



IGEMs/HERC Project Status Report
Idaho Incubation Fund Program
Mid Year Progress Report
December 31, 2013

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| Proposal No. | AHRC03 |
| P.I. Name: | Dr. Alan Hunt |
| Name of Institution: | Idaho State University/ Idaho Accelerator Center |
| Project Title: | Development of Commercially viable accelerator produced Isotopes |

Proprietary Information – not for public review

Executive Summary:

During the first half of FY2014 the IGEMs/HERC funded project **Development of Commercially Viable Accelerator Produced Isotopes**, the ISU/IAC team achieved substantial progress in the goal of providing a commercial supply of ⁶⁷Cu to the market. The key successes included:

- 1) Completed design, installation and testing of a new high power target system with automated sample removal
- 2) Completed installation and testing of the ICP-MS product quality verification tool at International Isotopes Inc. our private sector development partner.
- 3) Filed necessary paperwork with the NRC for a production shipment license.
- 4) Tested production at 3 kW of beam power creating the highest activity product to date
- 5) Further refined the separation and purification methods
- 6) Started work on invention disclosures for separation methods

FINANCIAL SUMMARY

| Project Budget/Financial Status as of December, FY 2014 | | | |
|---|---------|----------------------|--|
| Budget Item | Budget | Actual spend to date | Variance/Explanation |
| Salary + Tuition + Fringe | 284,500 | 132,251 | On spend plan |
| Travel expenses | 7,500 | 64 | Expected to increase when shipments begin to customers |
| Materials, services, Beam time and other expenses | 223,600 | 100,468 | Below budgeted spend |
| Total | 515,600 | 232,783 | |

Participants

During this period, the following personnel were partially or completely funded by this project:

Principal Investigator (Faculty)

Three Accelerator, mechanical and electrical engineers (IAC staff)

Radio-Chemist (IAC staff)

PhD Student

Researcher/ Program Manager/Business Development (IAC contractor)

OVERALL GOALS

This is the mid year status report for FY 2014 of the IGEMs funded project, **Development of commercially viable accelerator produced isotopes**. Our overall goals are to establish a **commercially viable, profitable and intellectual property protected** method of producing medical isotopes – initially the cancer therapy isotope ^{67}Cu . In addition, we want to **train a workforce** capable of producing medical isotopes and **establish production in Idaho** with a private sector partner.

PROJECT STATUS REPORT – Key Successes

For the period ending December 31th, 2013, (1H FY 2014), the following items were completed against the project plan:

1) Completed design, testing and installation of a high power target system with automated removal

Previously, our target system used air-cooling and a manual method to extract the target after irradiation. While air-cooling was adequate for up to 2 kW of beam power, higher power was needed for production quantities of isotope. As well, an automated system was necessary to remove the target and place it in a shielded container (i.e. a lead “pig”) for transportation. The automation protects the workers from high radiation doses in the activation cell and allows quicker access for transportation of the product. Figures 1, 2 and 3 show components of the cooling and transport system.



Figure 1 Water cooled target system inside the shielded activation area.

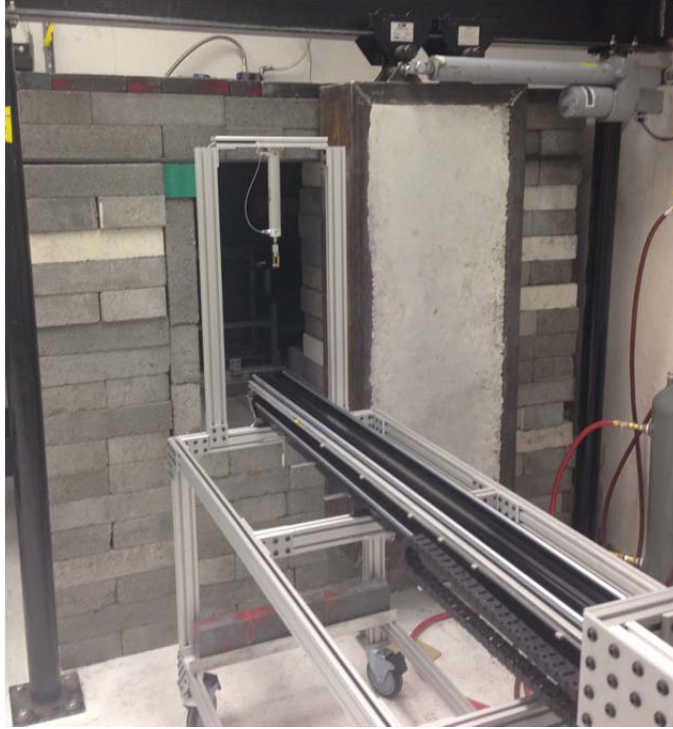


Figure 2 Transport system that removes target from activation area in lead "pig"

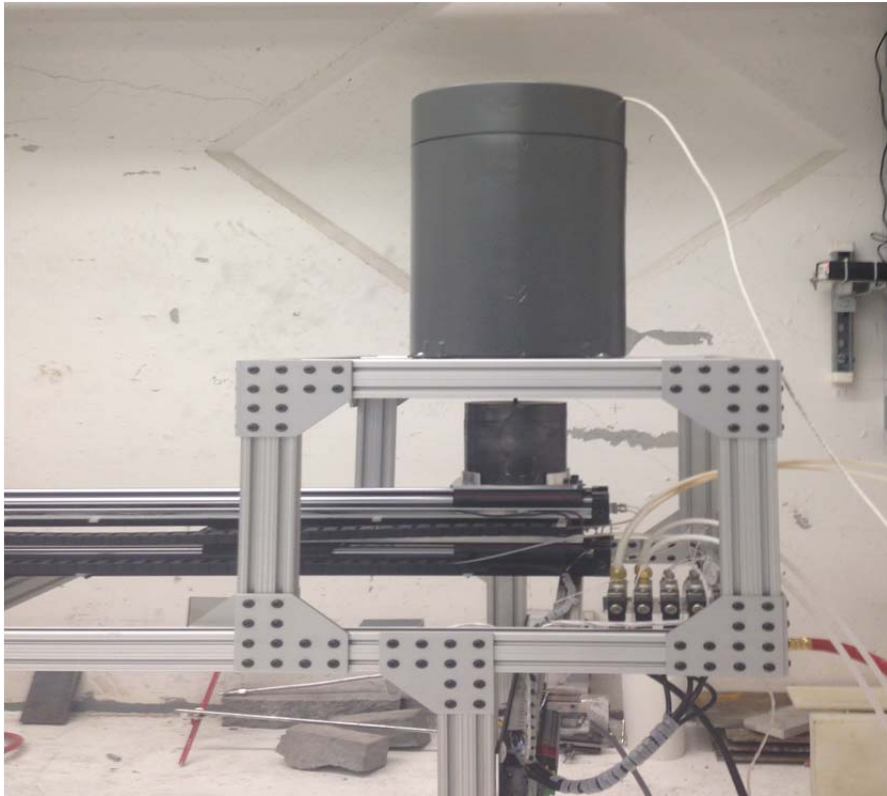


Figure 3 Lead pig in transport system situated under an ionization chamber used to determine product activity

2) Completed installation and testing of an ICP-MS analytical system at International Isotopes Inc.

Customers require verification of product quality prior to shipment. An ICP-MS (Inductively Coupled Plasma Mass Spectrometer) was made available by International Isotopes and installed adjacent to a production hot cell. After several months of installation and testing effort, the system has been used to verify the trace metal impurities in starting and processed material. The system will be used for production run quality assurance and is now available for use.

3) Filed necessary paperwork with the NRC for a production shipment license.

ISU and the IAC possess, handle and transport radioactive materials under what is known as a "Broad Scope License". This license lists all of the materials and quantities that ISU may possess at any given time. Our Broad Scope License allows us to maintain and transport up to 250 mCi of ^{67}Cu . We requested the NRC to allow us to ship ^{67}Cu isotope to cancer researchers for analysis. The NRC reviewed and denied our request and required us to prepare an application for a production license. This was an unexpected ruling since initial material was for research only and to aid in the development of the product. Regardless, we completed the several hundred page application and filed it with the NRC this period. The NRC requests approximately ~\$18,000 in fees which are trying to obtain from other funding. We have conferenced the NRC and requested expedited review of our application. We anticipate being able to ship material in the 3rd quarter of FY14.

4) Tested production at 3 kW of beam power creating the highest activity product to date

We utilized the new cooling and transport system to increase activity of our product by increasing beam power to 3 kW. The following graph shows the activity as a function of beam power as we stepped up the system from 0.5 kW to 3 kW. We are pleased with this result and believe it shows we will be able to achieve our expected target activity.

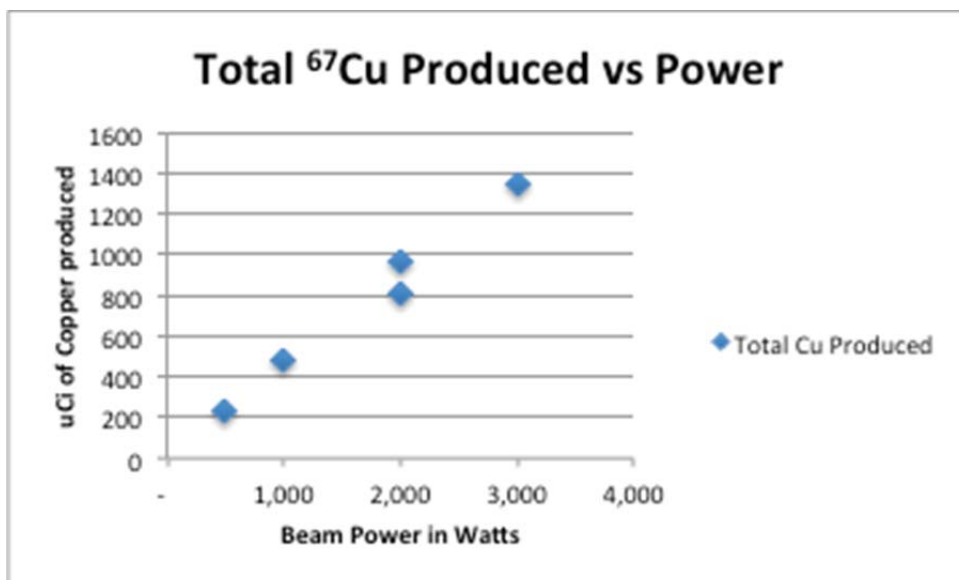


Figure 4 Total activity of ⁶⁷Cu produced vs power using the new water cooled system

5) Further refined the separation and purification methods

We have investigated numerous methods of casting and preparing the target for this activation. We have discovered that the quality of the casting and the details of the procedure of separation by both sublimation and column chromatography is critical to the total yield of the process. These discoveries are the subject of our pending intellectual property disclosures.

6) Started work on invention disclosures for separation methods

We believe that several novel ideas in our method of producing ⁶⁷Cu are patentable. We are working on invention disclosures and soliciting quotes for application preparation from patent attorneys.

Commercial and Partner activity

Our customer base includes City of Hope Cancer Research Center, Fred Hutchinson Cancer Research Center, Harvard Medical Center, and the University of Texas Southwestern Medical Center. We have decided to make our first test shipments to City of Hope in California and they are anxiously awaiting their arrival. Our delay is now receiving approval from the NRC to make our shipments.

Our private sector partner has supported our development efforts with expensive analytical equipment. Our ability to further involve them in the distribution of the product is again limited by the NRC's ruling. We are unable to even transfer product to them for joint development work. This will be resolved with the granting of the production license.

Prepared by Jon Stoner
Project Manager