STATE OF NEW MEXICO BEFORE THE SECRETARY OF ENVIRONMENT

NEW MEXICO ENVIRONMENT DEPARTMENT RADIATION CONTROL BUREAU

No. RCB 20-65

Complainant,

v.

LOVELACE BIOMEDICAL RESEARCH INSTITUTE,

Respondent.

STIPULATED FINAL ORDER

Pursuant to the authority set forth under 20.1.5.600(B)(1) NMAC, the New Mexico Radiation Protection Act ("Act"), NMSA 1978, Sections 74-1-3 to -16 (1953, as amended through 2003), and the New Mexico Radiation Protection Regulations ("Regulations"), 20.3 NMAC, the Secretary of the New Mexico Environment Department ("Department") hereby issues this Stipulated Final Order to resolve the proceedings relating to Amended Administrative Order Requiring Compliance and Assessing a Civil Penalty No. RCB 20-65 ("Amended ACO").

Pursuant to 20.1.5.600(B)(1) NMAC, the Department and Lovelace Biomedical Research Institute ("LBRI") have entered into a Settlement Agreement which is attached as Exhibit 1. The Settlement Agreement resolves alleged statutory and regulatory violations of the Act and the Regulations, as described in the Amended ACO. For the purposes of this Stipulated Final Order, LBRI admits the jurisdictional allegations of the Amended ACO and consents to the relief specified in the Settlement Agreement. IT IS THEREFORE ORDERED that the Settlement Agreement is hereby approved, and

the parties shall comply with the terms and conditions of the Settlement Agreement, which is

hereby incorporated into this Stipulated Final Order.

Digitally signed by James Kenney Date: 2021.06.17 19:41:57 -06'00' By:

Date:

James C. Kenney Secretary New Mexico Environment Department

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing "Stipulated Final Order" was sent via certified mail return receipt requested [70190700000210184453] and via email to the following parties of record on June 18, 2021:

Madai Corral Hearing Clerk, New Mexico Environment Department 1190 St. Francis Drive, S-2103 P.O. Box 5469 Santa Fe, New Mexico 87502 madai.corral@state.nm.us Public.facilitation@state.nm.us

Henry M. Bohnhoff Cynthia A. Loehr Rodey, Dickason, Sloan, Akin & Robb, P.A. P.O. Box 1888 Albuquerque, New Mexico 87103 <u>hbohnhoff@rodey.com</u> <u>cloehr@rodey.com</u>

Mia Napolitano Digitally signed by Mia Napolitano Date: 2021.06.18 10:06:44 -06'00'

Mia A. Napolitano Assistant General Counsel New Mexico Environment Department

EXHIBIT 1

SETTLEMENT AGREEMENT

SETTLEMENT AGREEMENT Page 1 of 16

SETTLEMENT AGREEMENT

This Settlement Agreement is made by and between the New Mexico Environment Department ("Department") and Lovelace Biomedical Research Institute ("LBRI") (collectively, the "Parties") for the purpose of resolving the Amended Administrative Order Requiring Compliance and Assessing a Civil Penalty No. RCB 20-65 alleging violations of the New Mexico Radiation Protection Act ("Act"), NMSA 1978, Sections 74-3-1 to -16 (1953, as amended through 2003) and the New Mexico Radiation Protection Regulations ("Regulations"), 20.3 NMAC.

I. <u>BACKGROUND</u>

A. PARTIES

1. The Department is an agency of the executive branch of the State of New Mexico created pursuant to NMSA 1978, Section 9-7A-4 (2005).

2. The Department is charged with the administration and enforcement of the Act and the Regulations. NMSA 1978, § 74-1-7(A)(5) (2000).

3. The Environmental Protection Division ("Division") is an organizational unit of the Department. The Radiation Control Bureau ("Bureau") is an organizational unit of the Division.

4. Pursuant to the Delegation Order dated May 24, 2021, the Secretary of the Department has retained signatory authority to execute Settlement Agreements and Stipulated Final Orders.

5. Respondent is a domestic non-profit corporation incorporated in New Mexico with a mailing address of 2425 Ridgecrest Dr. SE, Albuquerque, NM 87108 ("Facility"). The Facility is located on a privately-owned parcel of land which is accessed through Kirtland Air Force Base.

SETTLEMENT AGREEMENT Page 2 of 16

6. During all times relevant to this Settlement Agreement, LBRI has held New Mexico Radioactive Material License Numbers BB496-07, BB496-8, and BB46-09 issued to LBRI on February 24, 2014, administratively amended on March 22, 2017, and again amended on August 20, 2020 ("License").

B. HISTORY AND ALLEGED VIOLATIONS

7. LBRI submitted its License application to the Bureau on December 20, 2013, due to a change in jurisdiction from the United States Nuclear Regulatory Commission ("NRC") License No. 30-29237-01 to the State of New Mexico. This change was made in response to a transfer of real property from the United States Department of Energy ("DOE"), Office of National Nuclear Security Administration to the Respondent on June 21, 2013 through a Quitclaim Deed.

8. Pursuant to LBRI's License condition #32, "[t]he licensee shall prepare a Decommissioning Plan in accordance with provisions in 20.3.3.318.H and the NRC guidance NUREG 1757 and shall submit the Decommissioning Plan ("DP") for Department approval by May 30, 2017."

9. On July 31, 2017, LBRI submitted its DP to the Bureau, which was prepared by CN Associates, Inc. ("CNA"), on behalf of LBRI. The DP also served as the decommissioning funding plan submittal as required by 20.3.3.311(A)(1) NMAC.

10. The July 31, 2017 DP contained a decommissioning cost estimate of \$8,485,253.00.

11. LBRI's current financial assurance instrument is an irrevocable Standby Letter of Credit with Bank of the West in the amount of \$1,500,000.00, executed on March 3, 2015 and received by the Bureau on March 4, 2015.

SETTLEMENT AGREEMENT Page 3 of 16

12. The Bureau identified potential violations of the Act and the Regulations because LBRI's financial assurance instrument for \$1,500,000.00 does not cover the decommissioning cost estimate of \$8,485,253.00.

13. The Department and LBRI met several times during 2017, 2018, and 2019 to discuss the potential violations.

14. During an announced inspection of LBRI's Facility on March 11 and 12, 2019, one of the Bureau inspectors requested LBRI's most recent waste disposal records.

15. Based on the inspection, the Bureau identified additional potential violations of the License, the Act, and the Regulations and on April 30, 2019, the Bureau issued a Notice of Violation ("NOV") to LBRI for failure to provide disposal records that each licensee is required to maintain pursuant to 20.3.3.326(A) NMAC, 20.3.4.448(A) NMAC, and 20.3.4.448(C) NMAC.

16. On May 9, 2019, LBRI provided a response to the April 30, 2019 NOV and claimed that the requested waste records were made available to Bureau staff and attached a copy of the radioactive waste disposal records it has on file.

17. The Parties tried to resolve the violations alleged in the April 30, 2019 NOV in 2019 and 2020.

18. On October 28, 2020, the Department issued an Administrative Order Requiring Compliance and Assessing a Civil Penalty No. RCB 20-65 ("ACO") to LBRI alleging two violations of the Regulations:

• Violation 1: Failure to comply with 20.3.3.311(E)(1)(f) and (g) NMAC and 20.3.3.311(F) NMAC by failing to provide a financial instrument in the amount of \$8,485,253.00.

Violation 2: Failure to comply with 20.3.3.311(G) NMAC, 20.3.3.326(A) NMAC, and 20.3.4.448(A) and (C) NMAC by failing to maintain records of information important to the decommissioning of the facility.

19. The ACO assessed a civil penalty of \$182,400.00 for Violation 1 and a civil penalty of \$42,600.00 for Violation 2.

20. On November 16, 2020, the Department issued an Amended Administrative Order Requiring Compliance and Assessing a Civil Penalty No. RCB 20-65 ("Amended ACO") clarifying LBRI's address and alleging the same violations and civil penalties as the ACO.

On December 17, 2020, LBRI filed a Request for Hearing and Answer to Amended
 ACO. LBRI denied the alleged violations and objected to the proposed civil penalties.

22. On December 22, 2020, the Office of Public Facilitation issued a Notice of Docketing and Order of Hearing and Appointment of Hearing Officer.

23. The Parties engaged in settlement discussions pursuant to 20.1.5.600(B) NMAC to determine if the issues raised in the Amended ACO could be resolved without a hearing.

24. On January 27, 2021, the Parties filed a Joint Motion to Stay Proceedings and Request a Time Waiver with the Office of Public Facilitation to seek an alternate resolution in this matter.

25. On January 29, 2021, the Hearing Officer issued an Order Granting Time-Waiver and Stay of Proceedings to seek an alternate resolution in this matter.

26. The Parties continued to engage in settlement discussions pursuant to 20.1.5.600(B) NMAC to determine if the issues raised in the Amended ACO could be resolved without a hearing.

SETTLEMENT AGREEMENT Page 5 of 16

27. On May 7, 2021, the Parties met with the Hearing Officer for a status conference. During that conference, the Hearing Officer set a hearing date and a deadline for settlement negotiations.

28. On May 10, 2021, the Hearing Officer issued a Scheduling Order which provided a hearing date of August 23, 2021 and a settlement deadline of June 15, 2021. The Scheduling Order also required the Parties to submit an affidavit demonstrating that Division Director Sandra Ely has endorsed a settlement agreement between the Parties on or before June 15, 2021 in order to vacate the August 23, 2021 hearing.

29. The Parties continued to engage in settlement discussions pursuant to 20.1.5.600(B) NMAC in order to seek an alternate resolution in this matter on or before the June 15, 2021 settlement deadline.

II. <u>COMPROMISE AND SETTLEMENT</u>

30. The Department and LBRI have engaged in settlement discussions in an effort to resolve the Amended ACO without further administrative or judicial enforcement action.

31. As a result of these discussions, the Department and LBRI have entered into this Settlement Agreement.

32. The Parties admit jurisdiction and consent to the terms and conditions specified herein.

C. CORRECTIVE ACTION

33. In compromise and settlement of the alleged violations set forth in the Amended ACO, and upon consideration of the seriousness of the alleged violations and LBRI's good faith

SETTLEMENT AGREEMENT Page 6 of 16

efforts to comply, the Parties agree to the following actions. The Parties will act in good faith and exercise best efforts to accomplish all of these steps as swiftly as possible:

- A. Interim Financial Assurance
 - Within 30 calendar days following the effective date of the Stipulated Final Order, LBRI shall increase its financial assurance from \$1,500,000.00 to \$3,628,110.00 pending CNA's issuance of an updated Decommissioning Funding Plan ("Updated DFP") and the Department's review and approval of same.
 - ii. The interim financial assurance can be in the form of a surety bond so long as the surety bond complies with 20.3.3.311(F)(2) NMAC.
 - iii. If LBRI elects to use a surety bond as its financial instrument for the interim financial assurance, the Department shall accept the surety bond, so long as the surety bond complies with 20.3.3.311(F)(2) NMAC. The Department will not unreasonably withhold approval, or delay approval, of the surety bond. LBRI may cancel the current \$1,500,000.00 Standby Letter of Credit after the Department receives and approves the \$3,628,110.00 surety bond. .
- B. Updated DFP
 - The Parties agree that CNA will serve as the third-party consultant and will prepare the Updated DFP which meets the requirements in 20.3.3.311(A) and (E) NMAC. The Updated DFP shall recalculate LBRI's financial assurance and verify LBRI's current inventory, license possession limits, and waste

disposition records to include the isotopes and activities identified in the onsite, site-specific characterization.

- CNA shall develop the Updated DFP by conducting an on-site, site-specific characterization of the License Facility and land. The Parties shall work with CNA to develop the Updated DFP.
- iii. The Parties and CNA shall begin developing a detailed scope of work ("SOW")
 for the on-site, site-specific characterization within 30 calendar days following
 the effective date of the Stipulated Final Order.
- iv. Within 120 calendar days following the effective date of the Stipulated Final Order, LBRI or CNA shall submit the finalized SOW to the Department for its review and approval prior to its implementation. The Department will not unreasonably withhold approval of the finalized SOW.
- v. The SOW must include the following:
 - a. On-site inspection of the entire Facility and land and sampling to identify all radioactive materials located at the Facility, including but not limited to, all radioactive materials located inside and outside any buildings located on the Facility, and all radioactive materials located in areas where LBRI performed animal testing utilizing radioactive materials. The purpose of the on-site inspection and sampling will be to identify and characterize all radioactive materials located at the Facility, including but not limited to, all locations where radioactive materials were used, transported, disposed of, or stored. The sampling

SETTLEMENT AGREEMENT Page 8 of 16 will exclude the Hot Ponds Site and the Sewage Lagoon Site which have been remediated by DOE. The sampling will be limited to the surface, however if any surveys or samples show elevated levels of alpha, beta, or gamma, then CNA will determine what additional investigation is necessary for the site-specific characterization.

- b. Inventory audit which includes a review and examination of LBRI's inventory records (manifests, records of receipt, transfer, and disposal) and the tracking of all manifests, isotope disposals, and transfers based on receipt of materials. The inventory audit will exclude records of DOE's original acquisition of radionuclides that it transferred to LBRI but will include the inventory records at the time of NRC's transfer of LBRI's NRC License No. 30-29237-01 to the Department License.
- vi. The Parties and CNA shall also develop a timeline to complete the on-site, sitespecific characterization and the work contained in the SOW, within 45 calendar days following the Department's approval of the SOW. The timeline must consider unforeseen issues that CNA may discover and must include biweekly (every two weeks) conference calls with the Parties and CNA to allow the Department to measure CNA's progress. If the Parties and CNA cannot meet for a conference call, the Parties and CNA may discuss LBRI's progress via email. The Parties shall work as swiftly as possible to meet the timeframes established in the timeline.

- vii. CNA and LBRI shall implement the Department approved SOW within 60 calendar days following receipt of the Department's approval.
- viii. Once CNA has completed the Department approved SOW and on-site, sitespecific characterization, CNA will issue an Updated DFP with a recalculated financial assurance amount.
- ix. As required by 20.3.3.311 NMAC, the Updated DFP shall be submitted to the Department for its review and approval.
- x. So long as CNA implements the Department-approved SOW for the on-site, site-specific characterization and the Updated DFP meets the requirements in 20.3.3.311(A) and (E) NMAC, the Department will not unreasonably withhold its approval of the Updated DFP.
- xi. Within 30 calendar days following the Department's approval of the Updated DFP, LBRI shall modify its financial instrument in order to meet the recalculated financial assurance amount outlined in the Updated DFP.
- xii. If the Updated DFP requires financial assurance in an amount that is greater than \$3,628,110.00 (LBRI's interim financial assurance) and LBRI fails to increase its financial instrument within 30 calendar days following the Department's approval of the Updated DFP, LBRI shall pay a stipulated penalty of \$5,000.00 per day for each day after the initial 30 calendar days following the Department's approval that it fails to increase its financial instrument to reflect the financial assurance requirement in the Updated DFP. LBRI shall not contest or dispute, in any way, the stipulated penalty of \$5,000.00 per day in

SETTLEMENT AGREEMENT Page 10 of 16 the event that the Department brings an action against LBRI for the failure to meet this requirement.

xiii. LBRI may use a surety bond as its financial instrument and the Department shall accept the surety bond so long as it complies with 20.3.3.311(F)(2)
 NMAC. The Department will not unreasonably withhold approval or delay approval of the surety bond.

C. License Amendment

- i. Following the Department's approval of the Updated DFP, LBRI shall submit, within 90 calendar days of the Department's approval, a license amendment request to amend its license possession limits based on the results of the Updated DFP.
- ii. The Department shall approve of LBRI's license amendment application within
 90 calendar days of LBRI's submittal of same, so long as the license amendment application complies with 20.3.3.320 NMAC.

D. CIVIL PENALTY

34. In compromise and settlement of the civil penalties set forth in the Amended ACO, LBRI shall pay a total civil penalty of \$100,000.00 to the State of New Mexico within thirty (30) calendar days after the effective date of the Stipulated Final Order.

35. Payment shall be made to the "State of New Mexico General Fund" by certified or corporate check and sent to the following address:

New Mexico Environment Department Radiation Control Bureau Attention: Santiago Rodriguez, Bureau Chief P.O. Box 5469

SETTLEMENT AGREEMENT Page 11 of 16

Santa Fe, New Mexico 87502-5469

36. If LBRI fails to make a timely and complete payment of the civil penalty, LBRI shall pay a stipulated penalty of \$250.00 per day for each day a payment is not timely or complete. LBRI shall not contest or dispute, in any way, the stipulated penalty of \$250.00 per day in the event that the Department brings an action against LBRI for the failure to make a timely or complete payment.

37. In agreeing to the compromise \$100,000.00 payment, and in agreeing to the Department's characterization of the payment as a "penalty," LBRI is not admitting or otherwise agreeing to any violation of statute, regulation, or license provision or other wrongdoing.

E. JURISDICTION AND AUTHORITY

38. The Department asserts jurisdiction and authority over the subject matter of this Settlement Agreement pursuant to the Act, Regulations, and the Department's Adjudicatory Procedures, 20.1.5 NMAC.

39. LBRI admits to the Department's jurisdiction and authority as set forth above, and consents to the terms and conditions specified herein.

40. The Department retains the right to enforce the Stipulated Final Order and Settlement Agreement by judicial action, which decision shall be in its sole discretion.

41. In the event that the Department elects to file a judicial action to enforce the Stipulated Final Order and Settlement Agreement, the Department and LBRI agree that the action shall be heard by the First Judicial District Court of Santa Fe County, New Mexico, that the First Judicial District Court of Santa Fe County, New Mexico shall have exclusive jurisdiction and

SETTLEMENT AGREEMENT Page 12 of 16

venue over such action, and LBRI waives any right to challenge such jurisdiction and venue in any forum.

42. The Department and LBRI agree that the laws of New Mexico shall govern the construction and interpretation of this Settlement Agreement and Stipulated Final Order.

F. BINDING EFFECT

43. The Stipulated Final Order and Settlement Agreement shall be binding upon the Department and LBRI, and their successor agencies, officers, directors, employees, agents, subsidiaries, successors, assigns, trustees, and receivers.

G. EFFECTIVE DATE

44. This Settlement Agreement shall become effective upon execution by both the Department and LBRI through their duly authorized representatives and upon the final approval of the Stipulated Final Order by the Secretary of the Department.

H. DURATION

45. This Settlement Agreement shall remain in effect until LBRI and the Department comply with its terms or the Settlement Agreement is terminated or modified by written agreement of the Parties.

I. INTEGRATION

46. This Settlement Agreement merges all prior written and oral communications between the Parties concerning the subject matter of this Settlement Agreement and contains the entire agreement between the Parties.

J. MODIFICATION

47. This Settlement Agreement shall not be modified except by express written agreement of the Department and LBRI.

K. RESERVATION OF RIGHTS AND DEFENSES

48. This Settlement Agreement shall not be construed to prohibit or limit the Department from requiring LBRI to comply with any applicable state or federal requirements.

49. This Settlement Agreement shall not be construed to prohibit or limit the Department from seeking any relief authorized by the Act or Regulations for a violation that is not resolved by this Settlement Agreement.

50. This Settlement Agreement shall not be construed to prohibit or limit LBRI from raising any defense to an action by the Department for a violation that is not resolved by this Settlement Agreement.

L. MUTUAL RELEASE AND DISMISSAL

51. This Settlement Agreement addresses all claims raised by or which could have been raised by the Department and LBRI against the other regarding the legal and factual allegations in the ACO and Amended ACO. Accordingly, the Department and LBRI mutually release each other from any and all claims arising from or relating to the allegations in the ACO and Amended ACO.

52. Upon execution of this Settlement Agreement and Stipulated Final Order, ACO No.20-65 will be dismissed.

M. LIABILITY

53. LBRI assumes all costs and liabilities incurred in performing any obligation under this Settlement Agreement.

SETTLEMENT AGREEMENT Page 14 of 16

54. The Department does not assume any liability for the performance of any obligation under this Settlement Agreement.

N. DISCLOSURE TO SUCCESSORS-IN-INTEREST

55. LBRI shall disclose this Settlement Agreement to any successor-in-interest to the company and shall advise such successor-in-interest that this Settlement Agreement is binding on the successor-in-interest until LBRI complies with the terms and conditions of this Settlement Agreement or such time as this Settlement Agreement is terminated by written agreement of the Department and LBRI.

O. FORCE MAJEURE

56. Force majeure shall not apply to this Settlement Agreement.

P. AUTHORITY OF SIGNATORIES

57. The persons executing this Settlement Agreement represent that they have the requisite authority to bind the Department and LBRI, as appropriate, to this Settlement Agreement, and that their representation shall be legally sufficient evidence of actual or apparent authority to bind the Department and LBRI to this Settlement Agreement.

Q. SIGNATURE AND COUNTERPARTS

58. This Settlement Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same agreement. Electronic or faxed signatures shall be deemed the same as the originals.

ENVIRONMENTAL PROTECTION DIVISION NEW MEXICO ENVIRONMENT DEPARTMENT

Digitally signed

By:

by James Kenney Date: 2021.06.17 19:40:52 -06'00'

Date:

James C. Kenney Secretary of Environment

LOVELACE BIOMEDICAL RESEARCH INSTITUTE

By:

Date: _____

Dr. Robert Rubin CEO for Lovelace Biomedical Research Institute

Approved as to form: Digitally signed by Mia Napolitano Date: 2021.06.18 10:06:03 -06'00'

Mia Napolitano Office of General Counsel New Mexico Environnent Department 1190 S. St. Francis Drive Santa Fe, NM 87502 *Attorney for Complainant*

Date:

Approved as to form:

Henry M. Bohnhoff Cynthia A. Loehr Rodey, Dickason, Sloan, Akin & Robb, P.A. P.O. Box 1888 Albuquerque, NM 87103 *Attorneys for Respondent*

Date:

SETTLEMENT AGREEMENT Page 16 of 16

ENVIRONMENTAL PROTECTION DIVISION NEW MEXICO ENVIRONMENT DEPARTMENT

By:

Date:

James C. Kenney Secretary of Environment

LOVELACE BIOMEDICAL RESEARCH INSTITUTE

0 By:

Dr. Robert Rubin CEO for Lovelace Biomedical Research Institute

Date: 6-18-2021

Approved as to form:

Mia Napolitano Office of General Counsel New Mexico Environnent Department 1190 S. St. Francis Drive Santa Fe, NM 87502 Attorney for Complainant Approved as to form: Cymthin a. Joehn

Henry M. Bohnhoff Cynthia A. Loehr Rodey, Dickason, Sloan, Akin & Robb, P.A. P.O. Box 1888 Albuquerque, NM 87103 Attorneys for Respondent

Date:

Date:

SETTLEMENT AGREEMENT Page 16 of 16

.