March 29, 2013
SMT-2013-013
Project No. 0792

Enclosure 2
Closed Meeting Slides (Redacted)

SHINE™
Medical Technologies

Licensing and Technical Aspects Associated With Criticality Margin

April 17, 2013

Licensing Aspects – Bill Hennessy

Technical Aspects – Eric Van Abel

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Licensing regulations applicable to SHINE

- Production facility license under 10 CFR 50
- Class 103 license per 10 CFR 50
- Compliance with other regulations will be required by and part of the license
  - 10 CFR 30 (Byproduct material)
  - 10 CFR 40 (Source material)
  - 10 CFR 70 (Special nuclear material)

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Preliminary Layout and Facility Boundaries

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Safety Analysis Methods - IF

- The safety analysis for the Irradiation Facility (IF) will be the similar to that performed for an AHR (Aqueous Homogeneous Reactor).
- "A safety analysis report (SAR) accompanying the application must evaluate the performance of the reaction vessel relative to many of the same phenomena identified as licensing concerns for an AHR." (ISG pg. iv)
- The IF safety analysis method is outlined in ISG Sections 13a AHR Accident Analysis.
- This analysis will verify that the radiological consequences of accidents are within limits.
- The IF will be designed and operated to ensure that criticality does not occur during normal or abnormal conditions.

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Safety Analysis Methods - RPF

- Although not required by regulation, the use of an Integrated Safety Analysis for the RPF, and meeting the Performance Requirements of 10 CFR 70.61 have been found to be acceptable to the NRC staff for licensing a Production Facility, per ISG 13b.
- The guidance provided in 10 CFR 70, including 70.61 performance requirements, is used in the RPF Safety Analysis.

Safety Analysis Methods - RPF

- For the RPF …the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety.
- The "approved margin of subcriticality" is Keff <= 0.95
- Tanks, vessels, and processes which are expected to contain SNM in the RPF will be designed and/or controlled to meet the performance requirements of 10 CFR 70.61.
- The RPF will meet the same standard for radiological consequences as the IF

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Regulatory Summary

- The IF (reaction vessel) is considered to be separate and distinct from the RPF part of the plant, with unique licensing circumstances.
- The IF will be designed, and the safety analysis performed, equivalent to the design and safety analysis for an AHR. The safety analysis will verify that the radiological consequences of accidents are within limits.
- The IF will be designed and operated to ensure that criticality does not occur during normal or abnormal conditions.
- The RPF will meet the performance requirements of 10 CFR 70.61, including meeting Keff<=0.95, and radiological consequences the same as the IF

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Technical Aspects

An overview of reactivity control at the SHINE facility

Facility Boundaries

- Following slide shows preliminary layout of the facility with distinctions between the two distinct areas in facility
  - Irradiation Facility (IF)
    - Target Solution Vessel
    - Subcritical Assembly
    - Neutron Driver
    - Supporting systems
  - Radioisotope Production Facility (RPF)
    - Radioisotope extraction, purification, and packaging hot cells
    - Gaseous waste treatment systems
    - Solution cleanup
    - HVAC air handling units
    - Chemical and uranium storage
    - Waste management systems
    - Various supporting systems and components

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Preliminary Layout and Facility Boundaries

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Irradiation Unit

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- An Irradiation Unit consists of:
  - Subcritical Assembly
  - Neutron Driver
  - Concrete confinement structure (Irradiation Cell)
  - Supporting systems and components (e.g. Target Solution Dump Tank, cooling systems)

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Subcritical Assembly Preliminary Geometry

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Interconnecting Systems and Components

* TSV Off-gas System (TOGS) connects to headspace of TSV
* Primary Closed Loop Cooling System (PCLS) provides cooling to TSV
* Target Solution (TS) Hold Tank and TS Dump Tank connect to TSV fluid space

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Subcritical Assembly Dimensions

- Preliminary Design Values
  - All dimensions approximate
- TSV exterior dimensions Proprietary Information
  - Inner radius: Proprietary Information
  - Outer radius:
  - External height: Proprietary Information
  - Proprietary Information
    - Internal diameter: Proprietary Information
    - Centerline of cooling tubes mid-distance between TSV inner and outer radius
- Multiplier exterior dimensions Proprietary Information

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  - Inner radius:
  - Outer radius: Proprietary Information
  - External height:

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Target Solution Chemical Composition

- Proprietary Information
- Concentration of uranium is dependent on final TSV geometry, density models, and qualified computer models for neutronics
  - Based on preliminary design, uranium concentration range is: Proprietary Information
  - Given specific preliminary geometry, planned uranium concentration is Proprietary Information
  - Final uranium concentration will be based on final design and startup testing results
  - Expected tolerance during solution batching and measurement of Proprietary Information

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Target Solution Chemical Composition

- Uranium enrichment
  - Proprietary Information
- Other constituents
  - Sulfuric acid concentration
    - Proprietary Information
  - Low concentrations of fission products due to operation and reuse of solution
    - Typical fission product spectrum dominated by U-235 thermal fission
  - Peroxide catalyst agent
    - Work by Argonne National Lab has shown addition of a catalyst agent ensures uranyl peroxide precipitate does not form
    - Possible agents include: copper sulfate, iron (II) sulfate, iron (III) sulfate, potassium iodide
    - Many metals (including stainless steel) will also catalyze auto-destruction of peroxide
    - Expected concentration of catalyst in solution: Proprietary Information

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Subcritical Assembly Startup Process

- Startup process of TSV ensures system reactivity starts negative
- Prior to filling TSV:
  - Dump tank and TSV verified empty
  - Uranium concentration measured and verified
  - Neutron Driver High Voltage Power Supply de-energized (no deuterium beam)
- TSV pressure, temperature, and level measured during fill process
- TSV filled in discrete steps using 1/M methodology similar to research and power reactors
- Fill rate of system is physically-limited by design of fill path (piping and pump selection)

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Subcritical Assembly Startup Process

- Fixed neutron source and neutron flux detectors provide clear indication of subcritical multiplication in assembly
- Operators follow clear procedures with defined hold points to determine acceptance of flux given current fill volume
- Source Range High Flux trip provides redundant engineered protection against reaching critical
  - Flux trip setpoints determined during final design using qualified transient analysis codes
  - Code predictions and facility startup testing bound subcritical multiplication factor for given SR High Flux Trip setpoints
- Protection similar to reactor
  - Essentially, SHINE system is a "startup" that is stopped early (less fissile material)

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Subcritical Assembly Startup Process

- Normal startup process will yield subcritical system
  - Fill process stopped approximately Proprietary Information Proprietary Information below critical
  - Preliminary cold k_{eff} values approximately Proprietary Information
    - Cold k_{eff} values during startup are maximum k_{eff} values expected in the system for normal operation
  - Normal process concentration and temperature variations will result in acceptable startup with slight variations in fill volume
  - Irradiation process significantly decreases reactivity Proprietary Information
- Abnormal startup conditions have controls and protective measures to ensure safety
  - Abnormal uranium concentration
  - Uncontrolled fill
  - Significant temperature variation in TSV and Primary Cooling System (PCS)
  - Loss of offgas system flow or PCS flow

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Subcritical Control – During Irradiation

* Operators transition system to Irradiation Mode after acceptable startup
  * Fill valves closed (engineered interlock prevents opening)
  * Fill pump de-energized
  * TSV Offgas System and Primary Cooling System verified functioning normally
  * High-range flux monitors verified in range and acceptable readout
  * Source-range (startup) high flux trips bypassed
    * High-range high flux trips active
  * Driver energized
  * Neutron source strength ramped to full output

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Subcritical Control – During Irradiation

- During irradiation, minimal system changes expected
  - No manual solution adjustment possible (e.g. solution or acid addition)
    - Greatly reduces potential for human error to cause reactivity insertion
  - Primary Cooling System supply temperatures are maintained steady
  - TSV Off-gas System recombines hydrogen and oxygen into water, which condenses and is returned to TSV
    - Small amount of water "hold-up" in Off-gas system – small, expected reactivity increase
    - Excessive water hold-up in Off-gas system would lead to increasing power
      - Slow mechanism due to physical processes involved (evaporation and radiolytic decomposition)
      - Example: If all radiolysis products were not returned to system, a reactivity increase of approximately Proprietary Information Proprietary Information
      - Annunciator indicates power increase
      - Operator action trips TSV
      - If no operator action, control system would trip TSV when high neutron flux setpoint reached

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Subcritical Control – End of Irradiation

- At end of irradiation cycle Proprietary Information the process is stopped in a controlled manner
  - Neutron driver control system interrupts neutron production
  - After the neutron source is removed, fission process essentially ceases
  - Hydrogen and oxygen production drops to less than 5% of value during irradiation, and continues to decrease
  - Off-gas system continues to function normally
  - Primary Cooling System continues to function normally
  - Solution is drained to Target Solution Dump Tank for thermal cooldown and fission product decay

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Ensuring Subcriticality During Accident Scenarios

* The following events have the potential to increase the reactivity of SHINE's Subcritical Assembly, and therefore, decrease the margin to criticality
  * Inadvertent solution injection
  * Pressurization of Target Solution
  * Excessive cooldown of Target Solution
  * Moderator addition to Target Solution
  * Inadvertent addition of other material to Target Solution
  * Moderator voiding or lumping effects
  * Realistic, adverse geometry changes
* Other "traditional" reactivity insertion mechanisms are not applicable for SHINE
  * Rapid insertion of a portion of all excess reactivity loaded into core
  * Rapid insertion of a fuel element into a vacancy in core
  * Rapid removal of most reactive control rod

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Ensuring Subcriticality During Accident Scenarios

- SHINE has considered each of these potential reactivity insertion mechanisms during the preliminary design process

- Inadvertent solution injection
  - Only one defined fill path for Target Solution into TSV
  - Filling Mode:
    - Target solution injection is flow rate limited to limit rate of reactivity insertion
    - Process is controlled by licensed operators with approved procedures
    - Inadvertent (excessive) fuel injection is terminated by Source Range High Flux Trips
  - Irradiation and Shutdown Modes:
    - Fill valves are closed and interlocks prevent opening
    - Fill pump is de-energized
    - Despite these controls, if inadvertent fuel addition occurred
      - Reactivity of system would increase
      - Increase in reactivity would lead to high flux trip significantly before initial k_{eff} is reached

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Ensuring Subcriticality During Accident Scenarios

- Pressurization of Target Solution
  - Potentially due to inadequate recombination, deflagration, or detonation event
  - Pressurization of Target Solution decreases void fraction
  - Reactivity would increase
    - Preliminary estimates of void coefficient of reactivity:
      Proprietary Information
  - Power would increase
    - Annunciators alert operators to increased pressure and power
    - Power increases above the high flux trip setpoint will cause a dump of solution
    - Pressure increases above high pressure trip setpoint will cause a dump of solution
    - If no trip occurred and system remained pressurized, solution would remain subcritical, simply at higher k_{eff}
    - k_{eff} would remain below cold k_{eff} at startup

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Ensuring Subcriticality During Accident Scenarios

- Excessive cooldown of Target Solution
  - Severity of event very limited
    - Design of subcritical assembly is to maximize heat removal during normal operations
    - Cooling system and TSV operate near atmospheric pressure – "blowdown" event not applicable
    - Potential for cooling system malfunction, but cooldown rate is very limited
  - Cooldown of assembly increases reactivity
    - Preliminary estimates of temperature coefficient of reactivity: Proprietary Information
  - Power would increase
    - Power increases yielding fluxes above the high flux trip setpoint will cause a dump of solution
    - If no trip occurred and system continued to operate, solution would remain subcritical
    - Higher power would yield higher temperature and increased void, decreasing k_{eff}

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Ensuring Subcriticality During Accident Scenarios

- Moderator addition to Target Solution
  - Potential for water ingress into TSV due to Primary System Boundary failure (e.g. TSV failure or TSV Off-gas System heat exchanger leakage)
  - SHINE Target Solution is over-moderated
    - Addition of water to solution will decrease reactivity
  - As discussed in NUREG-1537 ISG, moderator addition has the potential to form a "reflector" prior to mixing with solution
    - Due to geometry of TSV and surrounding pool, credible water ingress scenarios are not expected to challenge the subcritical state of the assembly
    - Potential worst-case configurations will be evaluated in final design
- Inadvertent addition of other material to Target Solution
  - SHINE Subcritical Assembly does not include other systems to add additional materials to the Target Solution Vessel

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Ensuring Subcriticality During Accident Scenarios

- Moderator voiding or lumping effects
  - Potential exists in AHRs for void formation in cooling coils submerged in fuel
  - Voiding or lumping effects do not have a significant reactivity effect in SHINE's design
    - Vertical cooling tubes greatly reduce potential for void accumulation
    - Low temperature, low pressure operation reduce possibility of void formation due to boiling
- Realistic, adverse geometry changes
  - Vibration or seismic event could induce "sloshing" in the TSV
  - Vibration during normal operation is expected to be minimal as SASS is connected to robust structure of IU cell
  - Change in geometry of the solution in TSV during seismic event will change reactivity
  - Due to high aspect ratio design of TSV, sloshing of solution expected to have small reactivity effects (maintaining subcriticality of system)
    - Final design will analyze magnitude of effects
  - Significant sloshing will result in solution leaving through overflow lines, reducing reactivity

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Preliminary TSV Design

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Criticality Safety Outside the TSV

- Analyses lead by criticality safety engineer with extensive experience in commercial nuclear facility criticality safety
- Passive engineered design features are the preferred design approach
- All vessels with fissile solution except TSV are designed and/or controlled to meet the Upper Subcritical Limit
- Upper Subcritical Limit (USL)
  - USL = 1.00 - MOS - bias

    where,

    MOS = Margin of Subcriticality = 0.05 Δk, and

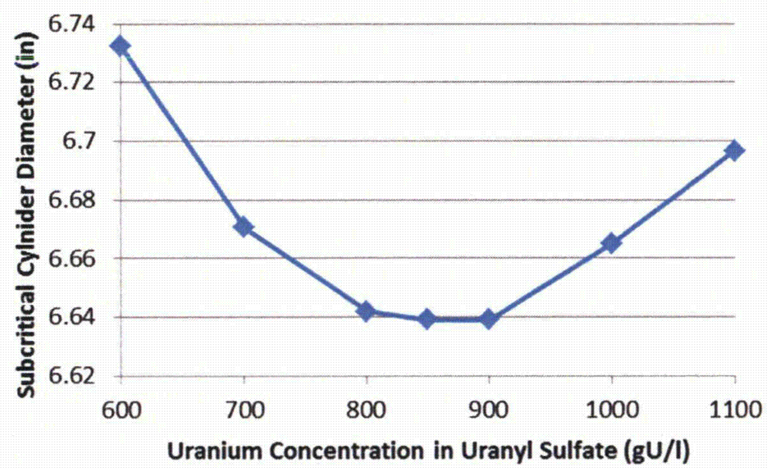
    bias = 0.016 Δk
  - Therefore the USL = 0.934
  - For an acceptable result, the MCNP ($k_{eff} + 2\sigma$) must be less than the USL value
- Criticality calculations performed with MCNP5, build v1.4 using ENDF/B-VI cross sections

Criticality Safety Outside the TSV

- Key assumptions for Nuclear Criticality Safety
  - 21 wt% ^{235}U to bound all incoming enrichments.
  - 0% sulfuric acid in modeled solutions
    - The presence of sulfuric acid lowers k_{eff} due to additional neutron absorption
  - $20^{0}C$ temperature assumed for all materials
  - Solute saturation is unlimited
    - Realistic saturation behavior is ignored in favor of showing peak reactivity
- Calculated vessel parameters ensure k_{eff} is below USL at "optimal" uranium concentration

Preliminary results for uranyl sulfate in cylindrical vessel

U Conc (gU/l)	Cyl Diam (in)
600	6.73
700	6.67
800	6.64
850	6.64
900	6.64
1000	6.67
1100	6.70



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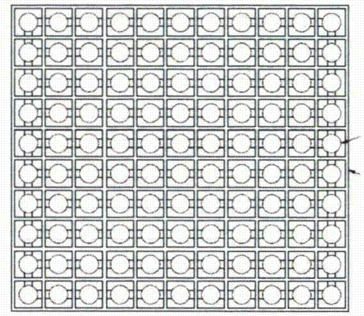
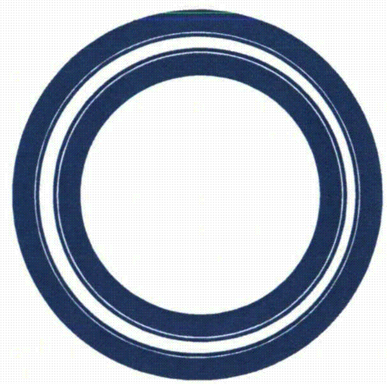
Criticality Safety Outside the TSV

- Four tank designs used to ensure criticality safety
  - Safe volume tank
  - Single cylindrical tank
  - Array of cylindrical tanks
    - Uses a neutron absorber material, Proprietary Information in a square array surrounding each tank
    - Proprietary Information
  - Annular tank
    - Uses a neutron absorber material, Proprietary Information as a liner inside and outside the annular tank thickness
    - Proprietary Information



Array of Cylindrical Tanks



Annular Tank

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Criticality Safety Outside the TSV

* Other NCS controls in the RPF:
  * Criticality safe geometry sumps and drains are installed to detect and divert spilled or leaked material to a Criticality Safe Sump Catch Tank
  * A hold tank combined with uranium concentration measurement are used ensure raffinate material discharged from the UREX has acceptably low levels of uranium
    * Raffinate then transferred to liquid radioactive waste tank
  * Safe geometry storage racks are used for incoming uranium metal and recycled uranium powder

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Subcriticality in the SHINE Facility

- SHINE design process has investigated subcriticality of TSV during startup mode, irradiation mode, and accident scenarios
  - SHINE subcritical assembly has adequate margin to criticality during normal operation and evaluated scenarios
- Startup of assembly is controlled through administrative, active, and passive features to ensure cold system reactivity is negative
  - Irradiation process induces significant negative feedback mechanisms, Proprietary Information Proprietary Information
  - Abnormal events during the fill process have controls and protective features
- Accident scenarios have potential to add reactivity to the system
  - Reactivity impact of pressurization is limited to the void defect
  - Excessive cooldown is inherently rate-limited and result in trip of TSV
  - Subcritical Assembly design prevents additions of solution after fill process
- Any approach to critical above allowable limits during startup and irradiation will be readily detectable and result in operator action or automatic TSV trip
- Outside the TSV, vessels containing fissile material in the facility are designed and/or controlled for a k_{eff} below 0.95 with adequate margins to account for process variations

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Questions?

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Enclosure 3
Affidavit of Richard Vann Bynum, PhD

SHINE™ Medical Technologies

AFFIDAVIT OF RICHARD VANN BYNUM

STATE OF WISCONSIN)
) ss.
COUNTY OF DANE)

I, Richard Vann Bynum, Chief Operating Officer of SHINE Medical Technologies, Inc. (SHINE), do hereby affirm and state:

1. I am authorized to execute this affidavit on behalf of SHINE. I am authorized to review information submitted to or discussed with the Nuclear Regulatory Commission ("NRC") and apply for the withholding of information from public disclosure. The purpose of this affidavit is to provide the information required by 10 CFR 2.390(b) in support of SHINE's request for proprietary treatment of certain confidential commercial information to be discussed during the non-public portion of the SHINE meeting with the NRC on April 17, 2013. The topic of this meeting will be the licensing and technical aspects associated with the criticality margin of the SHINE medical isotope facility. SHINE requests the confidential information contained in the presentation materials for the meeting be withheld from public disclosure as denoted in Enclosure 1 of SHINE letter to the NRC, SMT-2013-013.

2. I have knowledge of the criteria used by SHINE in designating information as sensitive, proprietary, or confidential.

3. Pursuant to the provisions of paragraph (a)(4) and (d)(1) of 10 CFR 2.390, the following is furnished for consideration by the NRC in determining whether the information sought to be withheld from public disclosure should be withheld.

    a. The information sought to be withheld from public disclosure at the referenced non-public meeting with the NRC is owned by SHINE, its affiliates or third parties to who SHINE has an obligation to maintain its confidentiality. This information is and has been held in confidence by SHINE.

    b. The information sought to be protected is not available to the public to the best of my knowledge and belief.

c. The information is of the type that is customarily held in confidence by SHINE, and there is a rational basis for doing so. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, confidential commercial information or information that is subject to export controls. SHINE limits access to these elements to those with a "need to know," and subject to maintaining confidentiality.

d. The proprietary information sought to be withheld from public contained in Enclosure 1 during the non-public portion of the April 17, 2013 meeting include, but is not limited to: structural configuration, primary and supporting systems of the medical isotope facility, and process and systems locations. This would include information regarding the types, quantities, and locations of materials stored on site as would be referenced in facility configuration drawings.

e. Information could be disclosed in the materials presented in Enclosure 1 that involves data or records concerning SHINE's physical protection, classified matter protection, or material control and accounting program for special nuclear material not otherwise designated as Safeguards Information or classified as National Security Information or Restricted Data.

f. Public disclosure of the information in Enclosure 1 would create substantial harm to SHINE because it would reveal valuable business information regarding SHINE's competitive expectations, assumptions, processes and current position. Its use by a competitor could substantially improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.

e. The information is transmitted to the NRC in confidence and under the provisions of 10 CFR 2.390; it is to be received in confidence by the NRC. The information is properly marked.

R.V. Bynum

Richard Vann Bynum, PhD
COO – SHINE Medical Technologies, Inc.

Date: 3/29/13

Subscribed and sworn to before me, a Notary Public, in and for the county and state above named, this 29 day of March 2013.

Patti McLean

Notary Public in and for the
State of Wisconsin
My Commission expires August 2013

PATTI MCLEAN
Notary Public
State of Wisconsin