# Initial Experience with an Independent Certification Program for Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

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**Purpose:** The ASTRO document *Safety is no accident: A FRAMEWORK FOR QUALITY RADIATION ONCOLOGY AND CARE* recommends external reviews of specialized modalities. The purpose of this presentation is to describe the implementation of such a program for Stereotactic Radiosurgery (SRS) and Stereotactic Body radiation Therapy (SBRT).

**Rationale:** The margin of error for SRS and SBRT delivery is significantly smaller than that of conventional radiotherapy and therefore requires special attention and diligence. The International Atomic Energy Agency (IAEA) recommends external audits as a necessary part of a comprehensive radiation oncology QA program, with such a audit reviewing all elements involved in radiotherapy, including staff, procedures, equipment, patient protection and safety. The World Health Organization (WHO) suggests that preventing radiotherapy errors could achieved in part through frequent audit and regular peer review of the specialist's protocols, procedures, procedures and personnel. Finally, the ASTRO document *SAFETY IS NO ACCIDENT* recommends an independent review of crucial aspects of any quality program, and that special treatment techniques including SRS and SBRT undergo external peer review initially and at regular intervals. The Novalis Certified program was created to fill an unmet need for specialized SRS / SBRT credentialing.

**Methods:** A standards document was drafted by a panel of experts from several disciplines, including medical physics, radiation oncology and neurosurgery. The document, based on national and international standards, covers requirements in program structure, personnel, training, clinical application, technology, quality management, and patient and equipment QA. The credentialing process was modeled after existing certification programs and includes an institution-generated self-study, extensive document review and an onsite audit. Reviewers generate a descriptive report, which is reviewed by a multidisciplinary expert panel. Outcomes of the review may include mandatory requirements and optional recommendations.


**Figure 1.** The Novalis Standard is based on international quality and safety documents, including those from the WHO, the IAEA, and ASTRO, and on SRS/SBRT-specific guidance documents from the ACR, ASTRO, AAPM and others.

Novalis Certified is a vendor and equipment-neutral credentialing program emphasizes the implementation of SRS/SBRT as a well thought out process, encompassing organizational elements, infrastructure, well documented policies and procedures, personnel, technology and QA requirements. Clinical goals and guidelines should be developed for each disease site. All necessary resources, including personnel, expertise, technology, and time should be identified well in advance. Personnel qualifications include appropriate disease-site specific, equipment and vendor training, with license, board certification and maintenance of certification as appropriate. Written SRS/SBRT-specific roles and responsibilities for all program personnel. An SRS/SBRT credentialing process, and the use of checklists to guide all program aspects are strongly encouraged. Peer review processes, institutional and departmental quality management programs, and a strong commitment to safety (safety culture) are absolute imperatives.

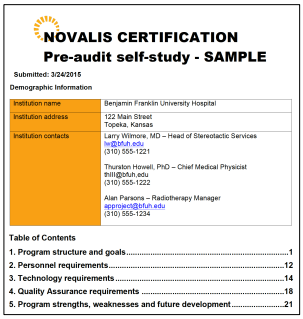

**Figure 2.** The certification program covers six broad areas, including institutional and program organization, infrastructure, policies & procedures, personnel, technology, and a comprehensive, well structured quality management program encompassing all aspects of quality assurance.

| QA Manager | QA Committee | Internal Review | External Review | Peer Review |
|---|---|---|---|---|
| Incident Reporting System<br>Process for failure mode analysis | Regular Meetings<br>Minutes must be be documented and distributed | Program is reviewed internally with frequency no greater than every two years | Program has external reviews (audits) to assess quality and safety | Program has a formal peer review for physicists and physicians |

**Figure 3.** A comprehensive quality management program includes a dedicated quality manager, an incident reporting system and processes for failure mode analysis, processes for peer review, and a QA committee with representation from all department specialties. The QA committee should hold regular meetings, and minutes on QA activities should be recorded and distributed throughout the department. The programs should undergo regular internal and external reviews.

The program also mandates numerous physics / technical requirements, including: appropriate use of specialized equipment for SRS/SBRT ; comprehensive commissioning incorporating a full range of SRS/SBRT planning and delivery techniques and parameters; use of specialized phantoms to perform end-to-end localization and dosimetric verification using image guidance systems for each treatment site in a manner that mimics clinical processes; independent assessment of beam data, particularly for small fields; and independent verification of absolute calibration.

**The Review Process:** The auditor interacts with institution, providing the Standard, a self study template and other relevant documents. The institution subsequently prepares pre-audit documentation: a completed self study as well as appendices containing site specific SRS/SBRT protocols; a description of the quality management program, peer review processes, error reporting framework and safety culture; copies of policies and procedures related to SRS/SBRT; personnel training, certification and continuing medical education records; equipment acceptance testing, commissioning and quality assurance records. After the documentation is received and reviewed by the auditor, a one-day on-site review is scheduled and performed. The auditor subsequently prepares and submits a report to the Expert Panel, along with a recommendation. It is up to the Expert Panel to grant certification; full or conditional certification can be given. Each institution receives a detailed report with a list of recommended and required actions.


NOVALIS CERTIFICATION

Pre-audit self-study - SAMPLE

Submitted: 3/24/2015

Demographic Information

| | |
|---|---|
| Institution name | Benjamin Franklin University Hospital |
| Institution address | 122 Main Street<br>Topeka, Kansas |
| Institution contacts | Larry Wilmore, MD – Head of Stereotactic Services<br>lw@bfuh.edu<br>(310) 555-1221<br><br>Thurston Howell, PhD – Chief Medical Physicist<br>thill@bfuh.edu<br>(310) 555-1222<br><br>Alan Parsons – Radiotherapy Manager<br>approject@bfuh.edu<br>(310) 555-1234 |

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**Figure 4.** Self study prepared by each institution and submitted with appendices documenting clinical protocols, training, policies/procedures, commissioning, and quality assurance.

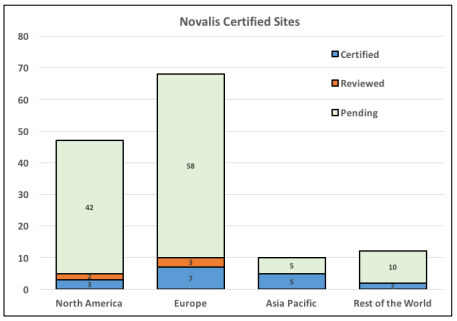


**Figure 5.** As of July, 2016, 17 sites have received full Novalis Certification. 5 sites have been audited and are awaiting decision, and over 110 additional sites are preparing documentation or scheduling their on-site review.

**Results:** 17 institutions have received Novalis Certification, including 3 in the US, 7 in Europe, 5 in Australia and 2 in Asia. Over 110 other centers are at various stages of the process. Nine reviews have resulted in mandatory requirements, including: incomplete documentation, no use of timeouts, insufficient staffing, and missing quality assurance procedures; however all of these were addressed within three months of the audit report. All reviews have produced specific recommendations ranging from programmatic to technical in nature. Institutions felt that the credentialing process addressed a critical need and was highly valuable to the institution.

**Conclusions:** Novalis Certified is a unique peer review program assessing safety and quality in SRS and SBRT, while recognizing international practice standards. The approach is capable of highlighting outstanding requirements and providing recommendations to enhance both new and established programs.

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