CONCEPT OF OPERATIONS PLANS FOR PHASE I OF THE:

THE INTERNATIONAL PILOT FOR GLOBAL RADIOLOGICAL SOURCE SORTING, TRACKING, AND MONITORING (GRADSSTRAM) USING EMERGING RFID AND WEB 2.0 TECHNOLOGIES TO PROVIDE TOTAL ASSET AND INFORMATION VISUALIZATION

A UNITED STATES- EUROPEAN UNION LIGHTHOUSE PRIORITY PROJECT FOR FOSTERING TRADE AND REDUCING REGULATORY BURDENS IN THE TRANSATLANTIC TRADE CORRIDOR

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Background

Thousands of shipments of radioisotopes developed in the United States (US) are transported domestically and internationally for medical and industrial applications, including to partner laboratories in European Union (EU) countries. Over the past five years, the Environmental Protection Agency (EPA), the Department of Energy (DOE), and Oak Ridge National Laboratory (ORNL)¹ have worked with state regulatory compliance personnel, key private sector shippers and carriers, the Department of Homeland Security (DHS), the Department of Transportation (DOT), the Department of Defense (DoD) and the Nuclear Regulatory Commission (NRC) on Radio Frequency Identification (RFID) tracking and monitoring of medical and industrial radioisotopes in commerce. The EPA Radiological Source Tracking and Monitoring (RadSTraM) project tested, evaluated, and integrated RFID technologies in laboratory settings, and at multiple private-sector shipping and distribution facilities (Perkin Elmer and DHL) using common radioisotopes used in everyday commerce². The RFID tracking was also tested in association with other deployed technologies including radiation detection, chemical/explosives detection, advanced imaging, lasers, and infrared scanning.

At the 2007 EU-US Summit, the leaders of the US Department of Commerce (DOC) and EU European Commission (EC) committed to pursue jointly directed Lighthouse Priority Projects. These projects are intended to "foster cooperation" and "reduce regulatory burdens" with respect to transatlantic commerce. The <u>Transatlantic Economic Council</u> (<u>TEC</u>) Lighthouse Project on Radio Frequency Identification (RFID) has been directed to "develop a joint framework for cooperation on identification and development of best practices for Radio Frequency Identification (RFID) technologies..." The RFID Lighthouse Priority Project commits both sides to endeavor to align U.S. and EU regulatory and policy approaches on RFID technologies, including pilot projects in the public sector.

The RadSTraM project was specifically cited as a candidate for a RFID Lighthouse Project by the EU/DOC collaboration in meeting their mutual goal of developing a "joint framework for cooperation on identification and development of best practices for RFID technologies." Concurrently, the Universal Postal Union (UPU)³ identified this project as a candidate for radioisotope packages shipped by the postal service between the United State Postal Service (USPS). and European Post Agencies.

¹ ORNL is the DOE's largest science and energy laboratory. As a DOE Management and Operating (M&O) contractor UT-Battelle, LLC, manages and operates the scientific and research facilities of ORNL under a performance based contract # DE-AC05-00OR22725. UT-Battelle, LLC is a privately held entity owned 50% by seven universities (Tennessee, Florida St, NC Sate, Virginia, Virginia Tech, Duke and Vanderbilt) and 50% by Battelle Memorial Institute. ORNL is a DOE Federally Funded Research and Development Centers (FFRDC). ORNL is also a DHS Laboratory. ORNL is the DOE designated lead Laboratory for the U.S. Radioisotope Production and Shipping Program.

² ORNL/TM- 2008/003 RADSTRAM: RADIOLOGICAL SOURCE TRACKING AND MONITORING, PHASE II FINAL REPORT, January 2007, Warren T.A., Walker R. M., et-al

³ Established in 1874, the Universal Postal Union (UPU) with its Headquarters in Berne (Switzerland), is the primary forum for cooperation between postal-sector players and helps to ensure a truly universal network of up-to-date products and services.

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Motivation

Highly radioactive sources are used in everyday life to treat cancer patients, as irradiators to preserve food, in industrial radiography to check for welding errors in pipelines, in well drilling and logging and in buildings for thermoelectric generation of electricity in remote locations as well as for a variety of other purposes. For example, there are reportedly some ten thousand radiotherapy cancer treatment units in use worldwide, with tens of thousands more radioactive sources used throughout industry. Radiological sources are essential to our societies, and there is not practical option to secure and control every item, everywhere.

There is not an accurate figure on how many radioactive sources exist throughout the world. Some of the isotopes of most concern include Cobalt 60, Strontium 90, Cesium 137, and Iridium 192. A huge number of societal applications of these materials make them inherently difficult to track and control. Many of these sources are lost, stolen, or simply abandoned when no longer required. In the US, for example, an average of about 300 sources of radioactive material are reported lost or stolen each year.⁴ Such "orphaned" radioactive sources give cause for immense concern and is of most concern in countries where civil authority and regulatory oversight are weak. Orphaned sources are found worldwide. In early 2002, for example, two canisters containing highly radioactive Strontium 90 were discovered in the former Soviet republic of Georgia. The three Georgian woodsmen who came upon them were severely burned by radiation. The US, the International Atomic Energy Agency⁵ (IAEA), and the Georgian government subsequently worked together to secure these field radioisotope thermoelectric generators, many of which exist in uncontrolled settings. There are many more examples of orphaned sources including significant quantities of Cesium 137 that had been used to preserve harvested grain in some countries.⁶⁷

The EPA RadSTraM Project findings have indicated that RFID tracking of radioisotopes in commerce is viable and desired by supply chain stakeholders. At the present time, however, there is no automated method, no international standard and no tracking infrastructure in place to track these shipments throughout the supply chain from the generator to the receiving facility, potentially masking danger.

⁴ IAEA, Training Course Series Number On, Safe Transport of Radioactive Materials, 3rd edition, Vienna, Austria

⁵ The IAEA's mission is guided by the interests and needs of Member States, strategic plans and the vision embodied in the <u>IAEA Statute</u>. Three main pillars - or areas of work - underpin the IAEA's mission: Safety and Security; Science and Technology; and Safeguards and Verification.

⁶ U.S. General Accounting Office, Nuclear Nonproliferation; U.S. and International Assistance Effort U.S. General Accounting Office, Nuclear Nonproliferation; U.S. and International Assistance Efforts to Control Sealed Radioactive Sources Need Strengthening, GAO-03-638

⁷ Bolton, John R., "Under Secretary for Arms Control and International Security: Keynote Address," International Approaches to Nuclear and Radiological Security Conference, London, (available at <u>http://www.state.gov/t/us/rm/14064.htm</u>), Sept. 30, 2002.

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The USPS has identified that the transmission of up-to-date shipment information in real time with parcels is a priority for research and development applications. Web 2.0 Social Networking solutions are high on the USPS research agenda for increasing efficiencies. Additionally the USPS desires a seamless tracking system between the US and EU nations.

The DOT has identified data and message transmissions between supply chain partners as a significant weakness in the international supply chain architecture and has been working to fill this gap with a solution that provides a mechanism for sharing supply chain data that is secure, simple, efficient and dynamic. The Federal Highway Administration (FHWA) Office of Freight Management (OFM) has invested in a service oriented data architecture called Electronic Freight Management⁸ (EFM).

The DOE Radioisotopes Shipping and Production Program, as well as all radioactive material supply chain stakeholders, are facing new Nuclear Regulatory Commission (NRC) requirements aimed at actively tracking all radioactive materials from cradle to grave. The NRC has recently codified the National Source Tracking System⁹ (NSTS) which adopts a phased approach for real-time tracking of radioactive materials shipments for NRC licensees. ORNL was the pioneer of the international radioisotope shipping and production business. Most radioisotopes made and used today were either made or discovered at ORNL. While most of the radioisotope used in the commercial sector are now produced and sold by the private market, ORNL still leads the world in the production of exotic, high-value and/or sensitive medical and research isotopes.

It is widely believed by the collaborators on the TEC Lighthouse Priority Project – GRadSSTraM that a phased multi-year International Pilot intended to demonstrate that RFID integrated with emerging Web 2.0 knowledge management technologies and standardized service oriented data architecture can serve as a prototype process network that will reduce regulatory burden, increase efficiency and mitigate risk for transatlantic shipments.

Technical/Operational Approach:

The USPS, UPU, DOT, DOE/ORNL, EPA and the EU will collaborate with worldrenowned universities, key international policy-makers, and major private-sector supplychain stakeholders to extend the RadSTraM Project and develop a TEC Lighthouse

⁸ A DOT-FHWA sponsored initiative that applies Web technologies to improve data and message transmissions between supply chain partners.

⁽http://ops.fhwa.dot.gov/freight/intermodal/efmmanifest/index.htm)

⁹ The National Source Tracking System (NSTS) will be a secure Web-based system to allow NRC licensees to record certain types of radioactive source transfers directly over the Internet. Until the NSTS becomes available, the NRC and Agreement States will continue using an interim database to record snapshots of data. The interim database has been in use since 2004 and currently meets the U.S. Government's commitment to implement a national source registry described in the International Atomic Energy Agency's <u>Code of Conduct on the Safety and Security of Radioactive Sources</u>.

Global Radiological Source Sorting, Tracking and Monitoring (GRadSSTraM) Project. The GRadSSTraM collaborators will develop the Phase I, II and III tasks in a joint US-EU pilot as defined in the *Commerce News Press Release 9-22-2008* as defined in the DOC-EU Fact sheet issued in April 2008.¹⁰

The Phase I tasks will include a pilot program to test and assess the efficacy of various RFID systems, selected sensor integrations, EFM standards oriented architecture and Web 2.0 applications for transatlantic radioisotope shipments shipped via the international postal system. The Phase I tasks will also establish RFID technologies for tracking and monitoring of the packaging and EFM service oriented architecture for the data and messaging transmissions between supply chain partners. The Phase II tasks will establish a prototype Web 2.0 application to provide total information and sensor visibility between specified supply chain stakeholder process networks thereby enhancing safety, security and interoperability in a dynamic environment. The Phase III tasks will establish the commercialization and technology transfer effort for the TEC Lighthouse GRadSSTraM Project.

This ConOps Plan will deal only with Phase I activities. It is anticipated that Phase II and III activities and their subject ConOps Plans will be defined after Phase I analysis, results and lessons learned have been published.

PHASE I ConOps Tests

The first step in the design and implementation of an RFID intelligent tag tracking system into the international supply chain process network for radioactive materials is for a validation of this technology to be completed to assess how to best apply it to the incommerce process. To this end, the GRadSSTraM Controlled Shipment Test Phase I will be conducted to assess the technology in a real-world environment using the DOE Isotopes shipping program at ORNL. This stage of the test plan addresses the Transatlantic supply chain using ORNL radioisotope shipments to and from the National Physical Laboratory¹¹ in Teddington, United Kingdom (UK). These shipments will be made via established process networks in the USPS and the Royal Mail.¹²

Operational Requirements for the tests include:

¹⁰ Radio Frequency Identification (RFID) For Sorting, Tracking, And Monitoring Of Medical And Industrial Radioisotopes In The Transatlantic Trade Corridor, Fact Sheet issued by DOC, EU, USPS and ORNL

¹¹ The National Physical Laboratory (NPL) in Teddington, UK is the UK's National Measurement Institute and is a world-leading centre of excellence in developing and applying the most accurate measurement standards, science and technology.

¹² Royal Mail is the national postal service of the United Kingdom. Royal Mail Holdings plc owns Royal Mail Group Limited, which in turns operates the brands Royal Mail (UK letters), Parcelforce Worldwide (UK parcels) and General Logistics Systems. Post Office Ltd., which provides counter services, is a wholly owned subsidiary.

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- Limited Quantity (Ltd Qty) Radioactive Material, RFID modified inner containers with electronic seal.
- USPS and Royal Mail designated Ltd Qty of medical radioisotopes packaged in strong tight containers per the applicable code or regulations
- Ten (10) roundtrip Ltd Qty radioactive material shipments between ORNL and NPL
- Packaging configured with active, passive, hybrid RFID tags or a combination thereof.
- Testing configuration and RFID listeners/actuators installed at ORNL, NPL, and USPS/Royal Mail designated terminal and distribution facilities.
- Web 2.0 data collection and distribution engine for disparate and distributed data integrated with ORNL, NPL, USPS and Royal Mail process networks
- Data analysis and incorporate Lessons Learned into Phase II and III tests.

<u>**Operational Tests**</u> will validate the performance of the RFID intelligent tags by documenting the following steps:

- a) Five separate single isotope shipments and five empty container shipments (ten total roundtrip shipments) over a four (4) month period. Shipments will originate from ORNL and proceed under normal USPS/Royal Mail operating conditions including varied environmental conditions, varied commodities on board vehicles, temporary staging in operating terminals with various commodities and normal transportation handling.
- b) Susceptibility and limitations of the interrogator and tags to interference from sources or operating conditions external to the interrogation system;
- c) To validate the radio frequency (RF) emissions that emanate from the interrogator and tags during the interrogation process.
- d) Susceptibility of the tags to normal postal handling and distribution.
- d) Ability to find misplaced shipments in the USPS/Royal Mail ConOps environment.

<u>Vendor Requirements</u> will validate a technological solution that would monitor medical radioisotope shipments while in transit using passive, active or hybrid RFID tags or a combination thereof. The criteria for vendor requirements are as follows:

- 1. RFID tags with Omni-directional read distances up to 50 feet at a frequency available worldwide.
- 2. The tag readers must recognize the tags when transported in metal trailers traveling at speeds up to 30 mph.
- 3. The readers must recognize tags in the presence of other tags.
- 4. Readers/Actuators furnished to read tags at seven (7) locations: ORNL (2), USPS (2), Royal Mail (2), and NPL
- 5. Tags will perform in any and all weather conditions and normal shipping and handling conditions.
- 6. The powering systems need a lifespan of seven years without maintenance.

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7. The software systems need an application programming interface providing programmatic access to tag data including, at a minimum, the tag ID a timestamp of when it is seen by a reader and five (5) other lines of data as designated by the project team.

General Test Procedure requirements are as follows:

- 1. Package the tags in USPS/Royal Post required containers according to a assigned test condition
- 2. Assign a GRadSSTraM shipment number to each package.
- 3. Input ORNL/NPL facility's shipping papers to Web 2.0 enabled database
- 4. Input USPS/Royal mail shipping papers to Web 2.0 enabled database
- 5. Create a unique shipment identifier in Web 2.0 enabled database that reflects at a minimum;
 - ORNL/NPL manifest unique identifier
 - USPS/Royal Mail unique identifier and tracking identifier
 - Unique safety and security identifier
 - the isotope and quantity,
 - the shipping condition
 - the container type
 - the GRadSSTraM shipment number.

A digital picture of the container and the paper work will be taken and input in the Web 2.0 enabled database.

<u>Timeline</u>

The TEC Lighthouse GRadSSTraM project will begin Testing will begin in March 2009

Month 1 – 2:

- Final Vendor Agreements
- RFID Tags Purchased
- Laboratory Testing and Validation
- Safety Planning and Documentation Complete and Approved
- Gateway Controllers Installed and Tested

Month 3 – 4:

• Operational Testing

Month 5:

• Data Collection and Validation

Month 6:

• Lessons Learned Reporting

Safety and Security Requirements

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All work will be performed under a properly executed ORNL Research Safety Summary (RSS) and applicable NPL Procedure. All USPS, Royal Post laws, regulations other procedures, regarding concerning transport and storage of radioactive materials will be met. All Export Control reviews will be performed and documentation will be in place before shipping starts. Any restriction will be integrated in to the project plan. The project safety and security documentation will be updated to reflect changes in this Test Plan if necessary.

Performance Objectives

The GRadSSTraM Pilot Phase I will demonstrate the following performance objectives:

- 1. Validate the performance of Web 2.0 enabled RFID tracking systems to monitor Express Post shipments of radioisotopes in the international supply chain.
- 2. Quantify the reliability of these tracking systems with regards to probability of tag detection and operational reliability at checkpoints and chokepoints in the supply chain process network
- 3. Determine if the implementation of these systems will help to reduce regulatory burden and enhance transatlantic trade.
- 4. Demonstrate that RFID tracking and monitoring of radioactive materials is ready for Phase II testing using commercial isotope shippers and carriers
- 5. Establish prototype standards architecture to enhance the ability of using tracking technologies internationally.