Job Title: **Controls and Automation Engineer / Senior Controls and Automation Engineer**

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.

The Controls Engineer will work to develop a particle accelerator based radioisotope processing system. The position will assist senior engineers with analyzing system requirements and will contribute to the development and execution of controls engineering tasks through design, planning, procurement, and execution, as well as coordinating with vendors and contractors. Some of these tasks include programming of PLC and HMI, as well as associated documentation, and other tasks involve instrumentation and diagnostics of the accelerator system. Also included is assisting in the development and implementation of Manufacturing Execution Systems (MES) and associated networking and data management systems. This individual will be required to work with cross functional teams, including RA/QA and Process Engineering to apply efficient cGMP processes to preserve data integrity and the quality of the final drug product, including the safety of all production and non-production personnel.

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

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

1. Design, revise, and commission controls based systems with input from cross-functional teams and senior staff.
2. Design, code, test, and debug programs and systems.
3. Create and implement controls and automated system designs that operate in high radiation, high RF environments.
4. Integrate commercial and custom control system hardware and software.
5. Create, modify, and maintain automation system documentation including project documentation, specification documents, and SOPs in a cGMP compliant state.
6. Ability to troubleshooting various controls systems, both in software and hardware, and provide training to operations personnel on controls operations.
7. Ensure effective maintenance and availability of controls equipment.
8. Support the validation of automation systems per cGMP and Regulatory guidance.
9. Understand and create electrical schematics and wiring diagrams and present drawings and project progress to peers and management related to automated system controls
10. Participate in process risk and hazard reviews and modify equipment/designs as necessary to ensure safe operation and appropriate specifications are captured.
11. Assist with the implementation of automation changes to existing hardware and software, supervising hardware and software modification done by outside vendors. Development of specifications and testing documentation.

Ability and willingness to travel both domestically and internationally up to 10% of the time.

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

20) Bachelor's degree in Engineering, or an associated discipline, and 5 or more years of experience with a concentration in Controls Engineering, including both software and hardware; or combination of education and experience.
21) Experience designing and implementing controls software for complex systems
22) Experience with hardware design and cabling principles
23) 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.
24) Demonstrated ability to work within a multidisciplinary team.

Preferable qualifications

1) Experience controlling particle accelerators
2) Experience with Siemens products
3) Knowledge of high power RF systems
4) Experience maintaining and integrating third party controls software
5) Experience with medical/pharmaceutical design and development and/or FDA/cGMP compliance
6) Experience within a production engineering environment in the specification, development and qualification production based systems and equipment.
7) Experience in requirements gathering and definition processes and tools

COMPUTER SKILLS
Demonstrated proficiency of PLC and HMI programming including databases and system interfacing languages. Experience with AutoCad Electrical or comparable design software. Proficient knowledge of Microsoft Office software programs including Outlook, Word, Excel, PowerPoint and Visio.

OTHER QUALIFICATIONS

- Familiar with FDA regulations
- Excellent communication skills, verbal and written
- 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