

Novalis Certification of stereotactic radiosurgery and stereotactic body radiation therapy programs: methodology and current status

James L Robar, PhD¹, Thierry Gevaert, PhD², Manuel Todorovic, PhD³ and Tim Solberg, PhD⁴

¹ Department of Radiation Oncology, Dalhousie University, Halifax, Nova Scotia, Canada

² Department of Radiotherapy, Universitair Ziekenhuis Brussel (UZB), Vrije Universiteit Brussel, Brussels, Belgium

³ Department of Radiotherapy and Radio-oncology, University of Hamburg, Hamburg, Germany

⁴ Department of Radiation Oncology, University of Pennsylvania, USA

Objectives

The Novalis Certification program is the only program in the world dedicated to providing a comprehensive and independent assessment of safety and quality in stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT). Certification is founded on the Novalis Standard, which was established from accepted guidance documents in the field¹⁻⁴.

Methods

The Novalis Certification program includes a review of SRS/SBRT program structure, adequacy of personnel resources and training, appropriateness and use of technology, program quality management, patient-specific quality assurance and equipment quality control. Currently ten auditors support the program, with six in North America, three in Europe and one in Asia, each bringing a minimum of a decade of experience in stereotactic practice. Centres applying for Novalis Certification complete a self-study 30 days prior to a scheduled one-day site visit by one to two reviewers. Reviewers generate a descriptive 77-point report which is reviewed and voted on by a multidisciplinary expert panel of 3 medical physicists, 2 radiation oncologists and 2 neurosurgeons. Outcomes of reviews include mandatory requirements and optional recommendations, with the former requiring resolution prior to award of Certification.

Figure 1. Prior to the site visit, the facility completes a comprehensive self-study based on the Novalis Standard (right). Reviewers assist the facility in ensuring all required information is provided.

NOVALIS STANDARD v 1.1	
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Figure 2. Preparatory review allows the site visit to be completed within a single day. The reviewer(s) meet with the entire stereotactic team, including department Chairs, lead radiation oncologists, neurosurgeons, medical physicists, radiotherapists and Quality Management personnel. At the end of the day, and exit meeting is held to discuss preliminary recommendations and requirements.

NOVALIS CERTIFIED Site Visit Agenda		
Location: Watson and Clark Radiation Oncology Centre		
Review Scope: Novalis Standard Version 1.1		
Date: 30 April, 2016		
Time: 8:15 am - 5:00 pm		
Participants: Head of Radiotherapy department, Physicists, Physicists/SRS/SBRT team leaders and members, Management Team		
Time	Topic	Participants
8:15 - 8:45	Opening Meeting Welcome to Radiotherapy Management Team Introduction of scope and agenda by Novalis Auditors Summary and overview of agenda to be observed	Chair: Radiation Oncology Chief: Medical Physics Radiotherapy Management Team, Stereo Team Leads
8:45 - 9:15	Tour of Department Observe the SRS / SBRT / SBRT treatment	Stereotactic Team Leads
9:15 - 9:45	Personnel Requirements Review of staff and their roles	Management Team, Stereo Team Leads
9:45 - 11:00	Clinical SBRS/SBRT Procedures Review of clinical SBRS/SBRT cases, prescriptions, dose constraints and treatment procedures	Physicians and Physical Leads of SBRS/SBRT, Stereo Team Leads
11:00 - 11:30	Quality Management Program Review of quality management, event reporting and safety improvement processes	Quality Management Representatives
11:30 - 12:15	Equipment Observation Observe second SRS / SBRT / SBRT treatment	Chief: Medical Physics, Head of Dosimetry, Stereo Physics Leads
12:15 - 12:45	Technology and QA Procedures Equipment evaluation, acceptance testing, commissioning, calibration	Chief: Medical Physics, Stereo Team Leads
14:00 - 14:45	Interdisciplinary Meeting Review of findings, and recommendations	Radiation Therapy, Radiotherapy, Neurosurgery, Radiotherapy Management Team, Stereo Team Leads
14:45 - 15:30	Close out Meeting Wrap up, review of findings, and recommendations	Chief: Radiation Oncology, Chief: Medical Physics, Radiotherapy Management Team, Stereo Team Leads

Compliance Classification	
Classification	Meaning
Compliant (C)	Full compliance with all recommendations
Opportunity (O)	Compliant in general, but with opportunity for correction / improvement for improvement
Partial (P)	Minor non-compliance with recommendations, including: - Non-critical errors. An isolated occurrence and/or - Not likely to result in the failure of the management system and/or - Not likely to result in the failure of the performance of the product or service. The Corrective Action shall be addressed within three months.
Major (M)	Minor non-compliance with recommendations, including: - A systematic failure of the management system and/or - A condition that may result in the failure of product/service or - A condition that may result in a situation in which the safety of the patient is compromised. The Corrective Action shall be addressed immediately and implemented within one month.

Figure 3. A standardized classification is employed to assess compliance with the Novalis Standard. Outcomes of the review include recommendations with regard to opportunities to improve programs, or mandatory requirements.

Results

To date, 16 institutions have received Novalis Certification, including 7 in Europe, 3 in North America and 5 in Asia Pacific (figure 4). 118 certification applications are pending; roughly one half and one third of these are sites are in Europe and North America, respectively. The first 15 reviews have generated a total of 9 requirements and 84 recommendations. A retrospective analysis (figure 5) shows that the most frequent requirement is improved documentation of procedures. The most frequent recommendations pertain to equipment/systems QA procedures and a need for additional, dedicated equipment and effective use of checklists / time outs.

Figure 4. Summary of number of facilities for which Novalis Certification is complete or pending review.

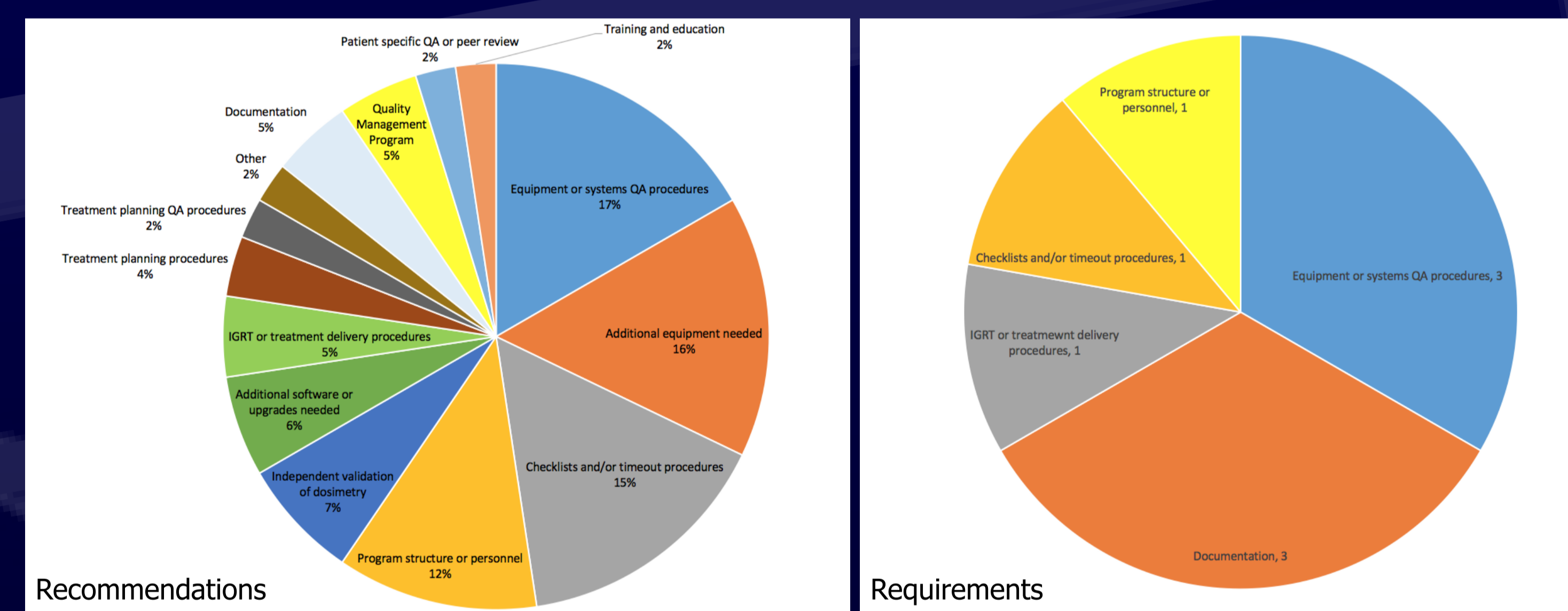
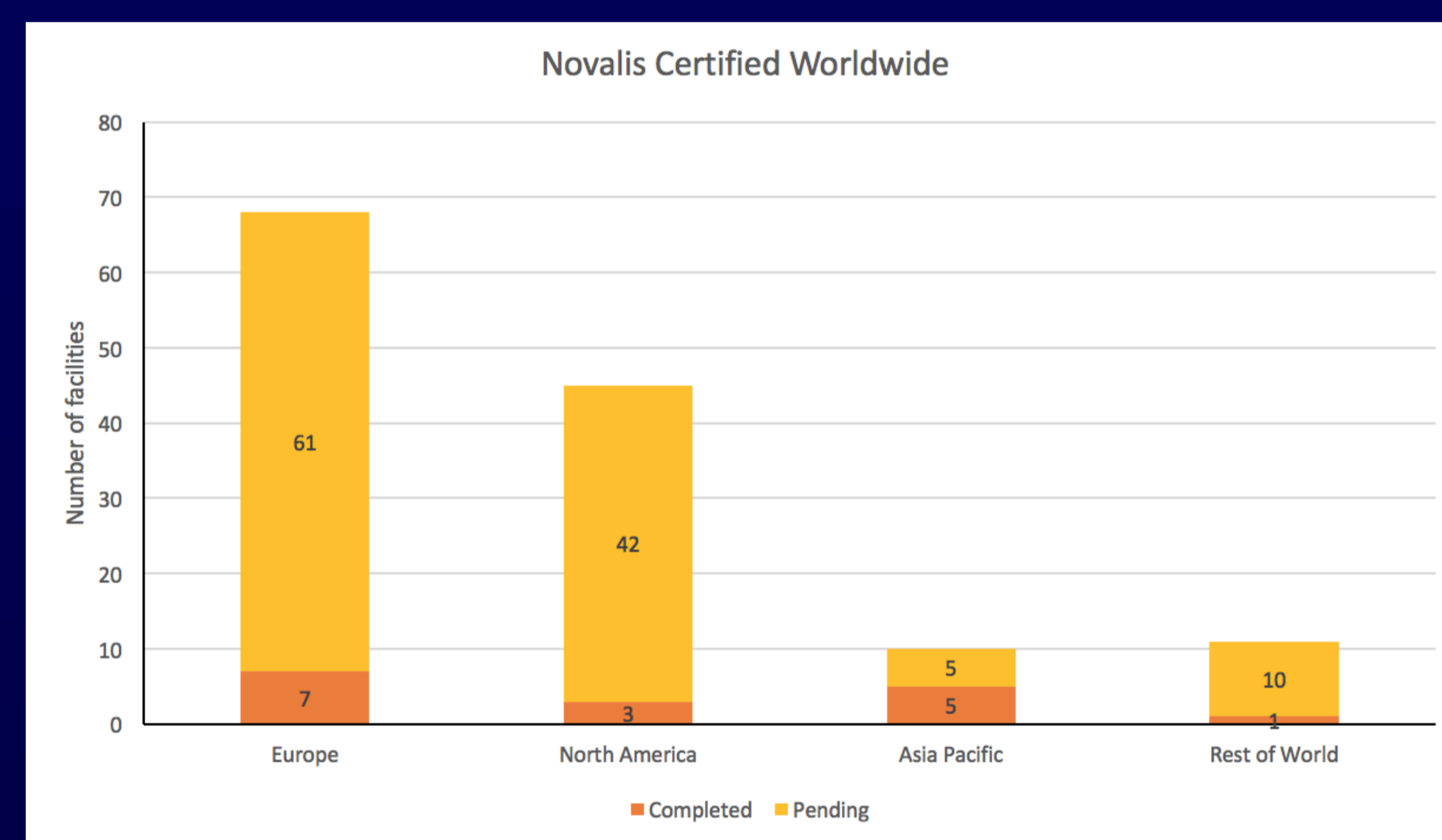


Figure 5. Summary of category of 84 recommendations (left) and 9 requirements (right) following 15 Novalis Certification reviews.

Conclusions

Novalis Certification is a unique and expanding peer review program that assesses safety and quality in SRS and SBRT and while recognizes high calibre of practice internationally. The standards-based approach is capable of highlighting outstanding requirements and providing recommendations to enhance both new and established programs.

References

1. T. Solberg *et al*, Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy: executive summary, *Pract Radiat Oncol* 2(1), 2012.
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