Medical Imaging Annex A: Comparison between ISO/IEC 17025 and RANZCR Standards of Practice for Diagnostic and Interventional Radiology Version 9

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The comparison between ISO/IEC 17025 and RANZCR Version 9 is provided as a guide for those practices who have previously achieved accreditation, or were working towards accreditation under ISO/IEC 17025.

Clause / content	RANZCR Version 9	ISO/IEC 17025			
Practice management system	**1-1**	**4.2**			
senior managements' responsibility	indicator 1	4.2.1	4.2.2a	4.2.3	
familiarity with policies and procedures	indicator 2	4.2.2d			
quality manual	**1-2**	**4.2.2**			
quality policy defines quality objectives	indicator 1	4.2.2			
quality policy content	indicator 2	4.2.2			
includes management system policies	indicator 3	4.2.2			
structure of documentation hierarchy	indicator 4	4.2.5			
reference to supporting documents	indicator 5	4.2.5			
role & responsibility of management and quality manager	indicator 6	4.1.5h	4.1.5i	4.2.6	
quality manager	**1-3**	**4.1.5i**			
identification & job description	indicator 1	4.2.6	5.2.4		
documentation	**1-4**	**4.3**			
document and control polices/procedures		4.3.1			
master list of documents		4.3.2.1			
appropriate to size & scope of service	indicator 1	4.3.1			
uniquely identified documents	indicator 2	4.3.2.3			
changes to (electronic) documents	indicator 3	4.3.3			
review and approval	indicator 4	4.3.2.1	4.3.2.2.b		
only current versions available	indicator 5	4.3.2.2.a	4.3.2.2.c		
handwritten amendments	indicator 6	4.3.3.3			
superseded documents	indicator 7	4.3.2.2.c			
Teleradiology - documented	indicator 8	4.1.5c			

Clause / content	RANZCR Version 9	ISO/IEC 17025			
responsibilities for examining & reporting sites					
records	**1-5**	**4.13**			
procedures for integrity, id, collection, storage, protection & disposal		4.13.1.1			
legible & retrievable records	indicator 1	4.13.1.2			
corrections to records	indicator 2	4.13.2.3			
records kept in accordance with regulatory requirements	indicator 3	4.13.2.1			
electronic records	indicator 4	4.13.1.4			
disaster recovery for electronic systems	indicator 5	5.4.7.2			
encryption of transmitted data	indicator 6	5.4.7.2.b	4.13.1.4		
corrective and preventive action processes	**1-6**	**4.9**	**4.11**	**4.12**	
identifying & investigating non conformances and implementing corrective actions	indicator 1	4.9			
identifying and implementing preventive actions	indicator 2	4.12			
records of corrective actions	indicator 3	4.11.3	4.12		
continuous quality improvement	**1-7**	**4.1**	**4.11**	**4.12**	**4.14**
program of CQI - C/A P/A internal audits assessments by external bodies					
continuous quality improvement (internal audit) schedule	indicator 1	4.14.1			
annual audits	indicator 2	4.14.1			
objectivity of auditors	indicator 3	4.14.1			
audit of corrective & preventive actions	indicator 4	4.14.3	4.11.5		
participation & compliance with EQAP	indicator 5	5.9.1			
use of EQAP to id areas for improvement	indicator 6	4.1			
feedback and complaints	**1-8**	**4.7**	**4.8**		
P/P for obtaining feedback & resolving complaints					
feedback from patients and	indicator 1	4.7.2			

Clause / content	RANZCR Version 9	ISO/IEC 17025			
referrers					
P/P for handling complaints	indicator 2	4.8			
records of complaints, investigations & C/A	indicator 3	4.8			
management review - regular review of practice management system	**1-9**	**4.15**			
records of reviews, action plans, outcomes, monitoring activities	indicator 1	4.15.2			
facilities for imaging procedures	**2-1**	**5.3**			
comply with legislation	indicator 1	5.3.1	5.3.2		
controlled access to facilities	indicator 2	5.3.4			
separation between incompatible activities	indicator 3	5.3.3			
cleanliness	indicator 4	5.3.5			
patient facilities	**2-2**	**5.3.1**			
optimise patient comfort	indicator 1				
disrobing facilities ensure privacy	indicator 2	4.1.3.c			
accommodate special needs of patient population	indicator 3				
Equipment - general	**3-1**	**5.5**	**5.9**		
equipment is available, functional, capable, calibrated, meets regulatory requirements, appropriate QA testing		5.5.1	5.5.2		
current compliance certificates	indicator 1	5.5.5.c			
compliance certificates held on site	indicator 2	5.5.5			
QC, calibration & maintenance of equipment	indicator 3	5.5.5f	5.5.5.g	5.5.10	5.9.1
records of remedial actions	indicator 4	5.5.5			
QA in accordance with manufacturer's & regulatory requirements	indicator 5	5.5.5.e	5.5.7		
Equipment Inventory	**3-2**	**5.5.5**			
name, manufacturer & serial number	indicator 1	5.5.5			
records for equipment acquired after 01-01-2000	indicator 2				
Equipment - sedation and	**3-3**	**5.5.1**	**5.3.1**		

Clause / content	RANZCR Version 9	ISO/IEC 17025			
monitoring					
equipment immediately available	indicator 1				
continuous pulse oximetry for IV sedation	indicator 2				
sedation of paediatrics	indicator 3				
Equipment - anaesthesia and monitoring	**3-4**	**5.5.1**	**5.3.1**		
equipment immediately available	indicator 1				
anaesthesia of paediatrics	indicator 2				
comply with regulatory requirements for anaesthesia	indicator 3				
Equipment - resuscitation	**3-5**	**5.5.1**	**5.3.1**		
resuscitation equipment and drug inventories	indicator 1				
equipment immediately available	indicator 2				
records of drugs and use by dates	indicator 3				
Computers and automated equipment	**3-6**	**5.4.7.2**			
Computers and automated equipment - general	**3-6-1**	**5.4.7.2**			
for acquisition, processing, recording, reporting, storage, retrieval of data					
documented instructions for the use of software	indicator 1	4.3.1			
procedures for data protection	indicator 2	5.4.7.2			
proper functioning of computers	indicator 3	5.4.7.2	5.5.2		
environmental conditions	indicator 4	5.3.1			
DICOM & IHE compliant	indicator 5				
>6months DICOM storage capacity	indicator 6	4.13.1.2			
Diagnostic workstations	**3-6-2**	**5.3**			
image manipulation	indicator 1	4.13	5.4.7.2	5.5.2	
functional features	indicator 2	5.4.7.2	5.5.1		
Monitors	**3-6-3**	**5.4.7.2**			
functional features	indicator 1				
Exchange of digital imaging data and reports - general	**3-7**				

Clause / content	RANZCR Version 9	ISO/IEC 17025			
requirements					
exchange media and file systems IHE compliant	**3-7-1**	**5.4.7.2**			
digital images on CD - ISO/IEC 10149 compliant	indicator 1				
file systems on CD - ISO 9660;988E compliant	indicator 2				
malicious software	**3-7-2**	**5.4.7.2.b**	**5.4.7.2.c**		
check discs for malware	indicator 1				
after checks, discs to be "closed" to further changes	indicator 2				
single use discs	indicator 3				
Media requirements	**3-8**				
media selection	**3-8-1**	**4.13.2.1**			
long term storage	indicator 1	4.13.1.4			
media for portable use	indicator 2				
Portable media content (IHE PDI profile)	**3-8-2**	**5.4.7.2**			
by 01-01-2010 all portable media IHE-PDI profile compliant	indicator 1				
readme .txt in root directory	indicator 2				
readme .txt includes information from label/external packaging	indicator 3				
information re DICOM viewer software	indicator 4				
providing data as Web Content	indicator 5				
reporting images on portable media	indicator 6				
Use of embedded DICOM viewer on portable media	**3-8-3**	**5.4.7.2**			
no auto-load	indicator 1				
instructions on media label and online manual	indicator 2				
viewer & help files available	indicator 3				
error messages	indicator 4				
browser requirements	indicator 5				
min requirements to run viewer on disc label	indicator 6				
Electronic reports	**3-8-4**	**5.10.7**			
electronic storage requirements for reports	indicator 1	4.13.2.1			
records stored for a minimum of 36 months	indicator 2	4.13.1.2			

Clause / content	RANZCR Version 9	ISO/IEC 17025			
Digital media labelling, packaging and storage	**3-9**	**5.8.4**			
portable media labelling	**3-9-1**	**5.10.2**	**5.8.1**	**5.8.2**	
labels with relevant info printed onto media	indicator 1	4.13.2.1			
minimum labelling information	indicator 2				
Portable media storage and packaging	**3-9-2**	**5.3.1**			
blank media stored in accordance with manufacturer's guidelines	indicator 1	4.6.2			
prevent overwriting of information	indicator 2				
packaging	indicator 3				
packaged media stored in accordance with manufacturer's guidelines	indicator 4				
external labelling	**3-9-3**	**5.10.2**			
font size >11	indicator 1	5.10.2			
positioning of label to protect patient privacy	indicator 2				
contents of envelop defined	indicator 3				
practice name & contact details on envelope	indicator 4				
instructions for loading CD, electronic help, etc	indicator 5				
labelled "confidential medical records"	indicator 6				
Reporting environment	**3-10**	**5.3.1**			
optimal conditions	indicator 1				
lighting & ergonomics	indicator 2				
quality control testing - general	**3-11-1**	**5.9**			
QC for each modality at defined intervals	indicator 1	5.9.1	5.9.2		
records kept - trend analysis	indicator 2	5.9.1			
records of remedial actions	indicator 3	5.9.2			
quality control testing - diagnostic workstation and Teleradiology equipment	**3-11-2**	**5.9**			
QIS/QC program for digital imaging & teleradiology	indicator 1				
environmental conditions	indicator 2				
aspects of QC program	indicator 3				

Clause / content	RANZCR Version 9	ISO/IEC 17025			
review of image quality by Medical practitioner	indicator 4	5.9.1			
QA includes SMPTE test pattern assessment	indicator 5				
PERSONNEL	**4**	**5.2**			
General - delivery, supervision, support & management of service by qualified staff	**4-1**	**4.1.5**	**5.2.1**		
Personnel - general	**4-1-1**	**5.2.1**			
Records include qualifications, regulatory registrations, licences & their currency	indicator 1	5.2.1			
job descriptions	indicator 2	5.2.4			
deputising arrangements	indicator 3	4.1.5.j			
procedures addressing potential conflict of interest	indicator 4	4.1.4	4.1.5b/d		
P/P relating to confidentiality and security of personal information	indicator 5	4.1.5.c			
recruitment of personnel	**4-1-2**				
systematic process for recruitment and selection	indicator 1				
documented process	indicator 2				
minimum requirements for position	indicator 3				
orientation	**4-1-3**	**5.2.2**	**5.2.3**		
orientation program for staff involved in delivery, supervision, support & management	indicator 1				
records of orientation	indicator 2				
training	**4-1-4**	**5.2.2**			
ensure resources available and personnel undertake ongoing training to comply with registration, licensing, competency					
internal & external training records maintained	indicator 1	5.2.2			
appropriate training in digital and teleradiology	indicator 2	5.2.2			
Qualifications, registration	**4-2**	**5.2.1**			

Clause / content	RANZCR Version 9	ISO/IEC 17025			
and licensing					
Qualifications - radiologist	**4-2-1**	**5.2.1**			
current medical board registration & DRANZCR/FRANZCR certificate or equivalent	indicator 1	5.2.1			
copies of radiation licences	indicator 2	5.2.1			
Remote reporting - Medical board registration & radiation licence for both examining & reporting sites	indicator 3	5.2.1			
current CPR training (3 yearly)	indicator 4	5.2.1			
qualifications - radiographer	**4-2-2**	**5.2.1**			
AIR Validated Statement of Accreditation (or equivalent) and records of CPD	indicator 1	5.2.1			
copies of radiation licences & registrations	indicator 2	5.2.1			
qualifications - nurse	**4-2-3**	**5.2.1**			
current registrations	indicator 1	5.2.1			
Qualifications Medical Physicist	**4-2-4**	**5.2.1**			
current ACPSEM accreditation or certified compliance tester	indicator 1	5.2.1			
Qualifications - service personnel	**4-2-5**	**5.2.1**			
procedure for obtaining confirmation of qualifications/certifications	indicator 1	5.2.1			
Qualifications - administrative staff	**4-2-6**	**5.2.1**			
records of training	indicator 1	5.2.1			
Continuing professional development	**4-3**	**5.2.2**			
CPD - general	**4-3-1**	**5.2.2**			
policy - support CPD participation	indicator 1	5.2.2			
CPD - radiologists	**4-3-2**	**5.2.2**			
evidence of on going participation in RANZCR CPD	indicator 1	5.2.2			

Clause / content	RANZCR Version 9	ISO/IEC 17025			
CPD - radiographers	**4-3-3**	**5.2.2**			
evidence of on going participation in AIR CPD or equivalent	indicator 1	5.2.2			
PROFESSIONAL SUPERVISION safety and quality of service					
General	**5**	**4.1.5.g**	**4.1.5.h**		
Radiologists professional supervision requirements	**5-1**				
personal conduct - direct supervision and task delegation	indicator 1	4.1.5.g	4.1.5.f		
triggers for radiologist input defined	indicator 2				
professional supervision protocols for teleradiology at both examination & reporting sites	indicator 3				
professional competence	**5-2**	**5.2.5**			
protocols ensure qualified/experienced staff	indicator 1	5.2.5			
supervision of insufficiently experienced staff	indicator 2	4.1.5.g			
Trainee radiologist - direct supervision	**5-2-1**	**4.1.5.g**			
roster show direct on site supervision "in" hours	indicator 1	4.1.5.g			
roster show access to qualified radiologist on roster "out" of hours	indicator 2	4.1.5.g			
student and PDY radiographers	**5-2-2**	**4.1.5.g**			
12 months of rosters to show direct supervision by qualified radiographer	indicator 1	4.1.5.g			
PDY supervision in accordance with AIR requirements	indicator 2	4.1.5.g			
Review of Appropriateness of request and patient preparation	**5-3**	**4.4**			

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Requests by approved allied health practitioners	**5-3-1**	**4.4.1**			
information required on request	indicator 1	4.1.1			
clarifying information with patient	indicator 2	4.4.2			
images provided un clinically useful format	indicator 3	4.4.1.a			
Review of request	**5-3-2**	**4.4.2**			
documented procedures for request review	indicator 1	4.4.1			
protocols include triggers for seeking radiologist input	indicator 2	4.4.1			
radiologist readily contactable to discuss request	indicator 3	4.4.1.c			
relevant patient info recorded eg allergies, pregnancy, previous studies	indicator 4	4.4.2			
if insufficient information provided, referrer (attempted) contacted	indicator 5	4.4.2			
any other information recorded eg MRI, angiography, contrast	indicator 6	5.8.3			
patient - informed consent	indicator 7	5.8.1			
substituted and additional procedures	**5-3-3**	**4.4.4**			
record of substituted and additional procedures	indicator 1	4.4.2	4.4.4		
records of attempted & actual communication with referrer	indicator 2	4.4.4			
patient consent to change of service	indicator 3	4.4.2			
patient preparation	**5-3-4**	**5.8.1**			
pre-examination preparation information available	indicator 1	4.4.1.a	5.8.1		
confirmation of correct patient information	indicator 2	5.8.1	5.8.2	5.8.3	
Utilisation of Medical imaging techniques	**5-3-5**	**4.4**	**4.7.1**		
representative information sheets on services	indicator 1	4.7.1			

Clause / content	RANZCR Version 9	ISO/IEC 17025			
Performance of the Imaging examination	**5-4**				
Performance of the Imaging examination - documented protocols	**5-4-1**	**5.4**			
documented protocols developed under professional supervision of radiologist	indicator 1	5.4.1			
indications for when radiologist must be available for examination	indicator 2	5.4.1			
sedation - trained radiologist immediately available	indicator 3	5.4.1			
protocols include - radiographic factors, positioning, sterile tray setup, after care	indicator 4	5.4.1	5.4.4		
performance of the Imaging examination - administration of contrast	**5-4-2**	**5.4.1**			
protocols include - patient screening	indicator 1	5.4.1			
protocols determine triggers for when radiologist must be contacted	indicator 2	5.4.1			
administration of contrast by personnel trained in venipuncture	indicator 3	5.2.5			
protocols state dose & type of contrast ,	indicator 4	5.4.1			
records of contrast administration	indicator 5	4.13.2.1			
medical practitioner available in case of contrast complications	indicator 6	4.1.5.g			
Interpretation and reporting	**5-5**	**5.10**			
single named radiologist responsible for report. Trainee also to be identified	5-5-1	5.10			
diagnosis performed on images of acceptable quality	indicator 1				
contents of imaging report	indicator 2	5.10.2			
use of electronic signatures	indicator 3	5.10.2.j			
countersigning reports	indicator 4				
amendments and addendums	indicator 5	5.10.9			
preliminary reports	indicator 6	5.10.2			

Clause / content	RANZCR Version 9	ISO/IEC 17025			
policy for provision of verbal and written reports to referrer	indicator 7	5.10.7			
comparisons to prior studies are reported	indicator 8	(5.10.5)			
Remote reporting - teleradiology	**5-5-2**	**5.10.1**			
protocols at transmitting and receiving sites appropriate to services provided	indicator 1	5.10.7			
minimum content of protocols	indicator 2	5.4.1			
teleradiology - minimum patient data required	indicator 3	5.10.2			
data transfer compression levels subject to on going clinical review	indicator 4	5.10.7			
communication of imaging findings and reports	**5-5-3**	**5.10.1**			
policy for report TAT	indicator 1	5.10.1			
regular reviews of TAT (at least annual) - CA if required	indicator 2	4.14.1			
protocol for reporting urgent & significant findings	indicator 3	5.10.7			
consultation with referrers	**5-5-4**	**4.7**			
policy for consultation with referrers	indicator 1	4.7			
consultation regarding digital imaging	indicator 2	4.7			
Quality	**5-6**	**5.9**			
Image Review - general	**5-6-1**	**5.9**			
documented peer based image review program for each modality -	indicator 1	5.9.1			
SAFETY	**6**	**5.3**			
safety of the practice environment	**6-1**	**5.3.2**			
identify defective equipment	indicator 1	5.5.7			
Infection control - general	**6-2**	**5.3**	**5.8.4**		
documented P/P for Infection	indicator 1	5.3			

Clause / content	RANZCR Version 9	ISO/IEC 17025			
control including sterilisation/disinfection					
comply with regulatory standards & health circulars	indicator 2	5.3			
Radiation safety	**6-3**	**5.3**			
ALARA	6.3.1	5.3			
P/P demonstrate ALARA	indicator 1	5.3			
compliance with radiation safety legislation	**6-3-2**	**5.3**			
retention of records required by state radiation regs and ARPANSA	indicator 1	4.13.1.1			
retention of C/A Notices issue by Radiation Regulatory Boards and any actions taken	indicator 2	4.11	4.13.1.1		
retention of any actions initiation from within practice	indicator 3	4.11	4.13.1.1		
Radiation safety officer	**6-3-3**	**5.3**			
appointed RSO and JD available	indicator 1	5.2.5			
monitor and communicate changes in legislation	indicator 2	4.1.6	4.3.2.2.b		
RSO coordinates record keeping with respect to radiation safety	indicator 3	4.13.1.1			
Waste management	**6-4**	**5.3**			
procedures for disposal of contaminated/medical waste,	indicator 1				
procedures for linen and laundry services					
use of contrast media	**6-5**	**5.4.1**			
procedure in accordance with RANZCR Contrast guidelines	indicator 1	5.4.1			
policy addressing storage & use of contrast media including multi-dose vials	indicator 2	4.6			
documented plan of management for adverse events	indicator 3	4.9			
plan addresses "emergency management of anaphylaxis in the community"					
staff with current CPR	indicator 4	5.2.5			

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certification					
identified Resuscitation Officer	indicator 5	5.2.5			
availability of resuscitation equipment & drugs		5.5.1			
Sedation and anaesthesia	**6-6**	**5.4**	**5.8**		
Use of sedation	**6-6-1**				
P/P for use, administration and management of sedated patients	indicator 1	5.4.1			
records of sedation include name of drug, person who administers	indicator 2	4.13.2.1			
use of anaesthesia	**6-6-2**	**5.4**	**5.8**		
P/P in accordance with ANZCA *Recommendations on the minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations*	indicator 1	5.4.1			
administration by trained anaesthetists	indicator 2	5.2.3			
use of medications for sedation and anaesthesia	**6-6-3**	**4.6.1**			
drug inventories shows proper drug storage	indicator 1	4.6.2			
PATIENT MANAGEMENT	**7**	**5.8**			
General	**7-1**	**5.8.1**			
P/P for patient management - transportation, reception, comfort, preparation, privacy, post-procedure observation & discharge	indicator 1	5.8.1			
P/P address teleradiology	indicator 2	5.8.1			
Patient identification and records	**7-2**	**4.13**	**5.8.2**		
unique patient identification eg full name and DOB or MR number	indicator 1	5.8.2			
correct patient ID on records and reports	indicator 2	5.8.2			
By 1-1-2010 all images to be retained min 6 months unless longer storage indicated	indicator 3	4.13.2.1			

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records include patient id, date, time (where necessary) & practice name	indicator 4	4.13.2.1			
name of person performing study is recorded	indicator 5	4.13.2.1			
when report contains images, a record of how images are provided and to whom	indicator 6	(4.13.2.1)			
Correct patient, site and procedure	**7-3**	**5.8.2**			
implemented "TIME OUT" protocol	indicator 1	5.8.2			
discharge procedure	**7-4**	**5.8.1**			
procedure for discharge of sedated / anaesthetised patients to responsible adult	indicator 1	5.8.1			
patient instructions regarding driving a vehicle, operating machinery, etc	indicator 2	5.8.1			
Informed consent	**7-5**	**5.8.3**	**5.8.1**		
information to patient regarding procedure	indicator 1	5.8.1			
information includes - pre (preparation), (post) discharge, fees, risks, trainees, role of persons at each stage of exam	indicator 2	5.8.2			
information for non-English speaking patients	indicator 3	5.8.2			
records of patient consent	indicator 4	5.8.3			
comply with RANZCR *A Doctor's duty to warn*	indicator 5				
Privacy policy	**7-6**	**4.1.5.c**			
Privacy policy	**7-6-1**	**4.1.5.c**			
implemented Privacy Policy	indicator 1	4.1.5.c			
any departures from National Privacy Principles are detailed	indicator 2	4.1.5.c	4.13.1.1		
patient consent to use information	**7-6-2**	**4.1.5.c**			
procedure for gaining patient consent	indicator 1	4.1.5.c			
procure includes proposed uses of personal information	indicator 2	4.1.5.c			
situations where consent	indicator 3	4.1.5.c			

Clause / content	RANZCR Version 9	ISO/IEC 17025			
required					
patient consent to be recorded in information system	**7-6-3**	**4.1.5.c**	**4.13.1.1**		
patient consent to be recorded in RIS	indicator 1	4.1.5.c	4.13.1.1		
RIS to flag any personal information that is subject to restricted consent.	indicator 2	4.1.5.c	4.13.1.1		