COVER SHEET FOR GRANT PROPOSALS

State Board of Education

SBOE PROPOSAL NUMBER: (to be assigned by SBOE)	AMOUNT REQUESTED: $49,800

TITLE OF PROPOSED PROJECT: Infrastructure to support Active Pharmaceutical Ingredient designation for Cu-67

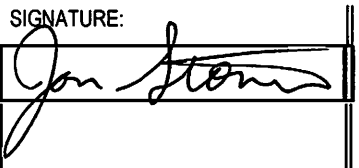
SPECIFIC PROJECT FOCUS:

This proposal requests funding to support the development of specific FDA required specifications, measurement equipment, equipment qualifications, and preparations for validation runs for the radioisotope ^{67}Cu. Idaho State University and the Idaho Accelerator Center have successfully developed a commercial process for the therapeutic and diagnostic radioisotope ^{67}Cu. Multiple shipments have been made domestically and internationally supporting precursor projects to phased FDA or international human trials. However, further development of drugs for human use requires meeting a set of predefined quality requirements as set by international guidelines and the FDA. Among those requirements are a set of specifications that define the standard operating procedures, quality metrics, control procedures and record keeping. The goal of these requirements is a reproducible high quality product that can be traced through its production.

Achieving at least some of the required components of FDA API designation grows the potential market for ^{67}Cu by allowing researchers to move drug ideas to the next stage. Achieving an FDA "Good Manufacturing Process" (GMP) designation dramatically increases the value of the patent pending process that ISU/IAC developed since it shows the process is consistent, reproducible, and complete. Washington University in St. Louis (one of the nation's largest providers of radio-isotopes) and a current recipient of our isotope follows this approach with its isotopes, ^{64}Cu the most recent example.

This proposal "kick starts" the API GMP process at the IAC by providing funding for some of the key measurement equipment (dose calibrator), hiring a drug industry consultant (versed in the requirements), and funding a student and our radiochemist with enough hours to complete some of the specifications and testing.

PROJECT START DATE: 7/1/17	PROJECT END DATE: 6/30/18
NAME OF INSTITUTION: Idaho State University	DEPARTMENT: Office for Research, Idaho Accelerator Center
ADDRESS: 921 S. 8th Avenue Pocatello, ID 83209 Stop 8046	
E-MAIL ADDRESS: resdev@isu.edu	208-282-2592

	NAME:	TITLE:	SIGNATURE:
PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR	Jon Stoner	Director Operations, IAC	
CO-PRINCIPAL INVESTIGATOR			

NAME OF PARTNERING COMPANY: Clarity Pharmaceutical	COMPANY REPRESENTATIVE NAME: Matt Harris, CEO

	NAME:	SIGNATURE:
Authorized Organizational Representative	Cornelis J. Van der Schyf, PhD	

SUMMARY PROPOSAL BUDGET

Name of Institution: Idaho Accelerator Center

Name of Project Director: Jon Stoner

A. PERSONNEL COST (Faculty, Staff, Visiting Professors, Post-Doctoral Associates, Graduate/Undergraduate Students, Other)

Name/ Title	Salary/Rate of Pay	Fringe	Dollar Amount Requested
Tim Gardner – RadioChemist	$5,500	$2415	$7915
Student	$3440	$310	$3750

% OF TOTAL BUDGET:	23%	SUBTOTAL:	$11,665

B. EQUIPMENT: (List each item with a cost in excess of $1000.00.)

Item/Description	Dollar Amount Requested
Dose Calibrator (Such as Capintec)	$7500
SUBTOTAL:	$7500

C. TRAVEL:

Dates of Travel (from/to)	No. of Persons	Total Days	Transportation	Lodging	Per Diem	Dollar Amount Requested
SUBTOTAL:						

D. Participant Support Costs:

	Dollar Amount Requested
1. Stipends	
2. Other	
SUBTOTAL:	

E. Other Direct Costs:	Dollar Amount Requested
1. Materials and Supplies	$600
2. Publication Costs/Page Charges	
3. Consultant Services (Include Travel Expenses)	$30,000
4. Computer Services	
5. Subcontracts	
6. Other (specify nature & breakdown if over $1000)	
SUBTOTAL:	$30,600
F.. Total Costs: (Add subtotals, sections A through E) **TOTAL:**	$49,770
G.. Amount Requested: **TOTAL:**	$49,800
Project Director's Signature:	Date:

INSTITUTIONAL AND OTHER SECTOR SUPPORT
(add additional pages as necessary)

A. INSTITUTIONAL / OTHER SECTOR DOLLARS

Source / Description	Amount
Purchased ^{67}Cu product	

B. FACULTY / STAFF POSITIONS

Description
PI funding covered by other grants and appropriated funds

C. CAPITAL EQUIPMENT

Description

D. FACILITIES & INSTRUMENTATION (Description)

IAC facilities including isotope accelerator, hoods, processing equipment, ICP-MS, HPGe detectors and other equipment.

HERC Incubation Fund Proposal FY18

Institution: Idaho State University

PI: Jon Stoner, Director of Technical Operations, Idaho Accelerator Center

Previous proposals or awards: HERC awarded a grant in 2013 for the development of the ^{67}Cu process. Previous proposals have been requested to support further isotope developments (^{123}I). This proposal focuses on the commercial FDA quality requirements for external customers and future licensors of the technology as opposed to the development of additional isotopes.

Proposal Title: Infrastructure to support Active Pharmaceutical Ingredient designation for ^{67}Cu.

Executive Summary: This proposal requests funding to support the development of specific FDA required specifications, measurement equipment, equipment qualifications, and preparations for validation runs for the radioisotope ^{67}Cu. Idaho State University and the Idaho Accelerator Center have successfully developed a commercial process for the therapeutic and diagnostic radioisotope ^{67}Cu. Multiple shipments have been made domestically and internationally supporting precursor projects to phased FDA or international human trials. However, further development of drugs for human use requires meeting a set of predefined quality requirements as set by international guidelines and the FDA. Among those requirements are a set of specifications that define the standard operating procedures, quality metrics, control procedures and record keeping. The goal of these requirements is a reproducible high quality product that can be traced through its production.

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Project Objectives: The objective of this proposal is to develop the capability at ISU/IAC to complete the specifications, qualifications, evaluations and validations to designate ^{67}Cu as an Active Pharmaceutical Ingredient per the FDA Q7 GMP Guidance document. Accomplishing this objective will increase the potential for ^{67}Cu drug development and future licensing of the technology. Full API designation, since it is difficult to achieve, will also lock in the IAC as the source for this isotope. This objective will also build a capability for implementing API processes at ISU – a necessary capability for growth of medical research and commercialization in Idaho.

Total Amount requested: $49,800

Resource commitments: Idaho Accelerator Facilities including the 48 MeV Isotope Accelerator, Radio-chemistry laboratory, Radio-chemistry process clean room, Support and analysis of product by end customers at Clarity Pharmaceutical and Washington University St. Louis. Idaho State University has continued to support the growth of medical research in Idaho and the development and commercialization of isotopes for medicine and industry.

Project Plan and Budget:

Market Opportunity:

^{67}Cu is being tested for use in radioImmunotherapy of various cancers. The technique combines the isotope with a protein or antibody that preferentially attaches to a cancer cell. The decay of the isotope kills the cell and also (in the case of ^{67}Cu) allows a SPECT camera to see the location of the cell(s).

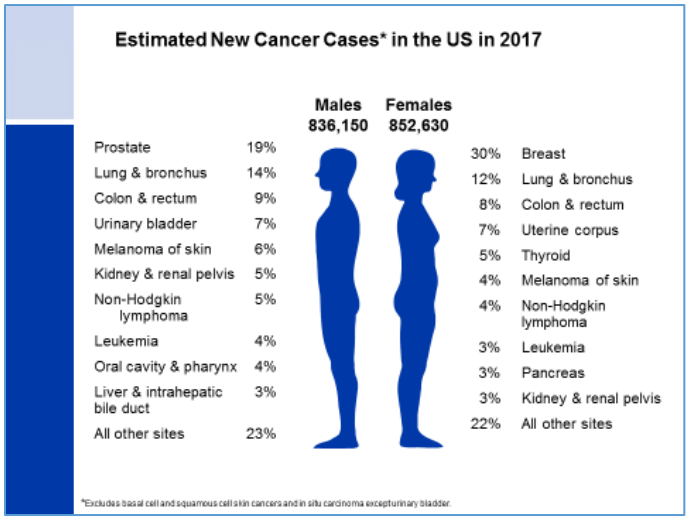

Figure 1 Statistics for Cancer occurrence in the US for 2017 (American Cancer Society - 2017)

Figure 1 shows the latest estimates from the American Cancer Society for new cases this year in the US – approximately 1.7 million. Immunotherapy (IT) or radioImmunotherapy (RIT) has been

tested on a fraction of the possible cancers with success on Non-Hodgkins Lymphoma, Colon, Ovarian and Neuro-endocrine tumors. Programs are starting to evaluate RIT for the highest incidence cancers, Prostate and Breast. From this data the TAM for ^{67}Cu based drugs could be up to 20% of annual cases. An estimate of the SAM would be a smaller fraction of approximately 10% of the TAM based on the alternative treatment options and the efficacy of any particular treatment. However, 2% of total cases is approximately 34,000 treatment opportunities per year. Two radioisotopes are currently used for RIT (treatment of Non-Hodgkin Lymphoma, NHL), ^{90}Y (Zevalin) and ^{131}I (Bexar). The treatment costs for these RIT drugs is between $10,000 and $35,000. Using an average of $20,000, the SAM value would be approximately $680 M of which the isotope value alone would be approximately 10-20%.

Competition

Researchers are evaluating ^{177}Lu and other isotopes, however, ^{67}Cu has a unique advantage in several physical characteristics and its ability to be paired with ^{64}Cu – a PET isotope. These characteristics allow pin-point dosimetry and lower toxicity to the patient.

Barriers to Entry

Developing drugs is an expensive proposition. Part of the cost is the requirement (for human testing) that the active materials in the drugs must reach quality levels specified by the FDA or other international agencies. ^{67}Cu, produced by the IAC, is achieving the highest purity levels ever noted for this isotope and far higher than any equivalent treatment isotope. Achieving API designation for ^{67}Cu along with IAC's process will create an even higher barrier to competitive isotopes.

Technology and Path to Commercialization

Based on funding from a State of Idaho HERC/IGEMs grant, IAC has developed a new method to generate ^{67}Cu, for which patent approval is pending (filed 2014). Since 2014, the IAC has shipped product to multiple customers: Washington University at St. Louis, Clarity Pharmaceutical, Australia , City of Hope Cancer Research Center, California State University, Fullerton, and University of Texas, Southwestern and is effectively the only US supplier of ^{67}Cu. So far in FY2017 the IAC has invoiced over $48,000 for isotope shipments, a greater than 10X growth over FY2016. The IAC has increased its process control and knowledge through routine shipments to customers and has received exceptionally good reports on the quality of product with specific activities (a measure of purity) more than 10 times greater than any historical supplier. The technology to produce ^{67}Cu was presented at the November, 2015 Fall American Nuclear Society meeting in Washington D.C.[1] as well as the May, 2016 SNMMI conference and the November, 2016 Theranostic World Conference in Melbourne, Australia. The only other advertised source of ^{67}Cu is through the DOE supplied by Brookhaven National Labs – at several times our price and much lower quality.

IAC technology will be commercialized through growth of sales of ^{67}Cu, drug development, and licensing of the underlying patented technology. ISU has already been approached by two companies interested in licensing ^{67}Cu (NDAs in place).

Project Plan:

This proposal intends to move as far as possible towards API designation by following the requirements of the FDA's guidance document Q7 GMP. The PI has discussed the requirements

with external consultants and has determined that the best course of action is to hire an experienced FDA consultant in a staff augmentation/oversight role. The consultant, IAC's radiochemist and a student, along with the PI, will develop the written specifications (Quality procedures, Standard Operating Procedures, and tracking documents), evaluate and qualify the critical process equipment, and then generate a Validation Master Plan. Validation is a requirement of the API designation and effectively verifies the quality procedures. In the course of this process, we expect to be required to replace our dose calibration system, the tool used to certify the activity of the material shipped off to the customers. Our budget contains a line item for this equipment. The schedule of activities:

1). Complete a RFP to established FDA API consulting companies (Q1, FY18)

2). Select a student (Q1, FY 18)

3). Complete the high level QA and SOP documents (Q2, FY18)

4). Complete the run tracking system and begin equipment qualification runs. Order capital equipment if required. (Q3, FY18)

5). If possible, draft Validation Master Plan (Q4, FY18)

At the end of this project we hope to be a significant way towards the information the FDA will require for API GMP approval. However, in general, this process takes more than one year and an extensive budget, therefore we are realistic in that we do not expect to achieve a level allowing us to file for GMP. The framework achieved should allow us to continue on our own to achieve the final objective.

Commercialization Partners

Clarity Pharmaceuticals contacted the IAC in August of 2015. Clarity is an established radiopharmaceutical company based in Australia and has completed phase 1 (human) trials on its ^{64}Cu based radiopharmaceutical diagnostic drug SARTATE^{TM}. Clarity's interest has been in developing a ^{67}Cu based drug for radiotherapy, a potentially excellent pairing with ^{64}Cu based SARTATE. ^{64}Cu is an isotope that decays releasing a positron and therefore is an excellent imaging isotope for PET (Positron Emission Tomography), the gold standard for nuclear medicine imaging. ^{67}Cu is a beta decaying isotope with a cell "kill" radius of 5-200 cells. In addition, ^{67}Cu releases a gamma-ray which can be imaged, has a 2.5 day half-life ideal for cancer therapy and is well tolerated by the body.

Clarity provided the IAC with samples of its patented sarcophagine "linking" chemical (called a chelator)[2] to conduct testing with IAC's ^{67}Cu isotope. The excellent results were published at the Society of Nuclear Medicine Conference in 2016 (the world's largest such industry conference). The CEO of Clarity, Dr. Matthew Harris is working to produce a drug capable of meeting the requirements of FDA GMP and subsequent human trials in Australia and the US. Clarity is exceptionally positioned to develop this drug since they have completed work using the other medical isotope of copper, ^{64}Cu. The "one-two" punch of a diagnostic ^{64}Cu based drug and a ^{67}Cu therapy based drug would provide oncologists a unique method of seeing the tumors, precisely determining the effective dose, and then delivering a tailored therapeutic dose for maximum benefit and limited side effects.

Initial drug development is focused on a treatment for "NETs" or neuroendocrine tumors, a type of tumor that occurs in neuroendocrine cells of many organs and is the second highest incidence of malignancy in the gastrointestinal system. NET malignant cells over express a unique antigen called somatostatin receptor 2 (SSTR2). A combination of a particular peptide (a protein called octreotate), Clarity's MeCoSar™ chelate ("linker"), and IAC's ^{67}Cu could target the SSTR2 providing the ability to image and destroy malignant cells[3]. Other malignancies over-express SSTR2 including pancreatic[4], gastrointestinal[5] and pulmonary neuroendocrine tumors[6], pituitary adenomas[7], breast carcinomas[8], meningiomas[9], neuroblastomas[10], medulloblastomas[11], pheochromocytomas[12], and paragangliomas[13]. The potential for treatment of neuroblastoma (NB) is significant and Clarity is fast-tracking its SARTATE™ product as a treatment for NB. NB is a childhood cancer affecting 10.2 per million children under 15 years of age in the United States. It is the most common type of cancer to be diagnosed in the first year of life and accounts for ~13% of paediatric cancer mortality[15]. The ability for a paediatric oncologist to see if the drug is in the child's tumours and then deliver a tailored dose, puts this project at the forefront of personalized medicine. Clarity strongly supports API designation for ^{67}Cu and will support our efforts through consulting and purchased product evaluations.

Washington University, St. Louis, is currently one of the leading suppliers of medical isotopes in the US and a provider of ^{64}Cu. The IAC is currently shipping high activity lots to Washington University for stability studies of various chelators with the isotope. WU has strongly encouraged the IAC to move their product towards an API status as they have with all

of their isotopes. They have indicated they will support us with consulting in our work towards API designation.

Institutional Support:

The IAC has unique accelerators and technology to support the production of ^{67}Cu. Over the 5 year development history of this isotope, ISU/IAC have invested in accelerators, radiochemistry laboratories, a dedicated ^{67}Cu processing cleanroom and analytical equipment. Commercial isotope technology development has been a critical operating strategy for the IAC for 6 years.

Expertise:

A broad set of skills will be utilized in this program. The PI, Mr. Jon Stoner, Director of Technical Operations at the IAC, brings more than 30 years of experience in technical development and management of commercial programs in the private sector with an additional 8 years of accelerator produced isotope research and operation experience at the IAC. He, along with Dr. Frank Harmon and radio chemist, Tim Gardner have driven the success of the ^{67}Cu program and started additional investigations into other isotopes. In addition the IAC has three accelerator engineers with over 40 years of combined experience in building, operating and maintaining accelerator equipment and installations. The IAC is the premier University facility in the US for accelerator operations with more accelerators and a broader range of programs than any other facility outside of a National Lab.

Budget: $49,800

Description	**Total Cost**
200 hours radio-chemist + fringe	**$7915**
400 hours student time + fringe	**$3750**
FDA Consultant	**$30000**
Capital Equipment (Dose Calibrator)	**$7500**
Materials and Supplies	**$600**

Appendix A

Facilities & Other Resources

Introduction

The Idaho Accelerator Center (IAC) was created by the Idaho State Board of Education in 1994. The IAC is charged with undergraduate and graduate education, conducting applied physics research, creating new applications of accelerator physics and supporting the economic development of Idaho. Current IAC research emphases include (i) isotope production through photonuclear reactions (ii) photon activation and nuclear forensics for environmental, archaeological and national defense applications, (iii) radiation effects in biological and solid-state systems, (iv) radiographic imaging (v) accelerator physics and (vi) fissile material detection for nuclear non-proliferation, safeguards and homeland security.

The IAC has 5 operating accelerators in a research facility with over 20,000 sq. ft. of laboratory space. This is one of the most extensive university accelerator laboratories in North America. The operational and user personnel at these facilities consist of scientists, engineers, safety personnel and administrative assistants. In addition, undergraduate and graduate students have ongoing research projects at the IAC.

Main IAC "Campus"-Accelerator Laboratory #1

The main IAC campus, was constructed in 1999 and initially consisted of office space and Accelerator Laboratory #1. This accelerator lab was built into the hills that surround Pocatello Idaho and the 2,010 sq. ft. hall is 20 feet underground providing ample radiation shielding. This accelerator hall houses a 44 MeV Short Pulsed LINAC, 25 MeV LINAC, and a 2 MeV Van de Graaff. In addition, this accelerator hall has a well shielded experimental cell that is separated by a six foot wall from the accelerator hall. This wall has four penetrations allowing collimated bremsstrahlung beams to be delivered to a "low" radiation environment, which is critical for precise photonuclear measurements. This accelerator laboratory and its two accelerators may perform supplemental irradiations for this project. A picture of the facility is shown below.

The Idaho Accelerator Center.

The 44 MeV Short Pulsed LINAC is an L-band traveling wave radio frequency accelerator operating at ~1.3 GHz. It is capable of delivering electron pulses with operator selectable widths between 70 pico to 2 micro-seconds at a repetition rate up to 250 Hz. This accelerator is currently capable of approximately 4 kW of average electron beam-power. The electron energy can be varied from ~4 to 44 MeV with an energy resolution of 0.5% to 4%, controlled by a set of retractable slits.

The 25 MeV LINAC in Accelerator Laboratory #1 is an S-band standing wave radio frequency accelerator operating at ~2.8 GHz. This machine is capable of approximately 2.5 kW of average electron beam power. The electron energy can be varied from ~5 to 25 MeV with an energy resolution of 5%, which can be reduced using collimators or slits. This accelerator has a broad parameter space, is easy to operate and when precise beam parameters or short electron pulses are not required this is often the accelerator of choice.

The 2 MeV Van de Graaff is a DC accelerator capable of accelerating different ions as well as electrons in a continuous beam. Currents vary by ion but range from 10 uA to 100 uA.

Main IAC "Campus"-Accelerator Laboratory #2

Accelerator Laboratory #2 houses the 10 kW 40+ MeV accelerator. It is a 777 sq. ft. accelerator hall built into the hill and is approximately 10 feet underground for radiation shielding. Beam parameters are from 1 to 9 micro-seconds width at 50 to 100 mA per pulse. Besides the accelerator, the room incorporates additional target cooling, shielding and monitoring and is used for isotope production.

Main IAC "Campus"-High Bay Laboratory

The IAC operate a 3 MeV high current (20 KA) pulse power machine. This accelerator produces high current pulses of approximately 20-30 nano-seconds and is capable of firing 5 times/hour.

Main IAC "Campus"-Idaho Imaging Laboratory

The IAC operates an additional adjacent facility housing 400 keV x-ray imaging systems and a 4 MeV Betatron. This facility provides radiographic imaging supporting projects in defense and civilian applications.

IAC – Chemistry Laboratory

The IAC main campus houses a 500 sq ft radiation chemistry laboratory with two hoods (one for radiation work). Analytical equipment includes a PE ELAN DRC II ICP-MS, NaI detector multi-channel analyzer, UV spectrometer, and various analytical chemistry supplies.

Detectors and Data Acquisition

Detector, target, accelerator and data acquisition equipment to support this project is abundant. The IAC currently possesses over five HPGe detectors that can be utilize for post-irradiation analysis. There is also a large array of photomultiplier tubes, scintillators, ^{3}He detectors and a Detector Science Laboratory to support this research. The data from these detectors can be acquired, by three different multi-parameter data acquisition systems that can handle up to 16 channels of data each. There are also two VME systems that are very flexible. Modules for these systems include a 16 channel multi-hit time to digital converter, 16 charge to digital converters, a 16 channel pulse height analog to digital converter and 16 channel scalars. Finally, the IAC has over 100 nuclear instrument modules that can be employed for various pulse shaping functions and logic control.

New detector and data acquisition development, if any is required for real-time target monitoring, place in the Detector Science Laboratory, which is a 1,100 sq. ft. lab specifically for the construction and testing of new detectors. This lab includes a dark room for photomultiplier work, chemical hoods for potential hazardous vent gasses and optical tables for precision wire placement. One of the two VME data acquisition system in normally located in the DSL for development work.

Radiation Effects Simulation and Radiation Transport Simulation Capabilities

The Idaho Accelerator Center has excellent computational capabilities. The MCNPX radiation transport simulation program incorporates MPI technique to perform simulations in parallel. Thus, to reduce calculation time all MCNPX calculations can be done on several high computing network clusters. The first cluster, BREMS, has 12 nodes, 52 cores, 64 GB of aggregate memory, and 108 GHz of aggregate CPU power. This cluster is dedicated to the Idaho Accelerator Center research activities. The second one is MINERVE, which has 12 nodes, 192 cores, 384 GB of memory, and 384 GHz of aggregate CPU power. This cluster is shared among all researchers at the College of Science and Engineering at Idaho State University.

Engineering and Technical Support at the IAC

The IAC has 5 personnel on its engineering and technical staff. Staff are responsible for construction of the various accelerator systems, accelerator operations, care of the overall facilities and all aspects of safety with an emphasis on radiation safety. Support facilities

heavily used by the technical staff include, the IAC machine shop, the IAC electronics shop and the IAC radiation dosimetry laboratory.

Appendix B PI CV and other support

C.V.

Jon L. Stoner
209 Stanford Ave.
Pocatello, ID
208-760-0692

EXPERIENCE

Director of Technical Operations **Date: March 2014 – present**
Idaho Accelerator Center
Office of Research
Idaho State University

CJ Tech Consulting LLC **Date: April 2008 – March 2014**
CEO/ Founder
Industry/University Research Consultant
Contracted Researcher at Idaho Accelerator Center

Concurrent Positions:
Chief Technology Officer, Sr. Vice President, R&D **Date: 2001- March 2008**
General Manager of Image Sensor Products
Sr. Vice President, Acquisitions and Strategy
AMI Semiconductor

Director Business Development, Director Standard Product BU **Date: 1996-2000**
AMI Semiconductor

Director R&D, Operations, and Foundry, Project Manager, Fab 10 **Date: 1987-1996**
AMI Semiconductor

Manager R&D, Senior Technical Staff, Operations Staff **Date: 1980-1988**
AMI Semiconductor

EDUCATION & TRAINING

- MS Physics – Idaho State University
- Graduate School University of Montana, Utah State University (Chemistry, Engineering)
- University of Minnesota School of Dentistry
- BA Chemistry – University of Montana with Honors
- Additional coursework in management, product development, and marketing

OTHER

- Member Idaho State University Radiation Safety Committee and Chair of Accelerator Safety Committee
- Member of Advisory Committee to Idaho State Board of Education on Engineering education – 6 years
- Member Advisory Board for BSU school of Engineering 8 years
- Governor appointed member EPSCORE (Experimental Program for Competitive Research) committee for State of Idaho 6 years

RELEVANT PUBLICATIONS

Radio-labelling Results from High Specific Activity e-LINAC Produced ^{67}Cu, Jon Stoner, Timothy Gardner, Matt Harris, Charmaine Jeffery, Theranostics World Congress 2016, November, 2016, Melbourne

High Specific Activity e- LINAC Production of 67Cu, Jon Stoner, Alan Hunt, Timothy Gardner, Frank Harmon, American Nuclear Society meeting, 12th Annual International Conference on Applications of Accelerators, November 2015, Washington DC

Optimization of Commercial Scale Photonuclear Production of Radioisotopes, Bindu KC, Frank Harmon, Valeriia Starovoitova, Jon Stoner, Douglas P Wells, 22nd International Conference on the Application of Accelerators in Research and Industry, August 2012, Fort Worth, TX

Cu-67 photonuclear production, Valeriia Starovoitova, Bindu KC, Frank Harmon, Jon Stoner, Douglas P Wells, 7th ICI, September 2011, Moscow, Russia

PATENTS (applications in progress)

Methods for producing medical isotopes
Device for producing medical isotopes

<u>Jon Stoner Current and Pending Support</u>

Current Support

State of Idaho Appropriated Line – 100%

<u>Current Grants</u>

Battelle Energy Alliance LLC $927,000 Stoner (PI)
2/01/17 - - 12/31/17
Construction of Accelerator for Photo-Nuclear Isotope Studies

Battelle Energy Alliance LLC (DTRA) $95,000 Stoner (PI)
7/01/16 - - 5/31/17
INL DTRA Collaborative Irradiations
The goal of this research is the evaluation of photonuclear processes to elucidate fission valley isotopes and other specific isotopes such as ^{44}Sc and ^{237}U for national security applications.
Role: PI

Idaho State Board of Education $75,000 Dale (PI)
7/01/16 – 6/30/17
Commercialization of Trace Element Detection Technology
The goal of this research is the development of methods using Photon Activation Analysis to determine sub-ppm levels of trace elements in various matrixes.
Role: co-PI

JPL (Cal Tech/NASA) $35,000 Stoner (PI)
5/23/16 – 9/30/17
Electronic Dipole Shield
The goal of this research is to test designs for electronic shields against high energy particles in space.
Role: PI

Battelle Energy Alliance LLC (DOE) $11,000 Stoner (PI)
2/01/16 – 1/31/17
Noble Gas Irradiations
The goal of this research is to determine methods of production of carrier free ^{133}Xe and ^{135}Xe.
Role: PI

Idaho State
UNIVERSITY

Office for Research
921 South 8th Avenue, Stop 8130 • Pocatello, Idaho 83209-8130

May 26, 2017

Idaho State Board of Education
Higher Education Research Council
650 W. State Street, 3rd Floor
Boise, Idaho 83702

Re: HERC Incubation Fund - Infrastructure to support Active Pharmaceutical Ingredient designation for Cu-67

Dear HERC Incubation Fund Committee:

Idaho State University strongly supports the proposal entitled " Infrastructure to support Active Pharmaceutical Ingredient designation for Cu-67", submitted by Mr. Jon Stoner of the ISU Office for Research and the Idaho Accelerator Center.

This project has great potential for the future commercialization of the copper-67 process developed at ISU. ISU and the IAC have completed extensive work in the patent pending process and delivery to multiple sites is growing dramatically. Full commercial potential will be achieved with an FDA API GMP designation for the process for which this proposal is a significant step. This proposal will work to bridge the gap between a research program with proven effectiveness and the effective application of this technique in a commercial environment.

Should you have any questions about this proposal, please don't hesitate to contact Mr. Stoner or me.

Respectfully,

Cornelis J. Van der Schyf
Vice President for Research & Dean of the Graduate School