Job Title: **Systems Engineer / Senior Systems Engineer– Particle Accelerator**

SUMMARY

NorthStar's mission is to transform the medical radioisotopes industry by becoming a global leader of innovative diagnostic & therapeutic medical radioisotopes. In fulfillment of this mission, NorthStar continues to develop groundbreaking isotope processing methods.

This position will assist the specification, development, implementation, qualification, and commissioning of particle accelerator based radioisotope processing systems. This position will also be responsible for the definition and creation of requirements/specifications/procedures related to the operation, qualification and maintenance of the systems, which can be transitioned to manufacturing. The successful candidate will be familiar with the operating principles and physics of electron accelerators, as well as the systems engineering involved with the implementation and commissioning of accelerators and their associated subsystems.

All projects and duties will be completed in compliance with applicable cGMP, FDA, and all other regulatory agencies standards.

The Systems Engineer is also responsible for assisting with the development and implementation of NorthStar Medical Radioisotopes quality system processes, which meet the requirements of applicable quality system regulations.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following, other duties may be assigned:

1. Support NorthStar's program to deploy accelerators in the production of radioisotopes.
2. Integrate commercial and custom accelerator subsystems to further NorthStar's mission.
3. Work with supporting scientists and engineers at Argonne and Los Alamos National Laboratories currently working on this project under National Nuclear Security Administration (NNSA) funding.
4. Develop and document system requirements, systems architecture, and systems level designs.
5. Collaborate with internal and external stakeholders and suppliers to design, purchase, and build equipment and processes that meet associated user, design, and production requirements.
6. Develop and optimize system workflows as related to data collection and production flow, in the form of Batch Production Records and Work Instructions, etc.
7. Assist with the development of processes and associated documentation related to system calibration, preventive maintenance, and repair of production systems.
8. Assist with the development and execution of product and system verification and validation strategies.
9. Assist with the development of Risk Management Plans and executing the Risk Management activities defined by the plan which would include Use/Misuse FMEA's, DFMEA's, PFMEA, and other risk management tools.
10. Anticipate and mitigate risk points. Make tradeoffs between design complexity, time and effort, schedule, cost, and quality while meeting safety and regulatory requirements.

QUALIFICATIONS

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

EDUCATION and/or EXPERIENCE
The level of this position will be set commensurate with experience.

Minimum qualifications

1) Master's or PhD degree in Engineering, Physics, or a related discipline with a minimum of 2 years relevant technical experience, inclusive of academic experience, in an accelerator based environment; or an equivalent combination of education and experience.
2) Experience in the development of particle accelerator equipment.
3) Must possess a strong knowledge of engineering disciplines and solid knowledge of related disciplines, Electro/Mechanical, Systems, Fluid Mechanics, Software, and Materials Science.
4) Ability and willingness to travel domestically occasionally, including possible visits to Argonne and Los Alamos labs. Minor international travel will be required. During install, commissioning, and qualification, daily presence in Beloit will be required.
5) Demonstrated ability to work within a multidisciplinary team.

Preferable qualifications

6) Specific experience with electron accelerators
7) Knowledge of Product Development Life Cycle ranging from product specification and concept development to product release
8) Experience with medical/pharmaceutical design and development and/or FDA/cGMP compliance
9) Experience with radioactive material processing.
10) Experience within a production engineering environment in the specification, development and qualification production based systems and equipment.
11) Experience in requirements gathering and definition processes and tools
12) Experience with system requirements decomposition/system architecture design
13) Understanding of medical device risk management processes and tools including risk management planning, Use Misuse FMEA, DFMEA, PFMEA.

COMPUTER SKILLS
Proficient knowledge of office software programs including project planning, Outlook, Word, Excel, and Visio.

OTHER QUALIFICATIONS

- Excellent communication skills, verbal and written
- Analytical thinker with interpersonal skills
- Ability to lead and function within project teams
- Ability to handle multiple tasks simultaneously
- Ability to work in a fast-paced environment
- Adaptable to change in the work environment
- Ability to work in a team environment, as well as independently