AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
S	1 | 5

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00002	12-May-2021	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
USA CONTRACTING CMD-APG. - W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROVING GROUND MD 21010-5401	W911SR	DCMA DALLAS - S4402A 600 NORTH PEARL STREET SUITE 1630 DALLAS TX 75201-2843	S4402A

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
RETRACTABLE TECHNOLOGIES, INC. 511 LOBO LN LITTLE ELM TX 75068-5295		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911SR2030004
	X	10B. DATED (SEE ITEM 13) 01-Jul-2020
CODE 1BFK3	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement of the Parties
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
See continuation page.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
(b) (6)	(b) (6) TEL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b) (6) (Signature of person authorized to sign)	5/12/2021	BY (b) (6) (Signature of Contracting Officer)	12 May 2021

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:
MODIFICATION P00002

The purpose of this modification is to incorporated changes to W911SR-20-3-0004, Technology Investment Agreement (TIA) as follows:

1. SECTION B: Establish CLIN 0002 and add funding in the amount of $27,365,232.00.

2. CLIN 0002 is fully funded.

3. SECTION J: Add Attachment B--SOO Collaborative Agreement 18 March 2021:

   a. To increase the capacity of 1mL Low Dead Space (LDS) safety syringe/needle assembly from (b) (4) syringes per year to (b) (4) syringes per year. This (b) (4) syringe domestic manufacturing capacity increase will require:

   b. (b) (4) square feet of expansion of controlled environment in RTI's building C adjacent to the current expansion. This expansion will allow for two (2) 1mL LDS automated syringe assembly lines. These two 1mL LDS automated assembly lines will require supportive machinery: (b) (4) and molding machines.

   c. (b) (4) packaging machines

   d. (b) (4) printing machine.

   e. (b) (4) spring machines.

   f. Additional auxiliary equipment to maintain controlled environment.

   g. (b) (4) square feet of expansion in building C for laboratory, gowning, break area, offices, and maintenance.

4. SECTION J: Incorporate additional Attachments.

5. This modification effort schedule objective is from time of award to 31 January 2022.

6. All other terms and conditions remain unchanged.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $27,365,232.00 from $53,664,286.00 to $81,029,518.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0002 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002			Job		$27,365,232.00 NTE
	TIA Additional Expansion COST Technology Investment Agreement (TIA) for Additional Expanding Domestic Production of Needles & Syringes IAW vendor project plan dated 18Apr2021. FOB: Destination PN/CN: Per Agmt SPEC NR: Per Agmt PURCHASE REQUEST NUMBER: 0011647237 MFR PART NR: Per Agmt VENDOR PART NR: Per Agmt PSC CD: 6615				
				ESTIMATED COST	$27,365,232.00
	ACRN AB CIN: GFEBS001164723700001				$27,365,232.00

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0002:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0002 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

POP 11-MAY-2021 TO 30-JUN-2030	N/A	BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT (b) (6) ROOM 23E07 O'NEILL HOUSE OFFICE BUILDING WASHINGTON DC 20515 FOB: Destination	W56XNH

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $27,365,232.00 from $53,664,286.00 to $81,029,518.00.

CLIN 0002:
Funding on CLIN 0002 is initiated as follows:

ACRN: AB

CIN: GFEBS001164723700001

Acctng Data: ^^^097^2020^^X^0360^000^^251^D^COVID19^^^^^1100^00008522^012215^USAS^USAS - UNDER SEC^USAS_COVID19^20_0360D_C

Increase: $27,365,232.00

Total: $27,365,232.00

Cost Code: A5XAH

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The below Table of Contents has been added

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
(b) (4)			

(b) (4)

(End of Summary of Changes)

Changes to the TIA –

Attachment B – Collaborative Agreement W911SR2030004 – SOO 20200622

The proposed changes to the current contract's Statement of Objectives (SOO) are proposed: (1) add paragraph C.3.4 and change the scheduled end date to not later than 31 January 2022.

C.3. Specific Objectives.

C.3.1. The recipient shall increase the throughput of existing domestic manufacturing capabilities by a minimum of 50% to enable the USG to expedite MCM administration/delivery to meet US COVID-19 MCM demand. Expansion/development sites include, but are not limited to:

- Expansion safety needle and syringe manufacturing capacity in Little Elm, TX

C.3.2. The minimum throughput target for the Retractable Technologies needle and syringe manufacturing capabilities is defined as achieving an added capacity of not less than (b) (4) safety needle and syringe units per year.

C.3.3 Upon completion of the effort, the USG, through BARDA, shall receive priority access to facilitate third party purchase of safety needles and syringes produced through this investment effort for COVID-19 medical countermeasures.

C.3.4 In addition to the throughput target specified in paragraph C.3.2, the recipient shall increase the U.S. production of 1mL low dead space safety syringes:

- Installation of two (2) 1mL automated syringe assembly lines capable of producing (b)(4) syringes per year
- As necessary, expansion of controlled environment in warehouse adjacent to the current expansion
- As necessary, expansion for laboratory, gowning, restrooms, break area, offices, and maintenance.

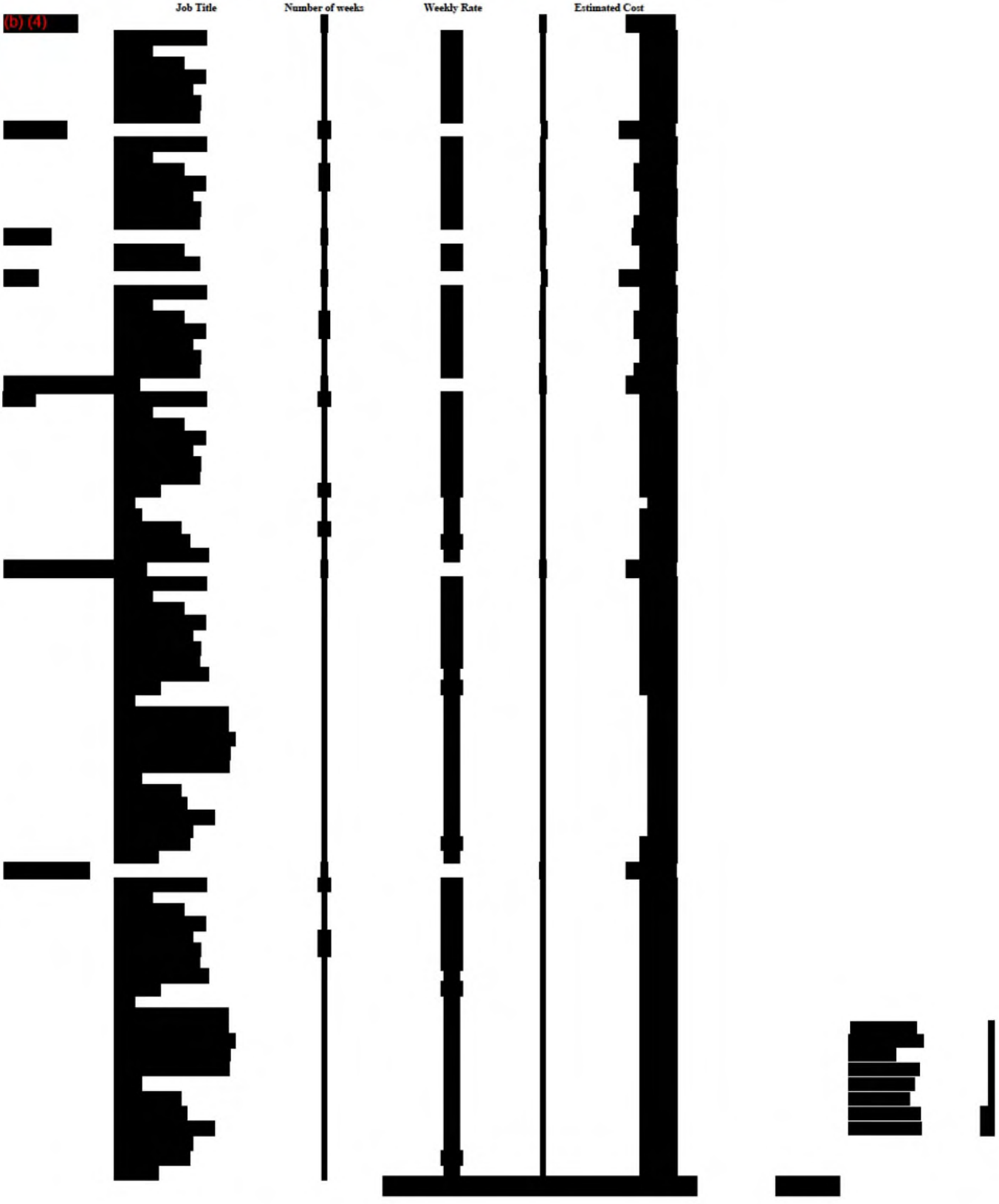
C.4. Schedule Objectives.

The schedule for this effort shall be from date of award through not later than 31 January 2022. Incremental capacity may become available quarterly beginning in 2021. However, more rapid acceleration is highly desired by the Government in order to meet critical COVID-19 response needs. As acceleration opportunities are identified, the recipient is encouraged to work with USG BARDA to make optional incremental funding to realize these opportunities. As incremental capabilities become available from different component facilities, they shall be placed online as quickly as possible and made available to USG BARDA to meet critical national COVID-19 demands.

Attachment 2
MSC-BAA-17-01-W911QY-17-S-0001 Amendment 0003
RETRACTABLE TECHNOLOGIES, INC.

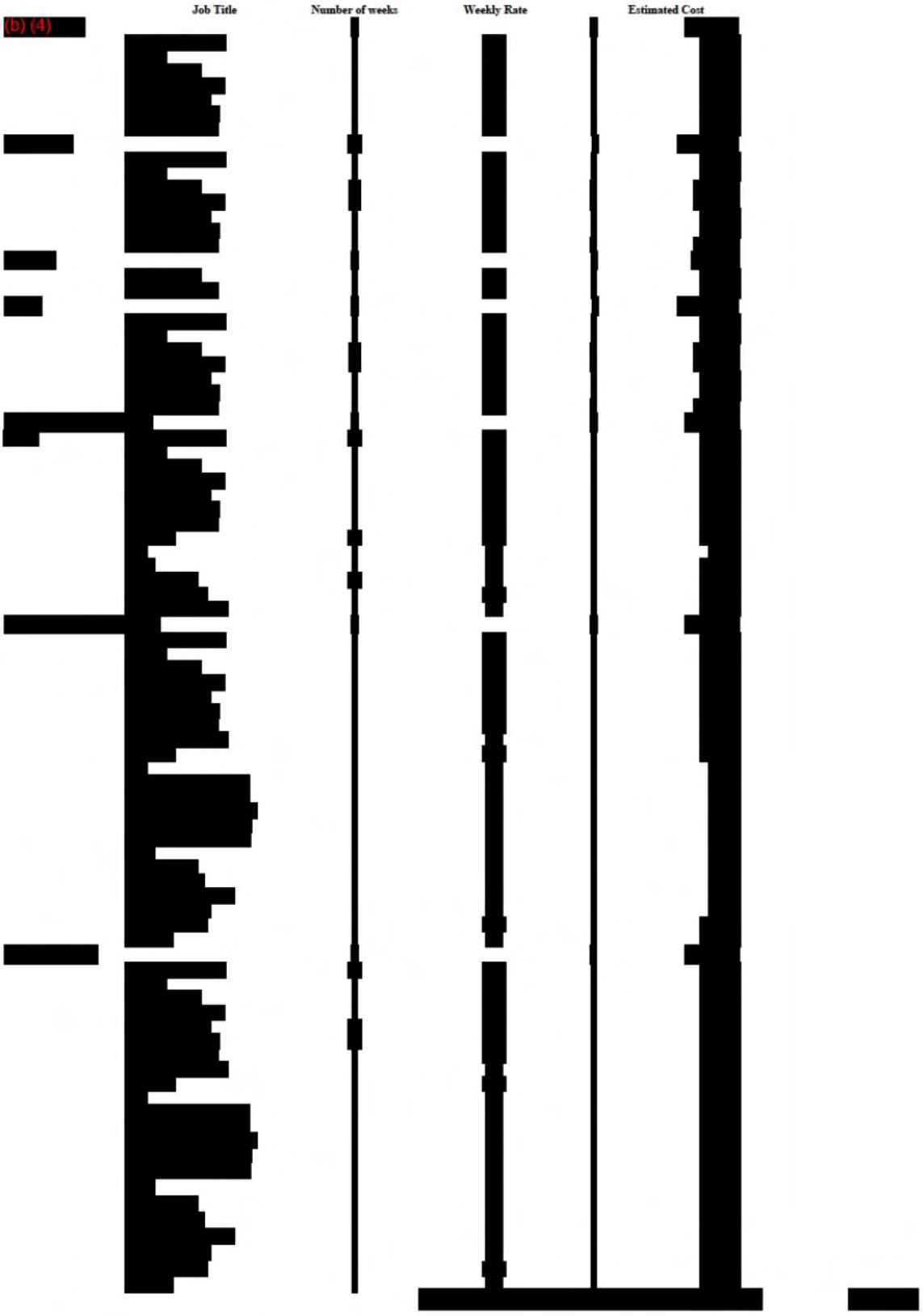
Estimated Direct Labor Hours with Costs to Implement Increasing Capacity to (b) (4) Units

1mL VanishPoint syringe/needle Automated Assembly Line (1)



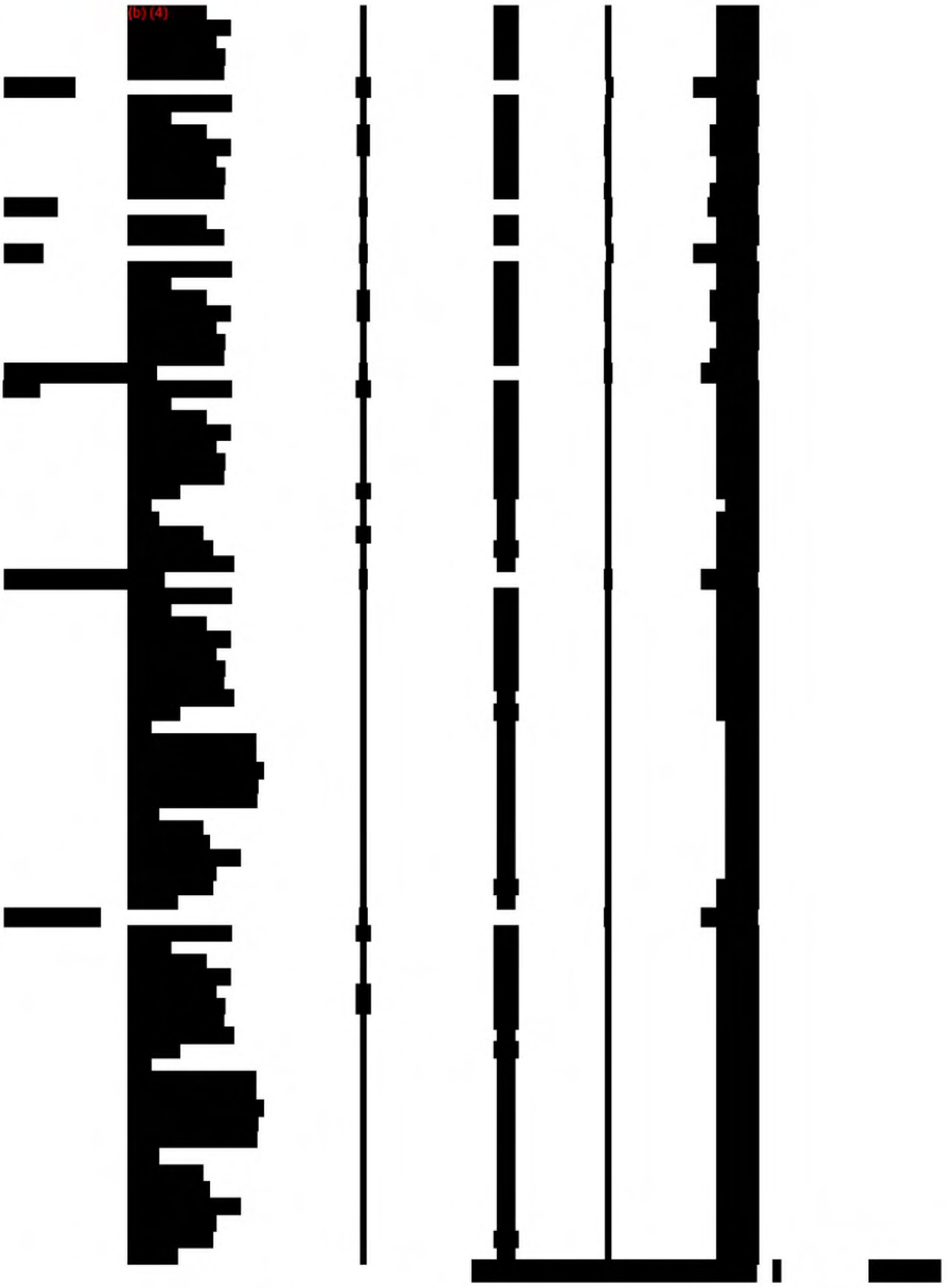
1mL VanishPoint syringe/needle Automated Assembly Line (2)

(b) (4)

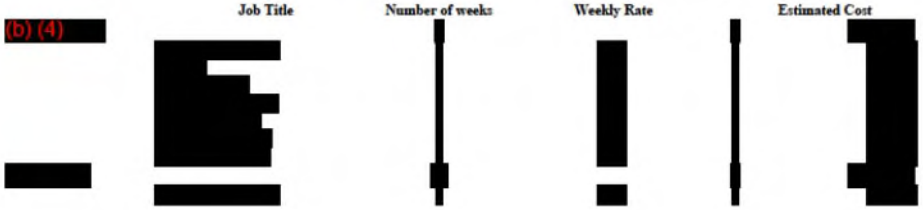


3mL VanishPoint syringe/needle Automated Assembly

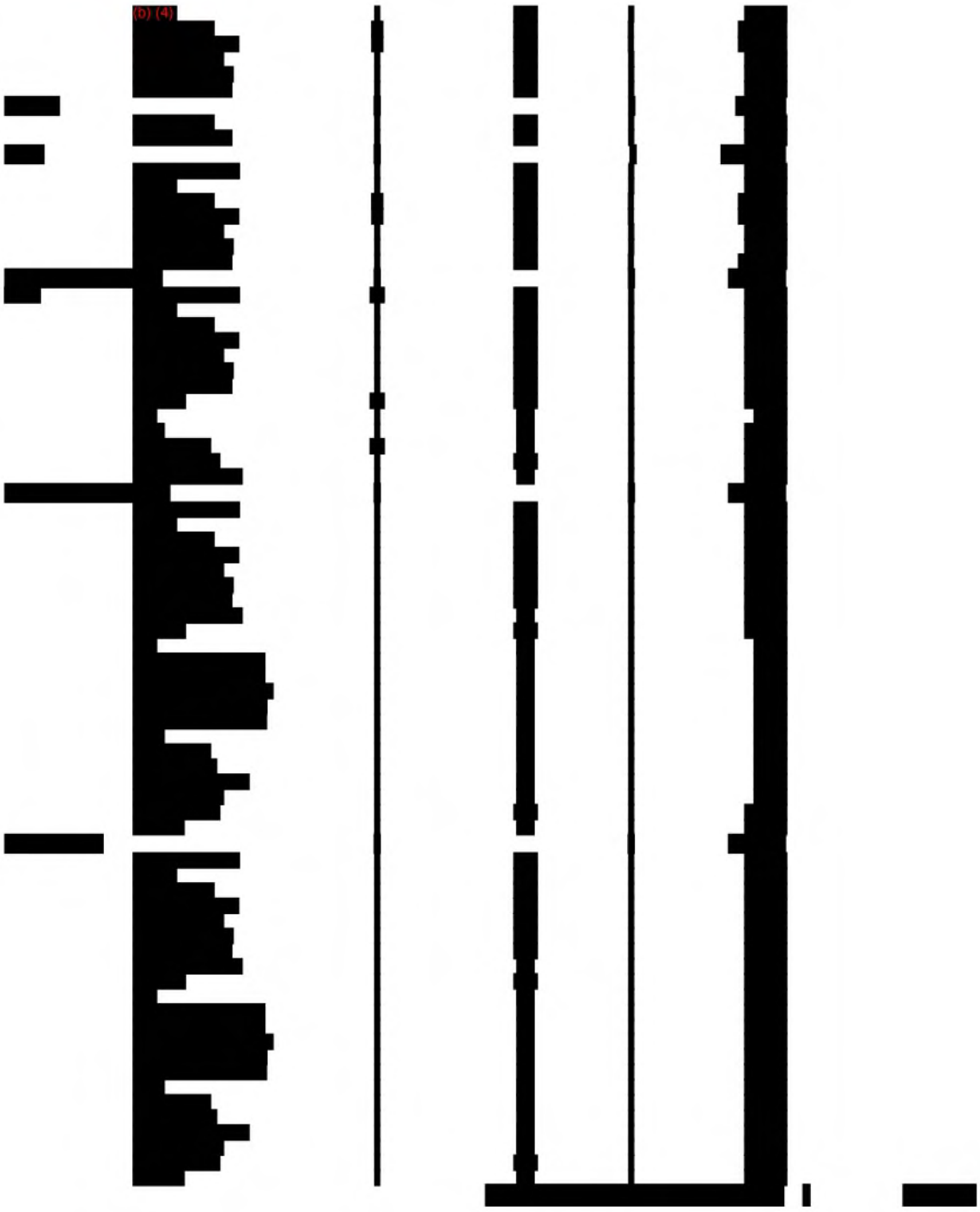
(b) (4)



EasyPoint Needle Automated Assembly

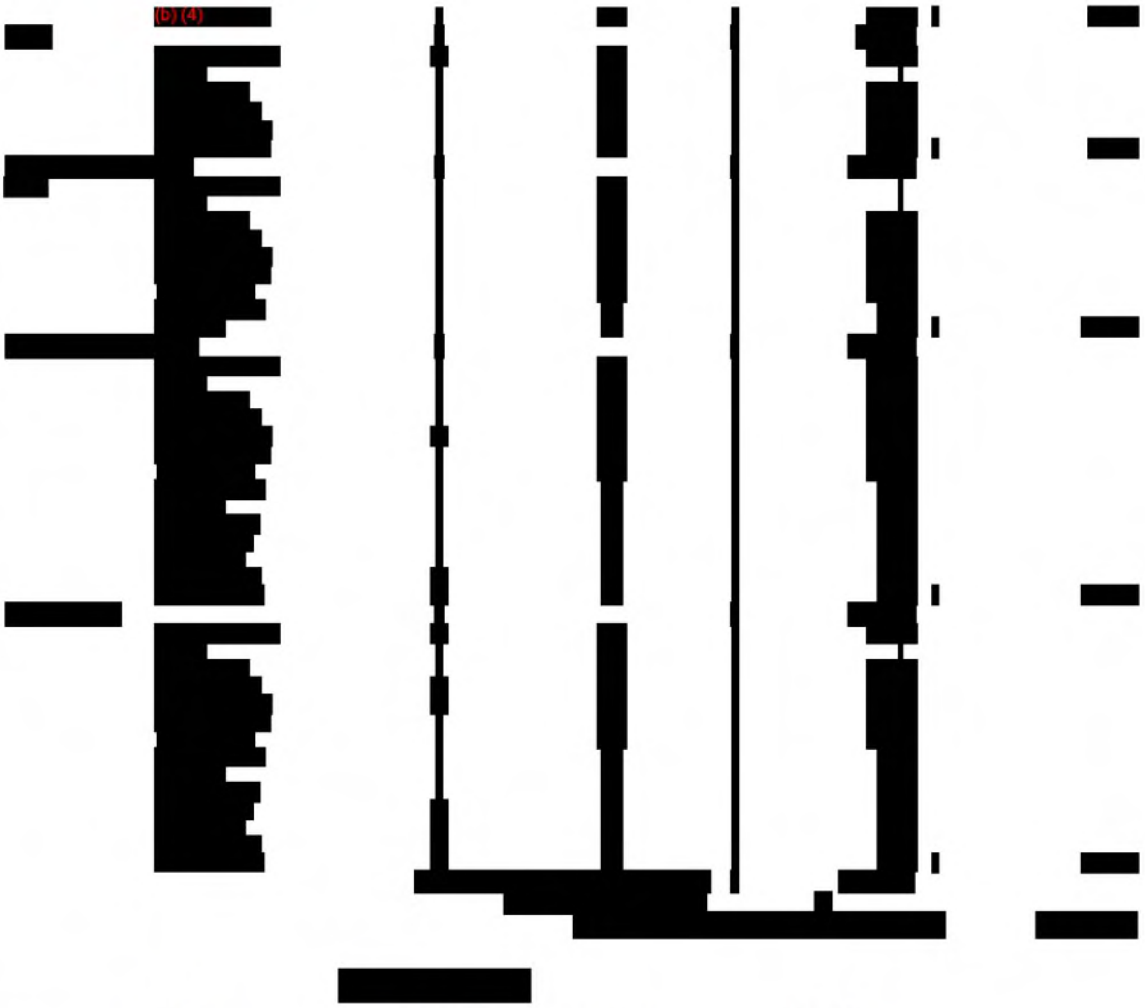


(b) (4)



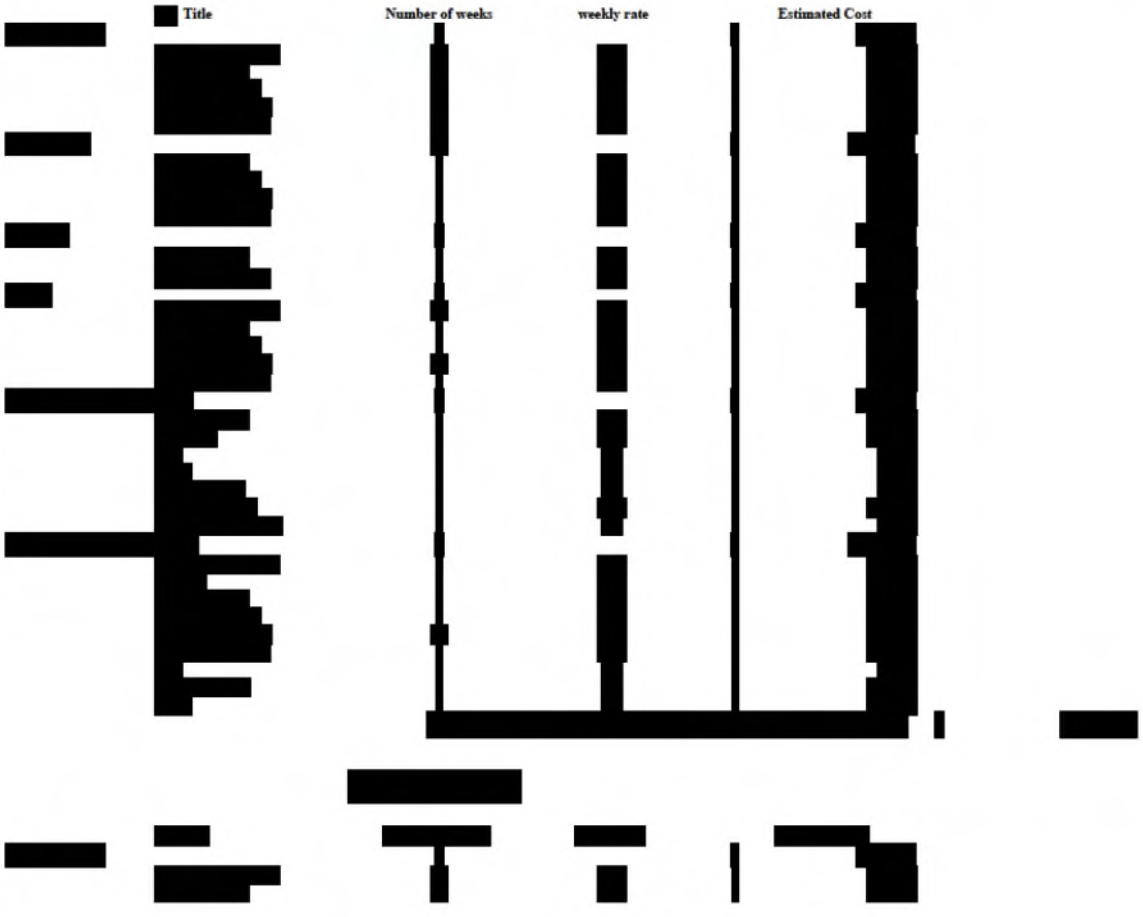
MOLDS

(b) (4)	Job Title	Number of weeks	weekly rate	Estimated Cost

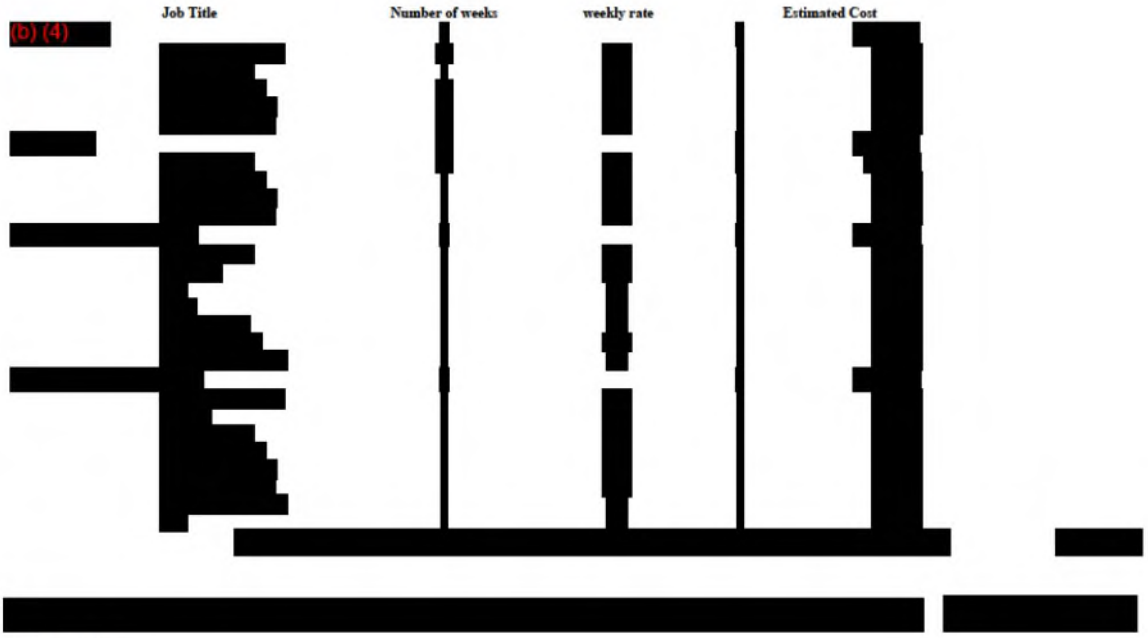

(b) (4)


Job Title
Number of weeks
weekly rate
Estimated Cost

(b) (4)

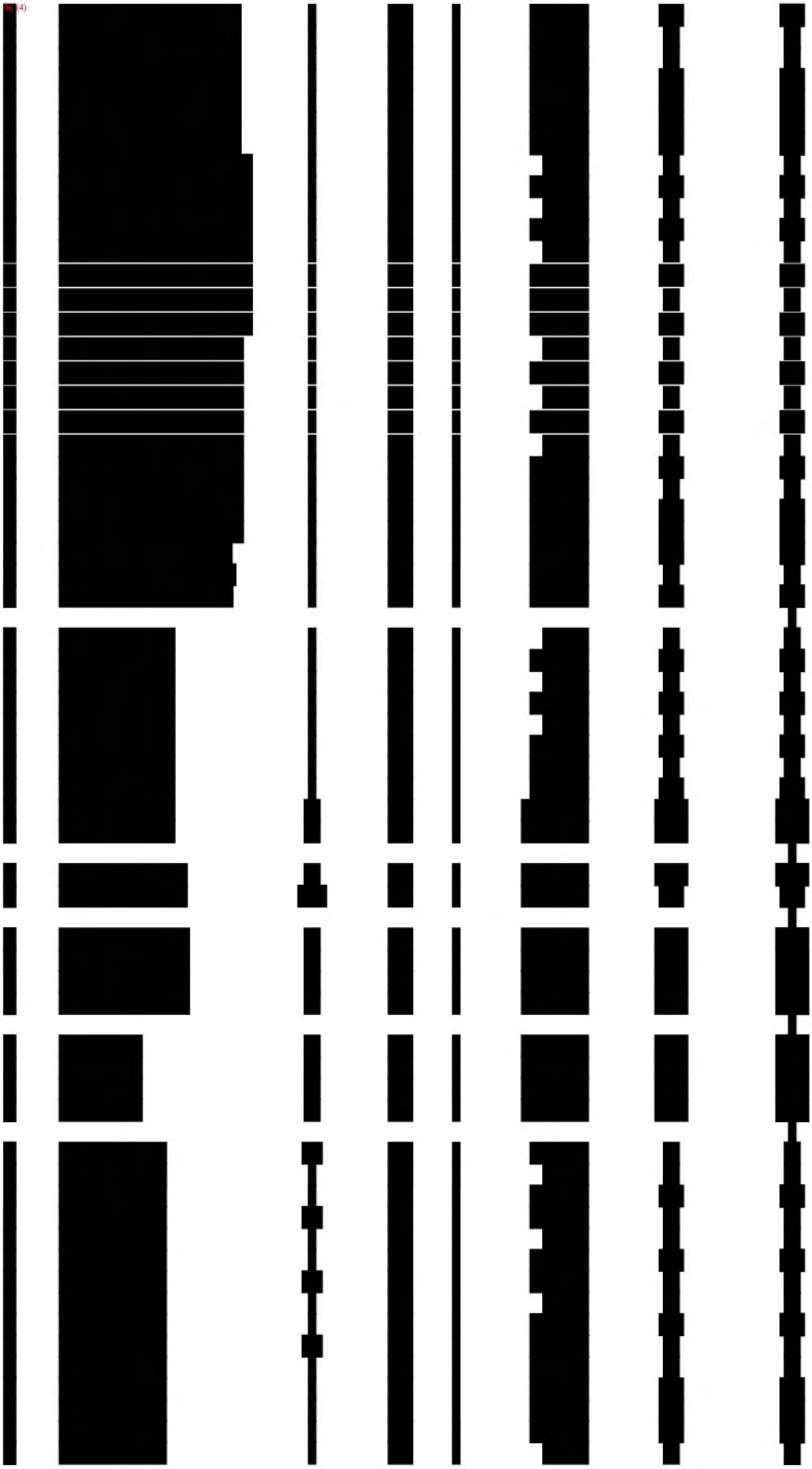


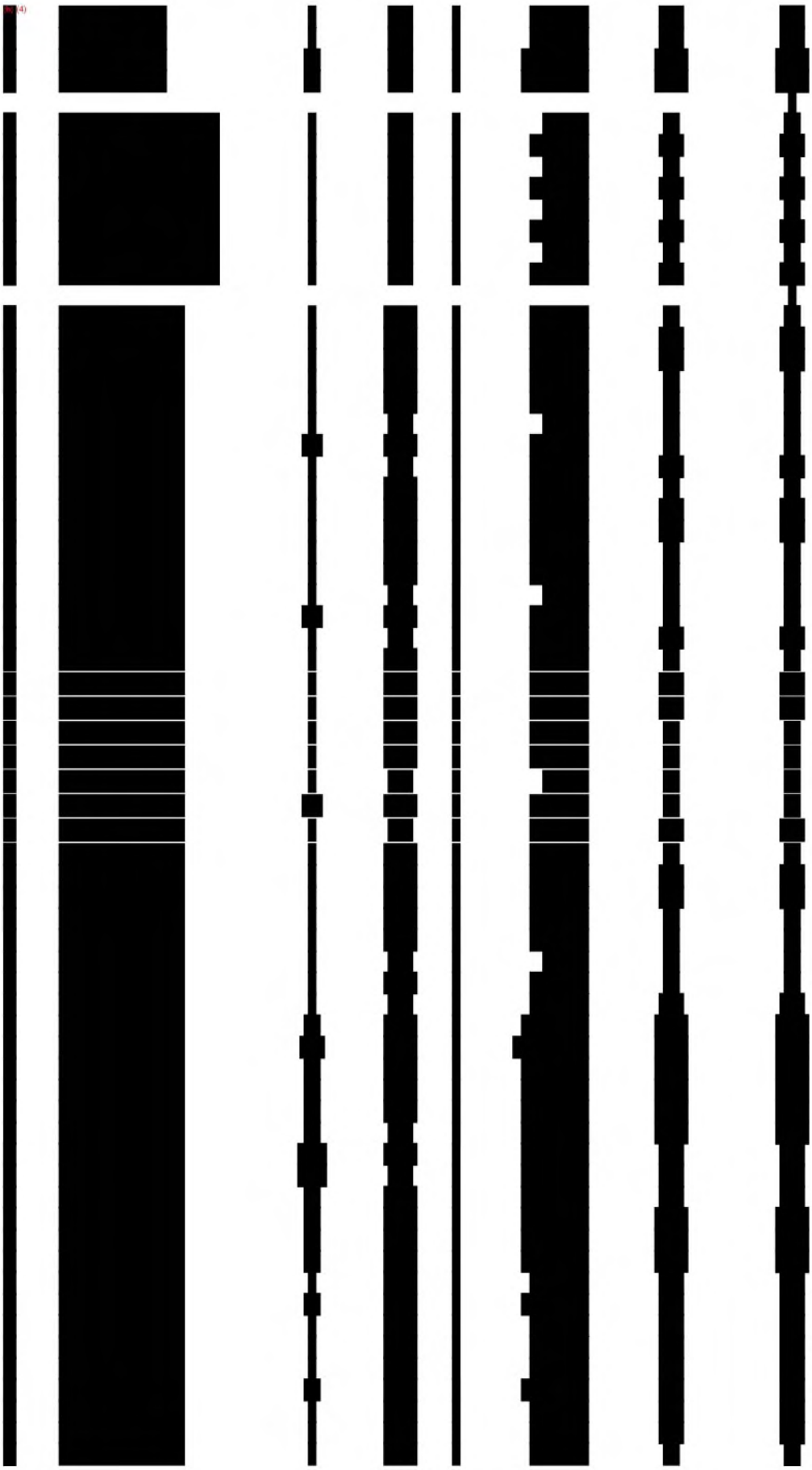
Controlled Environment and Auxiliary Equipment

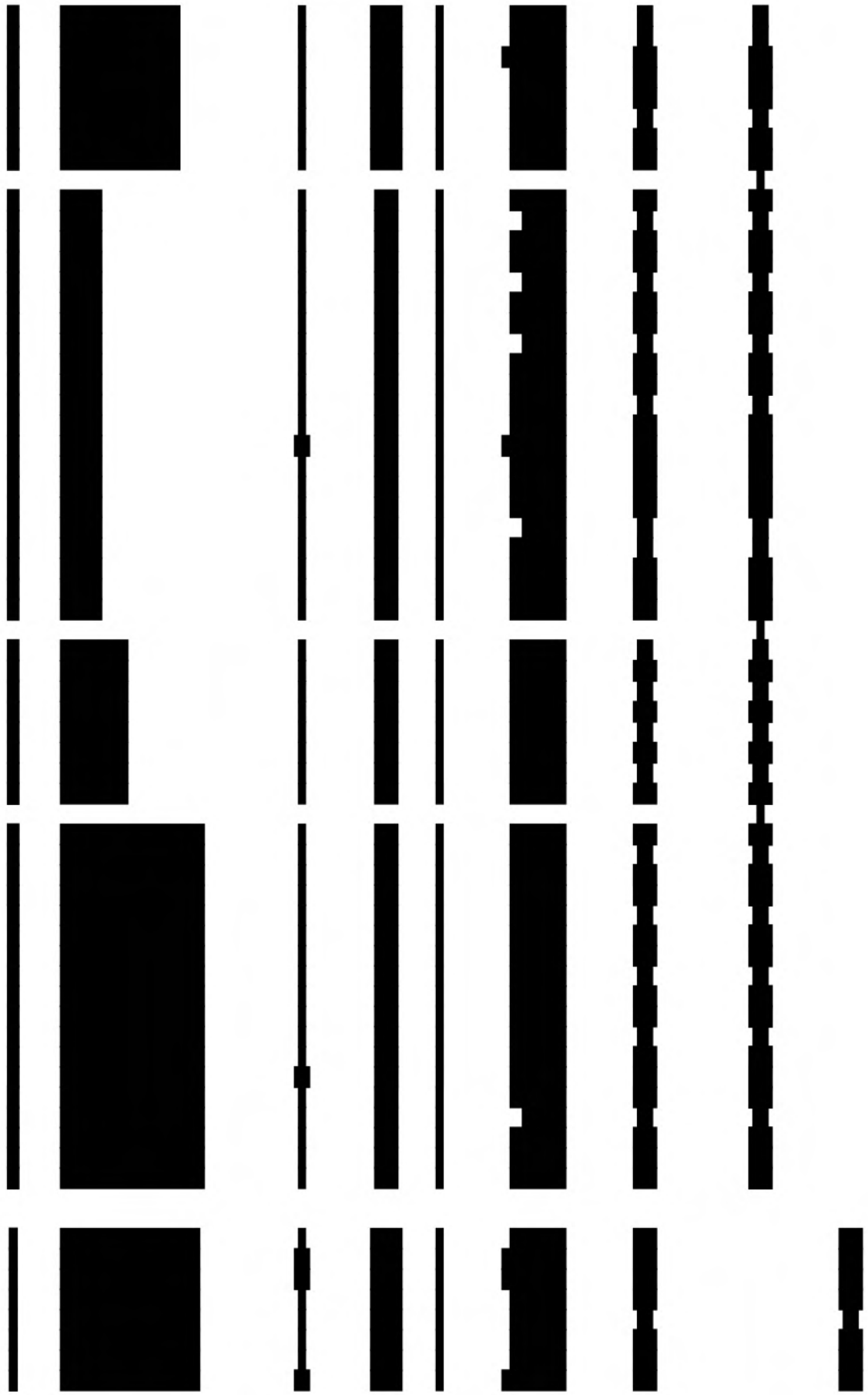


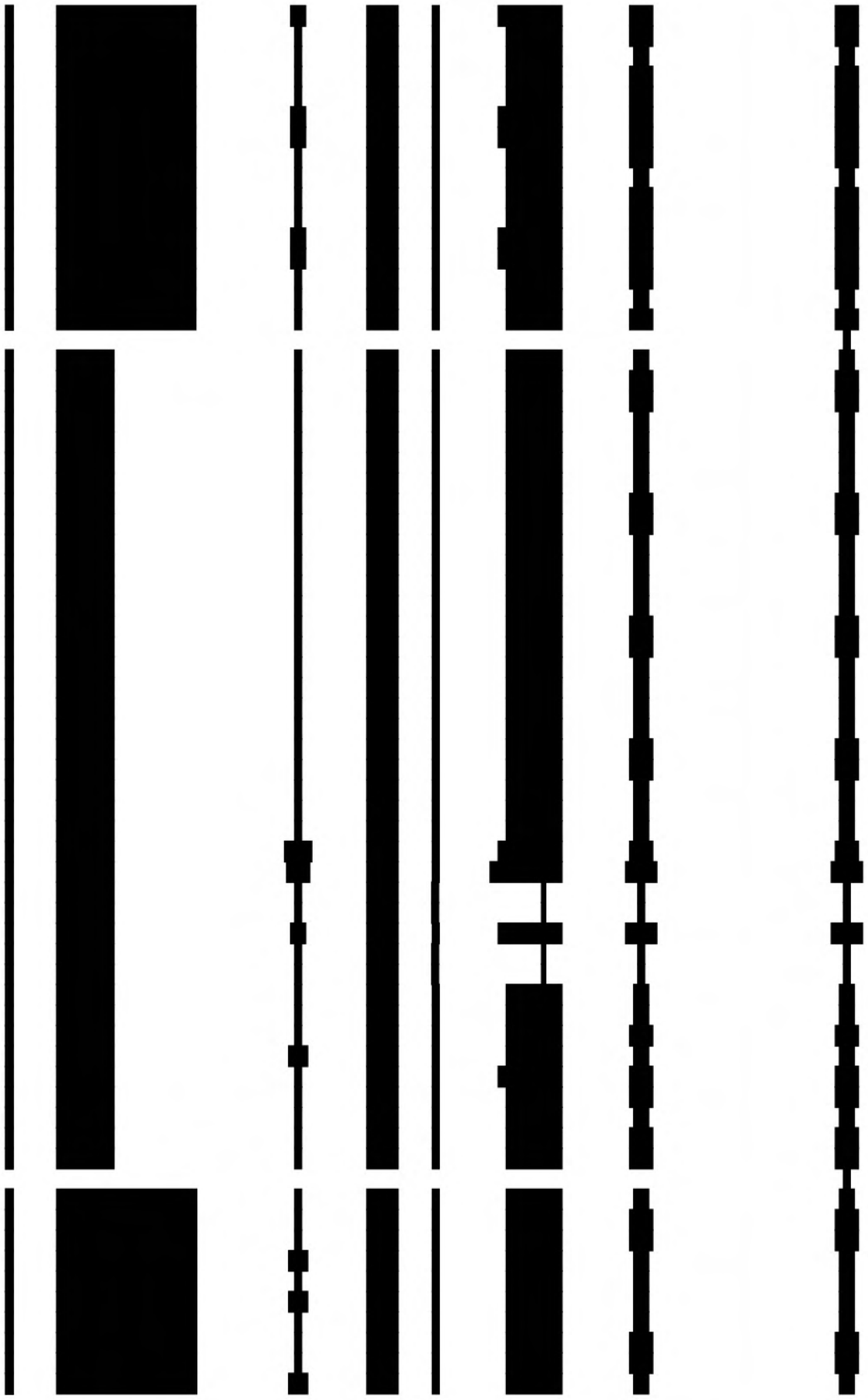
(b) (4)

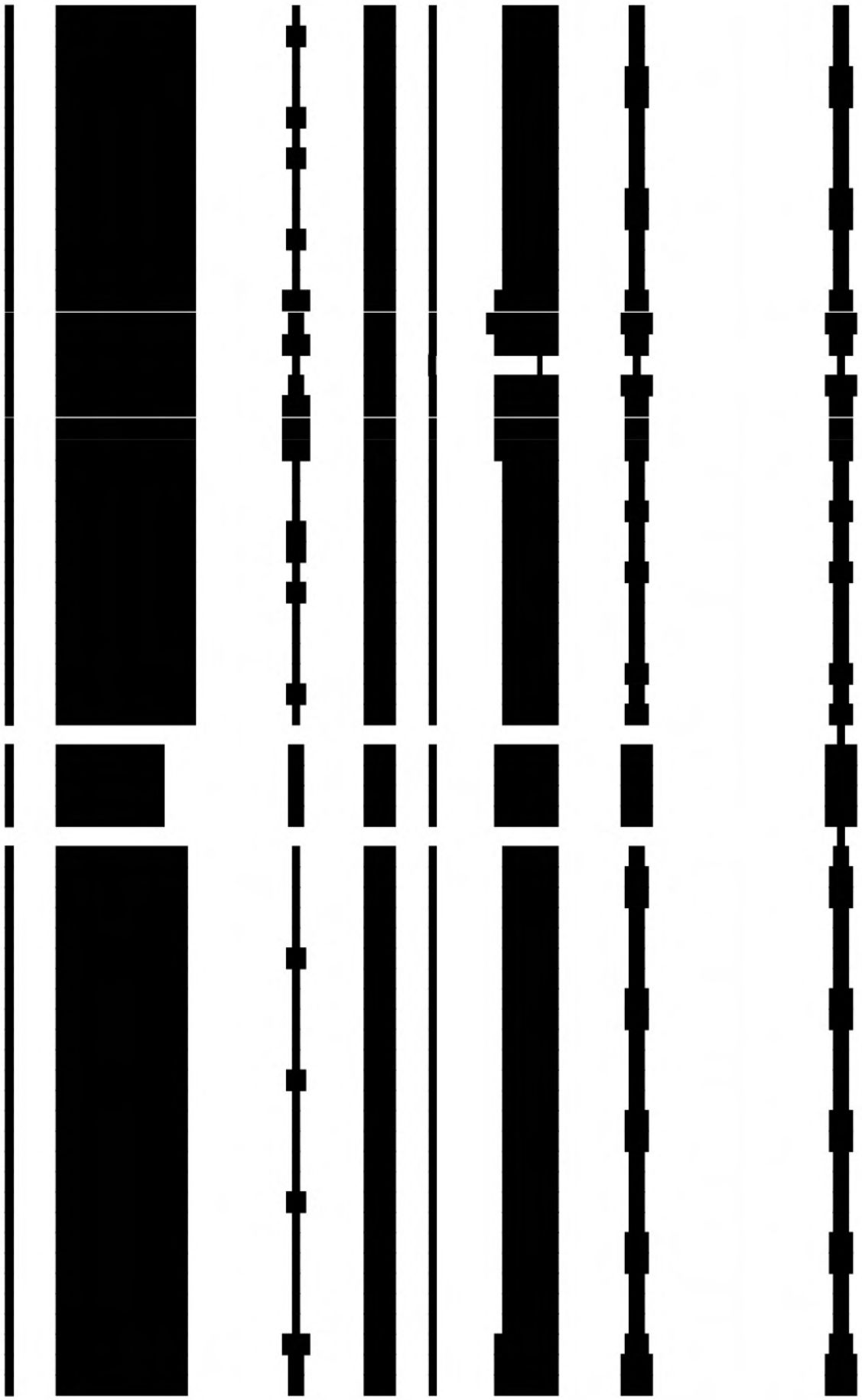
H/S	Job Title	Number of Weeks	Weekly Cost	Total Cost	Labor Hours	H	S
[redacted]							
[redacted]							
[redacted]							

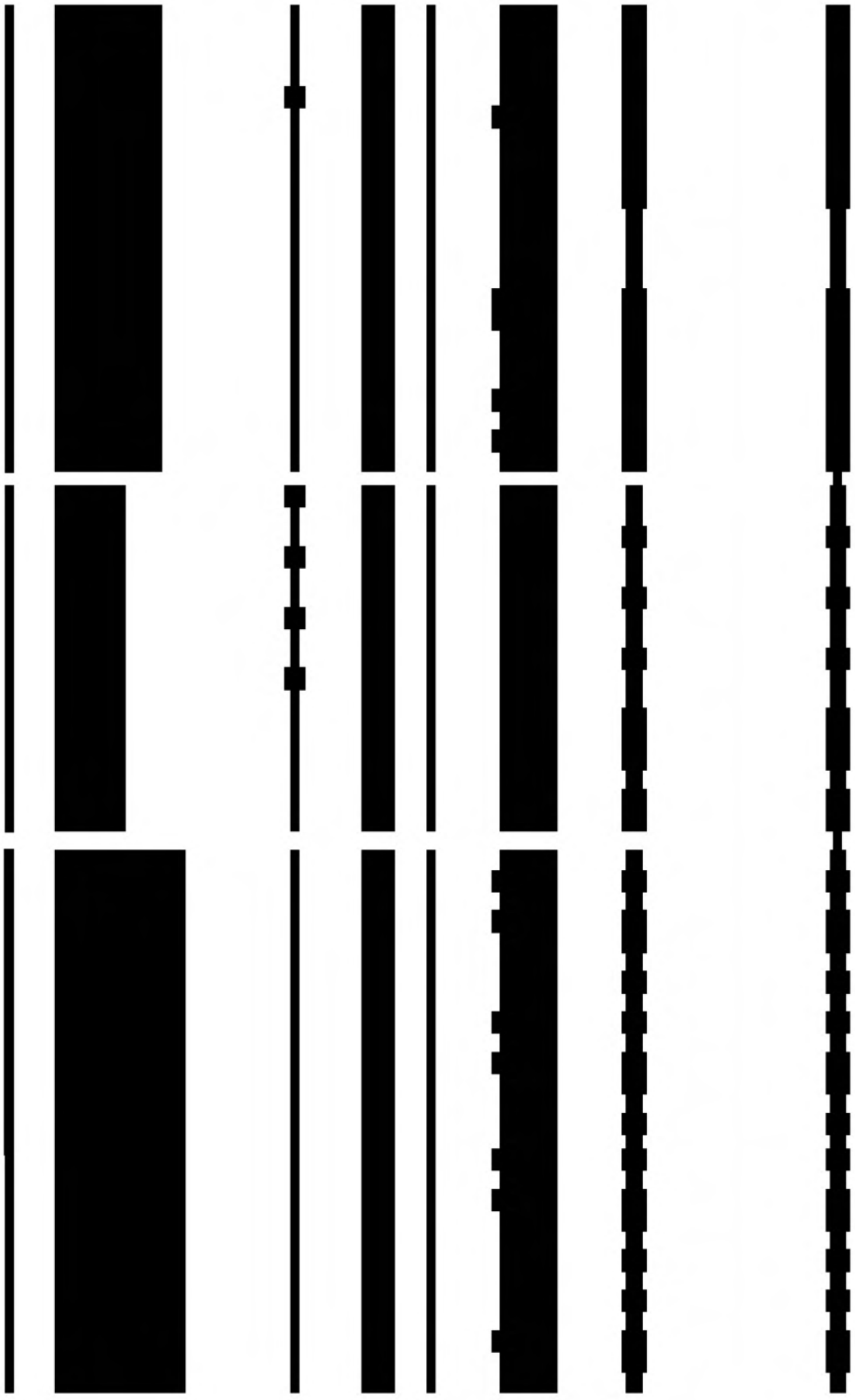












Confidential - RTI
1-Jun-20

Estimated Direct Labor Hours with Costs to Implement Increasing Capacity to (b) (4) Units

1mL Automated Assembly Line 1

(b) (4)

1mL Automated Assembly Line 2

(b) (4)

3mL Automated Assembly

(b) (4)

EPN Automated Assembly

(b) (4)

MOLDS

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Controlled Environment and Auxiliary Equipment

(b) (4)

(b) (4)

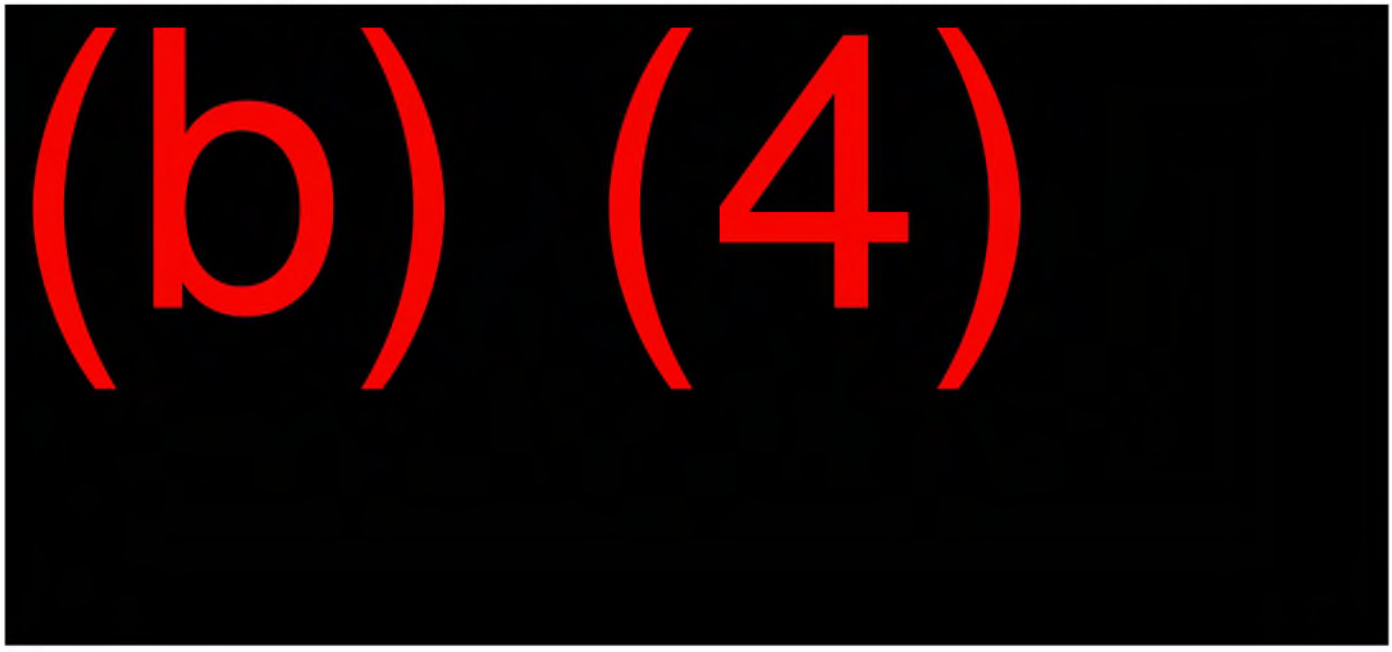
RETRACTABLE TECHNOLOGIES, INC.

www.retractable.com - rti@retractable.com
P.O. Box 9, 511 Lobo Lane, Little Elm, Texas 75068-0009
Tel (972) 294-1010 - Fax (972) 294-4400 - Toll Free (888)806-2626

TIA number:	**W911SR-20-3-0004**
Topic:	**Expanding Domestic Production of Needles & Syringes** Medical devices used to prevent or treat patients exposed to either chemical warfare agents (CWA), biological warfare agents (BWA) or infectious diseases
Organization submitting proposal:	**Retractable Technologies, Inc.**
Proposal title:	**Increasing U.S. Manufacturing Capacity of Low Dead Space Safety Injection Devices**
Administrative POC:	(b) (6), RN, Vice President of Clinical Affairs 511 Lobo Lane Little Elm, Texas 75068 (b) (6)
Technical POC:	(b) (6), Director of Operations 511 Lobo Lane Little Elm, Texas 75068 (b) (6)
Submitted on:	April 6, 2021 (original) April 18, 2021 (revision-1)

Retractable Technologies, Inc. – Technical Proposal
Increasing U.S. Manufacturing Capacity of Low Dead Space Safety Injection Devices

Contents



Innovative Claims for the Proposed Effort

Retractable Technologies, Inc. (RTI) is the manufacturer of VanishPoint® and EasyPoint® safety medical devices. (b) (4) [redacted] Our molding, assembly, and packaging expertise, combined with the appropriate and available facilities, will provide reduced lead times and essential supplies for the COVID-19 medical countermeasures and future events requiring safe needles and syringes.

RTI's safety injection devices have been used by Department of Defense (DOD) facilities, Department of Health and Human Services (DHSS) immunization campaigns, and in Veterans Affairs hospitals and clinics. Injection devices produced as a result of the manufacturing expansion efforts will provide additional availability of essential supplies.

The VanishPoint syringe was developed in part with grants from the National Institute on Drug Abuse, a subsidiary of the National Institutes of Health. VanishPoint syringes offer unique safety engineering that virtually eliminates exposure to the contaminated needle, and effectively reduces the risk of needlestick injuries and syringe reuse. VanishPoint syringes have been instrumental in reducing needlestick injuries and bloodborne pathogen exposure during other pandemic events. Effective safety injection devices are especially critical during pandemics, since needlestick injuries further deplete an already stressed healthcare workforce.

VanishPoint 1mL syringes have a low dead space (LDS) that maximizes dose efficiency. According to Pfizer documents, using a syringe with a dead space of no more than 35 microliters allows access of an additional dose from the 5-dose vial. The VanishPoint 1mL syringe has a low dead space, which is less than 35 microliters, meeting Pfizer's criteria for an extra dose. RTI has received reports from clinicians who state that they have gotten extra doses from Pfizer and Moderna COVID-19 vaccines when using VanishPoint 1mL syringes. Use of VanishPoint 1mL low dead space safety syringes allow access of 20% more vaccine doses compared to non-low dead space syringes.

VanishPoint safety injection technology is essential to:

- Protect frontline healthcare workers from injuries and exposure to disease
- Protect environmental service personnel and waste handlers from hazardous waste
- Prevent the risk of syringe and needle reuse in a hectic workplace with overwhelmed staff
- Maximize dose efficiency

VanishPoint retractable syringes have United States of America Food & Drug Administration (FDA) approval via the pre-market notification system (510k) and have been commercially available since 1997. EasyPoint retractable needles have FDA approval via the pre-market notification system (510k) and have been commercially available since 2016.

RTI certifies that VanishPoint retractable safety syringes with attached needles are manufactured under the Quality System requirements of the FDA Quality Systems Regulations (21 CFR 820), the Medical Device Directive (93/42/EEC), ISO 13485:2016, EN ISO 13485:2016, and the Medical Device Single Audit Program (MDSAP).

Technical Rationale and Approach - Plan for Accomplishment of Goals and Objectives

July 1, 2020 Technology Investment Agreement W911SR-20-3-0004
RTI shall achieve the goal of increasing production capacity of U.S. manufactured safety injection devices for vaccination (b) (4)

- 27,800 square foot expansion of controlled environment area within current warehouse/molding facility
- 55,000 square foot warehouse facility adjacent to RTI's current warehouse

(b) (4) Additional warehouse capacity will provide the ability to increase U.S. inventory for expedient shipment, as well as for added raw material inventory to reduce lead times.

April 6, 2021 RTI Proposal to Modify TIA W911SR-20-3-0004
RTI proposes the USG invest an additional $28 million dollars to increase the capacity of 1mL LDS safety syringe/needle assembly from (b) (4) syringes per year to (b) (4) syringes per year. This (b) (4) syringe domestic manufacturing capacity increase will require:

- (b) (4) square feet of expansion of controlled environment in RTI's building C adjacent to the current expansion
    - This expansion will allow for two (2) 1mL LDS automated syringe assembly lines
        - These two 1mL LDS automated assembly lines will require supportive machinery:
            - Additional auxiliary equipment to maintain controlled environment
- (b) (4) square feet of expansion in building C for laboratory, gowning, restrooms, break area, offices, and maintenance

RTI owns the intellectual property and supporting systems necessary for this effort.

Organization Chart for RTI's Program Team

RTI will utilize a multi-disciplinary team to achieve the objectives of this project. Thomas Shaw, RTI's CEO and the principal inventor of RTI's products, and Larry Salerno, RTI's Director of Operations, oversaw the building of RTI's current facilities, beginning in 1996. Mr. Shaw and Mr. Salerno were both integral to the design and acquisition of RTI's current 3mL and 1mL VanishPoint syringe assembly machines, molds and molding machines, as well as all other aspects of the manufacturing process.

Thomas J. Shaw has served as Chairman of the Board, President, and Chief Executive Officer since RTI's inception. Mr. Shaw is the primary inventor of RTI's products. Mr. Shaw's educational background in both Engineering and Accounting is integral to leading RTI's operations and this project. Mr. Shaw has extensive experience in industrial product design and has developed several solutions to complicated mechanical engineering challenges.

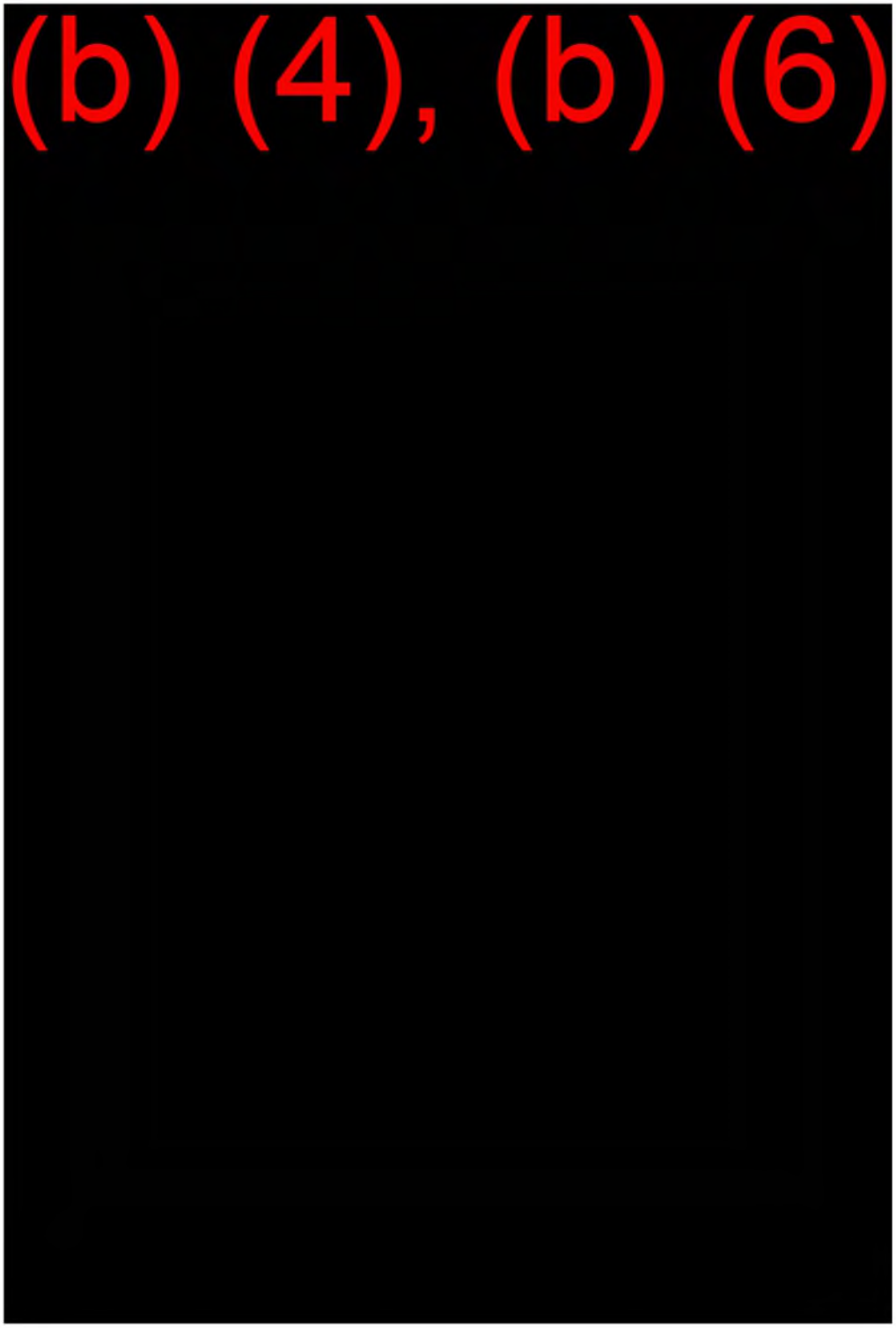
Lawrence G. Salerno, Director of Operations, has been with RTI since 1995. (b) (4)

- (b) (4)

[redacted]

Kathryn M. Duesman, RN, joined RTI in 1996 and currently serves as the Vice President of Clinical Affairs. She provides clinical expertise on existing products as well as those in development. Ms. Duesman works with international agencies to promote the use of safe technologies in developing countries and coordinates with other key personnel in the development of shipping schedules for products provided for immunization programs. Ms. Duesman served as RTI's account manager contact for BARDA's H1N1 immunization campaign in 2009. Ms. Duesman will serve as the Administrative Point of Contact for this project.

The following is an organizational chart of RTI's Capacity Building Project Management Team:



Potential for Use in Other Government Organizations and Other Non-Federal Parties

RTI's safety injection devices have demonstrated effectiveness in Department of Defense (DOD) facilities, Department of Health and Human Services (DHSS) immunization campaigns, and in Veterans Affairs hospitals and clinics. RTI has provided VanishPoint syringes to U.N. agencies such as UNICEF. In addition to hospitals, state health departments, and ambulatory care facilities, large retail pharmacies such as (b) (4) have been using RTI's safety syringes and needles successfully for several years.

Injection devices produced as a result of the U.S. manufacturing expansion efforts will provide additional, rapid availability of essential supplies for all appropriate entities.

Statement of Work

a). Objective of Proposed Project

July 1, 2020 Technology Investment Agreement W911SR-20-3-0004
The objective of this project is to increase RTI's U.S. manufacturing capacity of essential medical devices, specifically those essential devices required for vaccination purposes. (b) (4)

April 6, 2021 RTI Proposal to Modify TIA W911SR-20-3-0004
The objective of this proposal to modify W911SR-20-3-0004 is to add two (2) additional 1mL VanishPoint LDS safety syringe with attached needle assembly machines, necessary molds, and molding/packaging equipment. The costs for these additions will be substantially less due to progress made under the current TIA.

RTI proposes the USG invest an additional $27,365,232.00 in government funding for an estimated capacity increase of (b) (4) 1mL LDS safety syringes per year. RTI's estimated total capacity, with the 154 million unit increase, will be 358 million 1mL LDS safety syringes per year.

VanishPoint 1mL LDS safety syringes maximize dose efficiency. According to Pfizer documents, using a syringe with a dead space of no more than 35 microliters allows access of an additional dose from the 5-dose vial. The VanishPoint 1mL syringe has a low dead space, which is less than 35 microliters, meeting Pfizer's criteria for an extra dose. RTI has received reports from clinicians who state that they have gotten extra doses from Pfizer and Moderna COVID-19 vaccines when using VanishPoint 1mL syringes. Use of VanishPoint 1mL LDS safety syringes allow access of 20% more vaccine doses compared to non-low dead space syringes.

b). Detailed Description of the Approach to Accomplish the Stated Objective

RTI is taking a best practices and solid core value approach to accomplishing the expansion of domestic production of safety injection devices. (b) (4)

[redacted]

The products and component parts are part of RTI's Quality Management System (QMS), which is reviewed by the FDA during standard Level II inspections, as well as by RTI's notified body during certification and surveillance audits. RTI's QMS is a documented system following 21 CFR 820, ISO 13485:2016, Medical Device Directive 93/42/EEC, and MDSAP requirements regarding the manufacture of medical devices. The purchase, calibration, verification, validation, and implementation of the new building and equipment will be carried out using approved processes and procedures from RTI's QMS, such as those for Installation Qualification (IQ), Operation Qualification (OQ), and Performance Qualification (PQ).

Custom molds will be purchased for plastic parts. (b) (4)

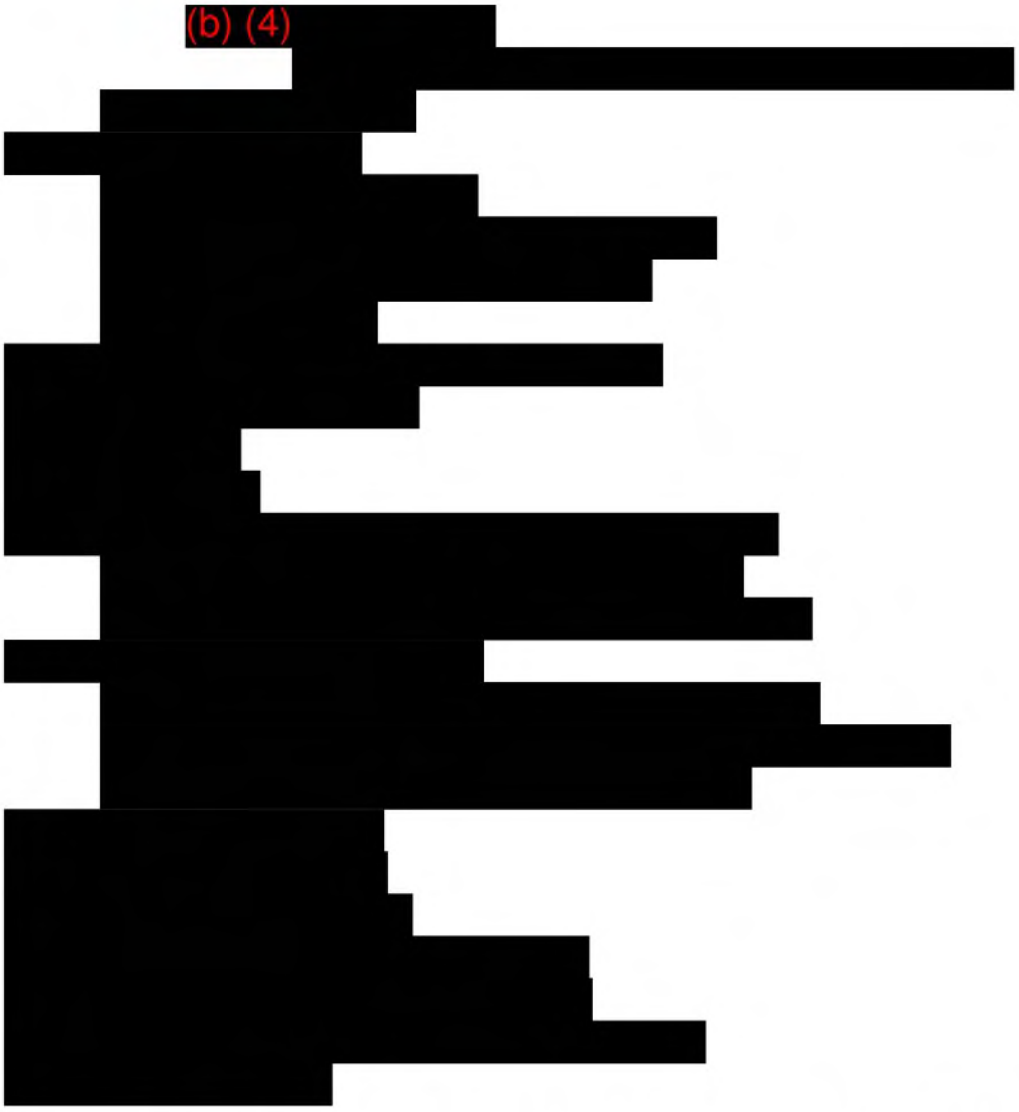
[redacted]

Personnel will be added as appropriate to complete the above tasks. Job descriptions are in place to ensure that personnel are qualified for their positions. Each job description has training requirements for tasks, procedures, drawings, and forms required to ensure competency. Employee training is regularly reviewed by supervisors to ensure there are no deviations or discrepancies.

c). Measurable Milestones Involved and Associated Completion Criteria for Each

(b) (4)

[redacted]



d). Deliverables to be provided to the Government in Support of the Proposed Tasks/Activities

Per the requirements outlined in the Statement of Objectives (section C.7.1.), RTI will provide a monthly report containing the following information:

- Summary of monthly progress for each of RTI's facilities/capabilities associated with this effort.
- Summary of progress towards established milestones for each facility/capability.
- Identification of any milestone that is slipping or missed and discussion of path forward to bring the milestone back to schedule, and impact on other milestones.
- Summary of risks, discussion of potential impacts and efforts to mitigate.
- Summary of overall schedule and changes from previous month.
- Financial summary of recipient costs incurred by month to date, invoices submitted, and Government payments made.

In addition, RTI will schedule, as needed, quarterly process reviews. An Annual Financial Status Report and a Final Report will be supplied, as per instructed.

e). Description of Facilities to be used for the Proposed Effort

July 1, 2020 Technology Investment Agreement W911SR-20-3-0004
RTI is located on 34 acres in Little Elm, Texas. Prior to the July 1, 2020 TIA, there were two buildings on the site totaling 120,000 square feet. This included controlled environments for injection molding, manufacturing, assembly, and packaging and 75,000 square feet of climate-controlled warehouse.

The July 1, 2020 TIA called for the construction of a 27,800 square foot controlled environment area within the 75,000 square feet of climate-controlled warehouse to accommodate:

- (b) (4)

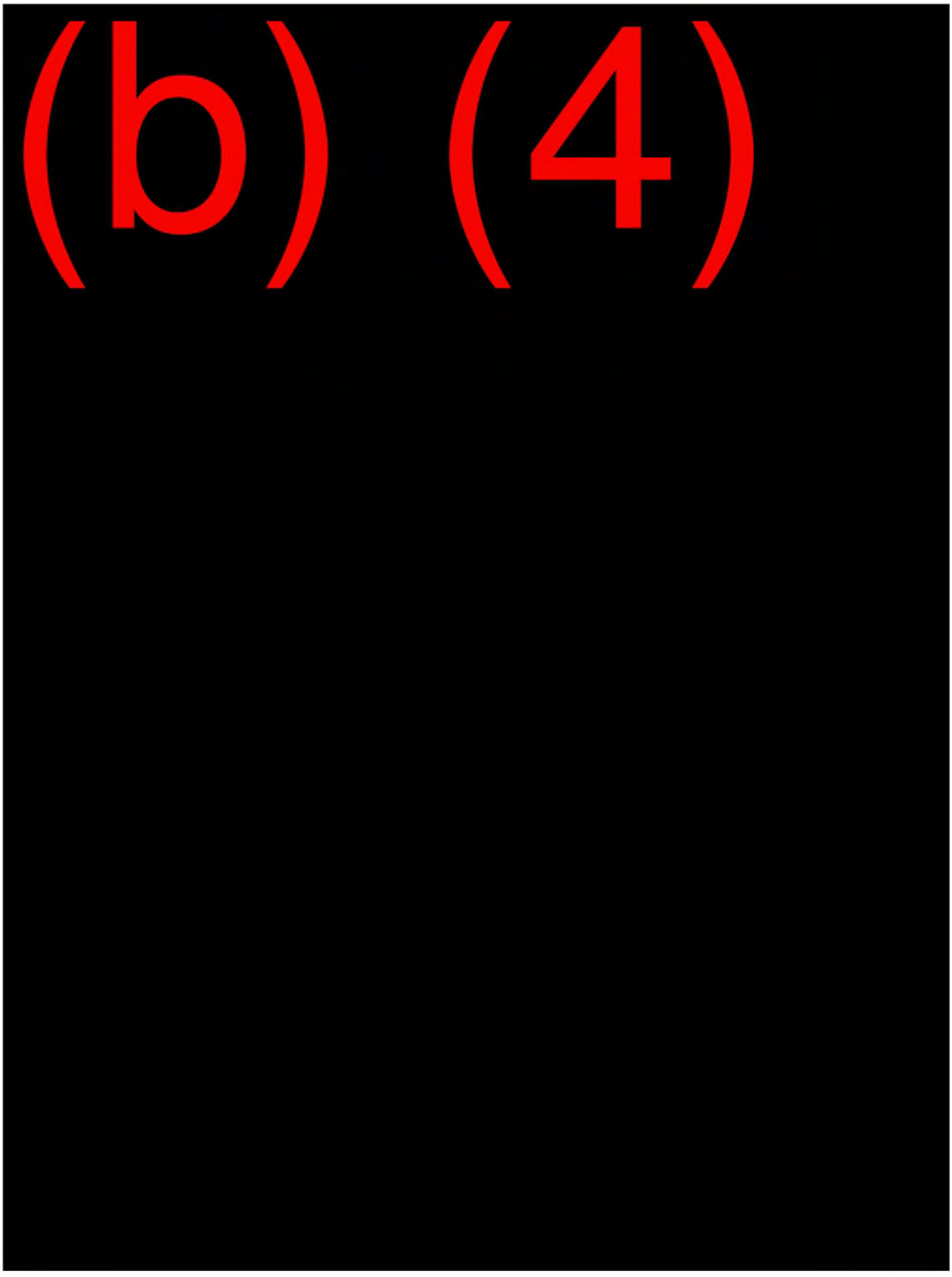
In addition, the July 1, 2020 TIA called for a new 55,000 square foot warehouse facility to be built adjacent to the current warehouse/molding facility. (b) (4)

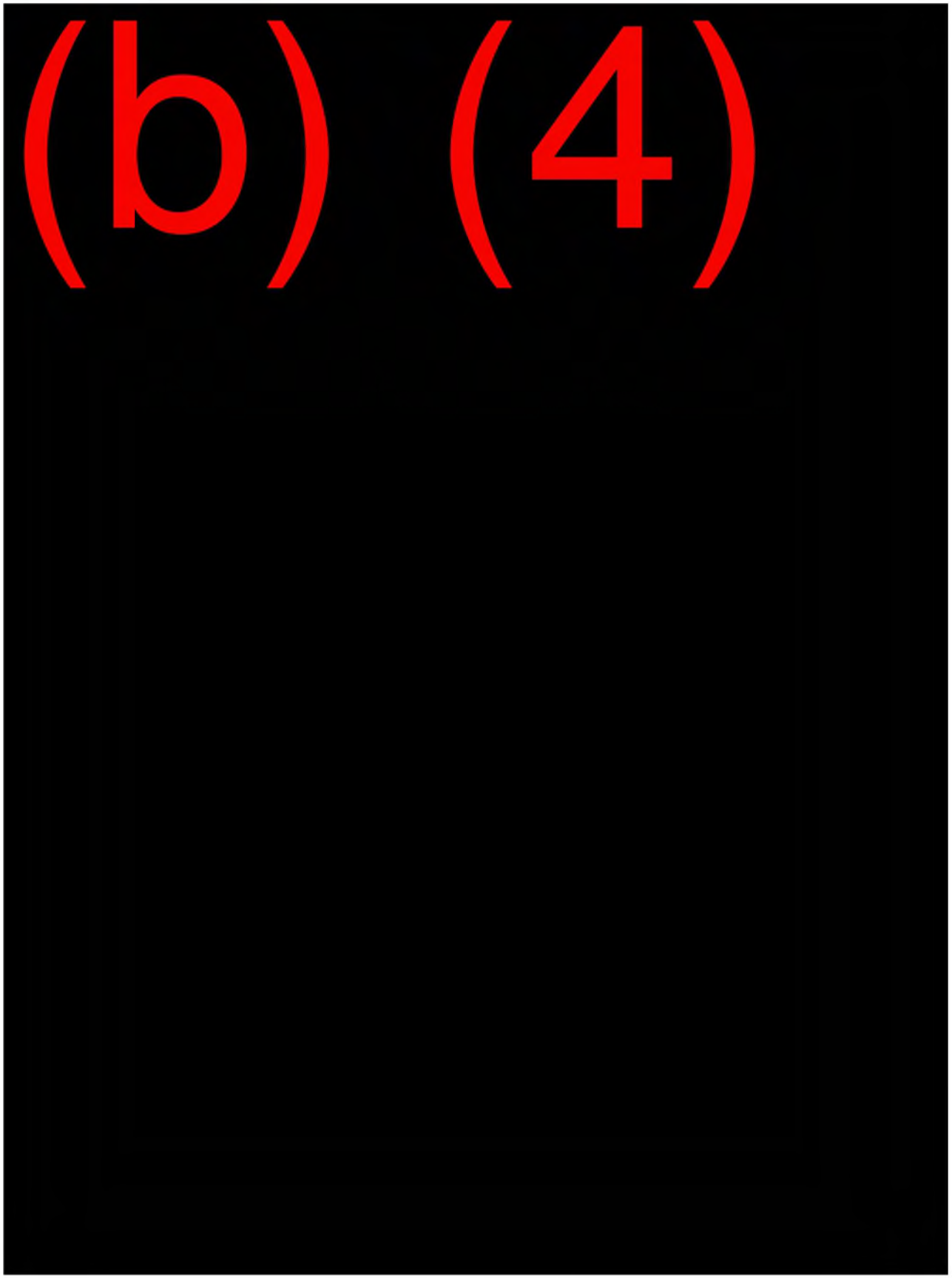
(b) (4)

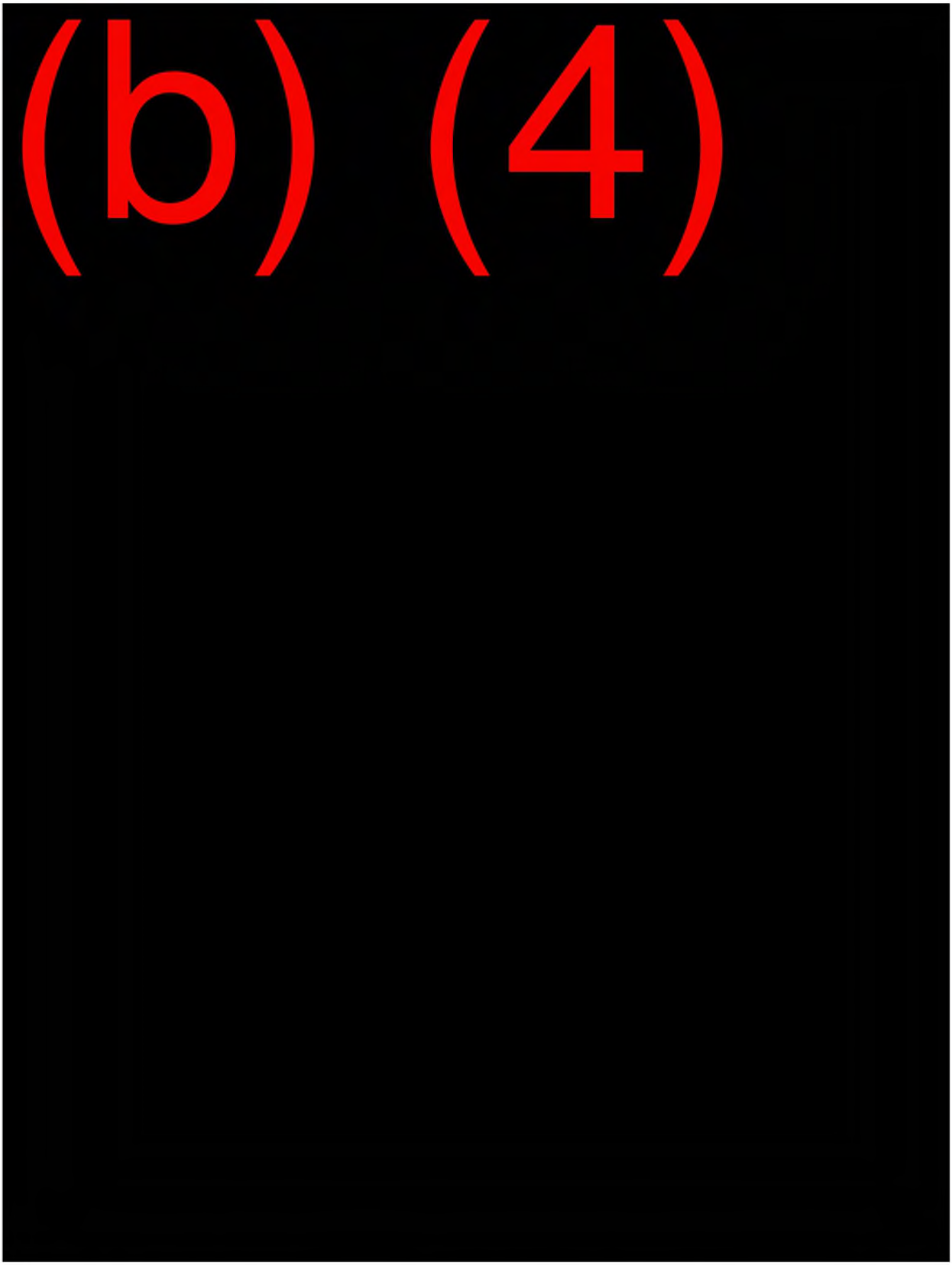
April 6, 2021 RTI Proposal to Modify TIA W911SR-20-3-0004
RTI proposes the following construction to increase the U.S. production of 1mL LDS safety syringes:

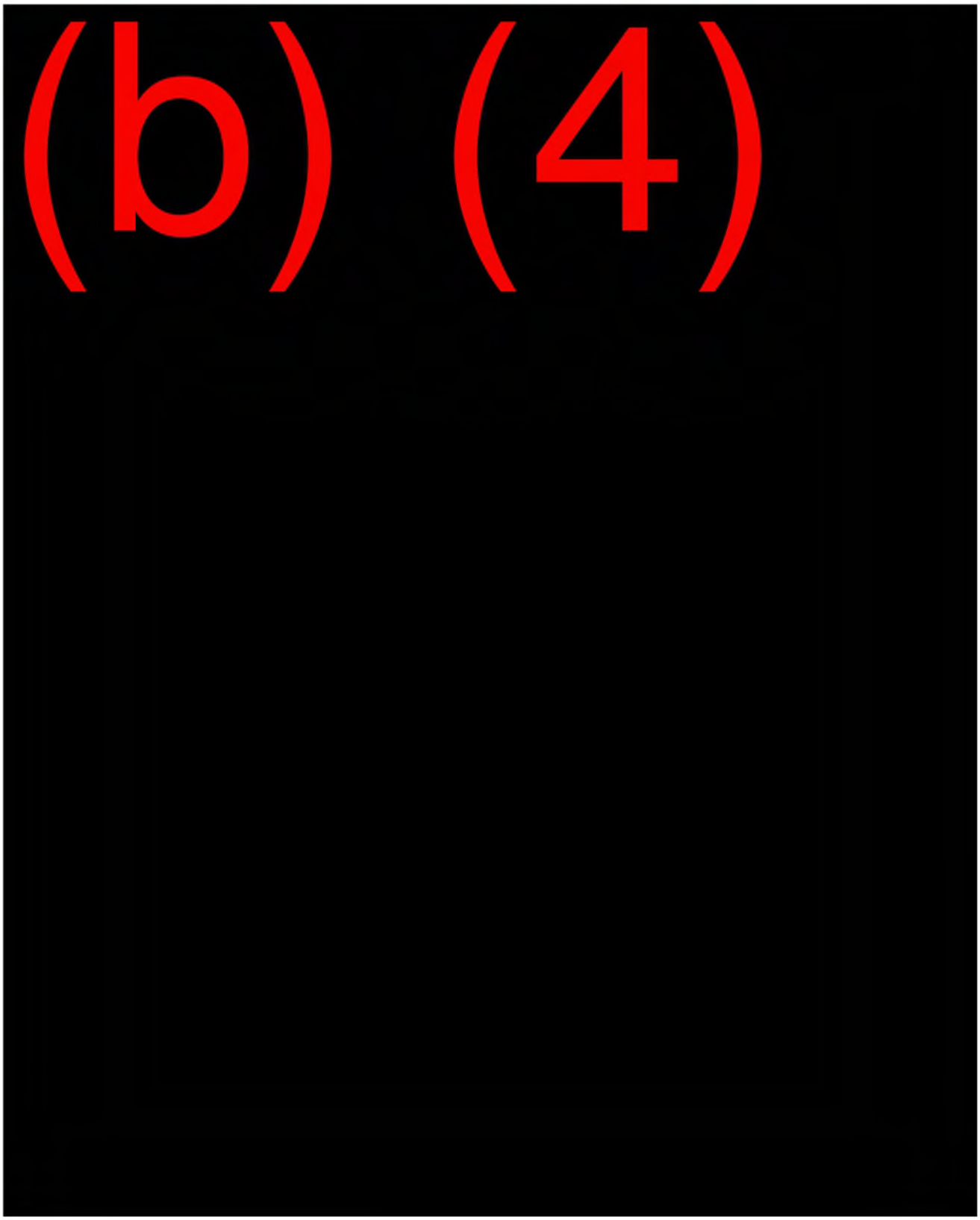
- (b) (4) square feet of expansion of controlled environment in warehouse C adjacent to the current expansion
    - This expansion will allow for two (2) 1mL LDS automated syringe assembly lines
        - These two 1mL LDS safety syringe/needle automated assembly lines will require supportive machinery:
            - Additional auxiliary equipment to maintain controlled environment
- (b) (4) square feet of expansion in building C for laboratory, gowning, restrooms, break area, offices, and maintenance

(b) (4)

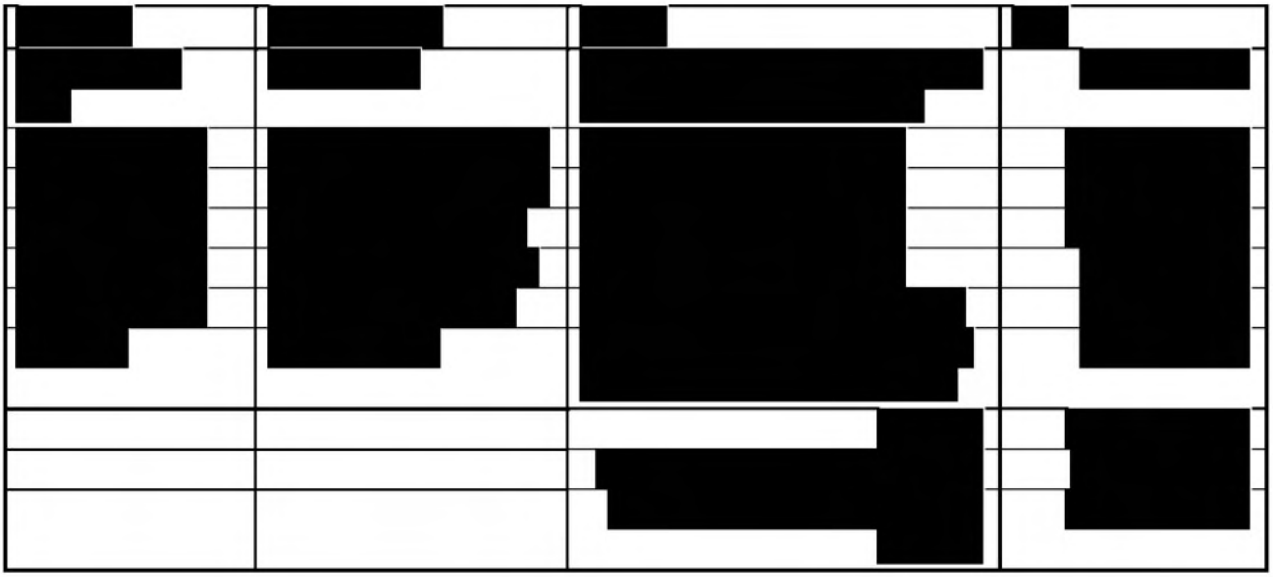

(b) (4)


(b) (4)


(b) (4)


(b) (4)

(b) (4)



(b) (4)

(b) (4)

[redacted]

[redacted]

[redacted]

[redacted]

(b) (4)

[redacted]

[redacted]

[redacted]


(b) (4)

(b) (4)

[redacted]

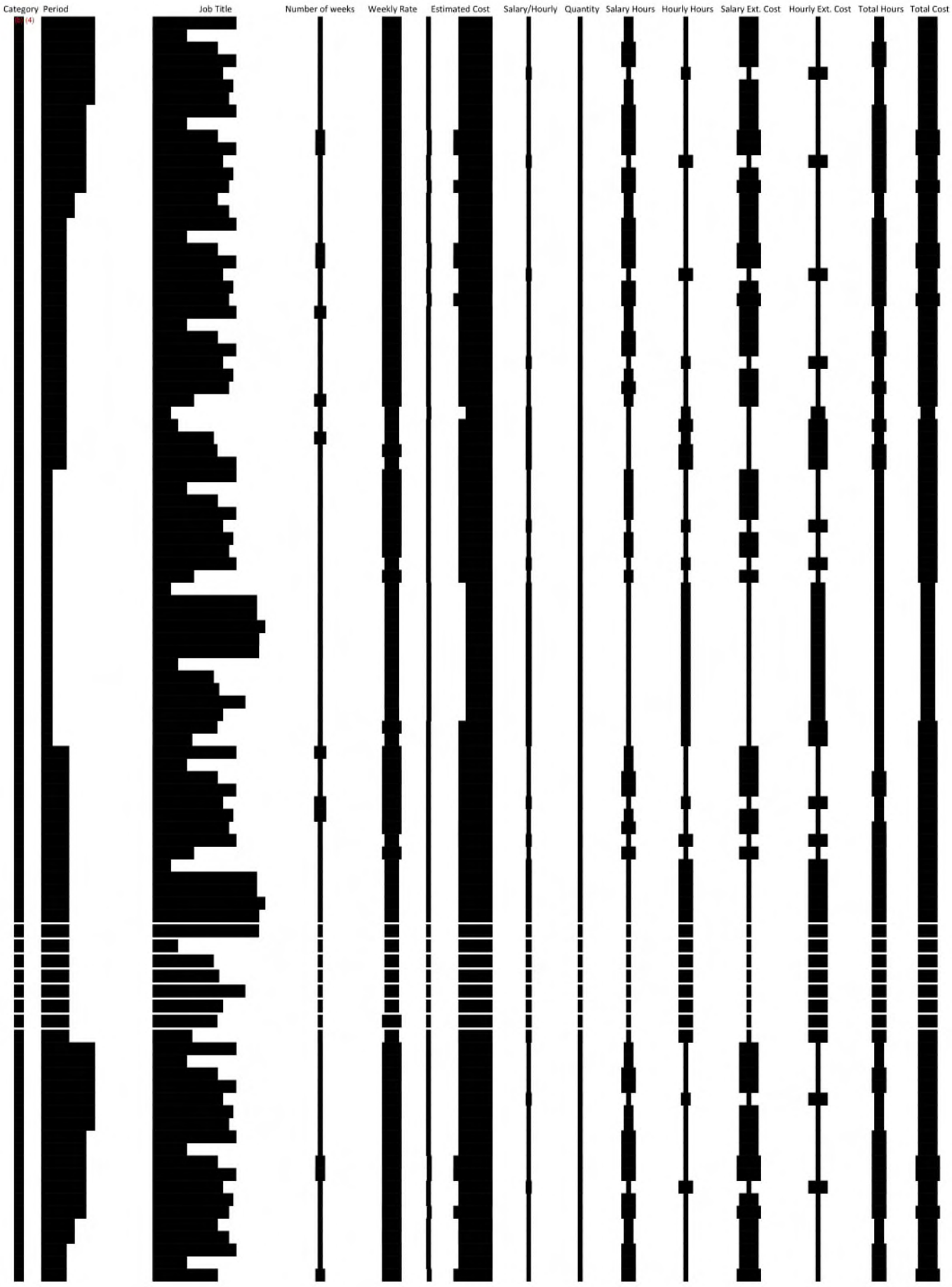
(b) (4)

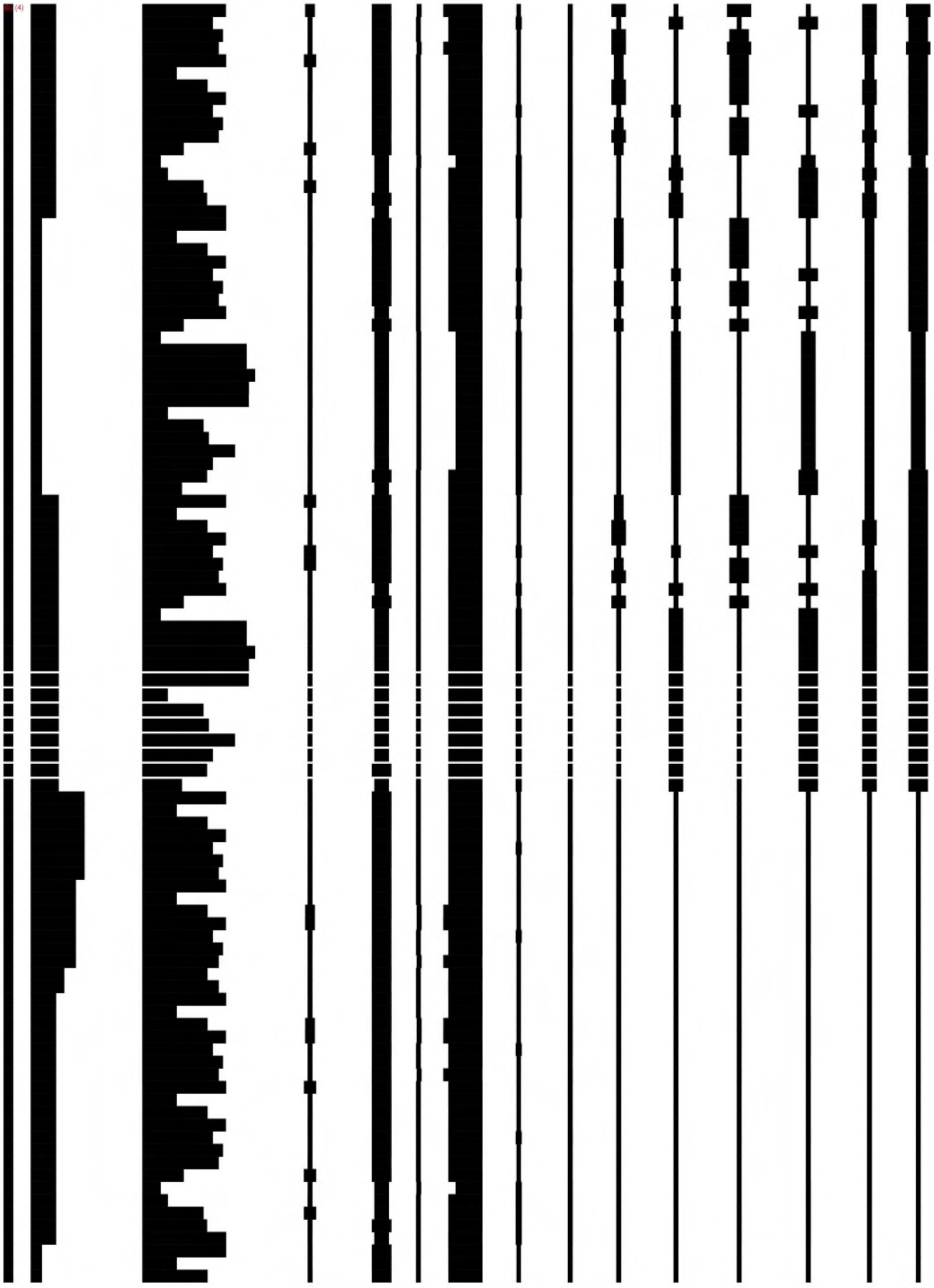
[redacted]

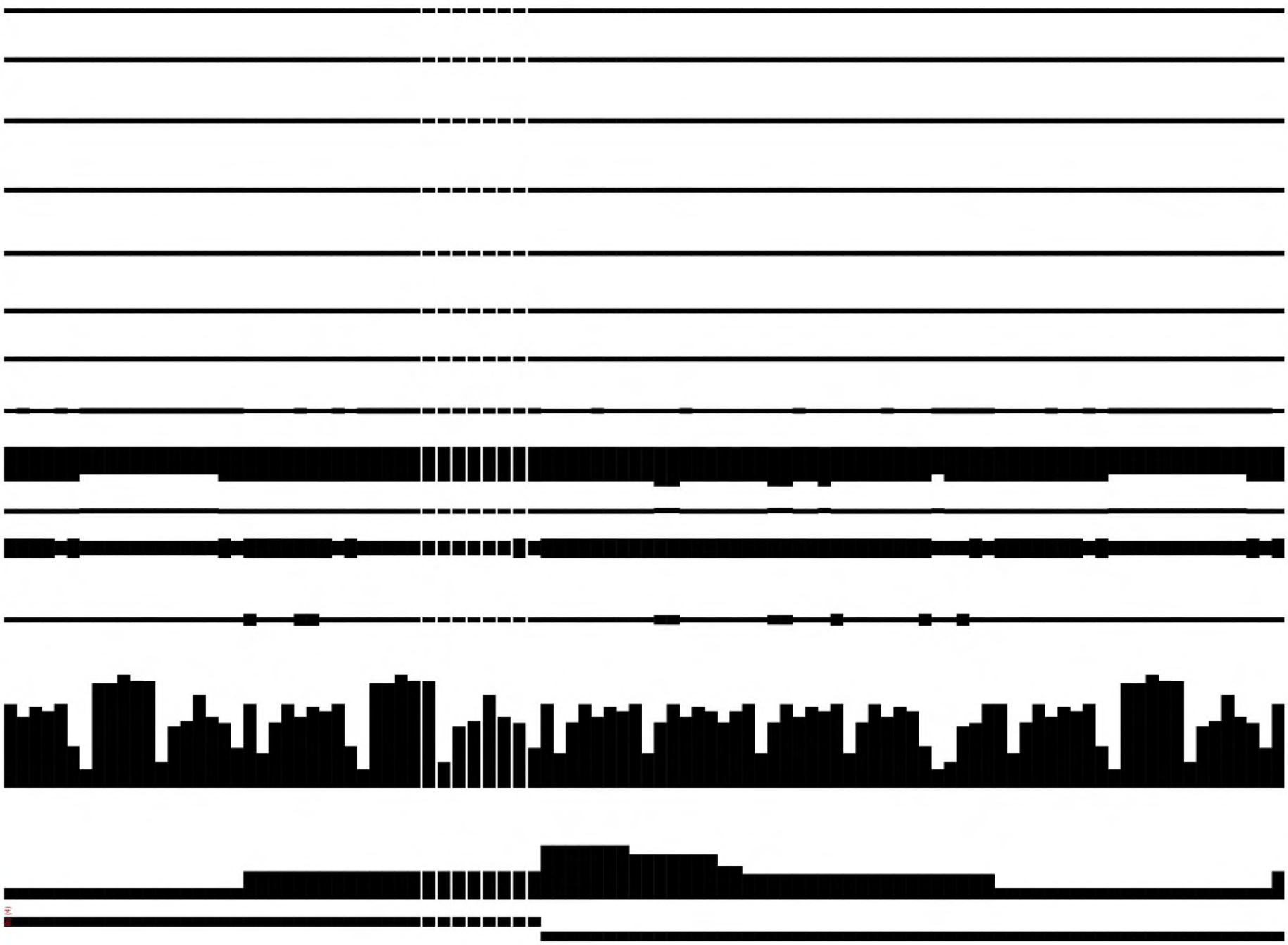
(b) (4)

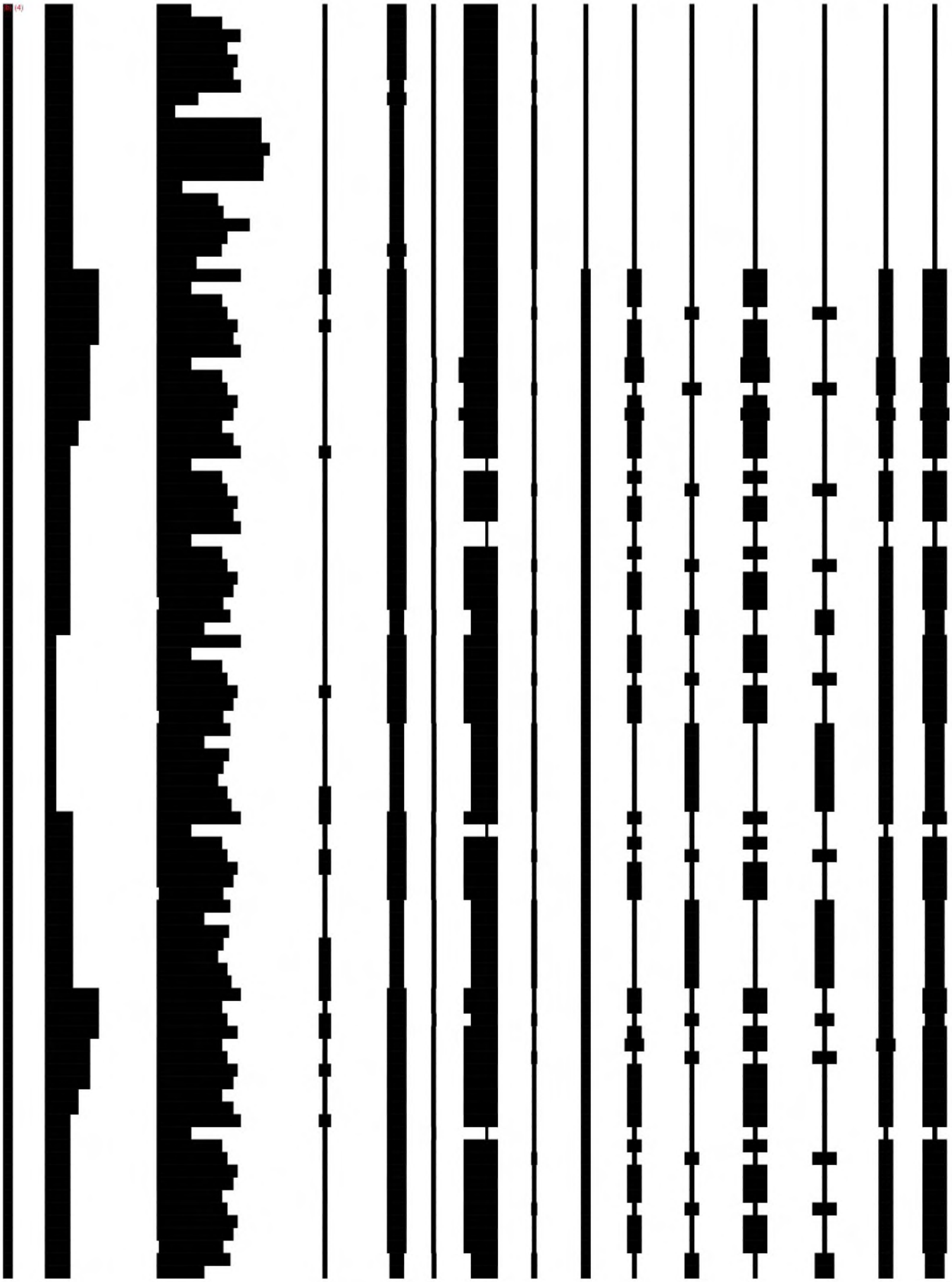
[redacted]

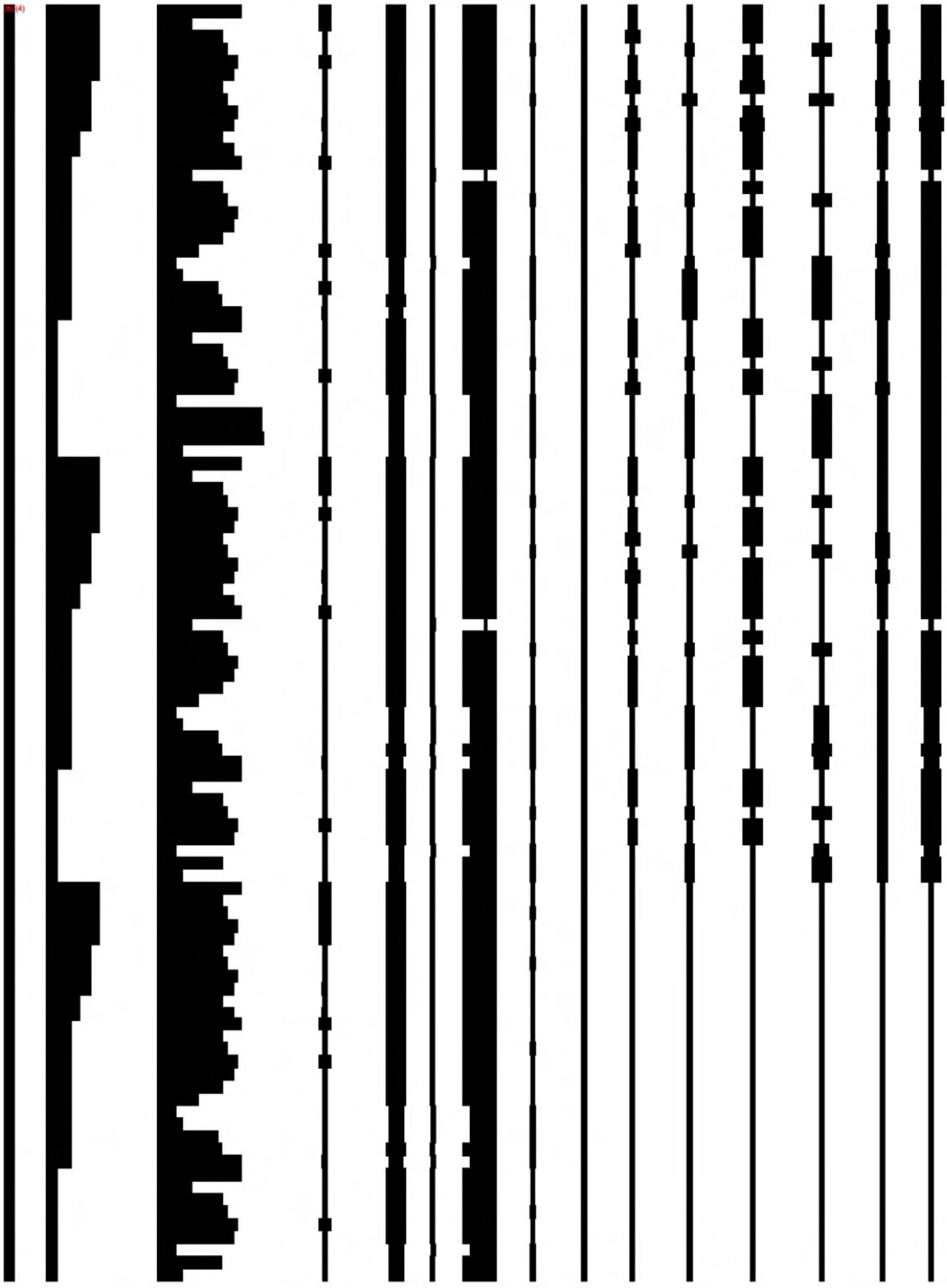
Category	Description	Quantity
01	1mL VanishPoint syringe/needle Automated Assembly Line (1)	1
02	1mL VanishPoint syringe/needle Automated Assembly Line (2)	1
03	3mL VanishPoint syringe/needle Automated Assembly	0
04	EasyPoint Needle Automated Assembly	0
05	(b) (4)	[redacted]
06	(b) (4)	[redacted]
07	(b) (4)	[redacted]
08	(b) (4)	[redacted]
09	Tubing Cutter	0
10	(b) (4)	[redacted]
11	(b) (4)	[redacted]

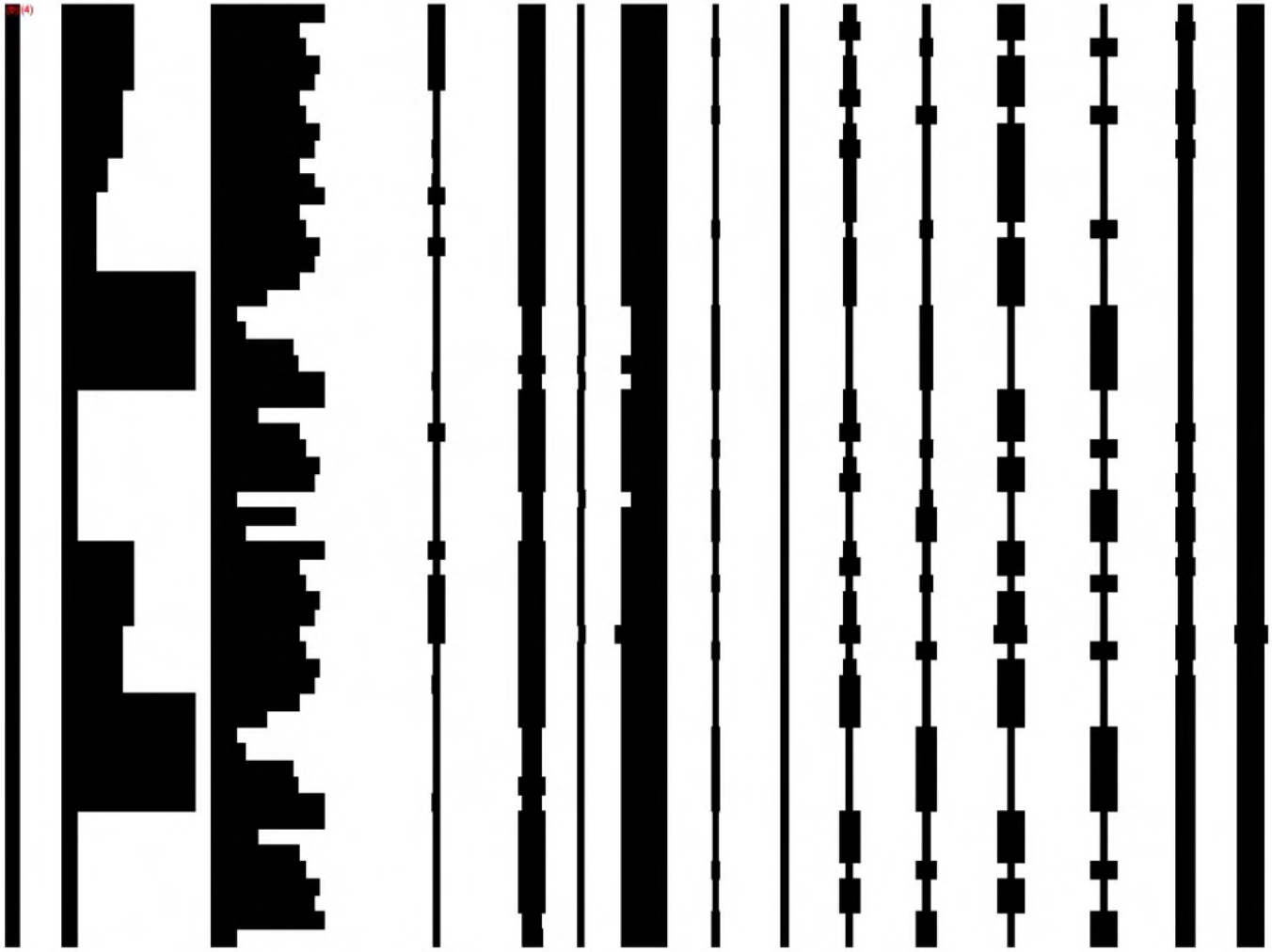

Category
(4)
Period
Job Title
Number of weeks
Weekly Rate
Estimated Cost
Salary/Hourly
Quantity
Salary Hours
Hourly Hours
Salary Ext. Cost
Hourly Ext. Cost
Total Hours
Total Cost

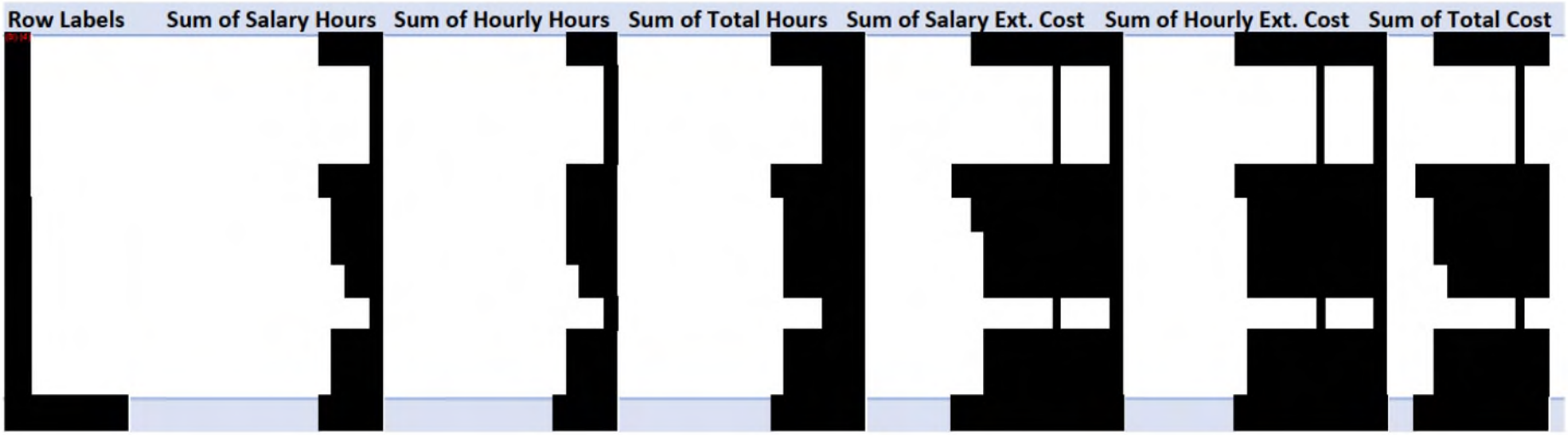


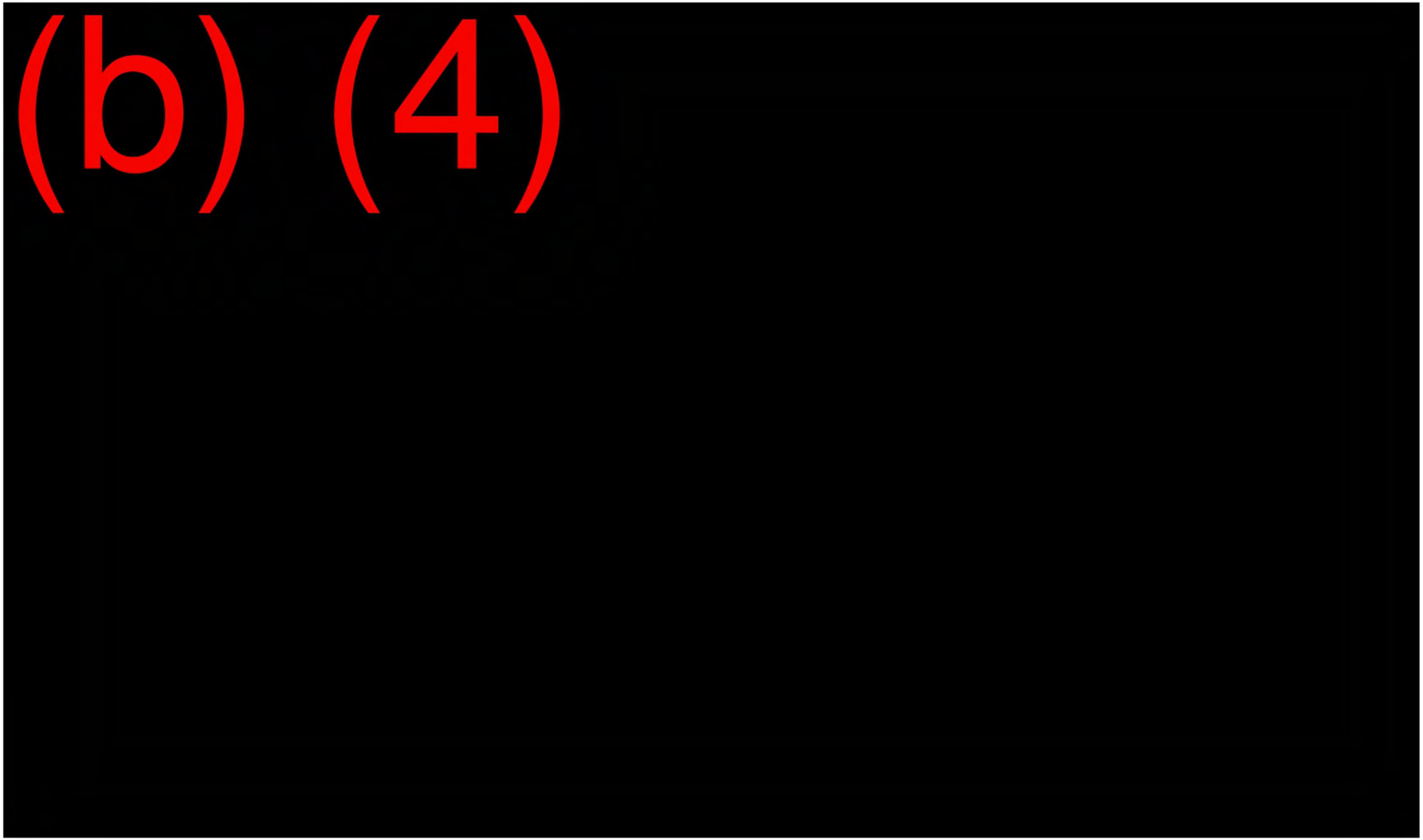









Row Labels
Sum of Salary Hours
Sum of Hourly Hours
Sum of Total Hours
Sum of Salary Ext. Cost
Sum of Hourly Ext. Cost
Sum of Total Cost


(b) (4)

RETRACTABLE TECHNOLOGIES, INC.

www.retractable.com - rti@retractable.com
P.O. Box 9, 511 Lobo Lane, Little Elm, Texas 75068-0009
Tel (972) 294-1010 - Fax (972) 294-4400 - Toll Free (888)806-2626

TIA number: **W911SR-20-3-0004**

Topic: **Expanding Domestic Production of Needles & Syringes**
Medical devices used to prevent or treat patients exposed to either chemical warfare agents (CWA), biological warfare agents (BWA) or infectious diseases

Organization submitting proposal: **Retractable Technologies, Inc.**

Proposal title: **Increasing U.S. Manufacturing Capacity of Low Dead Space Safety Injection Devices**

Administrative POC: (b) (6), RN, Vice President of Clinical Affairs
511 Lobo Lane, Little Elm, Texas 75068
(b) (6)

Technical POC: (b) (6), Director of Operations
511 Lobo Lane, Little Elm, Texas 75068
(b) (6)

Submitted on: April 6, 2021 (original)
April 18, 2021(revision-1)

DUNS Number: 838024255
CAGE Number: 1BFK3

DCMA Office: Army Contracting Command, Aberdeen Contracting Command
(ACC-APG) Natick and Edgewood Contracting Divisions (NCD and ECD)
(b) (6), Agreements Officer ACC-APG-Natick
8456 Brigade Street, E4215
Aberdeen Proving Ground, MD 21010-5401
(b) (6)

DCAA Office: DCAA, Central Region, North Texas Branch Office
2250 West John Carpenter Freeway, Suite 400
Irving, TX 75063
E-mail: dcaa-fao3531@dcaa.mil

This proposal is consistent with Retractable Technologies, Inc.'s established estimating and accounting practices and procedures.

Retractable Technologies, Inc. – Financial Proposal
Increasing U.S. Manufacturing Capacity of Low Dead Space Safety Injection Devices

Financial Summary

(b) (4) [redacted]

Estimated Value of the Agreement: $107,328,572

(b) (4) [redacted]

(b) (4) [redacted]

April 16, 2021 RTI Proposal to Modify TIA: **$27,365,232**

(b) (4) [redacted]

(b) (4)			
		Proposed Total Amount of Government Funding for Modification to increase 1mL LDS safety syringes capacity (b) (4)	$27,365,232.00

a). Direct Labor

(b) (4)

b). Indirect Costs

RTI is not currently requesting Government Funding for Indirect Costs.

c) Subcontractors

(b) (4)

(b) (4)

(b) (4)

April 6, 2021 RTI Proposal to Modify TIA W911SR-20-3-0004
RTI proposes Subcontractor Costs for the additional construction in existing warehouse space at RTI's property in Little Elm, Texas of (1) a 15,750 sf controlled environment and (2) 10,250 sf for laboratory, gowning, restrooms, break area, offices, and maintenance. The following table has estimated subcontractor costs.

(b) (4)

d). Travel
RTI is not currently requesting Government Funding for Travel.

e). Other Direct Costs
RTI is not currently requesting Government Funding for Other Direct Costs.

f). Equipment Purchases

(b) (4)

(b) (4) [redacted]

April 6, 2021 RTI Proposal to Modify TIA W911SR-20-3-0004
RTI proposes the following Equipment Cost to create additional two 1mL VanishPoint low dead space (LDS) safety syringe (with attached needle) lines capable producing in total (b) (4) syringes per year.

(b) (4) [redacted]

g). Materials
July 1, 2020 Technology Investment Agreement W911SR-20-3-0004
RTI was awarded Government Funding to warehouse three long lead time items in-stock to expedite surge capacity. The items are needles, top web, and spring wire. Back up documentation is available. The table below outlines the purchase of the materials.

(b) (4) [redacted]

April 6, 2021 RTI Proposal to Modify TIA W911SR-20-3-0004
RTI is not currently requesting additional Government Funding for Materials.

h). Cost-Sharing

(b) (4)

[redacted]

(b) (4)

[redacted]

i). Any Forward Pricing Rate Agreement

This is not currently applicable to RTI.

j). Proposers with a DCAA-approved cost accounting system, must submit appropriate DCAA documentation

This is not currently applicable to RTI.

k). Requests for Pre-Award Cost authorizations

RTI is not currently requesting pre-award cost authorizations.


(b) (4)

Retractable
Technologies, Inc.
Government Funding

July 1, 2020 Technology Investment Agreement W911SR-20-3-0004

Category	Sub-Category	Details	Cost
Subcontractor Cost	Construction	27,800 sf Controlled Environment in Existing Warehouse Space	(b) (4)
Equipment Cost	VanishPoint 1ml Line 1	Production Line Equipment	(b) (4)
Equipment Cost	VanishPoint 1ml Line 2	Production Line Equipment	(b) (4)
Equipment Cost	VanishPoint 3ml Line	Production Line Equipment	(b) (4)
Equipment Cost	EasyPoint Needle Line	Production Line Equipment	(b) (4)
Equipment Cost	Auxiliary Equipment	Non-Production Line Equipment	(b) (4)
Materials	Raw Materials	Long Lead Time Raw Materials - Needles, Spring Wire, Top Web	(b) (4)
		Subtotal	(b) (4)
		Subtract RTI Cash Investment	(b) (4)
		Total Amount of Government Funding	(b) (4)

April 18, 2021 RTI Proposal to Modify TIA W911SR-20-3-0004

Category	Sub-Category	Details	Cost
Subcontractor Cost	Construction	(1) (b) (4) sf Controlled Environment in Existing Warehouse Space (2) (b) (4) sf for Laboratory, Gowning Room, Restrooms, Break Area, Offices, and Maintenance Area	(b) (4)
Equipment Cost	(b) (4)	Equipment for Two 1ml VanishPoint Syringe Production Lines	(b) (4)
Equipment Cost	(b) (4)	Equipment for Two 1ml VanishPoint Syringe Production Lines	(b) (4)
Equipment Cost	Assembly Machines	Equipment for Two 1ml VanishPoint Syringe Production Lines	(b) (4)
Equipment Cost	Other Production Equipment	Equipment for Two 1ml VanishPoint Syringe Production Lines	(b) (4)
Equipment Cost	Auxiliary Equipment	Non-Production Line Equipment	(b) (4)
		Subtotal for Modification	(b) (4)
		Subtract Additional RTI Cash Investment for Modification	(b) (4)
		Proposed Total Amount of Government Funding for Modification to increase 1mL LDS safety syringes capacity an estimated (b) (4)	(b) (4)

Retractable Technologies, Inc.
W911SR-20-3-0004

Controlled Environment - TIA	Direct Labor	Indirect Costs	Travel	Materials	Other Direct Costs	Total
Total	(b) (4)					
Design						
(b) (4)						
General Provisions						
(b) (4)						
Construction						
(b) (4)						

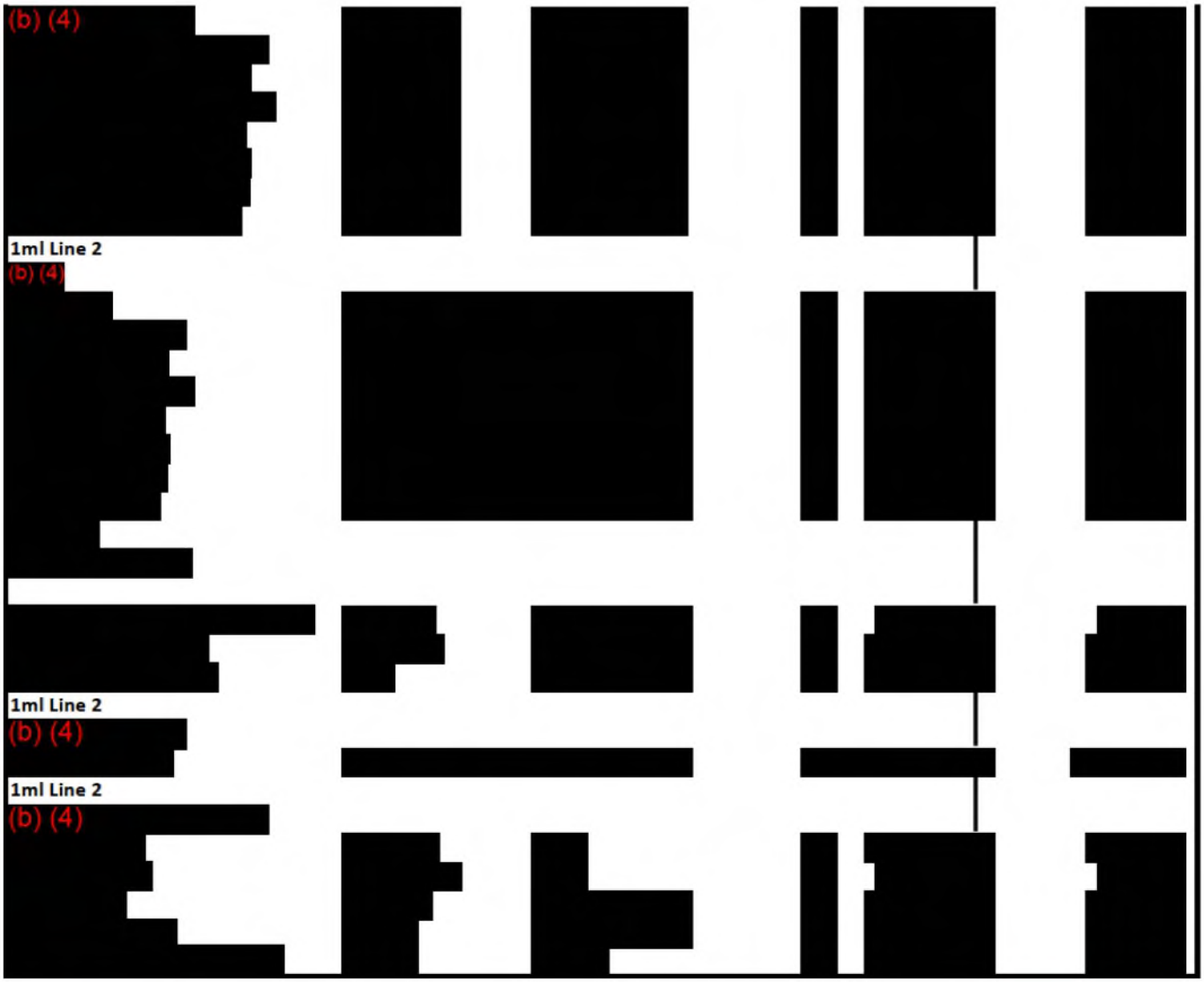
Retractable Technologies, Inc.
W911SR-20-3-0004

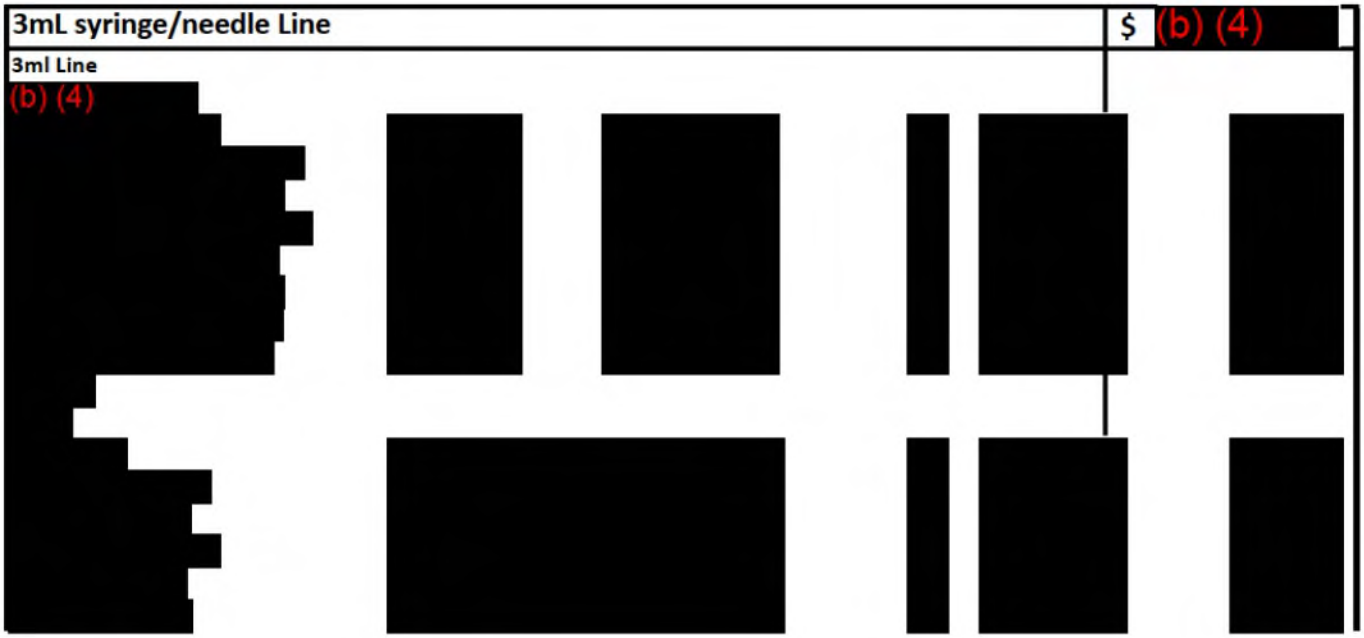
Controlled Environment - Modification to TIA	Direct Labor	Indirect Costs	Travel	Materials	Other Direct Costs	Total
Total	$(b) (4)					
Design						
(b) (4)						
General Provisions						
(b) (4)						
Construction						
(b) (4)						

Retractable Technologies, Inc. -
W911SR-20-3-0004

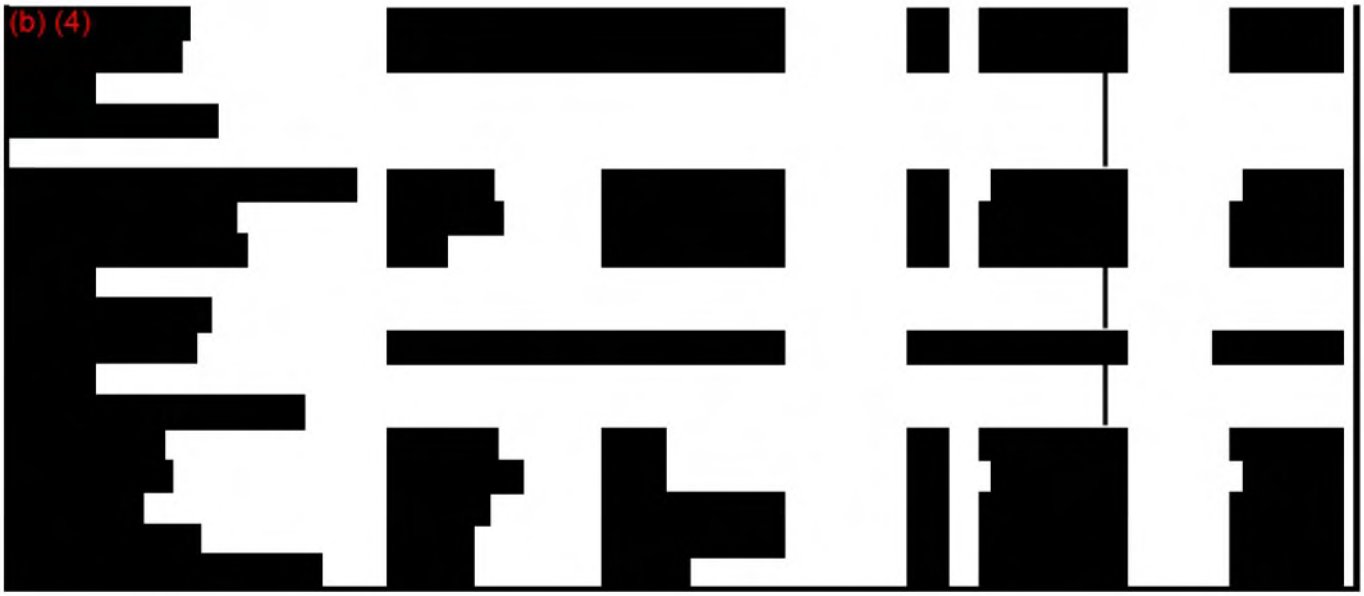
TIA - 2x 1mL LDS syr/ndl lines,
3mL syr/ndl line, EP needle line

Category	Supplier	Source of Cost	Quantity	Unit Cost	Extended Price
Total Equipment Cost					$ (b) (4)
1mL LDS syringe/needle - Line 1					$ (b) (4)
1ml Line 1 (b) (4)					
1mL LDS syringe/needle - Line 2					$ (b) (4)
1ml Line 2 (b) (4)					


(b) (4)
1ml Line 2
(b) (4)
1ml Line 2
(b) (4)
1ml Line 2
(b) (4)


3mL syringe/needle Line
$
(b) (4)
3ml Line
(b) (4)

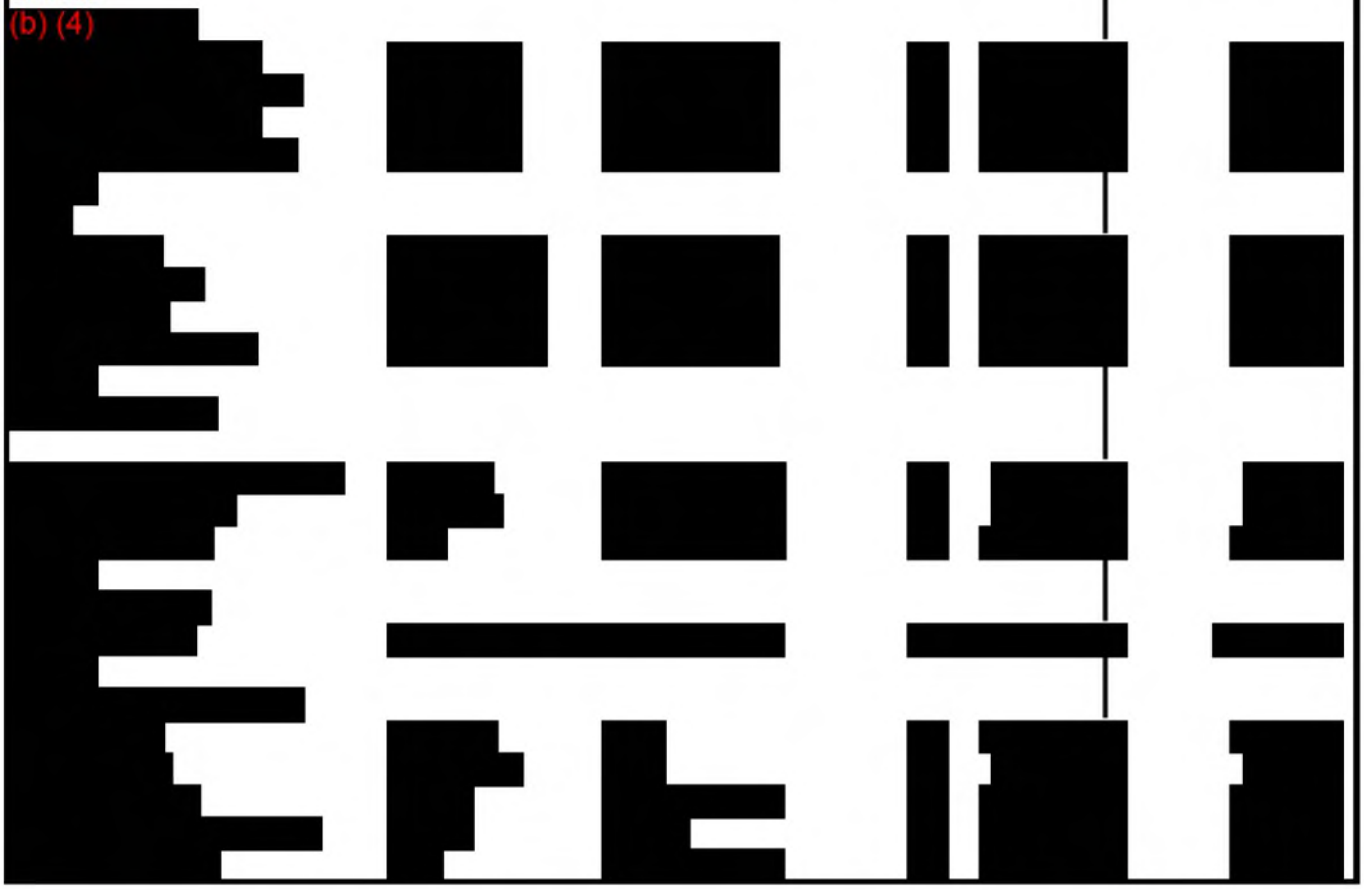
(b) (4)



EasyPoint needle Line	$ [redacted]

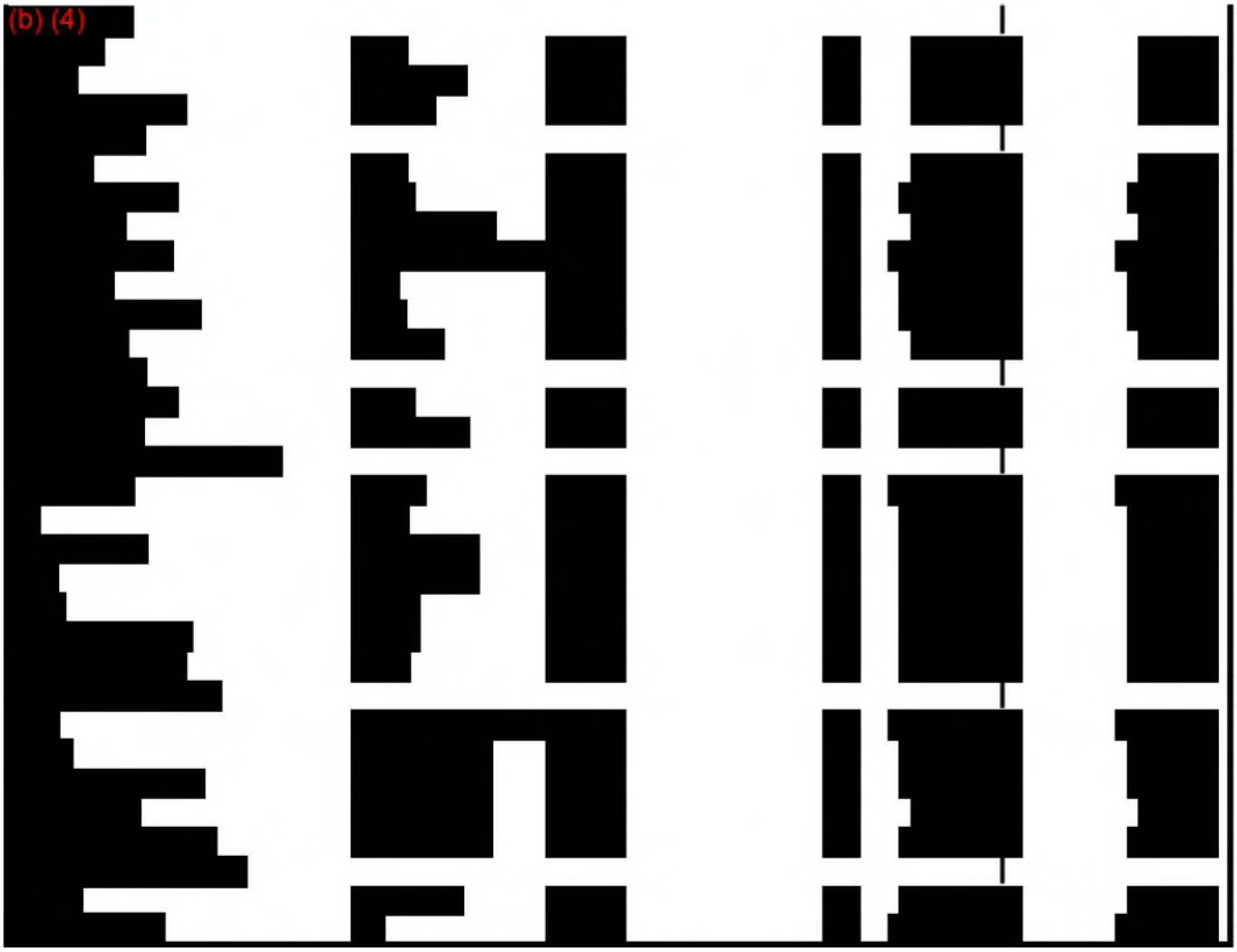
EPN Line

(b) (4)



Auxiliary Equipment	$ [redacted]

(b) (4)



RTI Confidential

6-Apr-21

Retractable Technologies, Inc.
W911SR-20-3-0004

Modification of TIA - Adding Two
1mL LDS safety syringe/needle Lines

Category	Supplier	Source of Cost	Quantity	Unit Cost	Extended Price
(b) (4)					
(b) (4)				$	(b) (4)
(b) (4)					
(b) (4)				$	(b) (4)
(b) (4)					
(b) (4)				$	(b) (4)
(b) (4)					
Other Production Equipment				$	(b) (4)
(b) (4)					
Auxiliary Equipment				$	(b) (4)
(b) (4)					

Retractable
Technologies, Inc.
W911SR-20-3-0004
Raw Materials

RTI Confidential
6-Apr-21

Retractable Technologies, Inc. Cost Share
BAA Number: MSC-BAA-17-01-W911QY-17-S-0001 Amendment 0003
Origial TIA and Proposed Modification

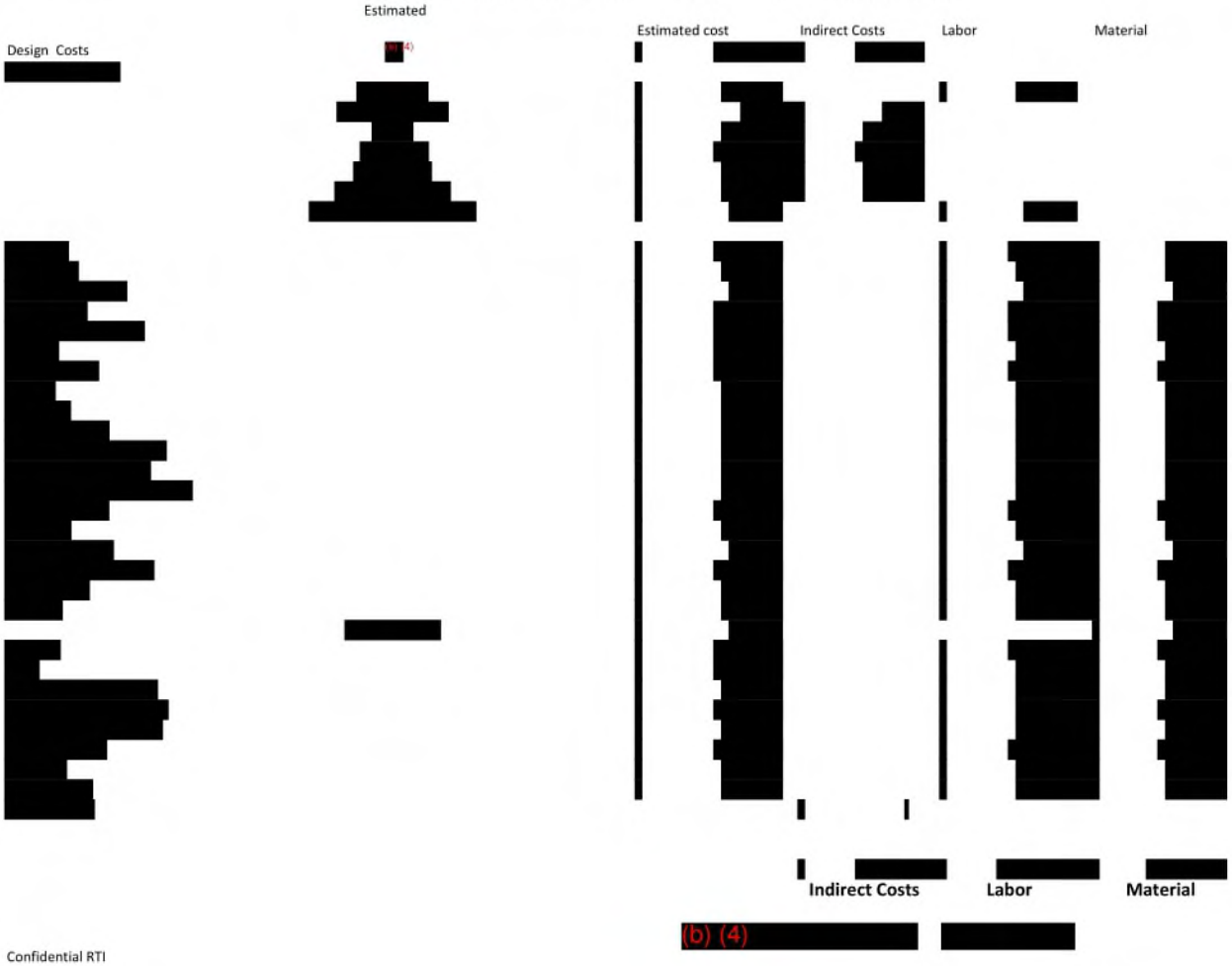
#	Category	Costs
(b) (4) [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
	(b) (4)	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]

Proposed Modification to increase 1mL LDS safety syringes capacity an estimated (b) (4) [redacted]

14	Additional Direct Labor Costs for Modification	(b) (4) [redacted]
	(b) (4) [redacted]	[redacted]
	[redacted]	[redacted]

RTI Confidential
Revised 4/18/2021

Estimated Costs of 55,000ft^2 Warehouse



Confidential RTI
Revised 6/17/2020

Retractable Technologies
511 Lobo Lane Lot 1 Block A

Area **34.9 acres**

(b) (4) [redacted]

Area of use for Project including Parking Building Lanscape and Fire Lane 610'X720' **10.826 acres**

(b) (4) [redacted]

Confidential RTI
12-Jun-20

Year		Utilities
2010	$	398,541.24
2011	$	339,197.35
2012	$	305,797.41
2013	$	307,124.38
2014	$	333,905.34
2015	$	308,561.05
2016	$	263,266.24
2017	$	260,484.86
2018	$	254,911.85
2019	$	254,825.54
YTD 2020	$	97,906.38
	$	3,124,521.64
Total - [redacted]	$	3,026,615.26
Average	$	302,661.53

[redacted]

12-Jun-20

Calibration

(b) (4)

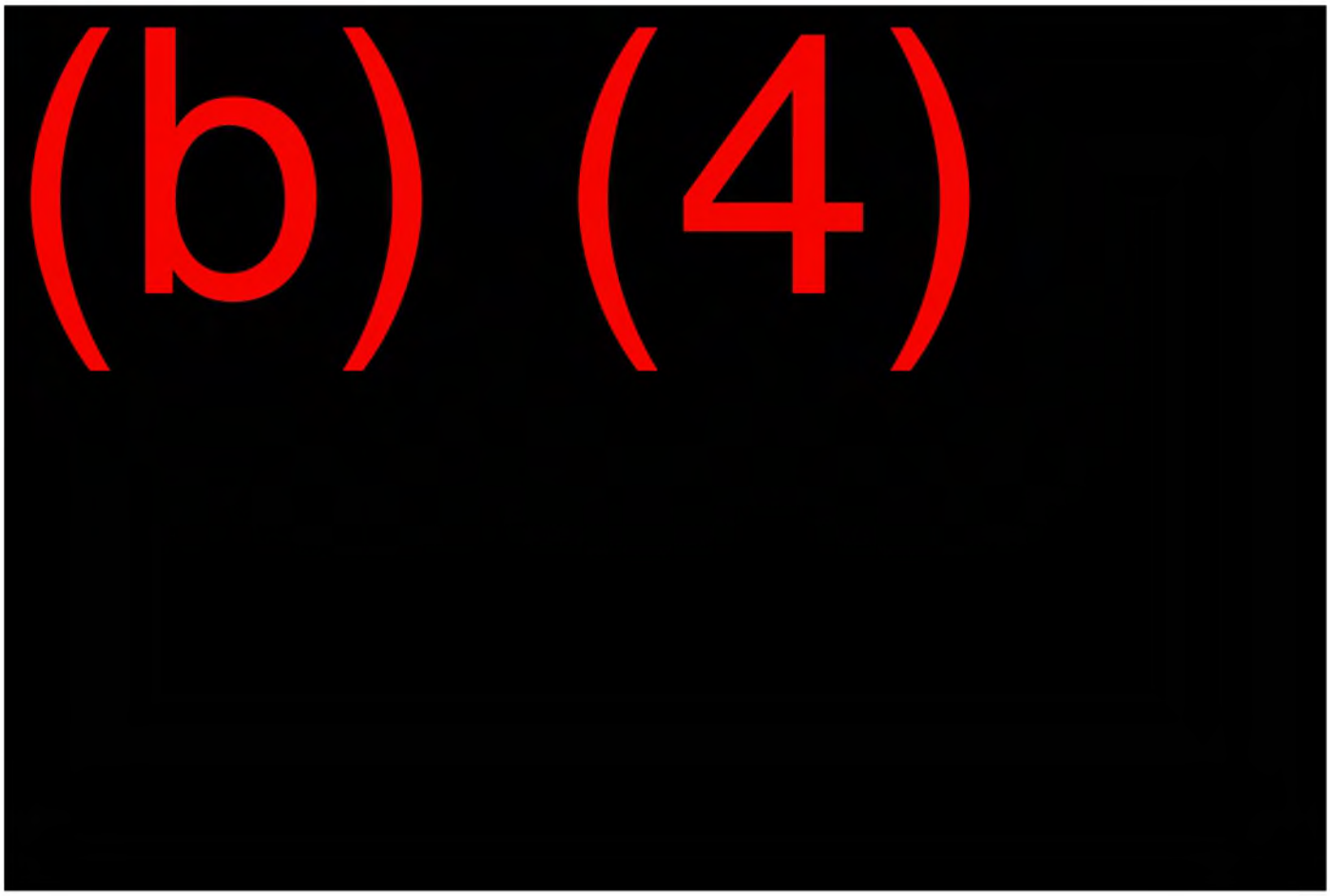
3

Initial Calibration cost for implementation

Assets	Cost to Calibrate	Cost
(b) (4)		

Maintenance

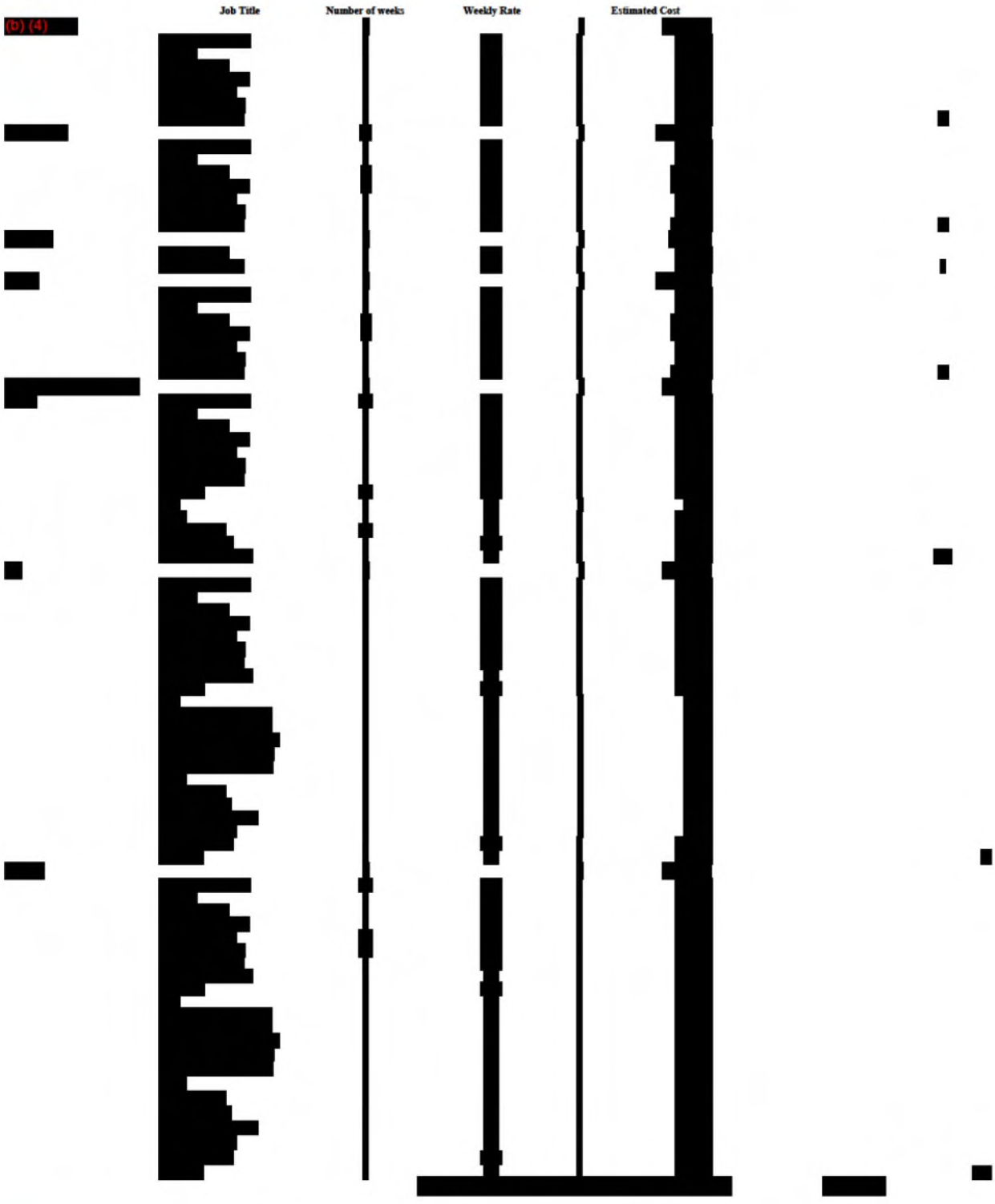
Retractable Technologies, Inc.
Projected labor and G&A cost breakout



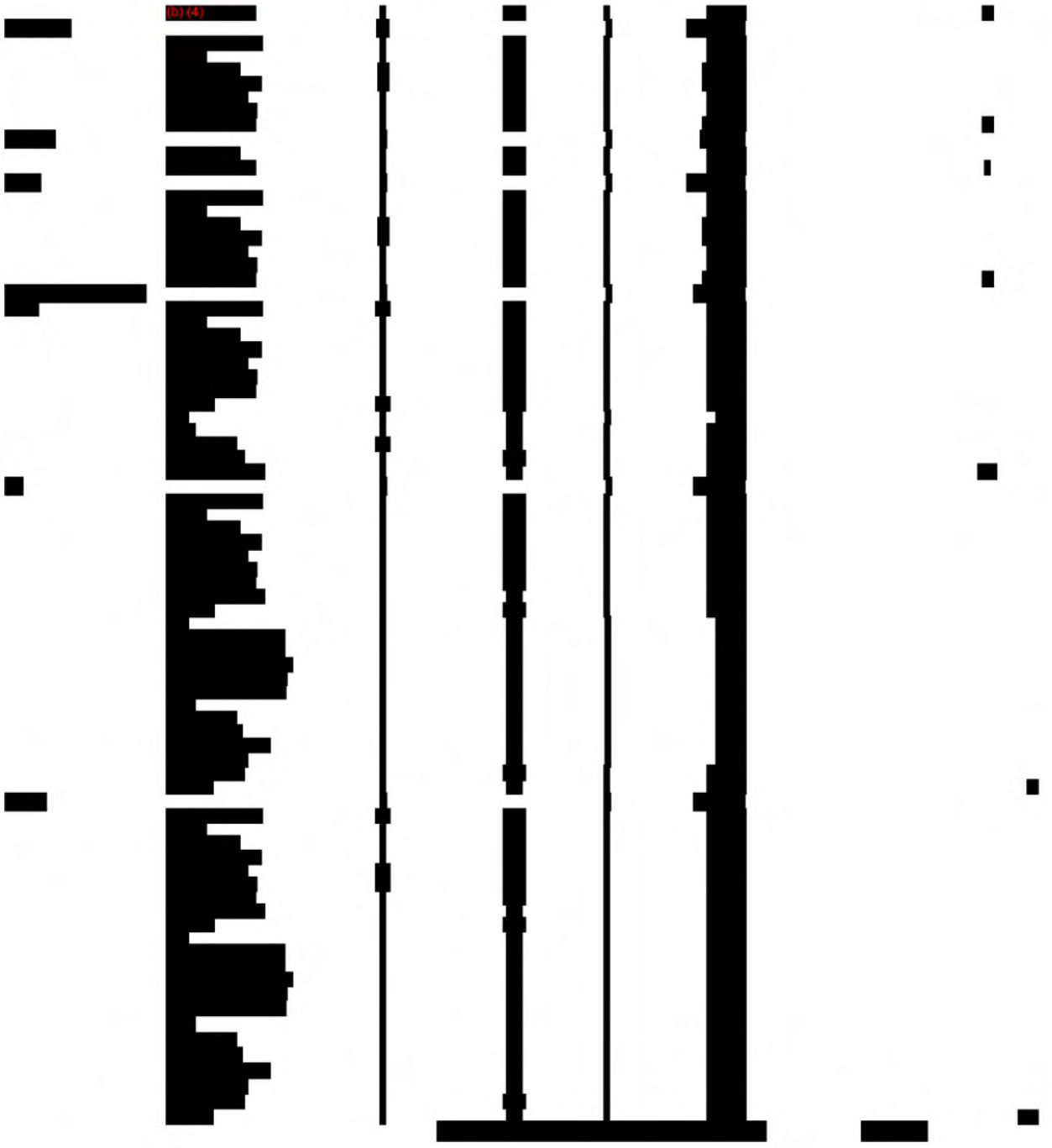
$ (b) (4) [redacted]

Estimated Direct Labor Hours with Costs to Implement Increasing Capacity to (b) (4) Units

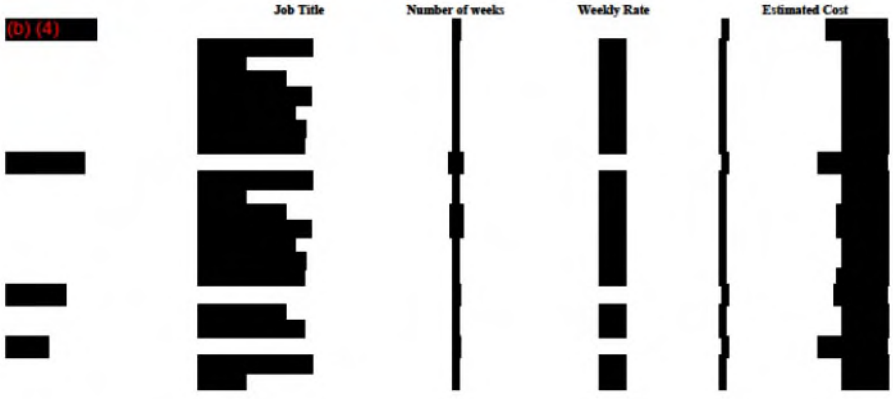
1mL Automated Assembly Line 1

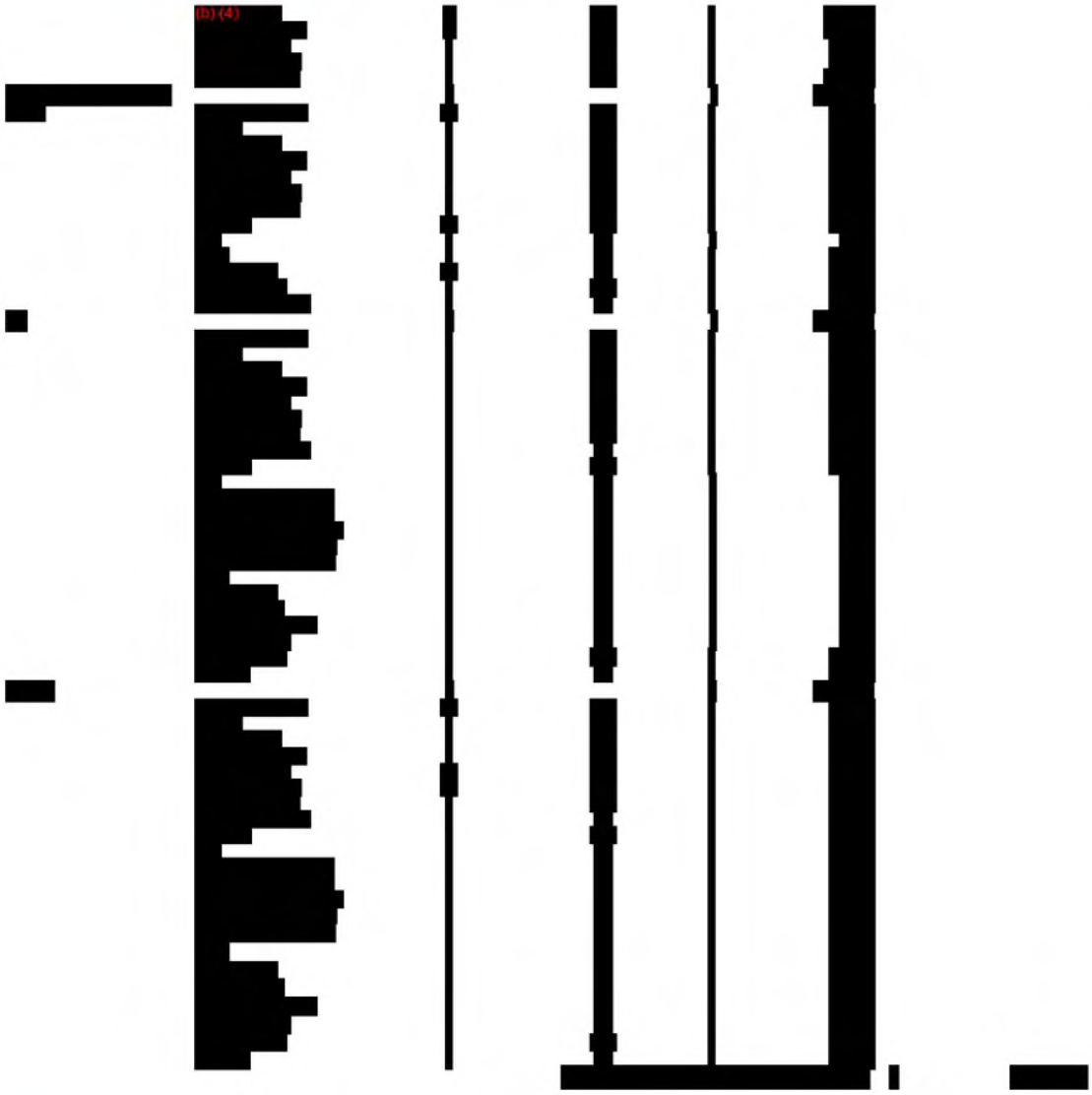


1mL Automated Assembly Line 2

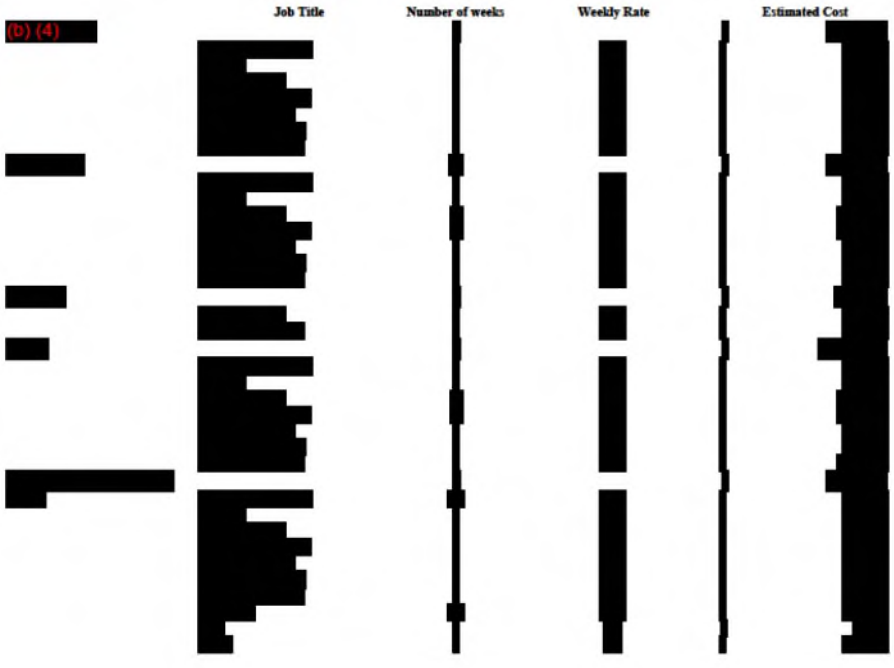


3mL Automated Assembly

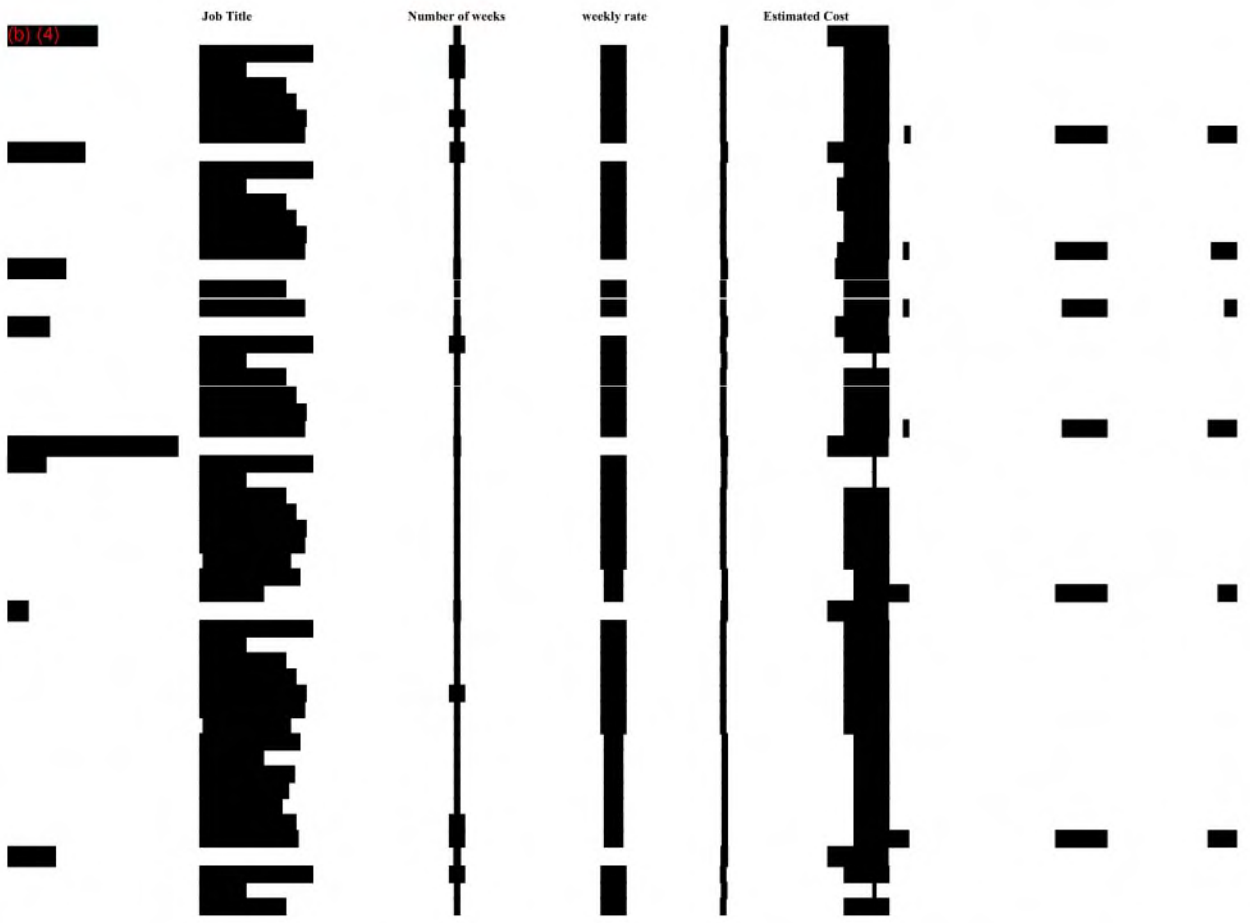


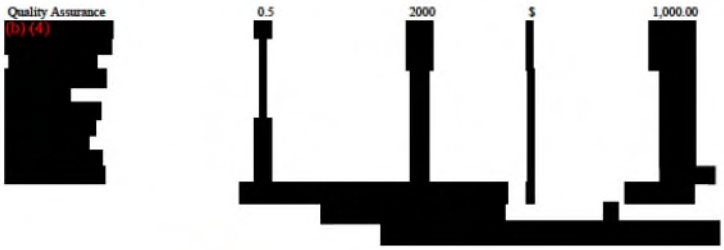


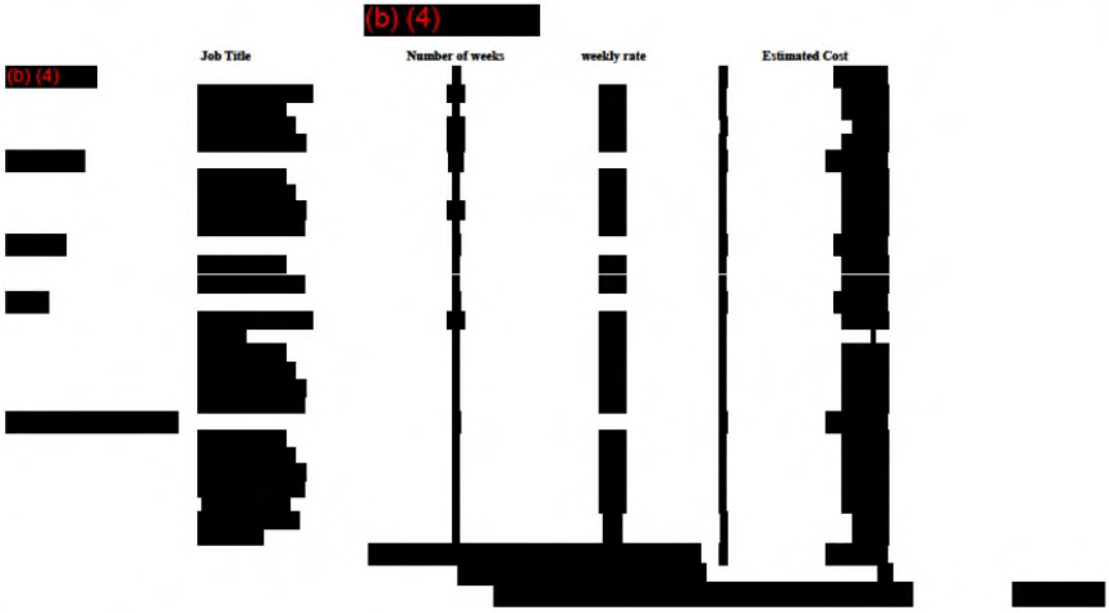
EPN Automated Assembly



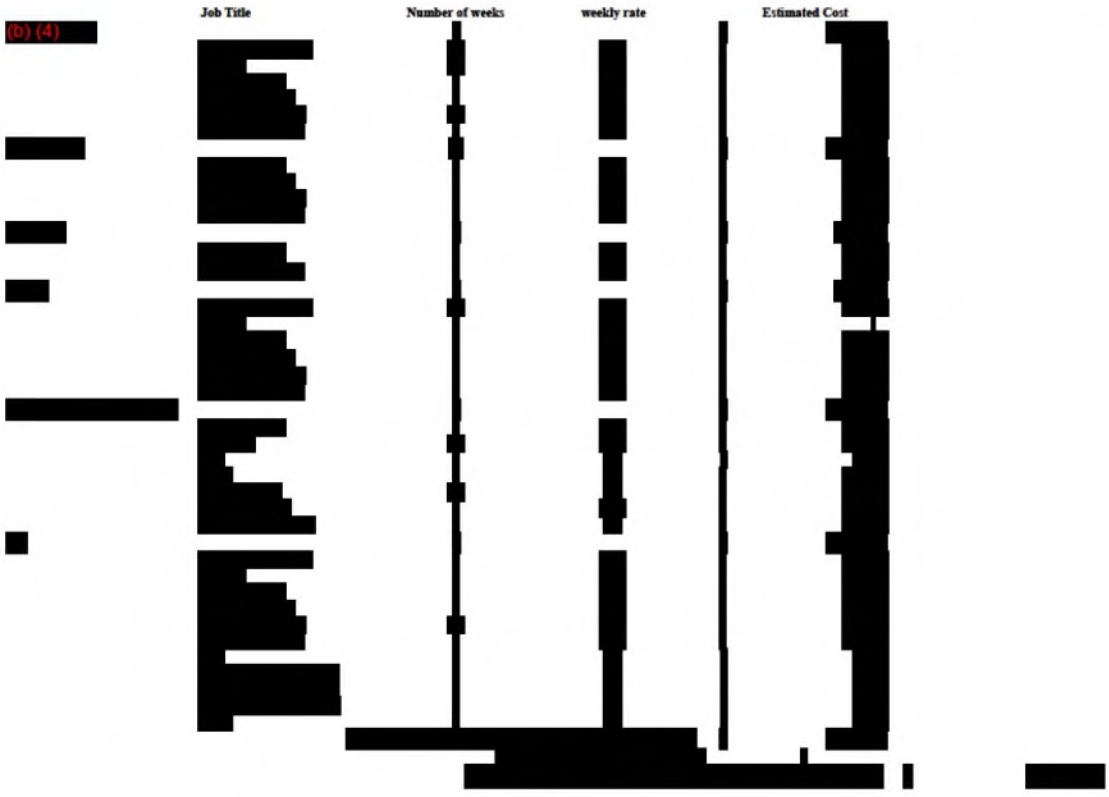
(b) (4)







Packaging Machines



Printing Machines

(b) (4)

Job Title	Number of weeks	weekly rate	Estimated Cost
[redacted]	[redacted]	[redacted]	[redacted]

Tubing Cutter

(b) (4)

Job Title	Number of weeks	weekly rate	Estimated Cost
[redacted]	[redacted]	[redacted]	[redacted]

(b) (4)

(b) (4)

Job Title	Number of weeks	weekly rate	Estimated Cost
[redacted]	[redacted]	[redacted]	[redacted]

(b) (4)	Validation Engineer	1	2000	$	2 000.00	8

Controlled Environment and Auxiliary Equipment

	Job Title	Number of weeks	weekly rate	Estimated Cost
(b) (4)				

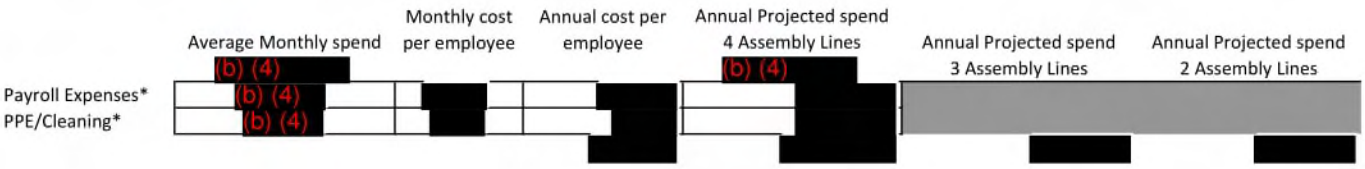
Estimated Direct Labor Costs for Implementation of Increasing Capacity to (b) (4) **Units** $ (b) (4)

Hours Required to Implement (b) (4)

$ (b) (4)

$ (b) (4)

Retractable Technologies, Inc.
Hazard Prevention/Infection Control



* Costs for at risk employees to stay at home (with pay) if exposed or sick, additional time paid time at each shift change to reduce contact, and social distancing measures (office separation, etc.)

** Masks, gloves, eyewear protection, face shields, hand sanitizer, heightened cleaning measures, etc.

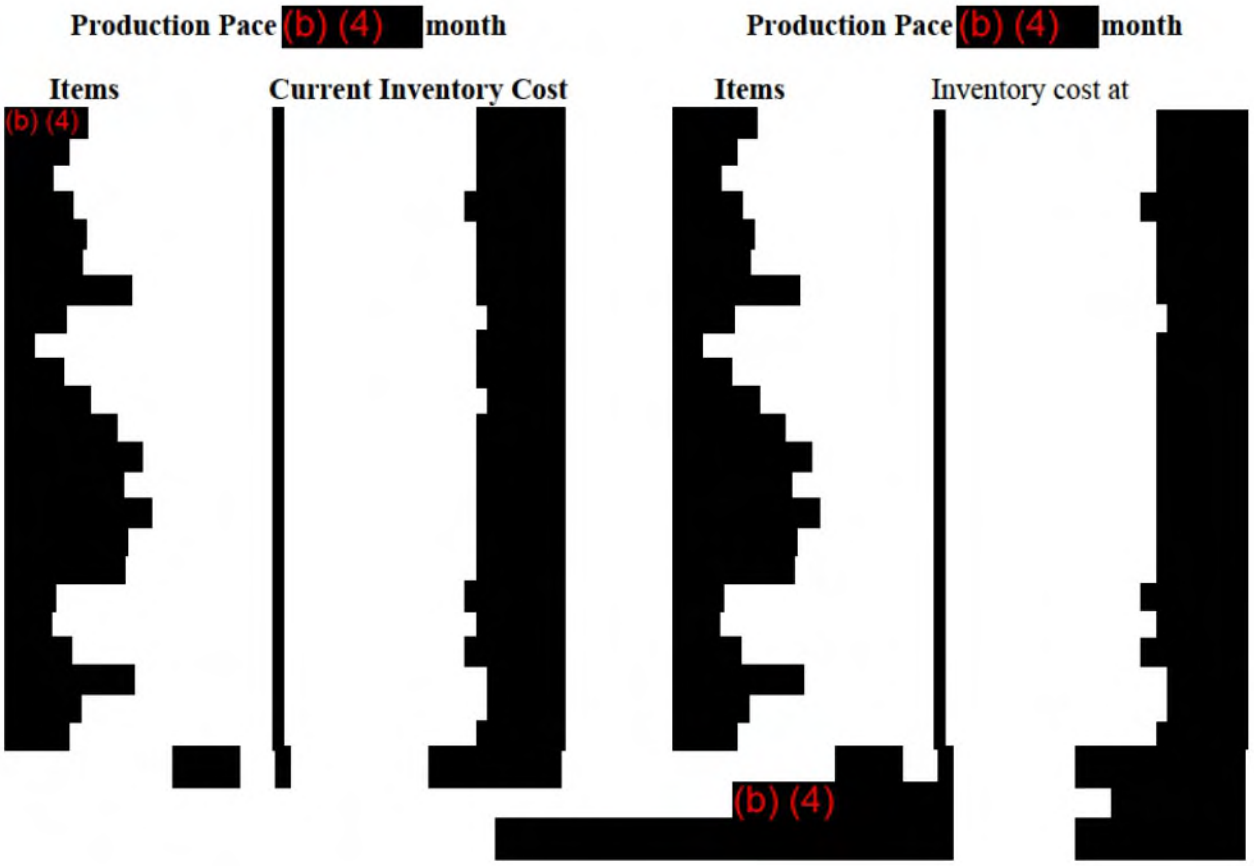
Confidential RTI
12-Jun-20

STATEMENTS OF OPERATIONS - USD ($)	12 Months Ended		
	Dec. 31, 2019	Dec. 31, 2018	Dec. 31, 2017
$41,797,179	$33,274,702	$34,493,838	
Cost of sales			
Cost of sales	27,659,223	23,052,900	24,522,250
Gross profit	14,137,956	10,221,802	9,971,588
Operating expenses:			
Sales and marketing	4,217,863	4,404,441	4,658,548
Research and development	516,095	621,365	740,567
General and administrative	6,432,158	6,786,041	8,351,053
Total operating expenses	11,166,116	11,811,847	13,750,168
Income from insurance proceeds		260,514	
Income (loss) from operations	2,971,840	-1,329,531	-3,778,580
Interest and other income	351,166	153,460	65,695
Interest expense	-166,897	-177,190	-210,761
Income (loss) before income taxes	3,156,109	-1,353,261	-3,923,646
Provision (benefit) for income taxes	7,875	-13,318	-187,608
Net income (loss)	3,148,234	-1,339,943	-3,736,038
Preferred stock dividend requirements	-702,618	-704,996	-704,996
Income (loss) applicable to common shareholders	$2,445,616	($2,044,939)	($4,441,034)
Basic earnings (loss) per share	$0.07	($0.06)	($0.14)
Diluted earnings (loss) per share	$0.07	($0.06)	($0.14)
Weighted average common shares outstanding:			
Basic (in shares)	32,672,475	32,666,454	31,958,121
Diluted (in shares)	32,672,475	32,666,454	31,958,121
Costs of manufactured product			
Cost of sales			
Cost of sales	$24,209,401	$20,108,798	$21,658,062
Royalty expense to shareholder			
Cost of sales			
Cost of sales	$3,449,822	$2,944,102	

Last 3 years of R/D Costs Average Cost over 5 years

$ (b) (4) [redacted] [redacted]

Retractable Technologies, Inc.
Raw materials and component parts summary



12-Jun-20

Travel Costs

Equipment	Trips	Days/Trip	Number of Destinations	Estimated Travel Costs
(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Detailed Engineer's Estimate and Project Cost

Agency: Town of Little Elm, Texas

Project Description: Lobo Lane Business Park

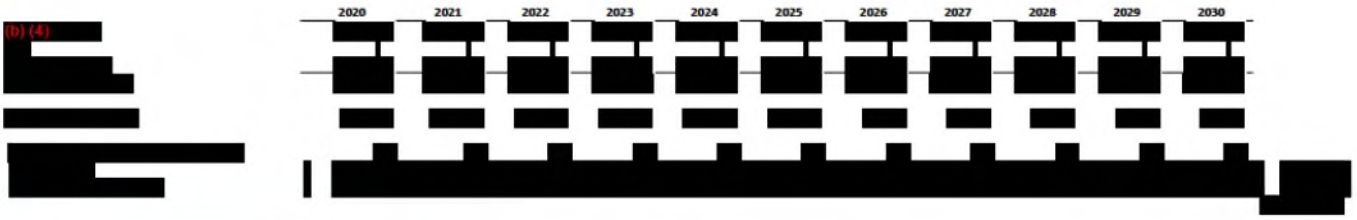
Project Location: Lobo Lane, Little Elm, Texas

Date of Estimate: June 4, 2020

Prepared by: (b) (6) [redacted]

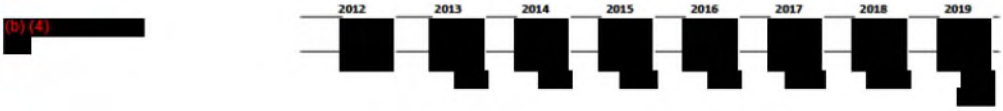
Item No.	Description	Quantity	Units	Unit Cost	Total	Local Match	Grant Request
1. Preliminary Engineering (PE)					$0.00		$0
[redacted]	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
2. Right-of-Way (ROW)					$0.00		
[redacted]	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
2.3	Utilities - none required for ROW category						
3. Construction					$0.00		
[redacted]	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]				[redacted]		
[redacted]	[redacted]				[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]		[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]		[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]				[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
4. Project Management					$0.00		
4.1	Project Management (Town staff time in-kind)				$0.00		
4.2	Grant Administration (Town staff time in-kind)				$0.00		
				(b) (4) [redacted]	[redacted]		
		0		**Contingency (10%):**			
					TOTAL: (b) (4) [redacted]		

Revised 6/17/2020

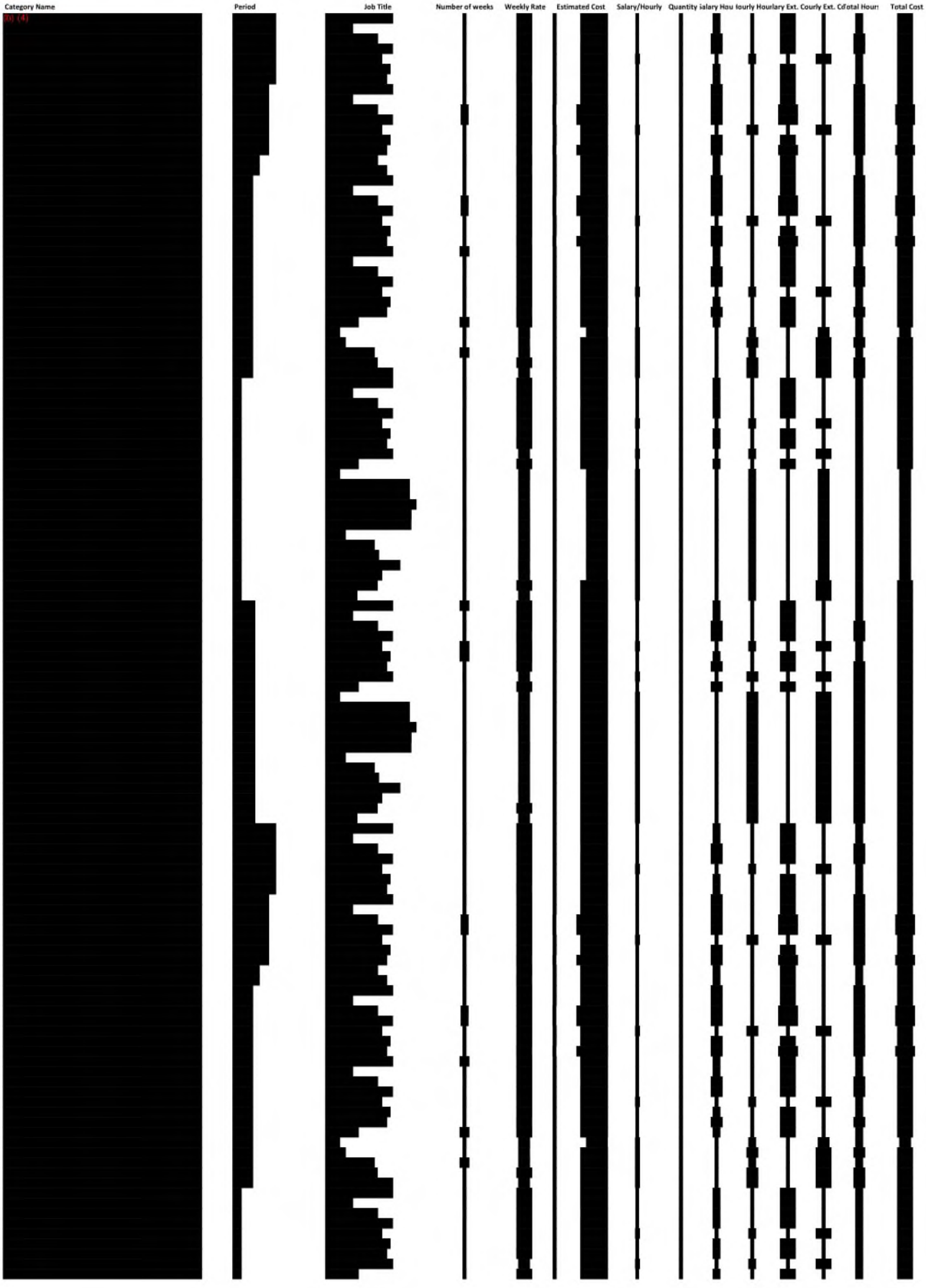


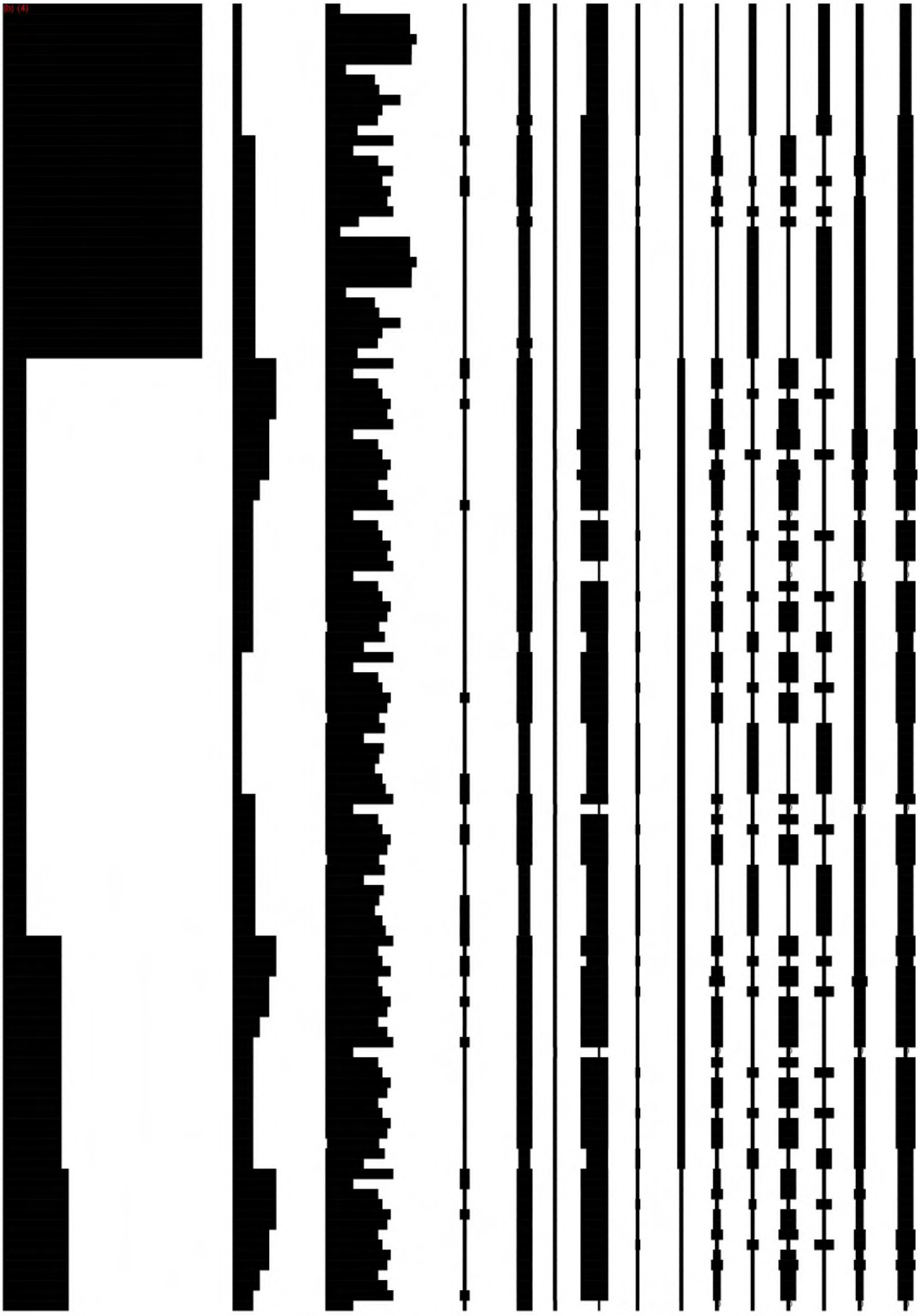
Row Labels	Sum of Estimated Cost	Sum of Yrly Depreciation
(b) (4)		

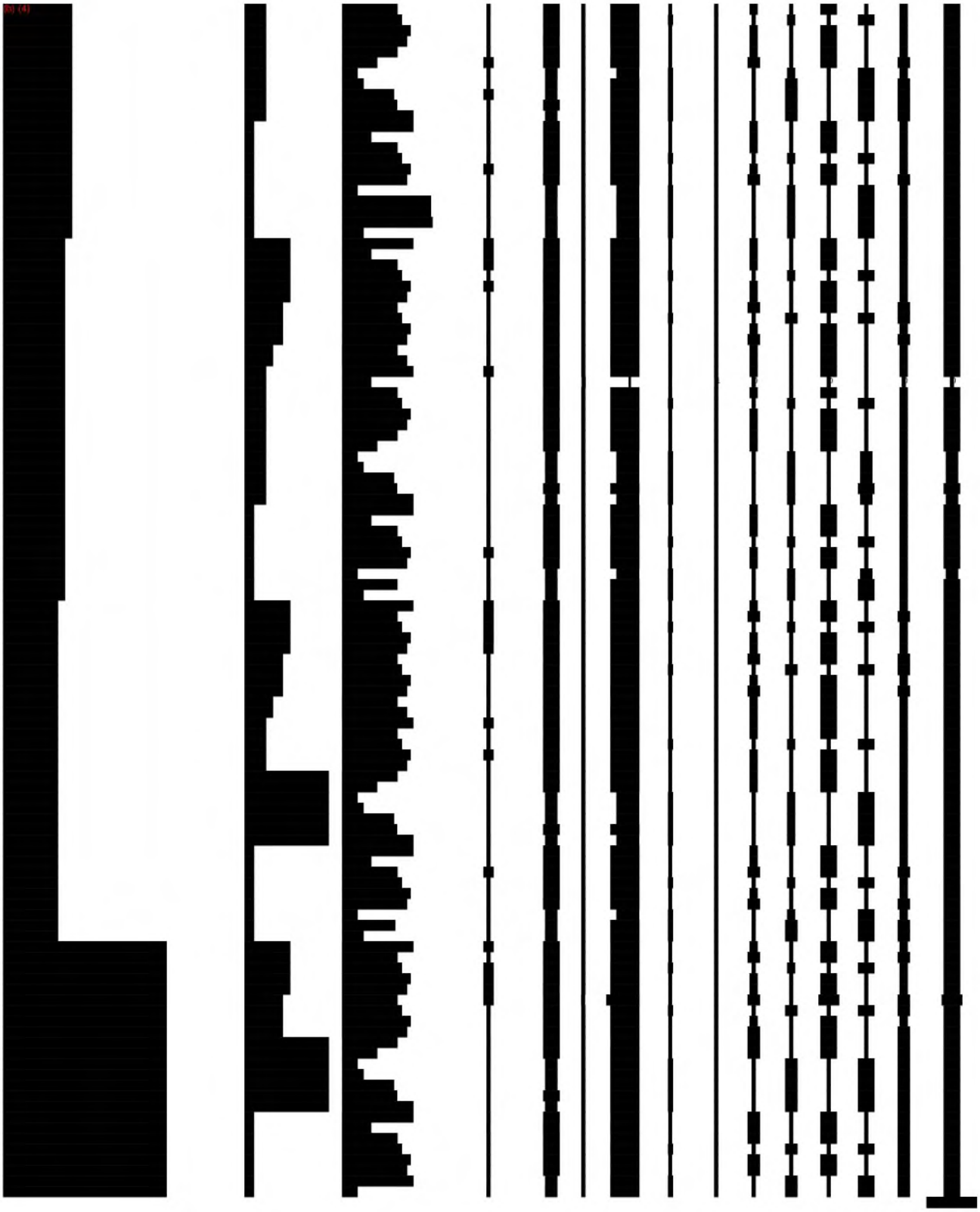
	2012	2013	2014	2015	2016	2017	2018	2019
Town of Little Elm	0.664971	0.664971	0.66497	0.661687	0.661687	0.657671	0.6499	0.6499
Little Elm ISD	1.54	1.54	1.54	1.54	1.54	1.54	1.64	1.5383
Denton County	0.282867	0.284914	0.2722	0.262	0.248409	0.237812	0.225574	0.225278
	2.487838	2.489885	2.47717	2.463687	2.450096	2.435483	2.515474	2.413478
		0.08%	-0.51%	-0.54%	-0.55%	-0.60%	3.28%	-4.05%



Estimated Direct Labor Hours with Costs to Implement Increasing Capacity Estimated 154 Million Units
Proposal for Modification







Certification Regarding Merchant Supplier – Defense Production Act, Title III

A. Definition of Merchant Supplier.

The term "merchant supplier" (also referred to as an "open-source supplier") is defined as a business concern that —

(a) is a production source which manufactures, supplies, and supports the use of its products by external customers independent of affiliation with internal or sister organizations; i.e., is not solely vertically integrated (restricted to supplying intra-company divisions, parent company, etc.);

(b) is committed to supporting a variety of specifications from eligible commercial and military customers;

(c) operates in a fair, equitable, and responsive manner under generally accepted business principles when responding to internal and external customers for commercial and military applications;

(d) does not, as a matter of policy, place restrictions or limitations on which eligible customers may buy or how they may subsequently use its products.

B. Other: The Merchant Supplier requirements are superseded by applicable regulations, including but not limited to ITAR.

C. Certifications.

(a) The Offeror certifies that it is a Merchant Supplier; and it will continue Merchant Supplier business practices for a minimum of 5 years after completion of this Defense Production Act, Title III investment.

(b) The Offeror certifies that it shall maintain the integrity of the competitive environment between all its customers, both internal and external, through demonstrated and documented processes that safe-guard all customer confidential sourcing information (such as specifications, order quantities, pricing, delivery schedules, financing agreements, etc.);

(c) The Offeror certifies that it will comply with Merchant Supplier audits, if requested and performed by the Defense Production Act, Title III Program Office.

As an authorized representative, I hereby make the above certifications on behalf of the offeror.

(b) (6)
Name/Title of Authorized Offeror Representative

(b) (6)
Signature of Authorized Offeror Representative

6 April 2021
Date

Certification Regarding Domestic Source – Defense Production Act, Title III

(a) **Definition of Domestic Source.**

The term ''domestic source'' means a business concern—

(1) that performs in the United States or Canada substantially all of the research and development, engineering, manufacturing, and production activities required of such business concern under a contract/agreement with the United States relating to a critical component or a critical technology item; and

(2) that procures from business concerns described in subparagraph (1) substantially all of any components and assemblies required under a contract/agreement with the United States relating to a critical component or critical technology item. Territories and Protectorates of the United States, and the District of Columbia are considered part of the domestic United States.

(b) **Other Related Definitions:**

Critical Component.—The term ''critical component'' includes such components, subsystems, systems, and related special tooling and test equipment essential to the production, repair, maintenance, or operation of weapon systems or other items of military equipment identified by the Secretary of Defense as being essential to the execution of the national security strategy of the United States. Components identified as critical by a National Security Assessment conducted pursuant to section 113(i) of title 10, United States Code, or by a Presidential determination as a result of a petition filed under section 232 of the Trade Expansion Act of 1962 shall be designated as critical components for purposes of this Act, unless the President determines that the designation is unwarranted.

Critical Technology.—The term ''critical technology'' includes any technology that is included in 1 or more of the plans submitted pursuant to section 6681 of title 42, United

States Code, or section 2508 of title 10, United States Code (unless subsequently deleted), or such other emerging or dual use technology as may be designated by the President.

Critical Technology Item.—The term ''critical technology item'' means materials directly employing, derived from, or utilizing a critical technology.

(c) Certifications. (1) The Offeror certifies that—

(i) In accordance with the Defense Production Act, Title III, the offeror hereby certifies that the company/corporation/organization they represent meets the definition of Domestic Source as shown above and in the Defense Production Act.

As an authorized representative, I hereby make the above certifications on behalf of the offeror.

(b) (6) [redacted]
Name/Title of Authorized Offeror Representative

(b) (6) [redacted]
Signature of Authorized Offeror Representative

6 April 2021
Date

(b) (6)

[redacted]

(b) (6)

[redacted]

(b) (6)

[redacted]

[redacted]

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