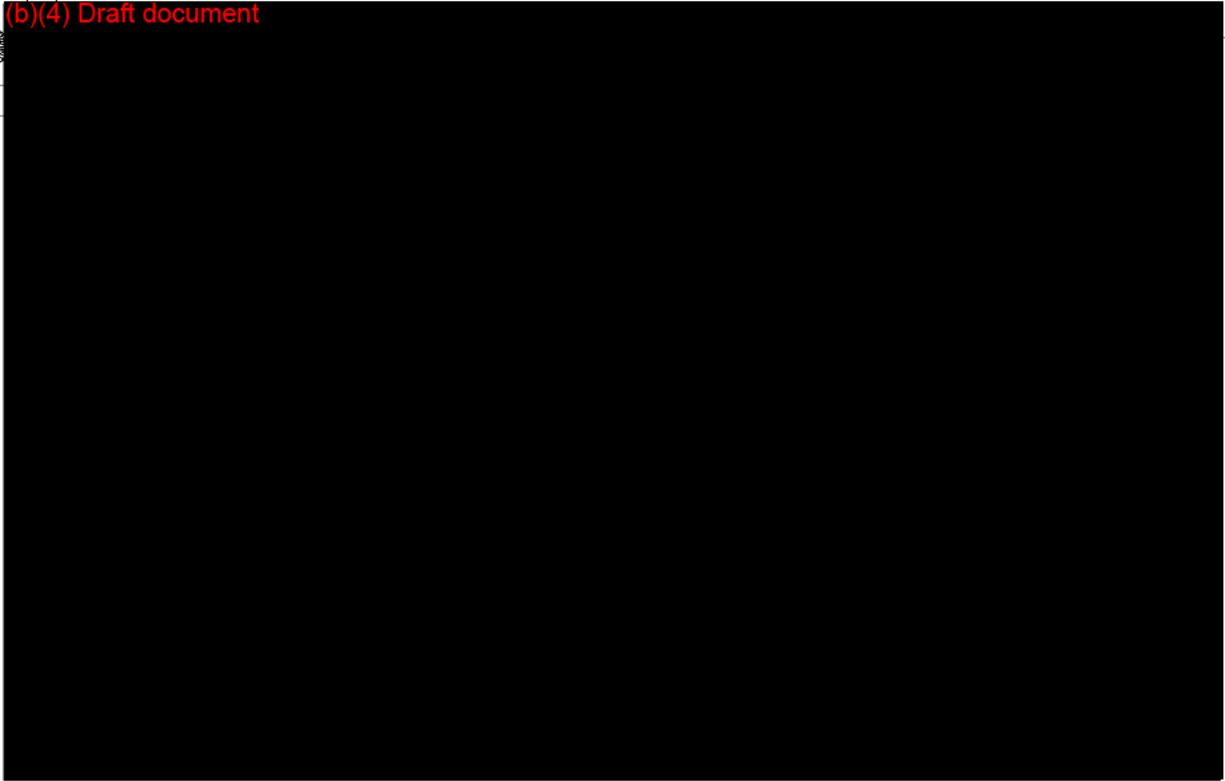


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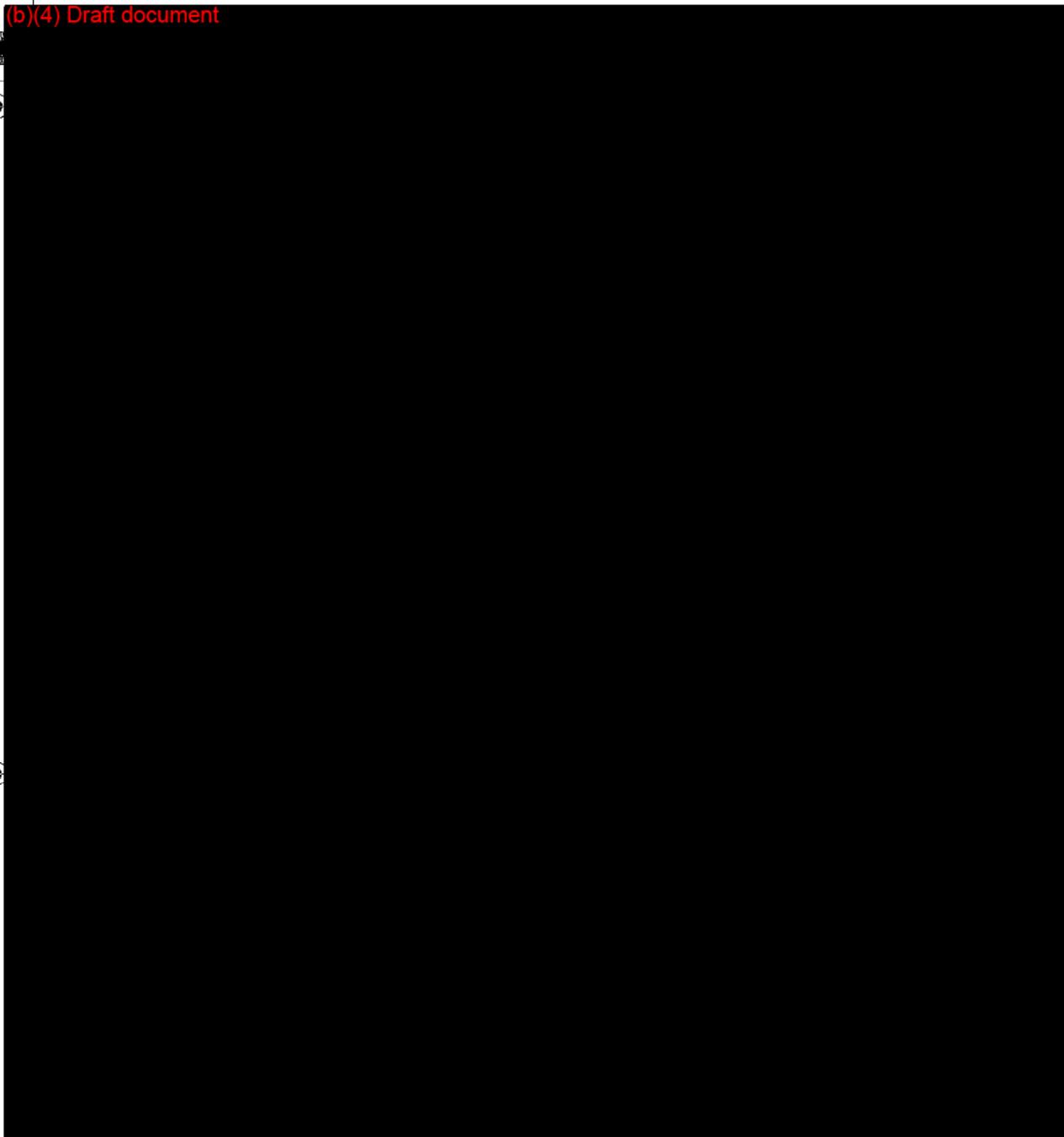
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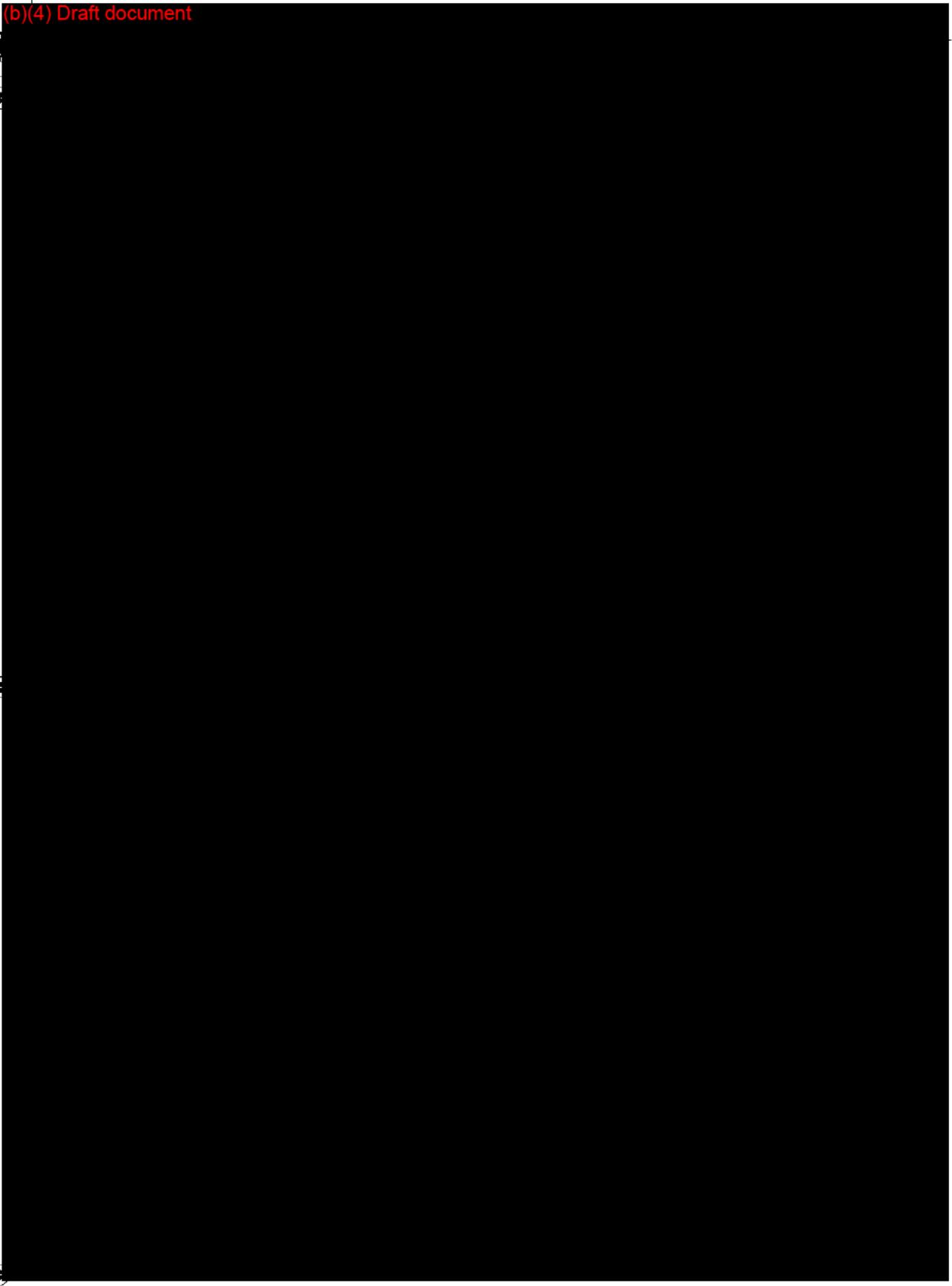
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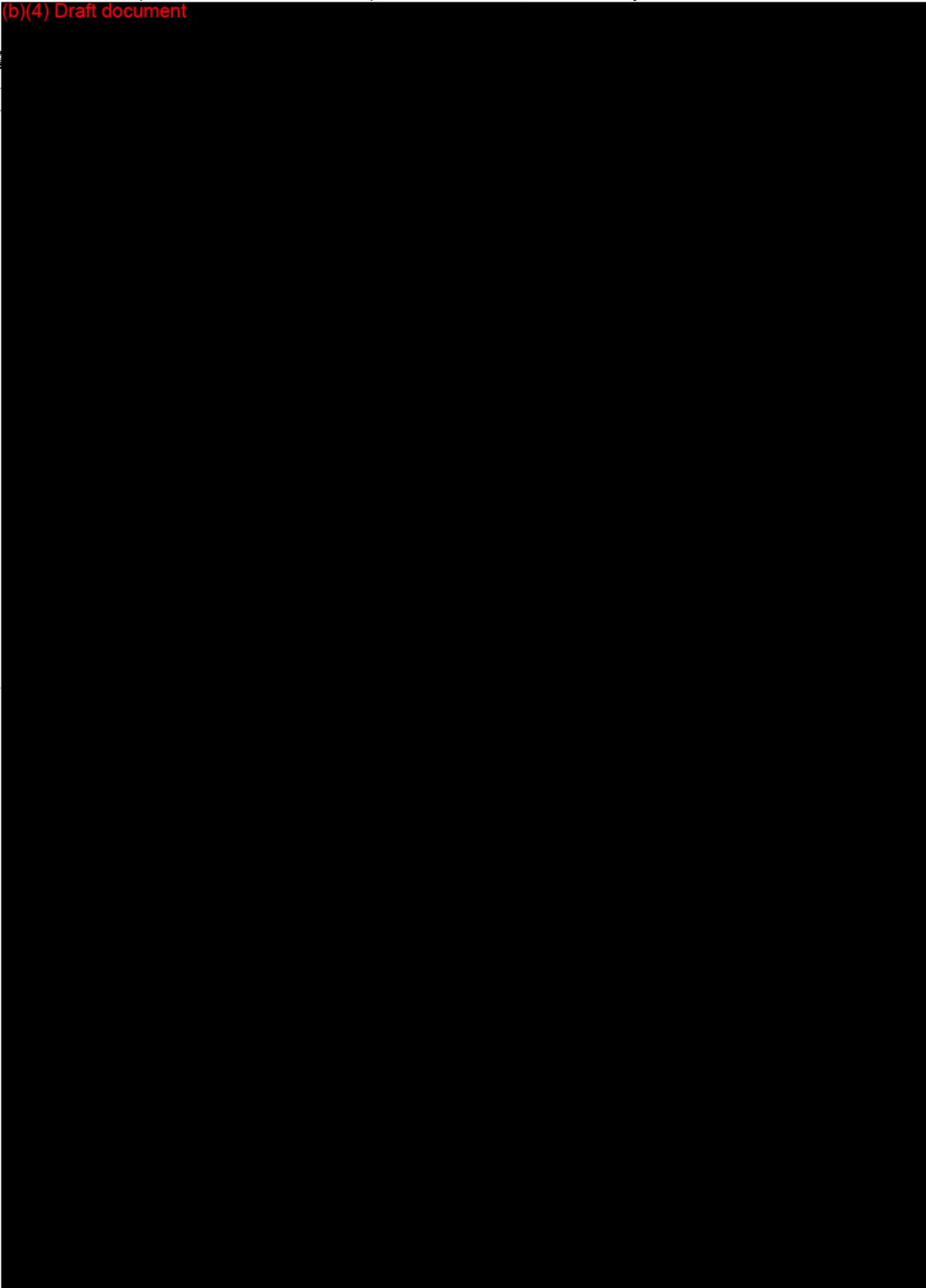
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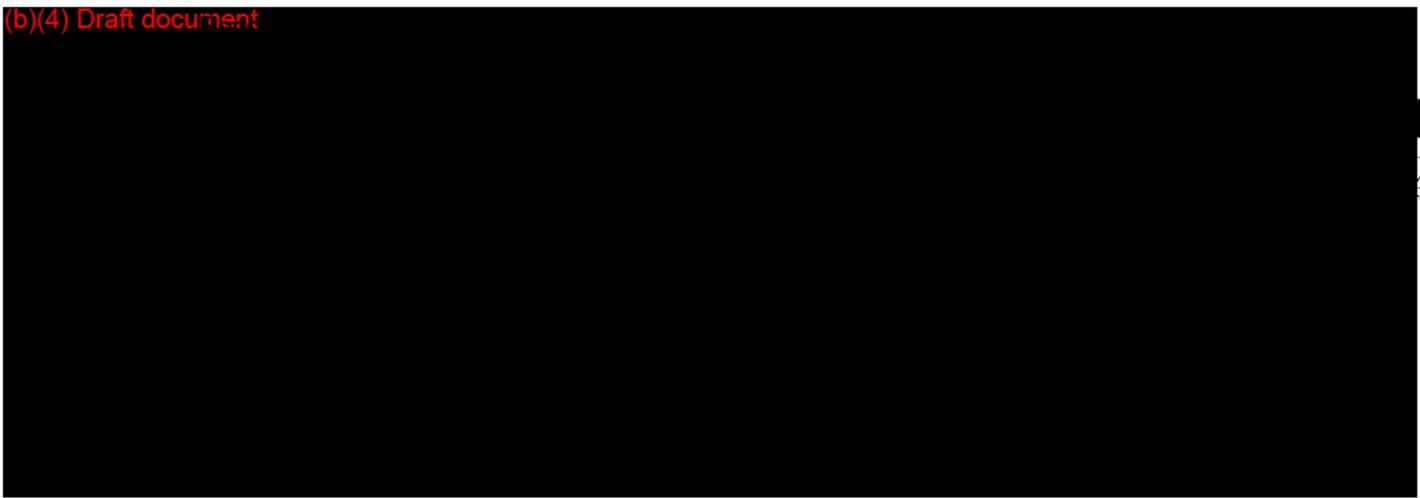
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**Attachment 10**  
**510(K) Summary**

## 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

### I. GENERAL INFORMATION

#### Device Name and Classification

Product Name: Syngo Colonography software package  
Common Name: 3D Reconstruction Software  
Classification Name: Accessory to Computed Tomography System  
Classification Panel: Radiology  
CFR Section: 21 CFR §892.1750  
Device Class: Class II  
Product Code: 90 JAK

#### Establishment:

##### **Importer/Distributor:**

Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway  
Malvern, PA 19355

**Registration Number:** 2240869

##### **Manufacturing Facility:**

Siemens AG  
Medical Solutions  
Henkestrasse 127  
D-91052 Erlangen, Germany  
***syngo* is a registered trademark of Siemens AG**

**Contact Person:** Mr. Jamie Yieh  
Senior Technical Specialist  
Telephone: (610) 448-1785 Fax: (610) 448-1787

**Date of Preparation of Summary:** November 26<sup>th</sup> 2002

### II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

#### **Device Description and Intended Use:**

This premarket notification covers Siemens Syngo Colonography software package. It is based on Siemens *syngo* software platform.

*syngo* Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools

with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-luminal view), the wall and the outside (extra-luminal view) of the colon. With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.

Due to all these capabilities the syngo Colonography software has the advantage of non-invasive evaluation of colonic lesions as compared to conventional colonoscopy.

**General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

**Substantial Equivalence:**

The Syngo Colonography software package, addressed in this premarket notification, is substantially equivalent to the following commercially available software package:

| <i>Predicate Device Name</i>                             | <i>FDA Clearance Number</i> | <i>FDA Clearance Date</i> |
|--|-----------------------------|---------------------------|
| GE CT Colonography/Navigator 2 Workstation               | K012313                     | 08/07/01                  |
| Siemens Fly Through                                      | K971717                     | 09/03/97                  |
| Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso) | K973010                     | 11/10/97                  |

The Syngo Colonography software package described in this 510(k) has the same intended use and similar technical characteristics as the commercially available software listed above.

In addition, many of the image processing, display and evaluation components of syngo Colonography are currently available on software options like the Volume Rendering Technique option, K923524/S2, cleared on May 17<sup>th</sup> 1994 and workstations like the syngo Multimodality Workstation, K010938 cleared on 26<sup>th</sup> June 2001 wherein the Fly Thorough software algorithms were transferred over to the syngo software platform. syngo Colonography packages these image processing and image display components in an optimized workflow palette.

In summary, Siemens is of the opinion that Syngo Colonography software package does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate software components and the predicate device.

**Attachment 11**  
**Reviewers Checklist**

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

**510(k) Number:** \_\_\_\_\_

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

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

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

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

- \* - May not be applicable for Special 510(k)s.
- \*\* - Required for Class III devices, only.
- \*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510]] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

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

|  | Present | Inadequate or Missing |
|--|---------|-----------------------|
| For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.) |         |                       |
| For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, <b>SEE Required Elements for a Declaration of Conformity to a Recognized Standard</b> , which is posted with the 510(k) boilers on the <b>H drive.</b> ]  |         |                       |
| For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.   |         |                       |
| For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.  |         |                       |
| For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.     |         |                       |
| Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.   |         |                       |

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

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

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

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

Passed Screening  Yes  No

Reviewer: \_\_\_\_\_

Concurrence by Review Branch: \_\_\_\_\_

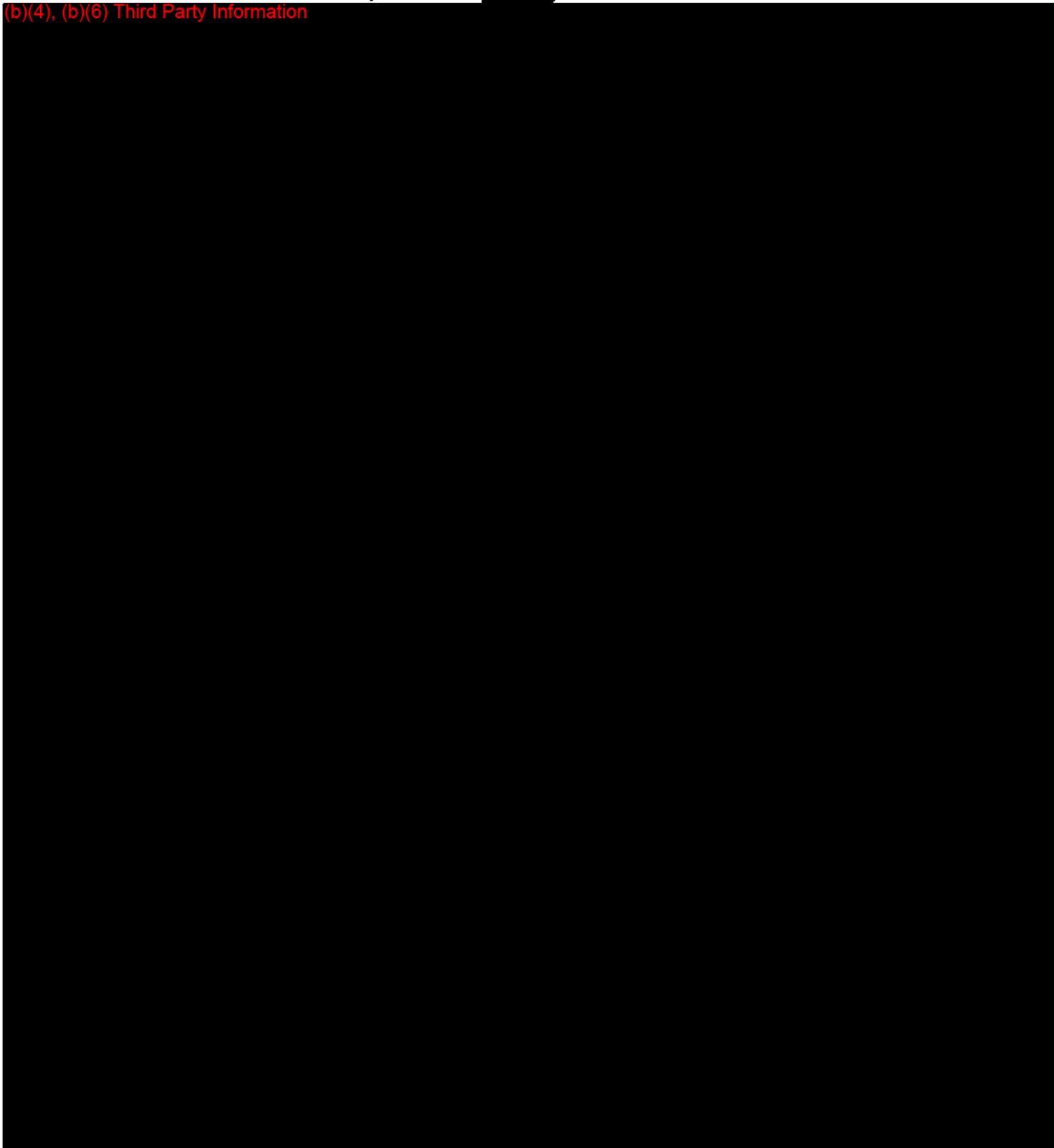
Date: \_\_\_\_\_

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

**Project Summary - (b)(4)** **Project Status: New**

*Client:* **Siemens Medical Systems, Inc. (b)(4)**

(b)(4), (b)(6) Third Party Information



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

From: 4/3/02  
Reviewer(s) - Name(s) R.J. DOYLE

Subject: 510(k) Number K 030982

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

YES

NO

NA

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

Is this device subject to Postmarket Surveillance?

YES

NO

Is this device subject to the Tracking Regulation?

YES

NO

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

YES

NO

Is this a prescription device?

YES

NO

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

YES

NO

Special 510(k)?

YES

NO

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

YES

NO

This 510(k) contains:

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

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

The required certification and summary for class III devices NA

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

Animal Tissue Source

YES

NO

NA

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

No Confidentiality

Confidentiality for 90 days

Continued Confidentiality exceeding 90 da

Predicate Product Code with class:

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

90 LLZ II 892.2050

Review: Tommy J. Moseley  
(Branch Chief)

RADA  
(Branch Code)

4/15/2003  
(Date)

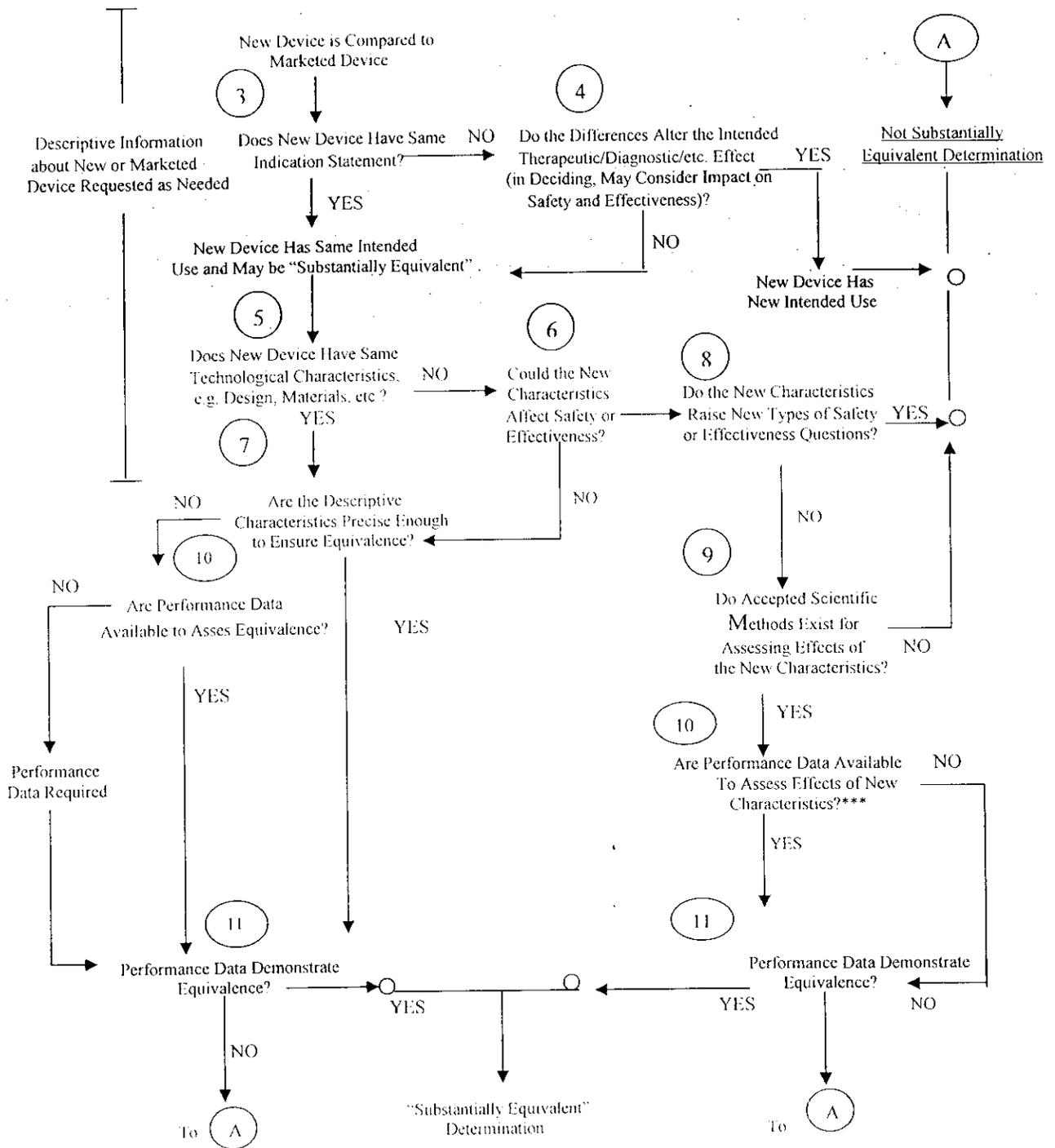
Final Review: David G. Seymour  
(Division Director)

4/7  
(Date)

Revised: 8/17/99

**THIRD PARTY**

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



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

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510(k) Review

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K030982

Traditional X    Abbreviated \_\_\_\_\_    Special \_\_\_\_\_    3<sup>rd</sup> Party X

Contact: (b)(6)  
(b)(4) Third Party Information  
(b)(4) Third Party Information

Company Name: Siemens Medical Solutions, Inc.  
Address: 51 Valley Stream Parkway  
Malvern, PA 19355

510(k) Number: K030982  
Tradename: syngo Colonography software package

Dated: 3/26/03  
Received: 3/28/03

Product Code: (b)(4)    Class: II    FR Classification No.:892.2050

Manufacturing Address: Siemens Medical Solutions  
Bereich Med  
Siemensstrasse 1  
91301 Forchheim  
Germany

Common Name: 3D reconstruction software package

Intended Use: To process MR or CT image data in a manner to support a physician in studying the inside, outside and wall of the colon.

Devices to which Equivalence is Claimed and Manufacturer:

Manufacturer: GEMS  
Tradename: CT Colonography/Navigator 2 Workstation  
Document Control: K012313

Manufacturer: Siemens  
Tradename: Fly Through  
Document Control: K971717

Manufacturer: Siemens  
Tradename: RealTime 3D Diagnostic Workstation  
Document Control: K973010

**Previous Submissions:** None

**Applicable Guidance:** Guidance for Image Management Devices, 7/27/00 and Software Contained in Medical devices 5/29/98

**Device Description:** The device is an image analysis software package that takes the volume data sets from either a CT or MR scanner and from them creates a display of the inside or outside of the colon. There are several different views presented including: Global View that shows the un-obscured colon, Scroll View that shows MPR or VRT slabs in the volume that can be scrolled through, and Endo View that shows the inside the lumen as would be seen through an endoscope.

**Differences between Device and Predicate:** A comparison chart is provided in Attachment 7. The Intended use of the device is essentially the same as that of the predicates. In the list of image processing capabilities of the device, Multi-tissue opacity control, classification of lesions using configurable descriptors and saved lesion location are not listed as capabilities possessed by any of the predicates.

### THIRD PARTY REVIEW CHECKLIST

|  |          |         |
|--|----------|---------|
| 1. Is this 510(k) eligible for third party review, i.e.:                               |          |         |
| a. Is the device on the list of eligible devices?*                                     | Yes<br>√ | No      |
| b. Can a determination of substantial equivalence be made without clinical data?       | Yes<br>√ | No      |
| c. Are you aware of the 510(k) holder being the subject of an Integrity Investigation? | Yes      | No<br>√ |

IF THE ANSWER IS “NO” TO A or B above, or “YES” to C above, PLEASE BRING THE SUBMISSION TO POS IMMEDIATELY.

Are the following elements included in the submission:

|   |          |    |
|---|----------|----|
| 2. A cover letter signed by the third party’s official correspondent clearly identifying:     |          |    |
| a. The purpose of the submission  | Yes<br>√ | No |
| b. The name and address of the third party  | Yes<br>√ | No |
| c. The name and address of the 510(k) holder  | Yes<br>√ | No |
| d. The name of the device (trade name, common or usual name, and FDA classification name)     | Yes<br>√ | No |
| e. The third party’s recommendation with respect to the substantial equivalence of the device | Yes<br>√ | No |
| f. The date the third party first received the 510(k) from the 510(k) holder                  | Yes<br>√ | No |

|  |          |    |
|--|----------|----|
| 3. A letter signed by the 510(k) holder authorizing the third party to submit the 510(k) on its behalf and to discuss its contents with FDA. | Yes<br>√ | No |
|--|----------|----|

|   |          |    |
|---|----------|----|
| 4. The complete 510(k) conforming to FDA’s established requirements relating to content and form of such submissions. | Yes<br>√ | No |
|---|----------|----|



|   |          |    |
|---|----------|----|
| 5. A complete review of the 510(k), signed by all personnel who conducted the third party review and by an individual within the third party responsible for supervising third party reviews, with a recommendation concerning the substantial equivalence of the device. | Yes<br>√ | No |
| 6. A certification that:  |          |    |
| a. The third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA   | Yes<br>√ | No |
| b. Statements made in the third party's review are true and accurate to the best knowledge of the third party   | Yes<br>√ | No |
| c. The third party's review is based on the 510(k) that it is submitting with the review  | Yes<br>√ | No |
| d. The third party understands that the submission to the government of false information is prohibited   | Yes<br>√ | No |

|   |          |    |
|---|----------|----|
| 7. Are the following forms included in the submission as discussed in the Center's guidance document entitled Third Party Review-An Instruction Manual for Conducting Reviews of Premarket Notifications: |          |    |
| a. Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Parts I and II)   | Yes<br>√ | No |
| b. Record of Deficiencies, if applicable (attachment 1a)  | Yes<br>√ | No |
| c. Indications for Use Form   | Yes<br>√ | No |
| d. 510(k) Summary or Statement (attachment 1c)  | Yes<br>√ | No |
| e. 510(k) Truthful and Accurate Statement (attachment 1d)   | Yes<br>√ | No |
| f. Third Party "Substantial Equivalence" (SE) Decision Making Documentation (attachment 2)  | Yes<br>√ | No |

**IF ANY OF THE ABOVE INFORMATION IS NOT INCLUDED WITH THE THIRD PARTY'S SUBMISSION OR IS NOT ADEQUATE, CONTACT THE THIRD PARTY AND ATTEMPT TO RESOLVE THE DEFICIENCY. PLEASE INCLUDE A MEMORANDUM TO THE RECORD OF THE TELEPHONE CALL. WHEN THE INFORMATION IS RECEIVED PLEASE REVISE THIS CHECKLIST OR COMPLETE A NEW ONE.**

COMMENTS: The third party identified eight deficiencies in the original submission. A revised submission was received 3/19/03 that satisfied these deficiencies. Also the sponsor has assigned a CT PRO Code (JAK) to the device. This is not the best PRO Code for a device that performs digital processing on images from both CT and MRI devices. Therefore, it has been placed in PRO Code LLZ where other virtual colonoscopy devices have been listed.

\*If the third party incorrectly classified the device and it is not a device type eligible for third party review please bring to POS.

Robert J. Doyle  
April 2, 2003



## Internal Administrative Form

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