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COMMENTARY

# Regional cancer centre demonstrates voluntary conformity with the national Radiation Oncology Practice Standards

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## **Abstract**

Radiation Oncology Practice Standards have been developed over the last 10 years and were published for use in Australia in 2011. Although the majority of the radiation oncology community supports the implementation of the standards, there has been no mechanism for uniform assessment or governance. North Coast Cancer Institute's public radiation oncology service is provided across three main service centres on the north coast of NSW. With a strong focus on quality management, we embraced the opportunity to demonstrate conformity with the Radiation Oncology Practice Standards. The Local Health District's Clinical Governance units were engaged to perform assessments of our conformity with the standards and this was signed off as complete on 16 December 2013. The process of demonstrating conformity with the Radiation Oncology Practice Standards has enhanced the culture of quality in our centres. We have demonstrated that self-assessment utilising trained auditors is a viable method for centres to demonstrate conformity. National implementation of the Radiation Oncology Practice Standards will benefit individual centres and the broader radiation oncology community to improve the service delivered to our patients.

# Introduction

The 2002 Report of the Radiation Oncology Inquiry: A Vision for Radiotherapy<sup>1</sup> identified a number of national issues in Radiation Oncology, including quality and safety. The Department of Health and Ageing (DoHA) provided funding in 2005 for the development of radiation oncology standards. This project was undertaken by the Tripartite Committee, consisting of representatives from the Royal Australian and New Zealand College of Radiologists (RANZCR) Faculty of Radiation Oncology, Australian Institute of Radiography (AIR) and Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM).

The Radiation Oncology Practice Standards<sup>2</sup> were published in August 2011, consisting of sixteen standards

across three sections: Facility Management (Standards 1–7), Treatment Planning and Delivery (Standards 8–11) and Safety and Quality Management (Standards 12–16) (Table 1). Responses from the Australian radiation oncology community to the *Long-term conformity assessment of radiation oncology practice standards: An options paper*<sup>3</sup> was published on the DoHA website (since removed) however no outcomes on the preferred assessment arrangements have been announced at the time of writing.

North Coast Cancer Institute (NCCI) commenced clinical operations in 2007 and consists of three integrated regional cancer centres situated along the north coast of New South Wales at Port Macquarie, Coffs Harbour and Lismore base hospitals (2010). With modern and comprehensive external beam radiotherapy facilities at each

Table 1. Radiation Oncology Practice Standards descriptors, 2011.<sup>2</sup>

FACILITY MANAGEMENT - Standards 1-7				
STANDARD 1 – STAFF	Staff competence is ensured by recruitment and selection procedures and maintained by staff development and a performance review system.			
STANDARD 2 - WORKFORCE PROFILE	The workforce is managed to ensure delivery of safe quality care.			
STANDARD 3 - MANAGEMENT OF RADIATION ONCOLOGY PATIENT RECORDS	Management of the radiation oncology patient record supports safe, quality care.			
STANDARD 4 – DATA MANAGEMENT	The management of data supports clinical activities and reporting requirements.			
STANDARD 5 - FACILITY INFRASTRUCTURE	The facility infrastructure promotes safe quality care and accountability in the delivery of radiation treatment services.			
STANDARD 6 - FACILITY PROCESS MANAGEMENT	The provision of radiation treatment services is timely, co-ordinated and equitable ensure optimal patient outcomes.			
STANDARD 7 – RADIATION THERAPY EQUIPMENT	Radiation therapy equipment performs to specifications that ensure accurate and safe clinical treatment.			
TREATMENT PLANNING AND DELIVERY - Standards	5 8-11			
STANDARD 8 - RADIATION TREATMENT PRESCRIPTION	The radiation treatment prescription documents the intended course of treatment for the individual patient.			
STANDARD 9 – PLANNING PROCEDURES	Comprehensive, safe and consistent planning procedures promote optimal treatment outcomes.			
STANDARD 10 - DOSIMETRY	A dosimetry system, consistent with national and/or international standards, ensures the safety and accuracy of the prescribed radiation dose for all clinical treatments.			
STANDARD 11 - RADIATION TREATMENT DELIVERY	Treatment is delivered correctly, accurately, safely and consistently with due consideration of the patient's rights and responsibilities.			
SAFETY AND QUALITY MANAGEMENT – Standards :	12-16			
STANDARD 12 – SAFETY, QUALITY AND IMPROVEMENT PROCESSES	Safety and quality processes ensure safe, quality patient care with a commitment to quality improvement.			
STANDARD 13 – RADIATION SAFETY	All radiation exposures are managed to minimise risk to patients, staff and the public.			
STANDARD 14 -INCIDENT MONITORING PROGRAM	Participation in incident monitoring programs provides confidence that radiation is safely delivered in a radiotherapy facility with a safety-conscious culture focused on learning and prevention of error.			
STANDARD 15 - DOSIMETRIC INTERCOMPARISON	Successful regular participation in dosimetric intercomparisons provides confidence the radiation dose is accurately delivered in a radiotherapy facility.			
STANDARD 16 - CLINICAL TRIALS PARTICIPATION	Participation in clinical trials conforms to international guidelines of good clinical practice.			

site NCCI was envisaged as a 'paperless department' from the start and uses the electronic medical record (EMR) MOSAIQ<sup>®</sup> (EMR) (Elekta Pty Ltd, Crawley, UK). Using the EMR to record toxicity assessments and conducting peer review with the RANZCR peer review instrument<sup>4</sup> are fundamental to our service and demonstrating conformity with *Radiation Oncology Practice Standards*.

# **Demonstrating Conformity**

Senior clinical leaders identified at an early stage that NCCI was well placed to demonstrate conformity with the *Radiation Oncology Practice Standards* and led the entire organisation to contribute and benefit from achieving that objective.

Various funding opportunities were available to expedite project completion however a conscious decision was made to build the project activities into our normal quality and management activities.

In response to the release of the draft practice standards NCCI created a 'traffic light' document in 2008, indicating full, partial or no conformity for each item. In August 2011 a small project team was convened and developed an iterative process to demonstrate full conformity with the standards. Progress was tracked against a spreadsheet that utilised the Required Evidence Checklist provided in the appendices of the *Radiation Oncology Practice Standards*.

In 2010, NCCI appointed a senior radiation therapist with a permanent clinical role and a focus on quality

Table 2. Monthly automated CTCAE report.

Rx CTCAE v4 H&N	0	1	2	3	4	5	Total	% >3
CTCAE Fatigue – v4	10	13	5	0	0	0	28	0.00
CTCAE Rash:dermatitis – v4	7	9	11	0	0	0	27	0.00
CTCAE Nausea – v4	18	7	3	0	0	0	28	0.00
CTCAE Vomiting – v4	25	2	1	0	0	0	28	0.00
CTCAE Infections (other) – v4	22	0	4	0	0	0	26	0.00
CTCAE Dysphagia – v4	14	4	8	2	0	0	28	7.14
CTCAE Pain in area of XRT - v4	10	10	8	0	0	0	28	0.00
CTCAE Dry Mouth – v4	10	13	5	0	0	0	28	0.00

Automated report showing count of toxicities assessed against CTCAE criteria. Bold numbers show two occasions that a Grade 3 toxicity was recorded for dysphagia in this monthly cycle. CTCAE, Common Terminology Criteria for Adverse Events; v4, version 4; Rx, radiotherapy; XRT, radiotherapy.

activities across NCCI covering documentation management, audit collation and analysis, co-chair and secretarial duties for NCCI's Quality and Technical Development Committee. This may be considered an additional resource however the role was defined and recruited with a focus on enhancing quality management across NCCI prior to the publication of the practice standards and has not been a resource dedicated exclusively to this objective.

DoHA advised us that no formal process was in place to assess conformity with the standards and consequently we engaged members of the Local Health District's Clinical Governance units at Lismore and Port Macquarie to perform an initial assessment of our conformity status. The auditors had relevant experience in gathering and presenting evidence for health service accreditation and specifically for medical imaging accreditation.

A formal audit of the evidence required to demonstrate conformity was signed off as complete on 16 December 2013.

This publication aims to provide guidance and encouragement to others so that the standards become implemented nationally as stated in the *National Strategic Plan for Radiation Oncology 2012–2022.*<sup>5</sup>

Ethics approval was not required to complete this project.

# Facility Management - Standards 1-7

The evidentiary requirements for Standards 1, 2, 5, 6 and 7 draw on management instruments required to operate a facility and meet ongoing statutory requirements. The buildings and infrastructure of the three NCCI sites are relatively new so reports and compliance statements regarding the buildings' fitness for occupation and adherence to the Health Facility Guidelines<sup>6</sup> is readily accessible. Evidence demonstrating safe quality care in the delivery of treatment services is demonstrated through the

production of Occupational Health and Safety Hazard reports and Environmental Protection Authority (EPA) Radiation Use licence registers. Staffing numbers are based on models determined by the NSW Ministry of Health to support the delivery of clinical services. Various planning tools<sup>7–11</sup> have been drawn upon to inform the functional briefs developed to implement NCCI radiation oncology services. In a regional setting, this is balanced with pragmatism to ensure that appropriate resources are available to provide a level of service commensurate with its objectives. This level of information should be readily available or accessible to any radiation oncology treatment centre.

Standards 3 and 4 required audits of clinical records to demonstrate evidence of quality service provision. All treatment activities at NCCI are predicated on Cancer Institute NSW protocols (eviQ) and other baselines for evidence-based practice. As a new department, NCCI was fortunate in that there was no 'tradition' of paper records or forms and has utilised MOSAIQ<sup>®</sup> (Elekta Pty Ltd (Australia Head Office)) as a comprehensive oncology-specific EMR from commencement in 2007. Access to the EMR and patient information is password protected and logged. The level of access is set by the EMR Administrators to be appropriate for their role, for example, administrative, prescribing clinician, visiting auditor.

All diagnoses are entered according to the appropriate International Classification of Diseases coding and staging systems. Automated reports are run regularly identifying any missing clinical data items such as pathology details, tumour laterality or stage. Automated reporting software (Crystal Reports; Crystal Decisions Inc., Vancouver, British Columbia, Canada) is used to interrogate the EMR database and create regular automated reports of Common Terminology Criteria for Adverse Events (CTCAE)<sup>12</sup> toxicity scores for all patients (Table 2).

# RANZCR revalidation audit scoring sheet

	Audit identifiers			
Name of person randomly selecting cases/auditor	Selector:	Auditor:		
Patient ID (may be anonymous)		1		
Treating radiation oncologist name or anonymous ID				
Number of specialist radiation oncologist peer reviewers (excluding treating RO or registrars, but includes fellows)				
Date simulated				
Primary site				
Stage	TNM: I/II/III/IV OR other system stage	<b>9</b> :		
Treatment intent	Curative/Palliative/Ben	ign		
Prior radiotherapy	Yes/No			
Audit timeframe in relation to radiation treatment delivery Will feedback be provided to treating radiation	Pre-radiotherapy/On ra radiotherapy Yes/No	adiotherapy/Post-radiotherapy/No		
oncologist Suggestions for audit tool review				

**Figure 1.** Royal Australian and New Zealand College of Radiologists (RANZCR) peer review instrument. RO, radiation oncologist; ID, identification; TNM, tumour, nodes, metastasis.

The automation of the reports ensures a timely, completed data set by those people best qualified to do it without being too onerous for any individual. High-quality data entry ensures the completeness of the medical record and a number of quality checks are built-in to the system with audits identifying items inadequately completed as well as any overly redundant checks. Individual patient records are randomly selected and audited at our weekly radiation oncologist's meeting using the RANZCR Peer review instrument. In a twelve-month period over 300 patients are audited (Fig. 1).

NCCI adopted the recommendations of the 2005 RANZCR document *Management of Waiting Lists for Radiotherapy*<sup>13</sup> and has embedded a prioritisation code into the electronic workflow for all patients prescribed radiotherapy. The coding allows for the immediate and unambiguous identification of patients requiring emergency treatment and meeting optimal waiting times for those patients with the most urgent need for treatment. EMR tools and automated, emailed reports assist the treating clinician to inform the patient of any anticipated delays and modify the care plan in a collaborative manner with the patient and other clinicians as required.

Mandatory key performance indicators and performance statistics are stored on a centralised, secure server readily available for audit.

# Treatment Planning and Delivery – Standards 8–11

closely involved with NCCI has been eviO (www.eviO.org.au), the Cancer institute NSW evidencebased cancer treatments website, from an early stage and has adopted all published eviQ radiotherapy protocols. Local documents have been developed to interface the eviQ protocols as clinical procedures, including contouring guides and planning parameters stipulating minor and major violations. NCCI uses a quality documentation management system to establish, monitor, review, and publish all clinical procedures for planning and treatment activities. A multidisciplinary protocol development and review committee manage the documentation requirements.

The use of comprehensive radiotherapy-specific care plans and prescriptions within the EMR means that all relevant parameters (patient, treatment intent, 'ready for care' date, 'must treat by' date, site, laterality, plan type, beam modality, total dose, dose per fraction, fraction scheduling) *must* be recorded and signed off by the treating radiation oncologist prior to treatment.

The regular RANZCR Peer Review Audit of randomly selected patients provides an additional check that all radiotherapy prescription items are completed correctly.

NCCI utilises an integrated radiotherapy treatment planning system for three-dimensional dosimetry that encompasses a number of different programs made accessible across the service sites. Dosimetry calculations within the system are calibrated relative to a reference linear accelerator at Coffs Harbour. This enables planning, quality assurance and treatment to occur on any of the linear accelerators within NCCI thus optimising the resources available. NCCI complies with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) code of practice and maintains records of all new equipment commissioning, equipment upgrades and individual patient quality assurance activities on dedicated servers and in patient records. **NCCI** anthropomorphic utilises phantoms verification software for a range of treatments including static and dynamic delivery via intensity modulated radiotherapy techniques (IMRT) and volumetric modulated arc therapy (VMAT). In vivo dosimetry utilises film, TLD or MOSFETs to ensure the most accurate reading is communicated to the clinicians and recorded within the patient's electronic record.

The National Safety and Quality Health Service Standards<sup>14</sup> were used to update and enhance NCCI's procedures to ensure correct patient, correct site and

correct procedure compliance. An audit of electronic approvals of the Site Set Up process pretreatment is evidence that NCCI has tangible strategies in place to ensure the correct matching of patients and their prescribed procedures. Safety parameters within a patient's treatment record include relevant tolerances set for variable parameters such as table position, gantry and imaging specifications. NCCI is fully compliant with the *Australian Charter of Healthcare Rights*, <sup>15</sup> with the principles included in all patient information packs and posters are displayed within each centre.

Audits are useful ways to engage with a wide range of staff and engage them not only in the audit process, but the culture of active quality management.

# Safety and Quality Management – Standards 12–16

NCCI demonstrates safety and quality processes to ensure safe, quality patient care with a commitment to quality improvement. NCCI's Radiotherapy Quality and Technical Development Committee meets monthly and discusses new protocols and technical developments, reviews recent audit activities, incident reports and the radiotherapy risk register.

# Monthly report: grade 3+ CTCAE toxicity

Date range of sample: 4/03/2014 - 18/03/2014

	most recent RT careplan	CTCAE data item	Observation date/time	CTCAE score
1 - Baseline assessment				
Shakespeare, Thomas				
		Glucose intolerance v4	13/03/2014 10:05:44AM	3
2 - Acute assessment				
Hill, Jacques D.				
	Skin cancer SCC (Definitive) C44	Rash:dermatitis -v4	18/03/2014 10:04:44AM	3
	H & N - Tongue C01	Mucositis XRT Related v4	05/03/2014 11:51:56AM	3
	H & N - Tongue C01	Mucositis XRT Related v4	12/03/2014 12:18:42PM	3
Dwyer, Patrick M.				
	H & N - Oropharynx C10	Mucositis XRT Related v4	10/03/2014 09:07:42AM	3
	Larynx - Late Stage (T3-T4) - Definitive	Dysphagia - v4	10/03/2014 03:35:36PM	3
	Larynx - Late Stage (T3-T4) - Definitive	Dysphagia - v4	12/03/2014 10:41:46AM	3
Mohd Tahir, Abdul Rahim				
	Skin cancer SCC (Adjuvant) C44	Pain in area of XRT - v4	17/03/2014 03:39:50PM	3
	H & N - Oropharynx C10	Dysphagia - v4	14/03/2014 04:09:49PM	3
	H & N - Oropharynx C10	Infections (Other) - v4	14/03/2014 04:09:49PM	3
McKay, Michael				
	Breast Palliative C50	Rash:dermatitis -v4	04/03/2014 09:09:32PM	3
	Breast, adjuvant Post Mastectomy (Chest Wall)	Rash:dermatitis -v4	05/03/2014 01:43:14PM	3
3 - Late assessment				
Shakespeare, Thomas				
	Post radical prostatectomy, salvage	Urinary Incontinence- v4	18/03/2014 09:23:21AM	3

**Figure 2.** Example of an automated report showing patient-specific data for toxicities recorded as Grade 3 or higher. Patient's names removed from the list for publication. CTCAE, Common Terminology Criteria for Adverse Events; v4, version 4; H&N, head and neck; SCC, squamous cell carcinoma.

# Prescription Simulation Computing Treatment Bolus Shielding Verification imaging

**Figure 3.** Annual incident data collection grouped to the *Radiation Oncology Practice Standards* Incident Reporting Framework classifications. New data items for Pre-Treatment were introduced in 2014. The frequency on the y-axis was intentionally left blank.

Clinical improvement activities include the collection of baseline and acute toxicities using the CTCAE grading system. Late toxicity is also recorded at patient follow up visits. Automated reports are e-mailed to all radiation oncologists and registrars identifying all patients scoring toxicities Grade 3 or higher (Fig. 2). The minimisation of acute and late treatment toxicity has been one of the main drivers for NCCI's adoption of IMRT and VMAT for the curative treatment of prostate, head and neck, cranio-spinal, gastrointestinal (GI), gynaecological, breast and lung cancers. Four dimensional techniques for planning and treatment of lung and upper GI cancers and Active Breathing Control technology (Elekta Pty Ltd (Australia Head Office)) to limit the movement of lung tumours have also been adopted to improve clinical outcomes. Additional quality improvement initiatives triggered specifically by the above audits include the automatic flagging of patients with significant weight loss to our dieticians and the implementation of a weekly multidisciplinary clinic for head and neck patients.

Work health and safety practices have been established for all staff members to ensure that access to potential high-risk areas, like the roof above the bunkers, is clearly signed and restricted to personnel who have been appropriately orientated to the work site. A comprehensive radiation safety manual includes all of the regulations and requirements to maintain radiation safety within NCCI and more broadly across the Local Health Districts. Dose monitoring for medical practitioners, EPA licensure for staff and all radiation equipment is monitored centrally as per the EPA's stipulation. <sup>16</sup>

NCCI uses the NSW state-based Incident Information Management System (IIMS) to record any incidents or near misses using a *Severity Assessment Code (SAC) Matrix*<sup>17</sup> per the NSW Health Incident Management

Policy Directive. To facilitate trend analysis<sup>18,19</sup> every clinical incident is encoded based on the mandatory sub-elements recommended in the *Radiation Oncology Practice Standards* Incident Reporting Framework. IIMS reports are managed locally and outcomes are shared across the

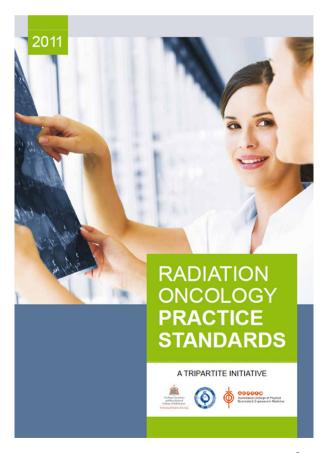


Figure 4. The Radiation Oncology Practice Standards front cover.<sup>2</sup>

three sites via various meetings and this approach has been shown to be beneficial.<sup>20–22</sup> Specific incidents are identified for additional discussion and review at monthly meetings. Our local clinical incident coding is based on the original work of South West Sydney Area Health Service's Cancer Services team<sup>23</sup> that has been identified as a model for national incident reporting. We have reviewed and enhanced the clinical incident codes based on our local analysis of incident trends and in consultation with other centres (Fig. 3).

Independent audit is crucial in the quality assurance programme of the organisation and has been a desirable quality assurance activity for international radiation oncology services. <sup>24–26</sup> This activity not only gives confidence in the delivery of radiation dose being accurate, it is also a measure to identify any shortcoming in the modelling. <sup>25,27</sup>

NCCI has certification of Level I dosimetric calibration intercomparisons for all six linear accelerators from independent accredited radiation oncology medical physicists and participates in dosimetric intercomparisons of at least one kilovoltage beam every 2 years. A certificate of Level III Audit for Lismore Radiation Oncology facility was provided after assessment by the Australian Clinical Dosimetry Service in 2012. Radiation therapists and radiation oncology medical physicists work collaboratively to prepare and conduct audits with clinical and technical perspective demonstrated in our credentialing activities for participation in Trans-Tasman Radiation Oncology Group (TROG) and other trials.

NCCI incorporates a busy clinical trials unit that ensures all trials are run according to Good Clinical Practice guidelines. The documentation for all radiotherapy trials is stored centrally and is readily accessible. Many radiation therapists and doctors at NCCI are members of TROG and follow their established guidelines to ensure good trial practice.

# Discussion

RANZCR's Faculty of Radiation Oncology is of the view that a full set of standards is implemented across all radiation oncology facilities in Australia<sup>29</sup> and with the release of the tripartite National Strategic Plan for Radiation Oncology the Radiation Oncology Practice Standards will eventually be implemented nationally (Fig. 4).

As an organisation, we elected to demonstrate that conformity with the standards can be achieved and maintained within the normal business operations of a busy radiation oncology treatment centre.

Our auditors appropriately requested that we provide supplementary evidence for many of the standards to demonstrate that our practices were at a level of excellence. Some of the hardest evidence to obtain required the engagement and cooperation of other hospital departments.

The effective use of an EMR and the RANZCR peer review instrument allows most of the required clinical evidence to be obtained through accessing data that is routinely collected. To achieve conformity with the standards it was not simply a matter of 'cutting and pasting' as additional audits needed to be identified and performed.

We strongly agree and advocate for a national system that allows the radiation oncology community to share from their collective experiences in clinical incident management.

From our experience with demonstrating voluntary conformity with the standards we would advocate for a hybrid self/peer assessment model. This could get a number of centres demonstrating conformity and develop a pool of peer assessors.

Governance would best be driven by the Tripartite Committee as it represents the most stable entity proposed in the Conformity Options paper and achieve the overall goal of our tripartite professions retaining ownership of the process and outcomes.

# Conclusion

It took over 2 years for this project to be completed despite our initial thoughts that there was little additional work required to demonstrate full conformity with the standards. A managed national scheme would ensure that the process is much quicker. The accumulation of the required evidence and additional quality improvement and assurance activities has already been of benefit to the department far beyond demonstrating conformity with the standards. We have a large number of robust audit tools in place that facilitate the ongoing provision of quality services. National implementation of the *Radiation Oncology Practice Standards* will benefit individual centres and the broader radiation oncology community to improve the service delivered to our patients.

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# **Conflict of Interest**

The authors declare no conflict of interest.

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