



STANDARDS OF QUALITY ASSURANCE IN INTERVENTIONAL ONCOLOGY

First Edition



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Standards of Quality Assurance in Interventional Oncology

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European Societies

ÖGIR	Austrian Society of Interventional Radiology
BSIR	British Society of Interventional Radiology
RCR	Royal College of Radiologists (United Kingdom)
NVIR	Dutch Society of Interventional Radiology
SFR	French Society of Radiology
FRI-SFR	Federation of Interventional Radiology - French Society of Radiology
DeGIR	German Society of Interventional Radiology and Minimally-Invasive Therapy
GSIR	Greek Society of Interventional Radiology
MACIRT	Hungarian Society of Cardiovascular and Interventional Radiology
ICIR	Italian College of Interventional Radiology
SERVEI	Spanish Society of Vascular and Interventional Radiology
SSVIR	Seldinger Society of Vascular and Interventional Radiology (Sweden)
SSVIR	Swiss Society of Vascular and Interventional Radiology
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CAIR	Canadian Association for Interventional Radiology
GACIR	Georgian Association of Cardiovascular and Interventional Radiology
HKSIR	Hong Kong Society of Interventional Radiology
ISVIR	Indian Society of Vascular and Interventional Radiology
ILSIR	Israeli Society of Interventional Radiology
KSIR	Korean Society of Interventional Radiology
MYSIR	Malaysian Society of Interventional Radiology
CVIR-SRS	Cardiovascular Interventional Radiology Subsection of Singapore Radiological Society
CVIR-CORS	Cardiovascular Interventional Radiology Section of Chapter of Diagnostic Radiology, College of Radiologists Singapore

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Introduction

Interventional oncology is a discipline that has expanded dramatically over the past few decades and now plays an ever-increasing and important role in the management of cancer patients. It offers minimally invasive treatment options that enable the safe and effective clinical management of patients.

Interventional oncology services depend on having the necessary skills and facilities locally. The experience, safety and wellbeing of patients must be integral to the design of the patient pathway and must facilitate best medical practice.

This document sets out the Standards of Quality Assurance that are required to safeguard patient safety and encourage good practice.

It also includes the requirement to collect data to assess the effectiveness and safety of procedures, develop the evidence base and ensure patients receive optimum care.

Acknowledgements

The CIRSE Standards of Quality Assurance in Interventional Oncology are based on a set of Standards for Radiation Oncology developed and published by the Royal Australian and New Zealand College of Radiologists, the Australian Institute of Radiography and the Australasian College of Physicists, Scientists and Engineers in Medicine [1]. CIRSE is greatly indebted to the Royal Australian and New Zealand College of Radiologists for making this document available and helping to adapt it to the requirements of interventional oncology, in an effort to increase the quality of care of cancer patients around the world.

The CIRSE Executive Board would like to recognise the Oncology Alliance Subcommittee, chaired by Andreas Adam, and its members Thierry de Baère, José Ignacio Bilbao, Afshin Gangi, Thomas Helmberger, Liz Kenny, Riccardo Lencioni, Philippe Pereira, and additionally Keith Ison and Shahzad Ilyas for their contribution in the creation of the International Accreditation Scheme for Interventional Oncology Services (IASIOS) and the establishing of the Standards of Quality Assurance in Interventional Oncology document.

The Scope of the Standards

The CIRSE Standards of Quality Assurance in Interventional Oncology focus on interventional procedures involved in the management of cancer patients. They look at the whole process of patient care and treatment and what is required to deliver it safely and effectively.

This document does not define clinical outcomes, as these will be specific to particular procedures and dependent on the condition of each patient. Neither does it address wider health system measures such as quality of life or the cost benefit of particular procedures. What it does, is provide a framework to help with development of these wider measures.

The Standards of Quality Assurance in Interventional Oncology are essential in achieving the main goal of IASIOS: to provide organisations with the opportunity to receive CIRSE accreditation. The document outlines in three sections the evidence that is required from organisations to be compliant and eligible for accreditation: 'Staff and Facilities', 'Treatment, Planning and Delivery', and 'Safety and Quality'.

The Standards of Quality Assurance in Interventional Oncology will be reviewed in the light of developments in interventional oncology practice.

Measuring Achievement of the Standards

The Standards of Quality Assurance are the basis for evaluation through the International Accreditation System for Interventional Oncology Services. The requirements listed in the documents allow for the organisation's achievements to be measured.

Organisations wishing to achieve certification of compliance with the Standards of Quality Assurance should contact the Interventional Radiology Accreditation Service (IRAS) for more details or visit www.iasios.org.

The Standards of Quality Assurance Framework

The Standards of Quality Assurance in Interventional Oncology are divided into three sections:

Staff and Facilities (Standards 1 to 6)

Treatment Planning and Delivery (Standards 7 to 9)

Safety and Quality (Standards 10 to 13)

It is important to note that the Standards are inter-related and must be considered as a whole. Supporting each Standard are a number of criteria and explanatory commentaries to assist with their interpretation. As the Standards must be taken in conjunction with each other, it follows that a commentary may relate to more than one Standard or criterion within the document. Required evidence does not necessarily relate to a single criterion; it may relate to several criteria in more than one Standard.

Many of the Standards in both Section 1, Staff and Facilities, and Section 3, Safety and Quality, are not exclusive to interventional oncology and may already be monitored, particularly if the facility is participating in a local quality assurance system or wider service accreditation programme. In this instance, evidence would still need to be provided to show compliance with these Standards of Quality Assurance in Interventional Oncology.

Structure of each Standard:

Each **Standard** refers to a corresponding goal or outcome. For example, Standard 3. Management of Patient Records and Clinical Data supports patient services and their development and provides information for administrative and regulatory purposes.

Criteria describe the key processes required to attain the goal. For example, Criterion 3.2 "Each facility retains a list of the essential core data that must be collected within each interventional oncology patient record."

A **commentary** provides information to assist in understanding how a criterion applies in everyday practice. Wherever possible, a commentary has been referenced.

The **required evidence** lists documents or records that the facility needs to be able to provide as evidence to demonstrate compliance with the Standards. For example, a list of core data kept on patients requiring interventional oncology services.

It is necessary for some of the required evidence that an internal audit is carried out by the organisation. The summary of the audit results need to be provided using the corresponding template that CIRSE will provide. The records used in these audits may be the same for required evidence 3c, 7b, and 8d.

Reference materials included within the Standards of Quality Assurance in Interventional Oncology are:

Definitions which explain the meaning of technical terms used in the Standards, in alphabetical order.

A bibliography listing all references.

Section 1:

Staff and Facilities

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'Facility', in this context, encompasses the whole environment used to deliver the interventional oncology service, including workforce and equipment.

1. Staff competence

Staff working in interventional oncology are competent to perform the procedures undertaken.

Competence is either defined locally (in which case it must be subject to peer review) or by conforming to an agreed national or international curriculum. Competence is achieved by training and is supported by effective recruitment, systematic selection processes and effective induction. It is maintained by staff development and a performance review system.

Criterion 1.1

Records are kept of current registration status, license to practise, and achievement of competence for all staff (as applicable).

Commentary 1.1

The qualifications, training and experience of those carrying out interventional oncology procedures, including interventional oncologists, radiographers, technicians and interventional radiology nurses, must reflect the skills and competencies required to deliver these services safely [2]. This includes temporary staff. Recruitment and systematic selection processes must ensure that individuals hold appropriate qualifications and are registered to practise as applicable to the jurisdiction. Similar considerations apply to specialist staff involved in supporting the facility.

Criterion 1.2

Local arrangements are made to assess the ongoing competency of staff. Performance review systems supported by staff development programmes [3] are in place and are applied at least annually.

Commentary 1.2

Performance review systems must be in place to ensure that competencies are maintained and keep pace with developments in interventional oncology. They should include elements of peer review and of clinical supervision where appropriate.

The performance review process should include a review of professional responsibilities and continuing professional education for all staff groups. It should set limits that specify the time individuals remain competent without practising and after which some form of re-accreditation or "revalidation" is required.

The volume of procedures undertaken is important for maintaining individual and organisational competence. CIRSE recommends that a comprehensive interventional oncology service should undertake at least 150 therapeutic procedures per year. For a highly-specialised service more than 30 procedures in one specific category (as outlined in required evidence 1(e) and stated in the Accreditation Requirements Manual) may be sufficient to maintain competence.

Criterion 1.3

Where training in interventional oncology is delivered by the facility, it is done against a local training plan.

Commentary 1.3

The background education required for staff supporting interventional oncology is delivered through various routes for the different professional groups involved. The curricula involved vary across different centres.

Staff training and development is undertaken at most interventional oncology centres. Where this is done, there should be an agreed training plan which sets out what will be achieved and the competencies to be attained.

Required evidence

- 1(a) Record that staff are appropriately registered/licensed to practise.
- 1(b) Records of regular performance review for individual staff, as kept in accordance with facility policy and/or professional requirements.
- 1(c) Evidence of appropriate individual continuing professional development activity.
- 1(d) Evidence of appropriate facility development activity. This includes providing education, undertaking research and development, and improving services.
- 1(e) Records listing:

The number of different types of therapeutic interventional oncology procedures per year, under the following headings:

- Ablations
- Radioembolisation
- Chemoembolisation
- Pain management
- Musculoskeletal interventions
- Other vascular oncology procedures
- Other therapeutic procedures in cancer care

- 1(f) Records of patient consultations (see glossary for definition).
- 1(g) Records and analysis of mortality and locally specified complications.

2. Workforce profile

Workforce numbers and skills are managed according to the workload, in order to ensure delivery of safe and effective care.

Criterion 2.1

Staffing numbers and skills are established to meet planned patient care capacity safely [2].

Commentary 2.1

Interventional oncology is a complex service that requires interaction between a broad range of professional and non-professional groups [4]. Staffing levels, staff experience and workforce profiles should ensure a safe and effective service to patients. Workforce profile must also be considered in relation to risk management and should not be a causal factor in adverse patient care incidents as evidenced by incident analysis data.

Interventional oncologists are clinicians who are involved in Multidisciplinary Meetings (MDMs), consider patient treatments and are then responsible for all aspects of patient care in interventional oncology. This includes initial consultations prior to making a decision to treat, patient preparation, treatment planning and delivery, post-procedure care and the treatment of complications and subsequent follow-up.

In addition, staffing levels must be sufficient to support service leadership and management.

Criterion 2.2

Staffing schedules incorporate time for patient care related activities applicable to the facility's service delivery profile.

Commentary 2.2

Workforce profiles must take account of time for direct patient care and for support activities. Direct patient care includes the procedure and all related aspects of an individual's treatment, including patient consultation, treatment planning, patient management pre-, peri- and post-intervention, and follow up. These considerations apply to all staff working in interventional oncology. Overall workload must be planned with time allocated to supporting activities including clinical and general administration, teaching and education, continuing education, research and development, quality assurance, safety and audit. [2,3]

Required evidence

- 2(a) Workforce planning must allow interventional oncologists to participate in MDMs, patient consultations and periprocedural care.
- 2(b) Staffing schedules that accommodate staff absences and time for professional development, whilst providing sufficient skilled staff to deliver a safe service when required.
- 2(c) A documented system which identifies when staffing support during delivery of a clinical service is inadequate*, with evidence of any occasions when corrective measures were implemented in order to safeguard high standards.

* NOTE: 'inadequate' means a deficit in the planned and recommended level of support that increases patient risk significantly.

3. Management of patient records and clinical data

Management of the interventional oncology patient record supports safe and high-quality care. It is good practice to include or reference the interventional procedure record within a patient's full medical documentation. Data about interventional oncology procedures must be collected, managed and reviewed to support and develop services and clinical activities, and to meet internal and external reporting requirements.

Criterion 3.1

A procedure specific record is available for each patient. This record includes details of planned activity and treatment outcomes and forms the primary, comprehensive source of information for the delivery of patient care in interventional oncology.

This record complies with local requirements and regional jurisdictional legislation and guidelines [5].

Commentary 3.1

Patient records store individual patient information and provide a reference base. The record should include items such as: demographic data, diagnosis, histologic subtype, stage, intent of treatment, relevant medical history, assessment, consultation notes and treatment record, and clinical correspondence including referrals. CIRSE will provide registered facilities with an itemised list of minimum requirements.

Interventional oncologists require access to the general patient record. The service may also keep additional records specific to interventional oncology procedures.

Criterion 3.2

Each facility retains a list of the essential core data that must be collected within each interventional oncology patient record.

Commentary 3.2

Gaps or inconsistencies in information may render the data inadequate for reporting, research or audit purposes. This minimum data set is used for each patient that meets the facility's clinical decision-making and reporting responsibilities. It may incorporate data required as part of national and/or international standards to support treatment development and clinical trials.

Criterion 3.3

Interventional oncology patient records and databases containing patient information are logged, secure, and accessible only to authorised personnel and are retained according to jurisdictional and local requirements.

Commentary 3.3

Security and retention of the patient record and databases are important, as there can be adverse consequences if confidentiality, integrity, availability, accountability, authenticity or reliability of information is compromised.

Criterion 3.4

Clinical data management is planned and systematic, and supports clinical audits, clinical trials, analysis of outcomes, and cancer registry requirements. Disease/diagnosis and staging data conform to recognised classification systems in accordance with facility policies.

Commentary 3.4

Successful planning, evaluation and quality assurance of interventional oncology services depends on the ability to collect reliable and standardised data sets. Comparison of procedural outcomes and clinical trials requires the use of equivalent data items and definitions [5].

Required evidence

3(a) Records management policy that includes a systematic process for:

- tracing patient records
- keeping records secure
- transferring, archiving and removing records as locally applicable

3(b) List of core data to be kept locally on interventional oncology patients.

3(c) Audit of at least 30 randomly selected records against the CIRSE minimum dataset demonstrating:

- that they are accurate, comprehensive and up-to-date;
- that current versions of ICD and staging systems (or recognised alternatives) are used;
- compliance with the CIRSE minimum dataset

NOTE: audits required under 7(b), and 8(d) may be carried out on the same records as those chosen for 3(c)

3(d) Contingency plan to cover loss of physical or electronic access to patient records

4. Facility infrastructure

The facility infrastructure includes both the physical facilities within which the service is provided as well as the methods, systems and processes that enable its delivery.

Leadership and management of the facility will promote high quality care and take accountability for delivering safe and effective interventional oncology services within an ethical framework.

Criterion 4.1

The facility has a strategic and operational planning and management system which addresses the operation and physical organisation of the facility. This system takes into account any changes needed.

Commentary 4.1

The planning, structure, leadership and management of interventional oncology services are important because they affect patient access and subsequent health outcomes. The strategic, operational and physical design of interventional oncology services influence each other and should be developed in parallel. Service leadership sets policy and direction for existing services and their development.

The strategic plan of an organisation links its objectives and planned outcomes with the environment and external infrastructure. It is developed with due consideration of:

- existing national benchmarks for access to interventional treatment;
- predicted population changes;
- broader organisational planning, where applicable;
- associated physical infrastructure, equipment and its future development, and staffing requirements;
- existing standards;
- multidisciplinary support services; and
- timelines for review and revision.

Arrangements for management responsibility and accountability must cover all aspects of the service, including:

- patient care
- patient safety
- the integrity of each procedure
- infection control and management
- incident investigation and service improvement
- audit
- the introduction of new and novel procedures
- contingency planning
- facilities management

Criterion 4.2

Facility management and performance take a multi-professional team approach to ensure accountability and safety in the delivery of interventional oncology services [6].

Commentary 4.2

Facility management includes the effective and efficient management of buildings, plant, equipment, supplies, external service providers, utilities and consumables.

The facility management team has representation from all relevant professions.

Criterion 4.3

The physical infrastructure and environment, including patient, staff and public amenities, are designed, managed and maintained to be adequate for supporting safe and effective practice in the delivery of interventional oncology therapy.

Commentary 4.3

Interventional oncology is a specialty that is particularly dependent on the availability of appropriately shielded facilities and equipment. The life-cycle management of buildings, plant, equipment and systems is an important consideration in maintaining quality service delivery. Planning for such facilities should include interventional oncologists and support patient pathways. It must provide flexibility in room design and shielding to allow for future changes of use and new technologies.

Design of the environment, treatment processes and patterns of patient care should respect the dignity, privacy and confidentiality of patients and their ethnic, cultural and religious practices and beliefs.

Criterion 4.4

Other clinical services are provided to ensure the effective delivery of interventional oncology services.

Commentary 4.4

Supporting services must be sufficient to deliver the service the patient requires.

Appropriate methods are in place for assessing the suitability of the patient for anaesthesia and sedation. Necessary anaesthetic support should be provided.

Required evidence

- 4(a) A documented current plan (strategic, operational, or business) covering a timeframe of 2 to 5 years that identifies the ongoing and development needs of the facility in order to maintain or improve the service provided.
- 4(b) Evidence of meetings to review performance and manage operational, risk and safety issues.
- 4(c) Records of Health and Safety inspections and actions.
- 4(d) Risk register showing evidence that patient risks have been considered within the operation of the facility.

5. Facility process management

Interventional oncology care is delivered at the appropriate time, in a way which is coordinated and equitable, to achieve optimal patient outcomes [2,7].

Criterion 5.1

The patient pathway and referral pathway [4] is co-ordinated to provide optimal patient outcomes within available resources.

Commentary 5.1

How an interventional oncology service is structured, planned and co-ordinated has a great effect on health outcomes and overall access to services. In addition, minimising disruption to planned treatment schedules is important if interventional oncology therapy is to achieve optimal outcomes. Any delays and their reasons should be recorded.

Patients who may benefit from interventional oncology procedures should be discussed at a Multidisciplinary Meeting (MDM). Interventional oncologists should attend all relevant MDMs to provide expert input to decision making. Following an MDM the interventional oncologist can assume ongoing patient management.

Criterion 5.2

Care is prioritised and provided in a timely manner and according to patient needs.

Commentary 5.2

All cases should be discussed at an appropriate MDM. The inclusion of interventional oncology expertise at relevant MDMs is needed to ensure adequate consideration of interventional oncology treatments.

Patient prioritisation should be based on clinical requirements, local resources and organisational policies on waiting times and patient access.

Required evidence

- 5(a) A documented policy for prioritising patients for treatment that:
- outlines the basis on which patients are prioritised
 - identifies the method used to classify, record and report waiting times
 - indicates strategies to minimise waiting times where appropriate
- 5(b) Data showing trends in waiting times and documentation of any response to unacceptable delays.
- 5(c) Contingency plan setting out how to manage situations where there is an unscheduled interruption to treatment.
- 5(d) Evidence that input from an interventional oncologist is available for all patient cases discussed at appropriate MDMs.

6. Medical devices and equipment

Medical equipment and medical devices [8] used for procedures in interventional oncology ensure accurate and safe clinical treatment.

In the context of this Standard, the term 'equipment' applies to all medical devices used in an interventional oncology facility. This will include equipment for patient monitoring and support; specialist interventional oncology medical equipment; and non-reusable medical devices used in each procedure, ranging from consumables to implanted materials.

Criterion 6.1

Requirements for new interventional oncology equipment are specified by qualified, trained, and experienced staff. Specifications for equipment used exclusively for interventional oncology procedures are determined by the interventional oncologist.

Commentary 6.1

Purchase specifications are used to evaluate different types of equipment when considering a purchase and to ensure items supplied are capable of performing the desired functions. Specifications should be based on a detailed statement of clinical and technical requirements and must take relevant standards into account. They should also include the provision of appropriate user training and maintenance by the manufacturer, vendor or other supplier as appropriate. Specialist technical advice should be taken into account when considering what aspects of equipment are essential, for example when identifying the need for particular imaging systems. Specifications should be written in conjunction with the multi-professional team, involving specialist advice as appropriate to the equipment being selected.

Criterion 6.2

New interventional oncology equipment and any subsequent updates or modifications are installed, acceptance tested, commissioned and used by appropriately qualified personnel.

Commentary 6.2

Installation is usually carried out by the equipment supplier. Major items will require the use of project management to ensure any modifications to facilities are coordinated with equipment installation. Medical physicists and/or clinical engineers should take responsibility for acceptance testing and for signing off the commissioning programme. The programme should clearly define: any baseline values for quality assurance and system operation; the scope of tests to be performed with respect to the intended clinical use; the staff groups to be involved; and the risk assessment for component or system failure.

Suitable arrangements need to be made when planning for the procurement, storage, management and use of devices, drugs and materials for new and novel procedures.

Criterion 6.3

There is a preventative maintenance programme for interventional oncology equipment that ensures safety, reliability, reproducibility and accuracy.

Commentary 6.3

The preventative maintenance programme should follow manufacturer recommendations. Any variations from these recommendations should be documented with explanations. All maintenance records are kept for at least the lifetime of the equipment, including communication from the manufacturers relevant to safety and operating functionality, which is disseminated within the facility as appropriate.

Medical physicists and/or clinical engineers are responsible for authorising return of equipment to clinical use following any repair, adjustment, upgrade or modification to the equipment that affects patient safety. This may include carrying out acceptance tests.

Consumables and materials used in interventional oncology procedures need to be stored and managed effectively so that they are fit for use when required.

Criterion 6.4

Where there are national and international guidelines for the quality assurance and testing of equipment used in interventional oncology, a quality assurance programme is set up.

Commentary 6.4

Quality control is a regular check of equipment to make sure it is working to the required specifications. Checks can be done by a variety of staff following agreed protocols. It may include regular assessment of image quality and appropriate calibration of equipment. Access to equipment for such measurements must be factored into routine use. As a minimum, checks should take place as part of annual equipment maintenance.

Quality assurance is the programme which makes sure quality checks are carried out regularly and that records are kept. A quality assurance programme is established and overseen by the responsible management group in the facility.

Required evidence

- 6(a) Evidence of interventional oncologist involvement in approving the specification of interventional oncology treatment equipment.
- 6(b) Evidence of acceptance testing and commissioning for all interventional oncology equipment.
- 6(c) Documented arrangements for the procurement, storage and management of usable and non-reusable devices, drugs and materials.
- 6(d) Maintenance programme details and records for all significant items of re-usable medical equipment.
- 6(e) A documented checking and quality assurance programme for interventional oncology equipment that includes, as relevant:
- a systematic approach for all equipment tests, specifying their frequency, tolerances and recording requirements;
 - a documented audit plan and programme;
 - records for every test undertaken;
 - a protocol for managing test failures and non-compliances that includes action levels, reporting requirements and action to be taken
- 6(f) Records of delays, unscheduled breaks in treatment and remedial action taken due to equipment failure.

Section 2:

Treatment Planning and Delivery

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Standards 7-9 address the way in which individual treatments are planned and delivered by the clinical team.

7. Planning for Interventional Oncology treatments

Plans for interventional oncology treatment document the intended course of treatment for an individual patient. They also consider how potential complications will be dealt with.

Criterion 7.1

Patients are subjected to pre-assessment routines appropriate to the procedure intended.

Commentary 7.1

Patients undergo a range of pre-treatment assessments. These include: assessment of fitness for anaesthesia or other pain relief procedures, suitability for a specific intervention, and level of risk or benefit to organs being treated or affected by the treatment.

Other requirements for pre-treatment assessment may be set out by a service. Some treatment modalities require specialist measurements to be made in advance. These can include specialist imaging and other diagnostic tests.

Criterion 7.2

Patients are informed of the benefits and risks of the proposed interventional treatment and consent is documented according to local protocol.

Commentary 7.2

Patients are given appropriate information to enable them to understand and prepare for the procedure.

Organisations [9] recommend the following guidelines when seeking consent from patients: it must be voluntary and given without coercion, duress, misrepresentation or manipulation. Consent must be specific with information being provided in areas of particular relevance to the patient. An interpreter should be used when a patient is not fluent in the language being used.

Pain relief must be discussed according to the needs of the patient and requirement of the procedure, in order to ensure patient comfort during and after the procedure.

Consent from the patient should be reviewed when there is a delay to the start of treatment which may impact on the patient's condition or treatment options, or new information has become available which may impact on the patient's consent.

Criterion 7.3

The interventional treatment plan documents essential information on the decision-making process and intended outcome of the procedure for patients and other professionals. This includes identifying areas to be treated and organs at risk, in addition to the approach to be taken in order to deliver the desired treatment and reduce or eliminate injury to organs at risk.

Commentary 7.3

The interventional treatment plan sets out how the interventional team intend to deliver the treatment. This plan contains at least the following items:

- identities of the responsible interventional oncologists;
- unique patient identification, including full name, date of birth, unique identification number and gender;
- baseline diagnosis and tumour staging;
- review of pre-procedural cross-sectional imaging;
- treatment intent;
- anatomical region to be treated;
- surrounding structures at risk and planned approach to reduce or eliminate injury;
- image guidance modality and other equipment to be used;
- planned approach to target lesion;
- drugs, equipment and medical devices used in each phase of the interventional treatment;
- pain management strategies;
- details of any other associated treatment requirements.

The benefits of having such a plan include the ability to make sure that all the necessary personnel, equipment, drugs, and other items needed to carry out the procedure are in place.

Required evidence

7(a) Documented consent policy for use in interventional oncology.

7(b) Audit evidence of at least 30 randomly selected records, covering at least three different types of tumours for patients treated with interventional oncology in the last 12 months, including:

- informed patient consent for interventional treatment and associated procedures; and
- any subsequent change to the consented procedure

NOTE: records used for 7(b) may be the same as those audited under 3(c), and 8(d).

7(c) Organisations produce interventional treatment plans.

7(d) Evidence of peer discussion regarding treatment plans.

8. Patient care during interventional treatment delivery

Treatment is delivered correctly, accurately, safely and consistently with due consideration of each patient's rights and choices. A planned treatment may need to be changed during a procedure due to various circumstances. Any change to the planned treatment is made in the patient's best interests. This contingency should be provided for when patient consent is obtained. Full anaesthetic support should be available when required.

Criterion 8.1

Verification methods maximise the likelihood of obtaining a good outcome from the intervention, including identifying the correct patient, correct procedure and correct site.

Commentary 8.1

To ensure that the right patient receives the correct treatment, more than one form of identification is needed prior to the commencement of each treatment. This may be name, address, date of birth, facility identification number or photographic identification. Checks must be performed as specified in local protocols, for example by the patient being asked to state their details. Arrangements must take account of situations where patients are not able or competent to provide the necessary details.

The CIRSE IR Patient Checklist [12], or similar, should apply to any invasive procedure, which is dependent on penetration of the skin under local or general anaesthesia (other than placement of peripheral IV access), in order to avoid potential errors [10,11].

Criterion 8.2

All equipment and accessories are checked and prepared for use prior to each procedure.

Commentary 8.2

Prior to starting the procedure and exposing the patient to any form of intervention or radiation, all equipment should be checked in accordance with local protocols and the manufacturer's instructions to verify it is working correctly. This requirement is additional to the need for all equipment to undergo scheduled maintenance checks according to manufacturer instructions, and includes any pre-procedure calibration and dosimetry checks. Devices and materials used in interventional oncology should be inspected to make sure sufficient stock is available and that items are prepared for use where required.

Criterion 8.3

Patients are observed during the procedure and monitored according to need.

Commentary 8.3

Appropriate clinical monitoring equipment allows observation of the patient during treatment, thereby promoting patient safety and maintaining pain control and patient comfort.

Patients may have special needs, for example those undergoing concurrent chemotherapy, paediatric patients, and patients with pacemakers. These patients may require more intense observation, ancillary support equipment and trained support personnel to ensure their safety and comfort during and after the procedure. This may mean putting specific processes in place to provide for these individuals.

Criterion 8.4

Patients' fitness and psychosocial needs are reviewed continuously throughout the course of planned treatment.

Commentary 8.4

Regular patient review prior, during and after delivery of the treatment(s) will facilitate early detection and management of complications. The treatment plan may need to be adapted during its delivery with appropriate modification and/or revision as necessary. Adequate provision for pain relief should be evidenced throughout the procedure.

Psychosocial care involves a whole-person approach, taking into account the person's past life experience, current situation and quality of life. It is good practice to provide feedback on the outcomes to the patient shortly after the procedure.

Criterion 8.5

Patients are monitored following the procedure and are given adequate pain relief or treated for other symptoms.

Commentary 8.5

Patients are monitored at regular time intervals to highlight any post procedural complications and provided adequate pain relief in order to maintain pain free recovery.

Criterion 8.6

Follow-up imaging is directed by the individual performing the interventional oncology procedure.

Commentary 8.6

Follow-up imaging should be performed in a clinically relevant time frame where required. It may also be required to identify any treatment complications.

Required evidence

8(a) Identification methods that verify patient identity and match the patient to the interventional treatment plan prior to each treatment session. This should include use of the CIRSE IR Patient Safety checklist or equivalent [12].

8(b) A documented process for checking equipment prior to use.

8(c) A defined system for the observation, monitoring and recording of patients' vital signs during treatment.

8(d) Audit of 30 patient treatments for evidence against 8(a), and 8(c).

NOTE: records used for 8(d) may be the same as those audited under 3(c), and 7(b).

8(e) Documented systematic processes for checking devices, drugs and materials before use.

9. Recording treatment parameters

Keeping technical records develops the evidence base to improve patient procedures. It will also improve the reliability of patient inter-comparisons.

Criterion 9.1

An appropriate record of measurements and technical parameters associated with individual patient treatments is kept.

Commentary 9.1

Achievement of this Standard shows a focus on the delivery of treatment and the intent to extend the evidence base for effective treatments.

Systematic recording of observations and measurements made before, during and after patient treatment can assist with the development of improved treatments and patient safety. Particular parameters recorded will vary depending on the treatment system but might include:

- A record of appropriate instrument settings and time used during the procedure. This may include indications of power delivery and other features provided by the manufacturer.
- A record of measurements or images created by the treatment system and of the output from any external monitoring or imaging equipment. For example, this may include the rate of temperature change, temperature distributions and tissue characteristics.

As techniques improve, more ways will be developed to improve the quantification of patient treatments and further criteria will be developed to support evidence-based treatment and improvement.

Required evidence

9(a) As available locally, a system for recording parameters, measures and information which is generated during and after patient treatment.

Section 3: Safety and Quality

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The Standards in this section address system aspects of patient safety and the application of good organisation and monitoring principles during clinical care (governance*).

10. Safety, quality and improvement processes

These processes set out how a unit manages safety and improves quality. They should include systems to ensure safe and effective care for individual patients, the introduction of innovative technology and techniques, and the process for continual improvement.

Criterion 10.1

Governance arrangements are in place to support safe practice, quality improvement and innovation, as well as the safe and considered introduction of new technologies.

Commentary 10.1

An appropriate committee or management structure is in place which monitors the quality of healthcare being delivered within interventional oncology. This is carried out by reviewing and auditing outcomes, complications, incidents and complaints.

Quality improvement in health services requires leadership and commitment at all levels. For example, interventional oncology radiographers possess skills in ensuring the best quality images are obtained safely and appropriately. This should include minimising patient dose from ionizing radiation; taking appropriate precautions with Magnetic Resonance (MR) systems; and using imaging equipment effectively with interventional equipment and procedures.

Quality improvement systems and policies assist in providing safe and quality care by continuously monitoring, auditing [2,4], and measuring performance. Systems which achieve this at an organisational level may include the interventional oncology service.

Continual improvement results when systems of work enable everyone in the organisation to build new knowledge, to test changes in daily work, and to learn from their practise.

Criterion 10.2

Risk to patients, staff, and the public is managed in accordance with both occupational health and safety and national and international standards, as well as the principles of safe practice.

Commentary 10.2

Effective governance requires a responsible body, defined risk management strategies, effective clinical and organisational audit and incident reporting paths, and clear policies and processes. For example, a hospital should have a policy and documented plan for managing infection control and to prevent accidents during procedures and episodes of patient care. This should include risk assessments and a risk register. Systems should be required to keep the policy, plan, and risk assessments up-to-date with regular audit and oversight. This is to provide assurance to the hospital's governing board, external health regulators and users that the appropriate policies and plans are being followed.

* 'governance' is defined as "those structures, systems and processes that assure the quality, accountability and proper management of an organisation's operation and delivery of service." See Definitions for more details.

Documented plans should be in place to cover health and safety risks, including the safe handling of drugs, protection of staff from infection by high risk patients, control of hazardous chemicals, and other risks.

The manner in which service is provided is as important as the service itself and it follows that quality must, to some extent, be defined in terms of patient and user perceptions. Methods of obtaining direct feedback from patients and caregivers are therefore vital in informing the quality improvement process.

All health facilities are likely to have such policies and plans in place and these should cover the interventional oncology service requirements.

Criterion 10.3

There are systems to monitor and evaluate the technical quality of care and patient outcome, to compare these outcomes to benchmarks for best practice [4], and to act upon the results accordingly.

Commentary 10.3

Technical quality of care refers both to the delivery of the correct procedure to the correct patient and correct anatomical site as planned, as well as the avoidance, identification, and treatment of any associated complications.

Healthcare decisions based on evidence-based best practice provide patients with care that most closely meets their individual needs. Systematic collection and review of both technical procedure and patient outcome details provides the basis for ongoing improvement.

Receiving and acting on patient experience feedback has been shown to improve service performance.

Successful regular participation in inter-service comparisons and audit provides insight into the quality of service and provides information to help the continued development of treatment safety and efficacy.

Inter-comparisons ensure continuing improvement of quality of care and maintenance of standards among participating centres by comparing the treatments planned and delivered for particular clinical conditions with those delivered under similar conditions in different and/or reference centres.

Required evidence

- 10(a) An overall description of governance arrangements and relevant committee minutes, quality and risk records showing system review.
- 10(b) Documented patient experience feedback and action taken.
- 10(c) Review of unit outcomes and trends, with comparisons against standards of practice documents and/or data from other units (where available).
- 10(d) Documented approach for the adoption of new and novel technologies and procedures.
- 10(e) Review of patient complications over the previous 12 months and lessons learned.
- 10(f) Evidence of quality improvement initiatives undertaken during the past 12 months.

11. Radiation safety

All ionising radiation exposures are managed to minimise risk to patients, staff and the public. Diagnostic and therapeutic procedures are optimised so that adequate clinical outcomes are obtained at minimal dose.

Criterion 11.1

The management plan for radiation safety defines responsibilities and delegations of all persons involved with radiation exposures and management of radiation safety.

Commentary 11.1

The responsible person must ensure that a radiation safety management plan is in place, in accordance with the legislation for that jurisdiction. The plan needs to address all aspects of radiation protection including roles and responsibilities in the facility.

To function properly, all staff must be aware of their role in radiation protection. The responsible person must ensure that staff know their role and allocate special responsibilities only to appropriately trained and authorised workers. Some roles are defined in national legislation and should be formally recognised in local policies.

Criterion 11.2

The organisation which provides interventional oncology services maintains a register of equipment, staff and safety notifications relating to radiation safety.

Commentary 11.2

Effective organisations should maintain a register of all their equipment used to deliver and measure ionising radiation. They should also keep records of any staff radiation doses for individuals exposed to ionising radiation.

As a result of events and incidents, periodic guidance may be issued by equipment suppliers and others concerning the safety of equipment and processes. Safe organisations should have processes in place to pick up and act on such notifications.

Criterion 11.3

Appropriate services, equipment and resources are available for radiation survey measurement in both routine checks and emergency situations.

Commentary 11.3

The facility is required to have access to suitable equipment to allow assessment and survey of the facility's equipment and premises in order to ensure radiation safety for patients, staff and the public. This includes the provision of individual dose monitoring for those working with ionizing radiation.

Criterion 11.4

There is a regular review of all radiation safety protocols and physical verification to confirm continuing radiation safety.

Commentary 11.4

Any plan for the management of radiation must be reviewed periodically to ensure it adequately addresses radiation protection and complies with regulations. Review with input from all professions concerned can promote the maintenance of a safety culture with all staff following safe work practices.

Required evidence

- 11(a) A system to manage radiation safety risks that includes:
- appropriate training requirements for clinicians undertaking interventional oncology procedures involving ionising radiation;
 - a documented policy that describes the management of pregnant patients who are being exposed to radiation;
 - a register of all radiation emitting equipment and radioactive sources; and
 - a register of all workers that shows the details of their licensed areas of work, specific responsibilities and records of radiation safety training and personal monitoring results.
- 11(b) Annual audit showing compliance with the management plan for radiation safety.

12. Incident monitoring programme

Participation in incident monitoring programmes provides confidence that procedures are safely delivered. It shows that a facility has a safety-conscious culture focused on continuous learning and the prevention of errors. This practice includes the reporting of near misses.

Criterion 12.1

The interventional oncology facility participates in an incident monitoring programme.

Commentary 12.1

Information from incidents and near misses provides a valuable opportunity to improve patient safety and outcomes. Promoting open reporting and providing feedback to staff on incident data and investigations are vital components of a successful incident management system. An open disclosure policy is highly recommended [13] whereby individuals are encouraged to report incidents without blame.

For the purposes of this Standard the terms 'incident' and 'event'* are interchangeable. Incidents or events may arise from: equipment, building or systems failures or shortages; operating errors; mishaps or other unusual occurrences.

The incident monitoring programme will report on incidents specific to the interventional oncology setting.

By aggregating incidents from multiple facilities, it should be possible to provide answers about the circumstances and contributing factors leading to these events, the actions taken by staff and the outcomes.

It is well recognised that narrative descriptions are the richest form of information for finding out the circumstances leading to an event and for determining if and how such an event can be prevented in future.

Required evidence

12(a) Documentation showing that the facility records incidents of all types (including near-misses), analyses the data, and takes action as appropriate.

12(b) Evidence of feedback of incidents and investigations to staff.

* *An incident or event includes but is not limited to an error, a near miss or any adverse event relating to patient care or patient, visitor and staff safety.*

13. Participation in clinical trials and research

Organisations that participate in clinical research need suitable governance and infrastructure.

Criterion 13.1

Any participation in clinical research conforms to international guidelines of Good Clinical Practice.

Commentary 13.1

Engagement of organisations in clinical research and contribution to registries is highly desirable.

Good Clinical Practice (GCP) is a set of internationally-recognised ethical and scientific quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people, to ensure quality and safety [14].

Participation in clinical research has benefits beyond the evidence it gathers as it helps to define high quality care and facilitates external review of patient care. The development of treatment guidelines may also be directly affected by evidence obtained from clinical research.

Criterion 13.2

Ethics approval is needed for clinical research. Also, equipment used for these purposes should have been through the necessary regulatory processes for approval.

Commentary 13.2

Various types of external regulatory and internal organisational approval may be required before starting clinical research. Organisational approval for new or novel treatments, including those using medical devices, should be covered by a plan, as required in Standard 10, with the aim of ensuring the organisation's legal and financial liabilities are covered.

Required evidence

13(a) Document showing ethics approval of all clinical research.

13(b) Records of Good Clinical Practice (GCP) training for staff running clinical research projects.

13(c) List of research participation.

Definitions

Acceptance testing	The process of verifying that equipment (both hardware and software) operates to performance specifications agreed between the vendor and customer according to a mutually agreed acceptance protocol. This happens initially when the equipment arrives at the organisation and additionally when it is handed back to the organisation after service work has been completed.
CE Marking	Recognition that a medical device is safe and fit for the purpose for which it is intended. EU legislation and national bodies set out how this is achieved.
CIRSE IR Patient Safety Checklist	A single-page document comprising pre-procedural (“Sign-in”) and post-procedural (“Sign-out”) components to ensure the safety of the patient. This document can be modified to suit the requirements of individual organisations.
Commissioning	The process of setting up an item of equipment and/or software and acquiring all relevant data required to make it clinically useable in a specific facility. Therefore, the commissioning process will depend on clinical requirements in a particular centre and other equipment available.
Consultation	<p>Initial consultation pre-treatment</p> <p>A formal and documented interaction between an interventional oncologist and the patient to discuss their care and options for treatment, the procedure recommended and likely benefit and potential complications of treatment. The treating interventional oncologist must be responsible for the discussion of and decision about treatment options with the patient. Sufficient time must elapse between the consultation and the start of treatment for the patient to make an informed and meaningful consent.</p> <p>Consultation post treatment</p> <p>A formal and documented interaction between an interventional oncologist and the patient to discuss the outcome of the treatment, the ongoing treatment plan, and the follow up plan.</p>
Dosimetry	The measurement of absorbed dose in matter resulting from exposure to ionising radiations. In the context of Standard 8, ‘Dosimetry’ refers to the measurement of physical dose and the provision of these dose measurements for the purpose of treatment monitoring.
Equipment	<p>For the purposes of the Standards of Quality Assurance in Interventional Oncology, equipment includes all medical devices (hardware and software) used for:</p> <ul style="list-style-type: none"> • patient imaging for planning, delivery and verification • delivery of treatment to a patient; and • monitoring, measuring and/or otherwise contributing to patient treatment and care.
Equipment check	To ensure proper functioning of all equipment relevant to the IO procedure, systematic checks should be performed. Procedures to check equipment may include scheduled maintenance checks according to manufacturer instructions, pre-procedure calibration and dosimetry checks. Devices and materials used in interventional oncology should be inspected to make sure sufficient stock is available and that items are prepared for use where required.

Governance	<p>The totality of measures in place within an organisation to ensure that it operates effectively and accountably. In a healthcare context, it can be considered under at least two headings: clinical governance and corporate governance.</p> <p>The UK National Health Service uses generally the following definition of clinical governance: "A framework through which...organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish." [15] This definition addresses the needs for high standards of care, transparent responsibility and accountability and constant improvement embodied in this set of Standards.</p> <p>Corporate governance in a healthcare organisation addresses, 'those structures, systems and processes that assure the quality, accountability and proper management of its operation and delivery of service' [16]. This includes everything from delivering an organisation's strategic goals to having systems in place to keep staff and patients safe.</p>
Image fusion	The act of combining a primary and secondary data set(s) in a 3D treatment planning system.
Incident	An error, near miss, or any adverse event relating to patient care or to patient, visitor and staff safety.
Interventional oncologist	Person who is registered as a medical practitioner, is a fellow of the appropriate professional body or equivalent and is licensed or otherwise authorised to practice in the field of interventional radiology providing care for patients diagnosed with cancer.
Interventional oncology facility	Any physical location at which interventional oncology is planned and/or delivered.
Interventional oncology patient record	The primary source of information for an interventional oncology procedure which includes the treatment plan, record of treatment and acquired images.
Interventional oncology service	The sum total of all interventional oncology facilities.
New	The first time a particular procedure or item of equipment is used in a particular organisation.
Novel	The first instance of application of a procedure or item of equipment.
Operational infrastructure	The management and business systems, structure and processes of the unit, the unit's services and staff.
Organisation	The legal entity to which an interventional oncology service is affiliated.
Organisational	The framework of the amenities, both physical and operational, that support an

infrastructure	organisational unit's operation and function. This basic architecture and its 'fit' with the environment determine how well the unit functions and how adaptive it is to change and future requirements.
Patient pathway	A patient's progress through a facility.
Quality assurance	All the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality. Quality assurance for interventional oncology equipment is the process of making sure equipment and techniques work as intended. It can include carrying out tests before equipment is used, to make sure it is producing the right effects. It can also involve periodic checks for possible faults, often as part of regular equipment servicing. Quality assurance inspections are usually a legal requirement for X-ray imaging equipment.
Quality care	Care based on commonly accepted best practice guidelines and the associated patient outcomes.
Quality control	The techniques and methods built into an organisation's operations to control individual processes and their outcomes.
Quality improvement	Actions taken to review and enhance the quality of a process and/or service.
Quality programme	Encompasses all quality activities as listed in the programme description document.
Radiation Protection Adviser/ Radiation Protection Supervisor/ Radiation Safety Officer/Medical Physics Expert/other similar titles	Suitably qualified and experienced persons who oversee aspects of procedures that include the use of ionising radiation in a workplace. These roles may also be responsible for the training of others. Detailed roles and responsibilities are defined by national standards and legislation.
Radiation safety	Measures taken to reduce the risk of exposure when working with sources of ionizing radiation. These may include the use of devices, equipment, distance, barriers and restrictive working practices.
Radiographer	A medical imaging and radiotherapy expert who is not a registered medical practitioner and who: <ul style="list-style-type: none"> • is professionally accountable for the patients' physical and psychological well-being prior to, during and following examinations or therapy • takes an active role in justification and optimisation of medical imaging and radio therapeutic procedures • is a key person in ensuring the radiation safety of patients and third persons in accordance with the "As Low As Reasonably Achievable (ALARA)" principle and relevant legislation

For more details and a list of national titles and professional qualifications for radiographers please see the EFRS European Qualifications Framework (EQF) Benchmarking Document: Radiographers (2014)

Ready for care	<p>Is when the patient is ready to commence treatment as agreed between the patient and the interventional oncologist. Patients are not considered to be ready for care if:</p> <ul style="list-style-type: none">• the interventional oncologist considers treatment should not commence because the patient is in a postoperative healing phase and/or a post chemotherapy phase;• any existing morbidities require prior therapy; or• a delay is requested by the patient.
Responsible person	<p>The person who has the overall management responsibility and control of radiation-producing equipment or medical practice. It may be a person, corporation, chief executive officer or director of medical services.</p>
Risk register	<p>A tool to document and manage risks. It will typically set out the likelihood and severity of each risk, together with any measures that have been put in place to reduce their impact</p>
Service	<p>See entry for 'Interventional oncology service'.</p> <p>Technical quality of careRefers to the delivery of correct treatment to the correct patient and to the correct anatomical site as prescribed.</p>
Treatment verification	<p>The process of imaging and evaluating the outcome of the interventional procedure against that set out in the treatment plan and the intention of the interventional oncologist during treatment.</p>
Waiting time	<p>The interval between the 'ready for care' date and the date treatment is delivered.</p>

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