



New Generating System for Tc99m Production

G.P. Messina, G.H. Isensee, J.T. Harvey, S.D. Moffatt

NorthStar Medical Technologies, LLC

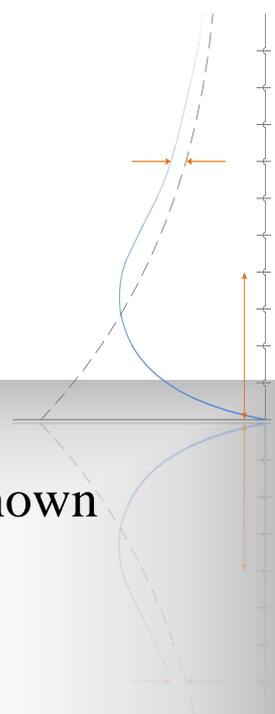
5249 Femrite Drive, Madison, WI 53718 – USA

**Mo-99 2014 TOPICAL MEETING ON
MOLYBDENUM-99 TECHNOLOGICAL DEVELOPMENT**

**June 24-27, 2014
Washington D. C.**

Topics

- Background on NorthStar's NDA path
 - Historical development of RadioGenix™ platform (formally known as TechneGen)
 - Submission and FDA Complete Response
- NorthStar path forward
 - Internal reviews
 - Focus Group feedback
 - System improvements to meet FDA and Focus Group comments
- Summary & Discussion



History of RadioGenix

- Early development initiated in mid-1990's
- Automated Radionuclide Separation System (ARS) first prototypes built in 2000/2001 time frame. This work was supported by the Comer Foundation
 - Early prototypes used demonstrate the technology viability
 - Early prototypes evaluated by several radiopharmaceutical industry and university groups
- NorthStar licensed IP and received possession of all prototypes in 2005
- NorthStar further developed IP to next generation (ARSII) in 2006/2007
 - Input from key researchers at MSKCC and AECOM
 - ARSII used in several pre-clinical R&D efforts in nuclear medicine
- Improvements identified with ARSII usage incorporated into V.1 of RadioGenix (f.k.a TechneGen) in 2011/2012 time period
- RadioGenix V.2 now being built incorporating enhancements learned during initial NDA preparation and customer focus groups
- RadioGenix is now in it's 5th generation of continued improvements

History of RadioGenix



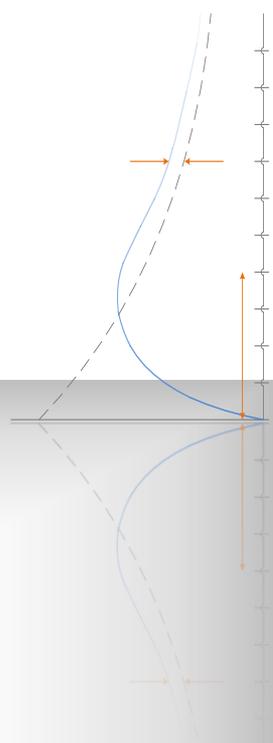
The Automatic Radionuclide Separation System (ARS) prototype in early 2000's licensed by NorthStar in 2005

History of RadioGenix



*The Automatic Radionuclide Separation System (ARSII)
marketed by NorthStar in 2008*

History of RadioGenix



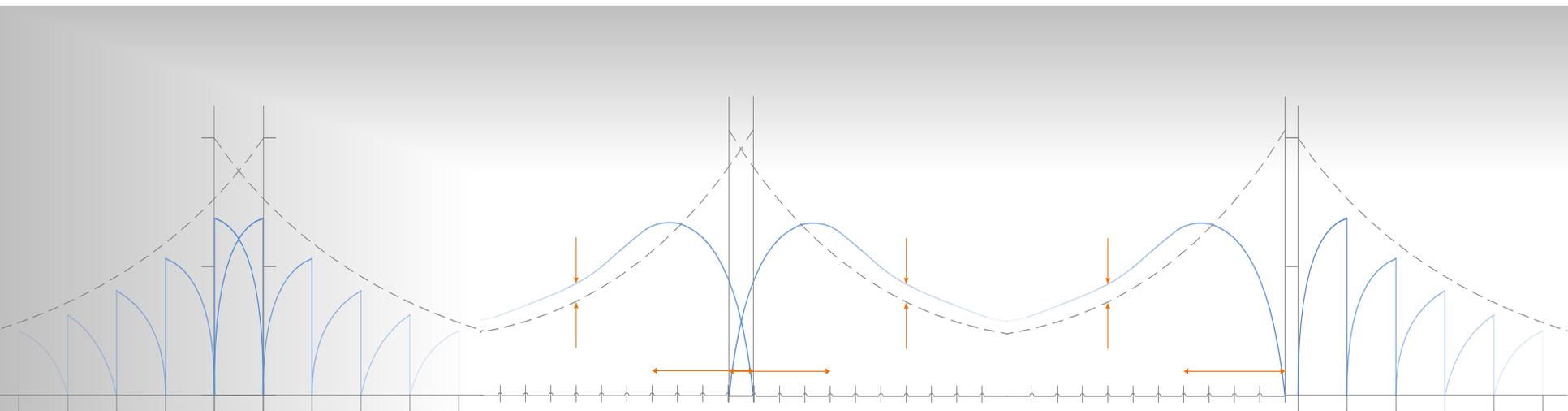
NorthStar/FDA Timeline

- October 2010 NorthStar met with the FDA to outline a path to NDA submission
- MURR submitted DMF for production in September 2012
- NorthStar submitted TechneGen DMF in October 2012
- January 2013 NorthStar submitted its NDA
- NorthStar received in March 2013 from FDA a PDUFA date of November 4, 2013
- NorthStar received its Complete Response letter from the FDA on November 4, 2013 outlining deficiencies primarily in two areas
 - Microbiological control
 - User Manuals
- NorthStar met with the FDA on February 27, 2014 to gain clarity on the CR letter
 - NorthStar has submitted to FDA its revised Microbiological Test Plan for comment
 - Meeting with FDA scheduled for July 2, 2014 to discuss



*APhA Meeting
Orlando, Florida*

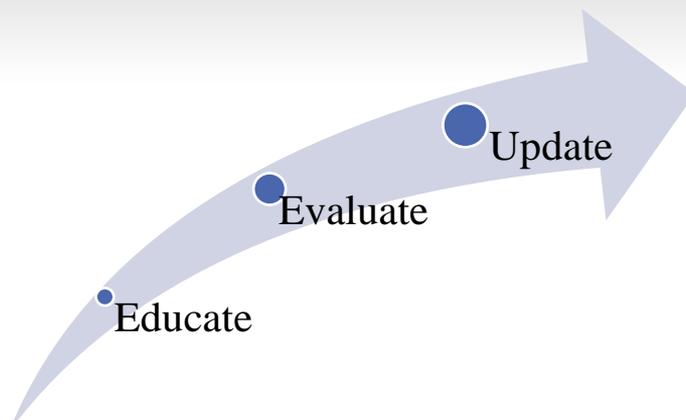
Customer Focus Session



APhA Customer Focus Group Session Format

- 4 Sessions Over 3 Days
 - ~ 80 of the 220 Nuclear Pharmacists who attended APhA attended the NorthStar Customer Focus Group Session
 - Three Demonstration Stations with Dedicated Service Engineer
 - “Idea Center” Station Highlighting Pharmacist Suggested Improvements
 - Artist Rendition of the Next Generation of RadioGenix; V2
 - Continuous Loop Video to Explain the Isotope Separation Process
 - Tablet Based Exit Interview

Session Flow



Participants

Entities Represented

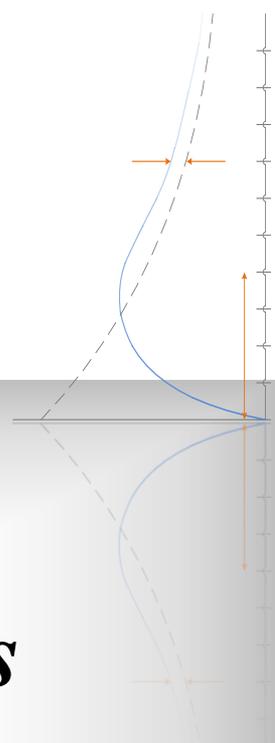
- Cardinal Health
- United Pharmacy Partners
- Triad Isotopes
- General Electric HealthCare
- PharmaLogic
- Influential Universities
 - Purdue, Oklahoma, New Mexico, Arkansas, Duke, Ohio State

Locations, Impact

- 150 Locations, National
- 80 Locations, Co-Op
- 64 Locations, National
- 32 Locations, National
- 8 Locations, Regional
- 6 Locations

Focus Group Findings

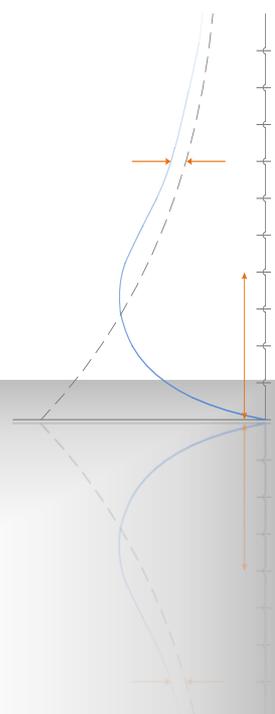
- Purpose:
 - To enlighten the current pharmacy population about NorthStar's imminent product offering and technology
 - To receive potential feedback from potential customers that we may wish to include in the new generation RadioGenix™
- Results:
 - Product offering received very favorable comments including;
 - Product had significant competitive advantages
 - The ability for the product to evolve was considered a much desired feature over the current generators
 - To those who had seen the previous generations, the changes proposed in the next generation RadioGenix made the system a much simpler system to use, and
 - The automated feature of the system was considered a big plus
 - Recommended Updates:
 - The majority of suggested updates were already being incorporated into the new design,
 - A number of proposed updates were added to the new design, and
 - The balance will be included in future revisions



RadioGenix Design Enhancements

RadioGenix Design Enhancements

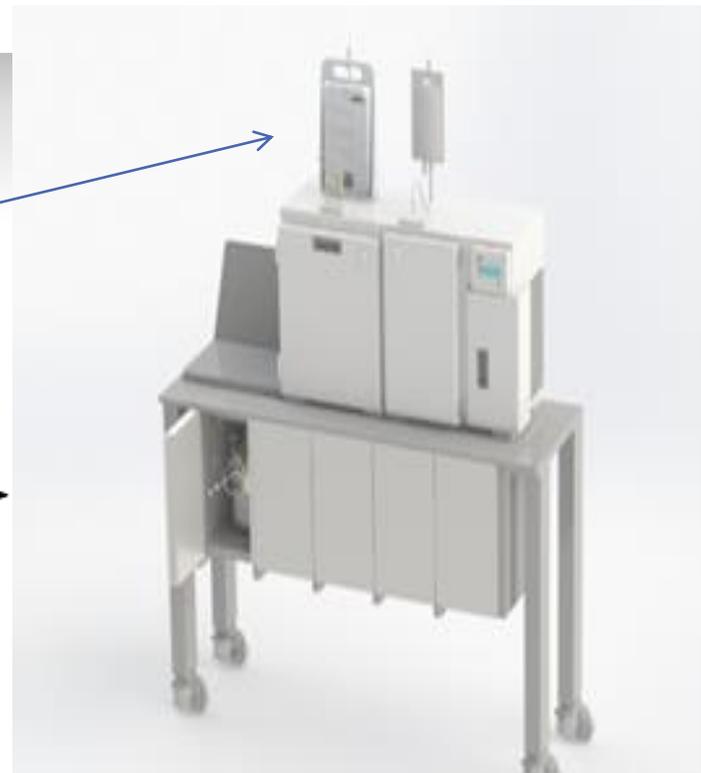
- Protocol enhancements
 - Reduced elution time
 - Reduction in waste volume
 - Yield increase
- Aseptic handling
 - Significant reduction in user manipulations
- Design reliability
 - Greater radiation and chemical materials compatibility
- User interface
 - Simplified user GUI
- Serviceability
 - Ease of onsite servicing of the system, reliability/uptime and safety



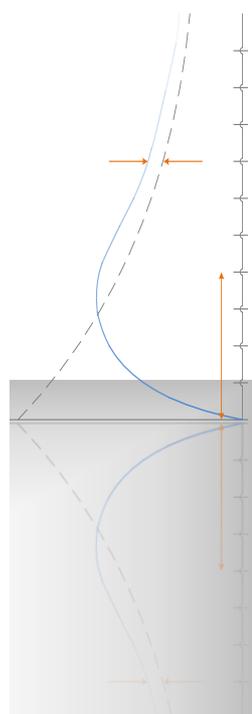
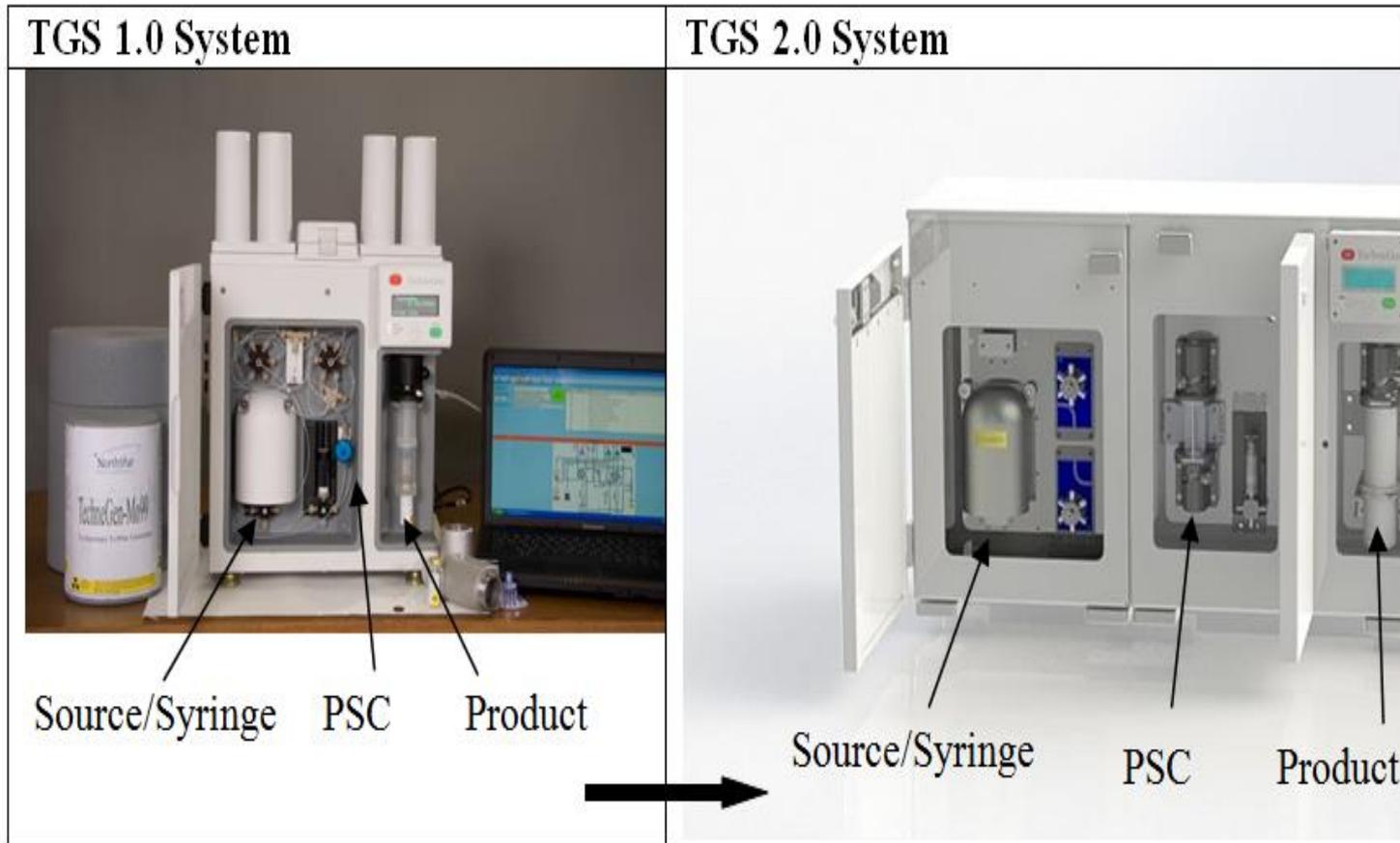
Source & Transfer Vessel Compartment Storage



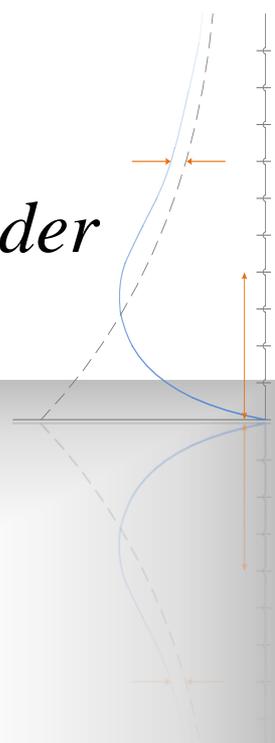
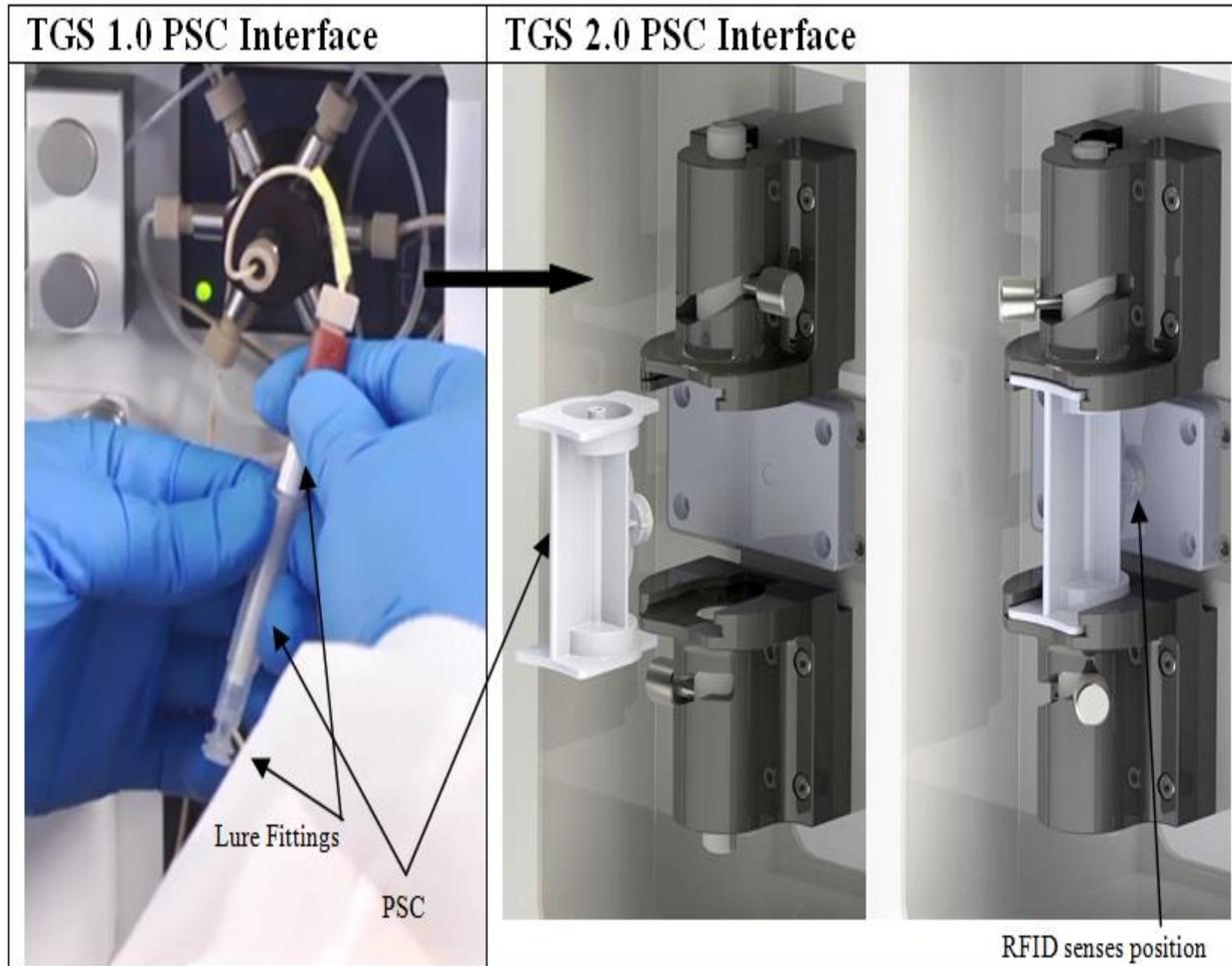
Reagent Containers and Attachments Simplified



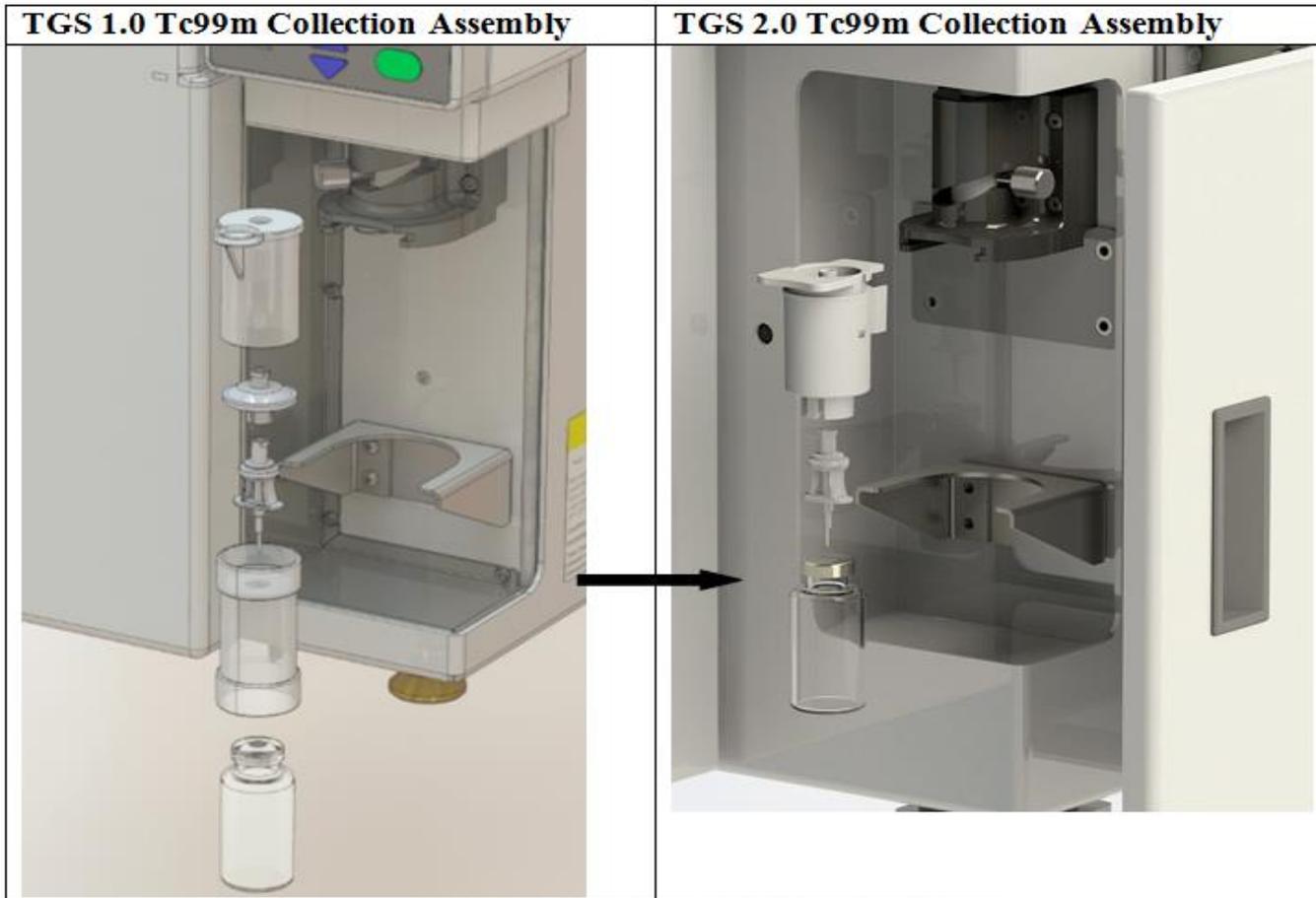
Primary Separation Cartridge-ABEC Compartment



Primary Separation Cartridge-ABEC Fixed Holder



Tc99m Collection Assembly – Filter Integrity Testing



Note: Vial Shields are not shown for clarity.

Schedule

- Final Amendment submitted to the FDA in 2nd Quarter 2015
- Production begins upon FDA approval
- Production capability will ramp from 100 6 Day curies per week to 3,000 6 Day curies per week no later than 1 October 2016 depending on market need.



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