LAWRENCE
LIVERMORE
NATIONAL
LABORATORY

LLNL-TR-739177

Medical Isotope Program: O-18, C-13, and Xe-129 Final Report CRADA No. TC-2043-02

K. F. Scheibner, J. Fought

September 28, 2017

Disclaimer

This work performed under the auspices of the U.S. Department of Energy by Lawrence Livermore National Laboratory under Contract DE-AC52-07NA27344.

Medical Isotope Program: O-18, C-13, and Xe-129

Final Report
CRADA No. TC-2043-02
Date Technical Work Ended: May 1, 2006

Date: May 11, 2006 Revision: 0

A. Parties

This project was a relationship between Lawrence Livermore National Laboratory (LLNL) and Spectra Gases, Inc.

The Regents of the University of California
Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, CA 94550
Karl F. Scheibner
Tel: (925) 423-3138
Fax: (925) 423-8716

Spectra Gases, Inc.
3434 Route 22 West
Branchburg, NJ 08876
Jack Faught
Tel: (908) 252-9300
Fax: (908) 252-0811

B. Project Scope

This was a collaborative effort between the University of California, Lawrence Livermore National Laboratory (LLNL) and Spectra Gases, Inc., to develop new and cheaper sources of Oxgyen-18 (O-18), Carbon-13 (C-13), and Xenon-129 (Xe-129), and to develop new applications of these stable medical isotopes in medicine resulting in a substantial increase in stable isotopes that are important to human health sciences.

As the project developed, the scope was modified to build additional world production enrichment capacity for the stable, health-significant isotopes O18 and C13 only. The interest in Xe129 waned once the market study had been conducted. It was decided to concentrate the project resources on oxygen and carbon isotopes. Work was to be conducted at the Kurchotov Institute in Moscow, employing Kurchotov employees who had previously worked on weapons of mass destruction. The goal was to create additional world capacity of these Health-Critical isotopes, produce a sustainable income stream and provide alternative, steady and permanent (non-WMD) employment for the relevant Kurchotov employees. Prior to the project, the industrial partner, Spectra Gases, Inc. (SGI) had invested significantly in building this additional

capacity, but strictly with their own funds. The schedule kept slipping and deliverables were not being met. As a result, SGI turned to the IPP program for assistance. With the additional funds that SGI put up, matching the IPP funds, and strong project management, the IPP project was very successful. The project was completed on time and all the major deliverables met. These included monthly progress reports, bi-annual meetings (either in New Jersey at SGI headquarters, or at Kurchotov) and the hardware for doing the isotope enrichment was designed, built, tested, and made operational all under the IPP project. By the time the project concluded, the separation equipment was just beginning to come on line and production was beginning to ramp up.

This CRADA resulted from an IPP proposal funded through DOE to further its non-proliferation goals. This collaborative effort also included the Kurchotov Institute in Moscow, Russia through the Russian company, Cryocarbon, Ltd.

LLNL was primarily responsible for administering and monitoring the contract, both in terms of technical progress, as well as, costs and schedules. In addition, LLNL was responsible for developing the enrichment and optimizations models, as well as providing technical review, oversight, and consultations.

Spectra Gases, Inc. was primarily responsible for providing the marketing expertise and experience, and engineering know-how and guidance. In addition, Spectra Gases was responsible for insuring good business standards of their Russian Partners, in terms of accounting, and market relevance, as well as direct and in-kind matching support.

The Kurchatov Institute provided the majority of the hardware, technical expertise and engineering, as well as, the production sites and related support.

The major deliverables were as follows:

1. O-18 Enrichment
    - 1.1 Report on O-18 packing results (Kurchatov) and model predictions (LLNL)
    - 1.2 Commitment to build O-18 columns (Spectra Gases)
    - 1.3 Begin production of enriched O-18 (Kurchatov)
    - 1.4 Review developed operating point for greater than eighty percent (80%) O-18 production (Spectra Gases and LLNL)
    - 1.5 Report on economic viability of greater than eighty percent (80%) O-18 (Spectra Gases and LLNL)
    - 1.6 Final O-18 report and commercialization plan (Spectra Gases and LLNL)

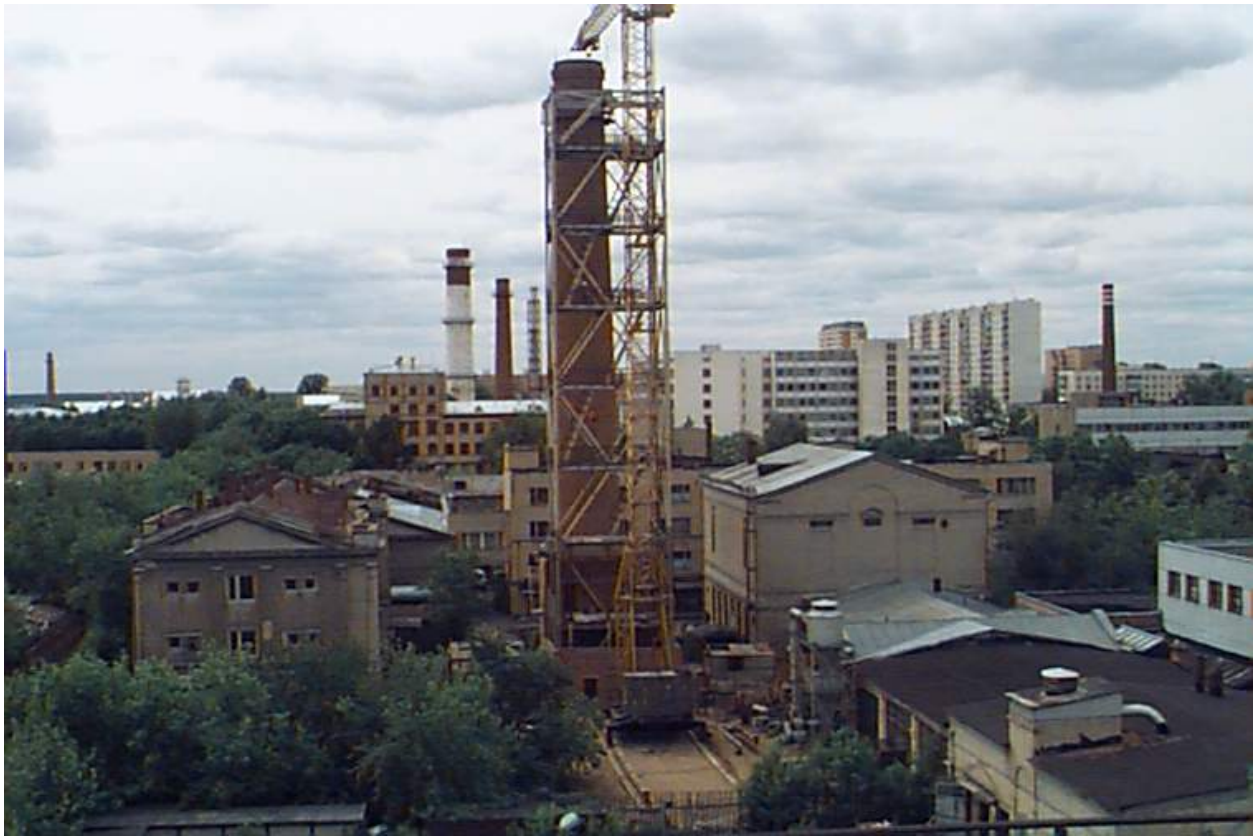
2. C-13 Enrichment
    - 2.1 Activate C-13 columns and begin enriched C-13 production (Kurchatov)
    - 2.2 Report on first stage C-13 enrichment (Kurchatov)
    - 2.3 Report on measured performance versus modeled performance (Kurchotov)
    - 2.4 Report on predicted economic viability of second C-13 stage (Kurchotov and LLNL)
    - 2.5 Final deployment decision of second C-13 MPD decision (Spectra Gases)

2.6 Update and report performance models (Spectra Gases and LLNL)
2.7 Final C-13 report and commercialization plan (Spectra Gases and LLNL)
2.8 Measure and report sensitivity of IRMS with membranes for breath analyzer (Kurchatov)
2.9 Measure and report spectroscopic selectivity of photolysis of methanal (LLNL)
2.10 Measure and report enrichment factor of static cell photolysis of methanal (LLNL)
2.11 Develop and report conceptual design of methanal enrichment system (LLNL)
2.12 Develop and report preliminary design of methanal enrichment system (LLNL)
2.13 Final report and commercialization plan for prototyped analyzer (Spectra Gases and LLNL)

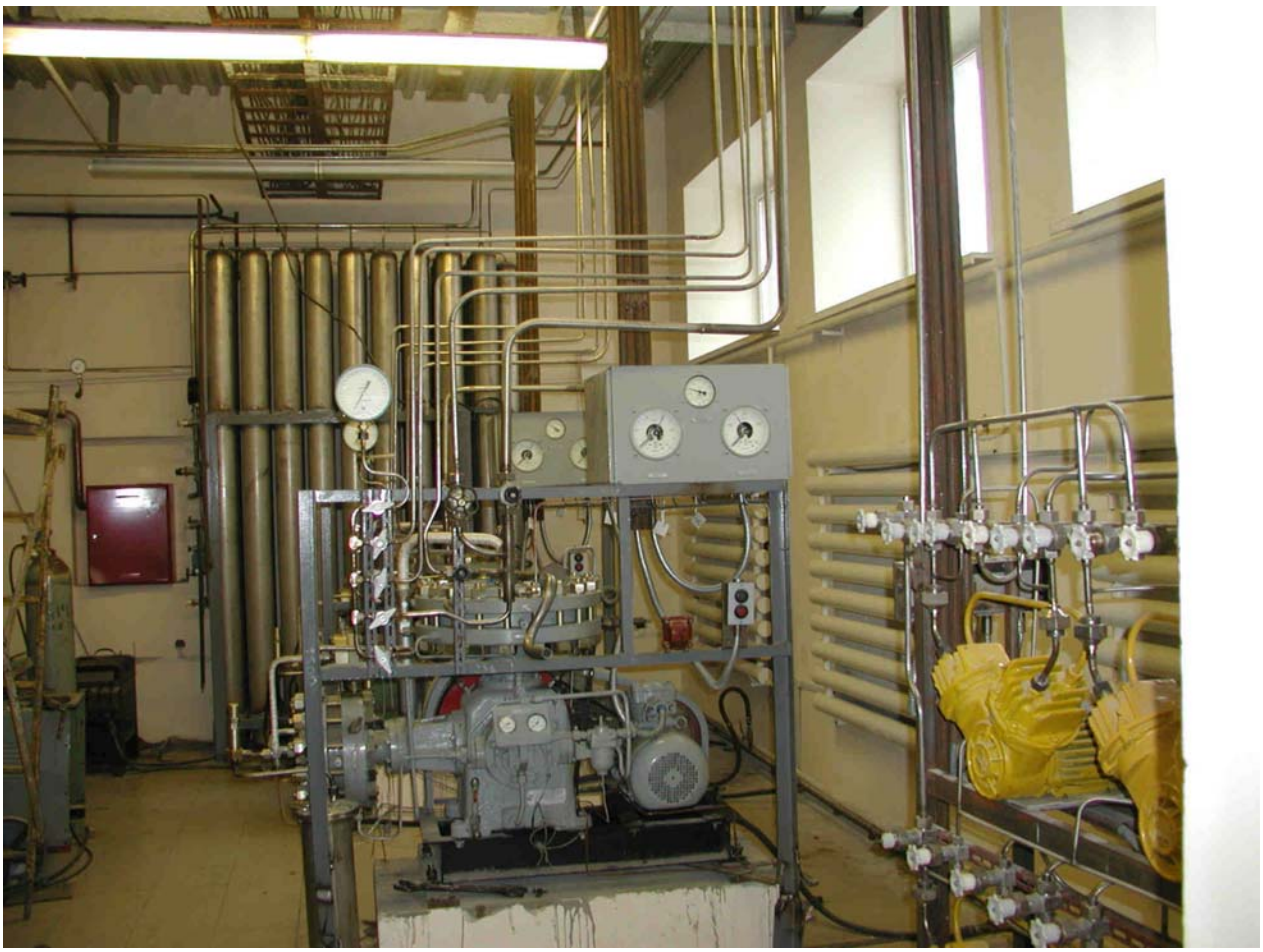
The deliverables for isotopes O-18, and C-13 were successfully completed. However, as mentioned, the tasks and deliverables for Xe-129 were not accomplished due to undeveloped markets.

C. Technical Accomplishments

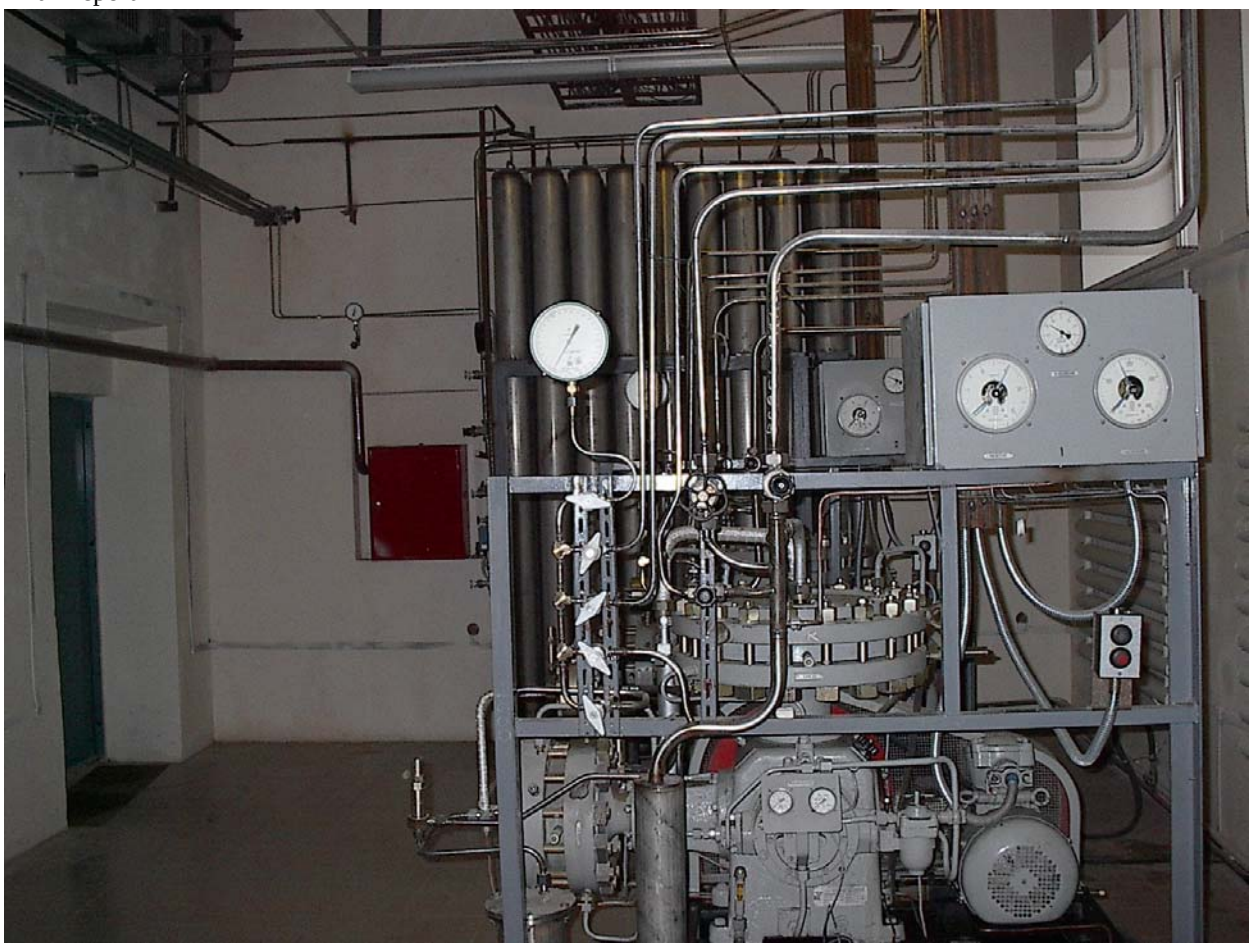
Additional world capacity for both O-18 and C-13 were successfully built. Below are a few pictures from the Kurchotov Institute showing some of the hardware.



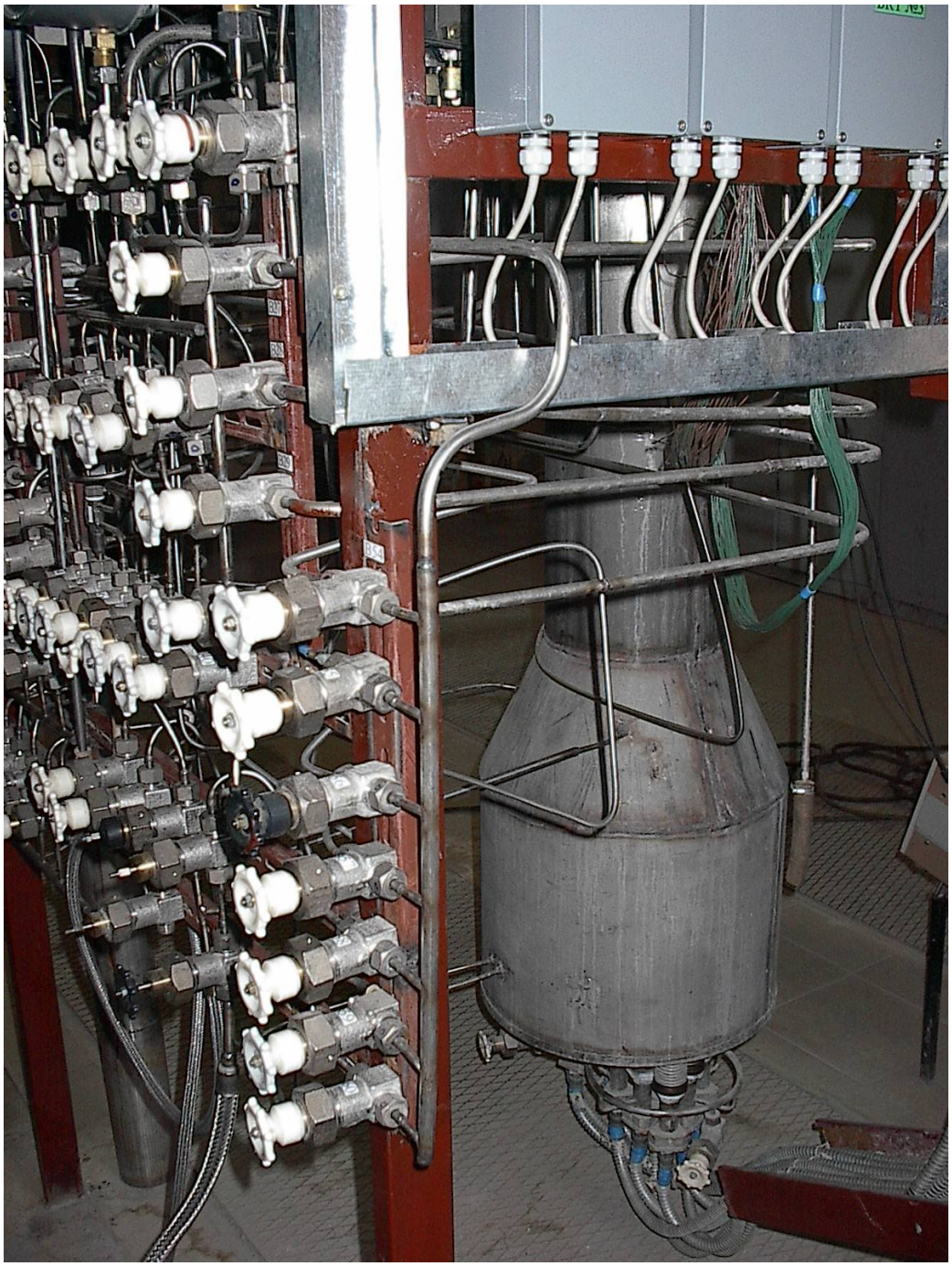
Picture 1: View of the cryogenic distillation tower at the Kurchotov Institute for isotopic separation of the carbon isotopes through the cryogenic distillation of CO.



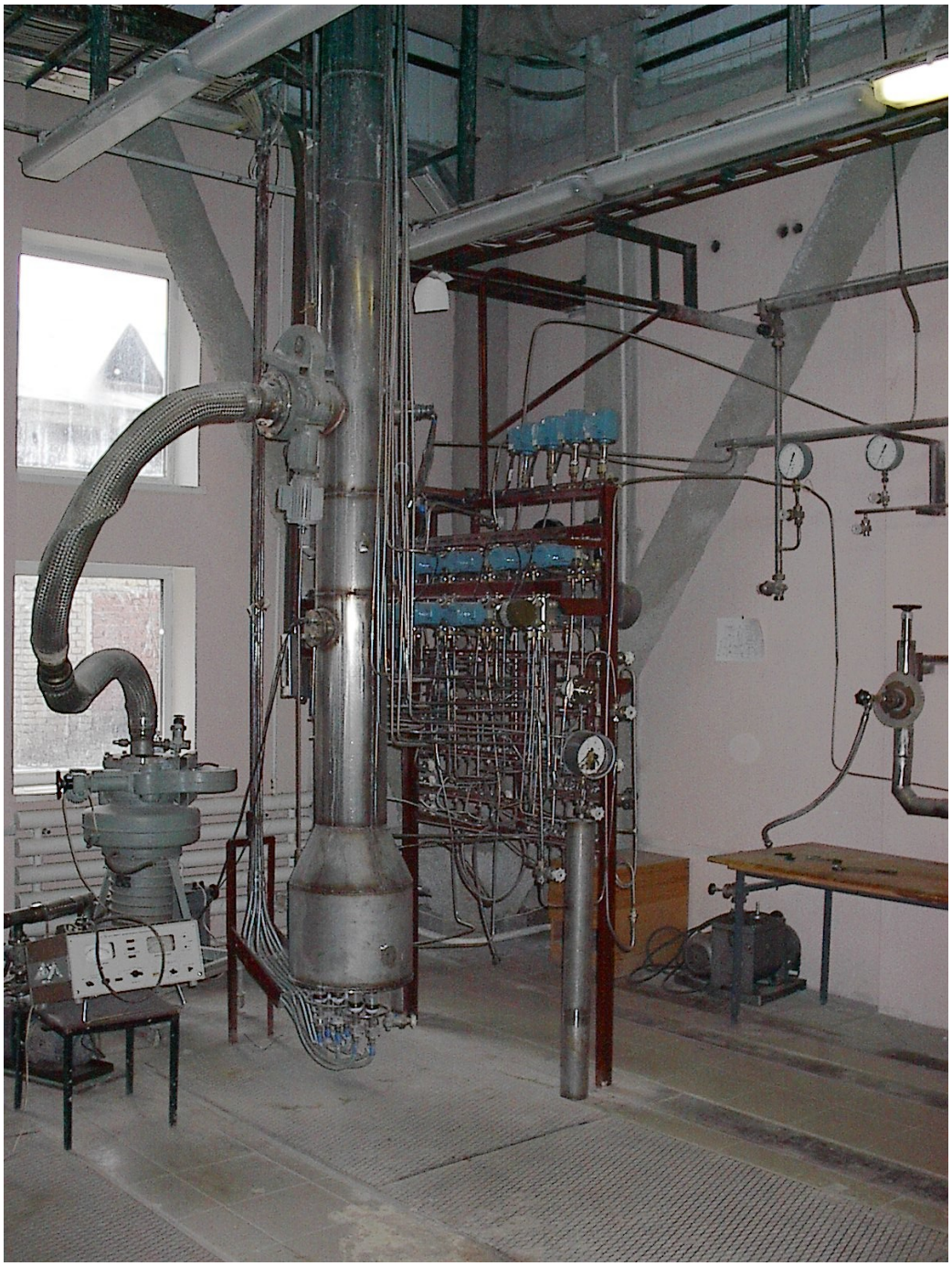
Picture 2: Pumps for circulating the Liquid Nitrogen coolant for the distillation of CO.



Picture 3: Pumps and gauges used to monitor and control the circulation of water vapor for the isotopic separation of O16 from O12.

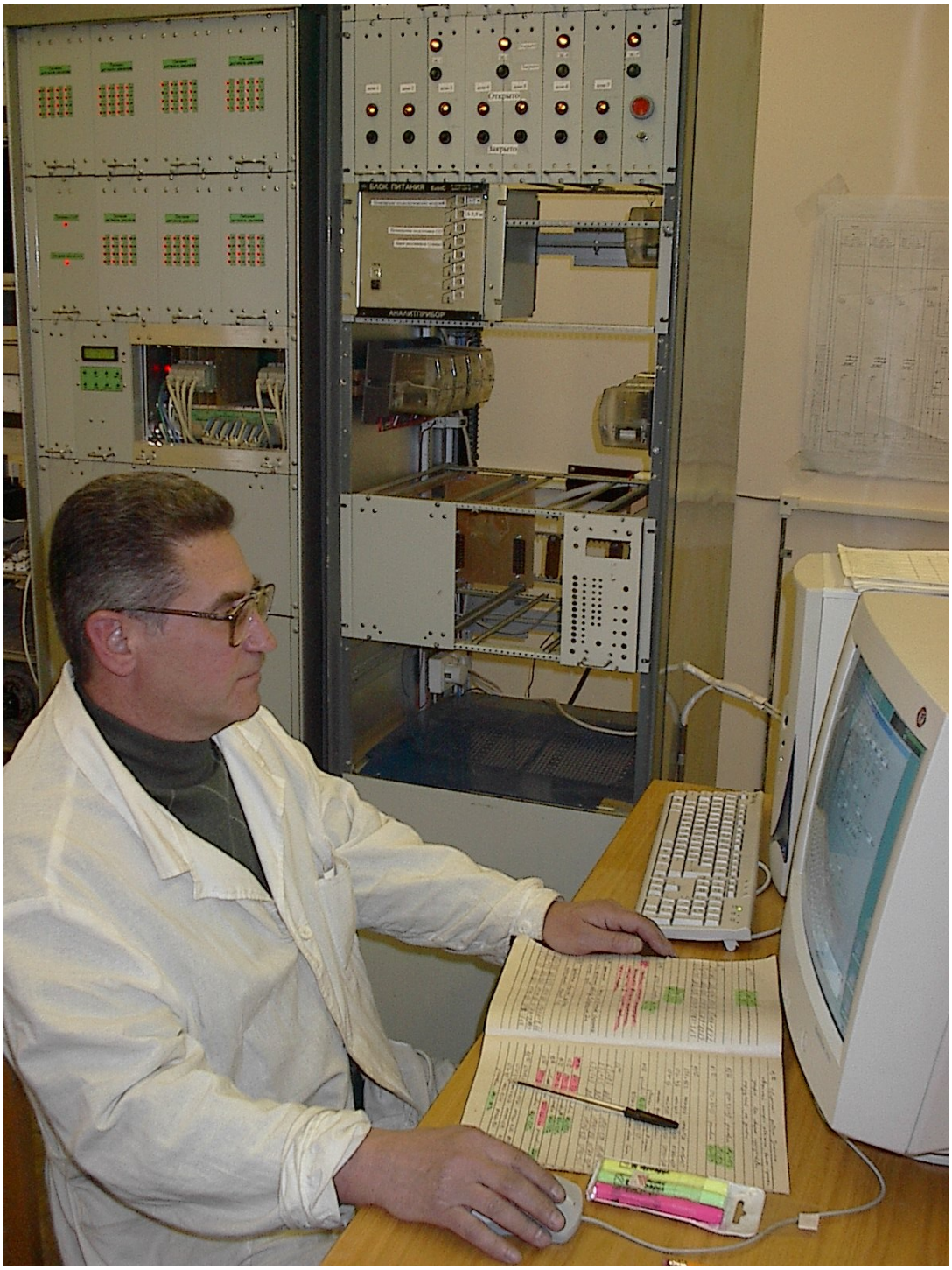


Picture 4: Water vapor condensor for the first stage of isotopic separation using the slight isotopically sensitivity of the rates of boiling between O-16H2 andO-12H2 to effect the isotope separation.



Picture 5: Distant view of water vapor condensor.

Picture 6: Hardware for making packing materials for the distillation columns.



Picture 7: Control system for process control, process integration and process evaluation

As can be seen in the above photos, production capacity was built, resulting in a) increased world capacity of C-13 and O-18, b) a steady income stream resulting from sales, and c) permanent jobs for Kurchotov Institute employees who had previously worked on WMDs.

D. Expected Economic Impact

As a result of this effort, and a steady income stream resulting from sales of health critical isotopes has been created, paying for permanent jobs, and allowing Kurchotov Institute personnel to consider other investments into health care technologies.

D.1 Specific Benefits

Benefits to DOE

This CRADA is consistent with and furthers DOE's goals for proliferation prevention.

Benefits to Industry

This CRADA leveraged earlier and substantial investments by a US company that was substantially at risk for being lost. The IPP funds facilitated the completion of the project that netted permanent jobs at Kurchotov for employees formerly working on WMD, a steady income stream, and a financially attractive new source of isotopes for the industrial partner.

E. Partner Contribution

[Summarize the major project contributions by the industrial partner(s) including results of their activities. If the deliverables have been met, and the Industrial Participant(s) plans to manufacture the product, or add additional amounts for marketing, etc., that information should also be included. In this section also include a positive affirmation that no subject inventions were created during the CRADA project or provide a list of such inventions disclosed by the industrial partner.]

The major project contributions by the industrial partner were, 1) Project Management, 2) Administrative Support, 3) financial contributions to salaries, operating support, startup, equipment, etc., 4) market analysis, 5) sales and marketing, and 6) projection of new business opportunities. A separate agreement between the industrial partner and the Kurchatov Institute was formalized whereby the production at Kurchotov would be sold to Spectra Gases at some (unknown to me) price and time frame. There were no subject inventions created during this CRADA.

F. Documents/Reference List

Reports
None

Copyright Activity
None

Subject Inventions

There were no subject inventions disclosed for this project.

Background Intellectual Property

There was no BIP disclosed for this project.

G. Acknowledgement

Industrial Participant's signature of the final report indicates the following:

1) The Participant has reviewed the final report and concurs with the statements made therein.
2) The Participant agrees that any modifications or changes from the initial proposal were discussed and agreed to during the term of the project.
3) The Participant certifies that all reports either completed or in process are listed and all subject inventions and the associated intellectual property protection measures generated by his/her respective company and attributable to the project have been disclosed and included in Section E or are included on a list attached to this report.
4) The Participant certifies that if tangible personal property was exchanged during the agreement, all has either been returned to the initial custodian or transferred permanently.
5) The Participant certifies that proprietary information has been returned or destroyed by LLNL.

Jack Faught — Date
Spectra Gases, Inc.

10/16/06

Karl F. Scheibner, LLNL PI — Date
Lawrence Livermore National Laboratory

10/24/06

Karena D. McKinley, IPAC Director — Date
Lawrence Livermore National Laboratory

Attachment I – Final Abstract

Industrial Partnerships and Commercialization

Mail Station L-795

Ext. 2-6416

Fax 3-8988

October 16, 2006
85606.10ljs

MEMORANDUM

To: Memo to File

From: Lori Straley

Subject: Spectra Gases, Inc. CRADA Final Report – TC-2043-02

The CRADA Final Report for TC-2043-02, Spectra Gases, Inc., has been submitted for review and signature without the partner's signature. This is in accordance with DOE procedures.

The first letter and final report were sent to the partner on July 31, 2006 for signature. When response was not received, a voice message inquiry was left with the partner on August 25, 2006 regarding the status the CRADA Final Report. The partner did not respond to the inquiry and a second letter was send on August 29, 2006 indicating if the signed report was not received by September 14, 2006 we were planning to proceed with the signature process. As of October 16, 2006, the signed final report has not been received.

University of California

LAWRENCE LIVERMORE NATIONAL LABORATORY

Medical Isotope Program: o-18, C-13, and Xe-129

Final Abstract (Attachment I)
CRADA No. TC-2043-02
Date Technical Work Ended: May 1, 2006

Date: May 11, 2006 Revision: 0

A. Parties

This project was a relationship between Lawrence Livermore National Laboratory (LLNL) and Spectra Gases, Inc.

The Regents of the University of California
Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, CA 94550
Karl F. Scheibner
Tel: (925) 423-3138
Fax: (925) 423-8716

Spectra Gases, Inc.
3434 Route 22 West
Branchburg, NJ 08876
Jack Faught
Tel: (908) 252-9300
Fax: (908) 252-0811

B. Purpose and Description

This was a collaborative effort between the University of California, Lawrence Livermore National Laboratory (LLNL) and Spectra Gases, Inc., to develop new and cheaper sources of Oxgyen-18 (O-18), Carbon-13 (C-13), and Xenon-129 (Xe-129), and to develop new applications of these stable medical isotopes in medicine resulting in a substantial increase in stable isotopes that are important to human health sciences.

As the project developed, the scope was modified to build additional world production enrichment capacity for the stable, health-significant isotopes O18 and C13 only. The interest in Xe129 waned once the market study had been conducted. It was decided to concentrate the project resources on oxygen and carbon isotopes. Work was to be conducted at the Kurchotov Institute in Moscow, employing Kurchotov employees who had previously worked on weapons of mass destruction. The goal was to create additional world capacity of these Health-Critical isotopes, produce a sustainable income stream and provide alternative, steady and permanent (non-WMD) employment for the relevant Kurchotov employees. Prior to the project, the industrial partner, Spectra Gases, Inc. (SGI) had invested significantly in building this additional capacity, but strictly with their own funds. The schedule kept slipping and deliverables were not being met. As a result, SGI turned to the IPP program for assistance. With the additional funds

that SGI put up, matching the IPP funds, and strong project management, the IPP project was very successful. The project was completed on time and all the major deliverables met. These included monthly progress reports, bi-annual meetings (either in New Jersey at SGI headquarters, or at Kurchotov) and the hardware for doing the isotope enrichment was designed, built, tested, and made operational all under the IPP project. By the time the project concluded, the separation equipment was just beginning to come on line and production was beginning to ramp up.

This CRADA resulted from an IPP proposal funded through DOE to further its non-proliferation goals. This collaborative effort also included the Kurchotov Institute in Moscow, Russia through the Russian company, Cryocarbon, ltd.

LLNL was primarily responsible for administering and monitoring the contract, both in terms of technical progress, as well as, costs and schedules. In addition, LLNL was responsible for developing the enrichment and optimizations models, as well as providing technical review, oversight, and consultations.

Spectra Gases, Inc. was primarily responsible for providing the marketing expertise and experience, and engineering know-how and guidance. In addition, Spectra Gases was responsible for insuring good business standards of their Russian Partners, in terms of accounting, and market relevance, as well as direct and in-kind matching support.

The Kurchatov Institute provided the majority of the hardware, technical expertise and engineering, as well as, the production sites and related support.

The major deliverables were as follows:

1. O-18 Enrichment
   - 1.1 Report on O-18 packing results (Kurchatov) and model predictions (LLNL)
   - 1.2 Commitment to build O-18 columns (Spectra Gases)
   - 1.3 Begin production of enriched O-18 (Kurchatov)
   - 1.4 Review developed operating point for greater than eighty percent (80%) O-18 production (Spectra Gases and LLNL)
   - 1.5 Report on economic viability of greater than eighty percent (80%) O-18 (Spectra Gases and LLNL)
   - 1.6 Final O-18 report and commercialization plan (Spectra Gases and LLNL)

2. C-13 Enrichment
   - 2.1 Activate C-13 columns and begin enriched C-13 production (Kurchatov)
   - 2.2 Report on first stage C-13 enrichment (Kurchatov)
   - 2.3 Report on measured performance versus modeled performance (Kurchotov)
   - 2.4 Report on predicted economic viability of second C-13 stage (Kurchotov and LLNL)
   - 2.5 Final deployment decision of second C-13 MPD decision (Spectra Gases)
   - 2.6 Update and report performance models (Spectra Gases and LLNL)
   - 2.7 Final C-13 report and commercialization plan (Spectra Gases and LLNL)
   - 2.8 Measure and report sensitivity of IRMS with membranes for breath analyzer (Kurchatov)

2.9 Measure and report spectroscopic selectivity of photolysis of methanal (LLNL)
2.10 Measure and report enrichment factor of static cell photolysis of methanal (LLNL)
2.11 Develop and report conceptual design of methanal enrichment system (LLNL)
2.12 Develop and report preliminary design of methanal enrichment system (LLNL)
2.13 Final report and commercialization plan for prototyped analyzer (Spectra Gases and LLNL)

The deliverables for isotopes O-18, and C-13 were successfully completed. However, as mentioned, the tasks and deliverables for Xe-129 were not accomplished due to undeveloped

C. Benefit to Industry

This CRADA leveraged earlier and substantial investments by a US company that was substantially at risk for being lost. The IPP funds facilitated the completion of the project that netted permanent jobs at Kurchotov for employees formerly working on WMD, a steady income stream, and a financially attractive new source of isotopes for the industrial partner.

D. Benefit To DOE/LLNL

This CRADA is consistent with and furthers DOE's goals for proliferation prevention.

E. Project Dates

May 1, 2002 through May 1, 2006