



International Collaboration on Cancer Reporting

# **ICCR Harmonisation Guidelines**

Version: 2.1

## Document history

<b>Version</b>	<b>Description</b>	<b>Date</b>
Version 0.1	Initial draft	Aug 2012
Version 0.2	Refinement of initial draft	Sept 2012
Version 0.3	Review by ICCR	Oct 2012
Version 0.4	ICCR team updates included	Oct 2012
Version 0.5	Refinement of ICCR updates	Nov 2012
Version 0.6	Published for open consultation as part of the Guidelines for ICCR Dataset development document	Nov 2012
Version 0.7	Final version for review	August 2013
Version 1.0	Agreed by ICCR DSC committee	March 2014
Version 1.1	Updates included – tumour thickness and general rules for dataset development	March 2014
Version 1.2	Updates agreed	June 2014
Version 1.3	Inclusion of block identification key	December 2014
Version 1.4	Change to specimen type/site to specimen submitted, tumour multi-focality to tumour focality and confirmation of Block identification key.	January 2015
Version 2	Document ratified by DSC	February 2015
Version 2.1	Removal of block identification key	June 2016

## 1. HARMONISATION OF DATA ELEMENTS

To promote harmonisation the use of the following terms is recommended where they are to be included in a dataset:

Term	Comment
<b>MACROSCOPIC FINDINGS</b>	Heading – used to group elements from the macroscopic inspection of the specimen
Operative procedure	Describes the range of procedures which may be used with this specimen – eg radical prostatectomy for prostate specimens
Specimen orientation	This refers to the information received from the surgeon/clinician regarding orientation of the specimen by marking sutures, clips or other techniques.
Specimen/s submitted	Record the body part, organ or tissue received in the laboratory ie the result of the operative procedure. All components of the anatomical specimen received must be listed at the required level of detail e.g. the relevant quadrant within a breast specimen; the specific segment of bowel e.g. ascending colon
Specimen laterality	Used in conjunction with the specimen type or site eg breast /right
Specimen integrity	Used to describe the quality of the specimen which may impact on the determination of an accurate diagnosis.
Specimen description	General description of the specimen which may include such features as shape, colour, etc
Specimen dimensions	Quantitative measure(s) of the specimen received in mm
Specimen weight	Quantitative measure of the weight of the specimen received in g
Tumour focality	This refers to separate foci of the same tumour within a single organ eg thyroid. Specific use cases may apply in some cancers eg breast.
Number of tumours	Used in conjunction with ‘tumour focality’. Specific use cases apply eg thyroid and kidney, this does not apply to multiple synchronous primary tumours, in which case a separate dataset is required.
Tumour site	This refers to the site of the tumour within the anatomical structure received eg cardia, fundus, antrum for gastric specimens.
Tumour description	This is used to describe the tumour and may include such features as shape, colour, texture, ulceration haemorrhage etc
Tumour dimensions	Quantitative measure(s) of the tumour in mm.

<b>Term</b>	<b>Comment</b>
Tumour perforation	Used to record that the tumour has /has not been received intact/fully encapsulated.
Maximum tumour dimension	A measure in mm of the greatest length. Where there are multiple tumours it is implied that this is for the largest tumour.
<b>MICROSCOPIC FINDINGS</b>	Heading – used to group elements from the microscopic (morphological) inspection of slides.
Histological tumour type	Histological tumour type is used when type is assessed only by histology.
Histological subtype/variant	Histologic subtype/variant is usually used in conjunction with Histological tumour type where this type is assessed only by histology
Histological grade	Use histological grade when assessed by histology only – ie. counting mitoses, assessment of other morphological features eg pleomorphism, necrosis, gland formation/features of differentiation etc. Histologic grading includes grading according to specific grading systems eg Gleason, FIGO, FNCLCC etc.
Microscopic description	This is used when a narrative description is required. Where information can be recorded in discrete fields this is preferable.
Mitotic count /Mitotic index	This is a calculation of the number of mitoses per mm <sup>2</sup> . The term mitotic rate is inaccurate as it is not a measure in units of time. Mitotic count and Mitotic index are functionally identical.
Necrosis	Used to record the presence or absence of necrosis
Ulceration	Used to record the presence or absence of ulceration
Depth of invasion	An indication of the greatest depth of invasion. This may be in mm or it may be described in terms of the infiltration of anatomical layers.
Tumour thickness	Direct measurement in mm, taken at right angles to the skin or mucosal surface, usually from that surface (unless otherwise specified, e.g. for Breslow thickness of melanoma) to the deepest part of the tumour.

Term	Comment
Extra- ( <i>organ/nodal/capsular</i> ) spread	Per the following examples: <ol style="list-style-type: none"> <li>1) Extra – <i>organ</i> spread. Where the word ‘organ’ is replaced with a specific/named organ eg extra-thyroid spread. Refers to extension of the tumour external to the specified organ.</li> <li>2) Extra-<i>nodal</i> spread is used for spread of tumour beyond the lymph node.</li> <li>3) Extra-<i>capsular</i> spread is used when the tumour spreads beyond the confines of an organ capsule eg ovary, thyroid, adrenal</li> </ol> <p>Note: this excludes prostate specimens.</p>
Lymphovascular invasion	Indication of invasion into the lymphatics or vascular system.
( <i>specific anatomical structure</i> ) invasion	This refers to invasion of a specific anatomical structure eg <b>myometrial</b> invasion. These should be specific to support TNM staging.
Coexistent pathology	Used to describe any other relevant non-neoplastic pathology. This is generally used with a list of the most common/relevant pathologies found.
Response to neoadjuvant therapy	Used to record the volume and state of tumour remaining following treatment.
Margin status	Margin status may be used to record the overarching findings eg involved/not involved or it may be used as a heading grouping other specific margin related features together. See Note 5.
( <i>name of relevant margin</i> ) margin	Use when recording involved or not involved. Include the specific name of the margin eg <b>peripheral</b> margin, <b>deep</b> margin etc.
Distance of tumour to ( <i>specific</i> ) margin	Use with the name of a specific margin eg distance of tumour to <b>deep</b> margin, measured in mm
Lymph nodes status	Lymph node status is used as a heading grouping other specific lymph node related features together.
Number of ( <i>specific site</i> ) lymph nodes submitted	Include the specify type/group of nodes where possible eg Number of <b>sentinel</b> lymph nodes submitted.
Number of ( <i>specific site</i> ) lymph nodes examined	Include the specify type of node such as sentinel/non-sentinel/specific node group eg Number of <b>sentinel</b> lymph nodes examined
Number of positive ( <i>specific site</i> ) lymph nodes	Include the specify type of node such as sentinel/non-sentinel eg Number of positive <b>sentinel</b> lymph nodes
Size of largest nodal metastasis	A quantitative measure in mm of the largest dimension.
<b>ANCILLARY STUDIES</b>	Heading – used to group a set of elements related to specific ancillary tests eg FISH, molecular genetics etc.
Immunohistochemistry	Subheading (under ancillary)

Term	Comment
Molecular genetic analysis	Subheading (under ancillary)
Cytogenetic analysis	Subheading (under ancillary)
Electron microscopy	Subheading (under ancillary)
<b>SYNTHESIS AND OVERVIEW</b>	Heading used to group 1) synthesised information – that is information which is the result of the integration and interpretation of information from two or more modalities to derive new information eg staging, type in which more than histologic means are used; 2) summary data (composite of previous information) and 3) the overarching case commentary (pathologists opinion)
Pathologic Staging	Heading – used to group a number of elements on staging eg Primary Tumour, Regional lymph nodes, Distant metastases e. AJCC 7 <sup>th</sup> edition is usually used but specific use cases apply. The specified staging system and version should be included in the name. Note: pathologists often do not receive information on distant metastasis and cannot determine this from the specimen received and therefore including an option of “not applicable” is advised.
Tumour type	Tumour type is used when determination of type uses non-histological criteria – eg. FISH, Cytogenetics, molecular or flow studies.
Subtype/variant	Subtype/variant is usually used in conjunction with Tumour type where this type is not determined solely by histologic means.
Tumour grade	Use tumour grade when grade is determined by non-histological criteria
Diagnostic summary	Summary of key points previously recorded.
Overarching comment	Pathologists conclusions/interpretation/synthesis

**Notes:**

1. Not all terms listed above will be used in all cancer specific datasets. Those most appropriate from the list above should be used where applicable. Additional cancer specific parameters and terms eg Breslow thickness may be used in addition to the terms above.
2. Plural should be listed as *nnn (s)* eg Tumour site(s)
3. In general element names must not include a potential response eg Lymphovascular invasion present, or presence of ulceration. These should be stated as Lymphovascular invasion or ulceration etc
4. The term Margin is not appropriate when used for punch biopsy and shave specimen. Use the term “tissue edges” instead in these instances.

## 2. HARMONISATION OF RESPONSES

The following response terms are recommended.

Recommended Terms	Meaning/implications of use	Recommended use
Not identified	A response which implies that the parameter was not observed within the sections reviewed.	USE for microscopic findings eg LVI, Perineural invasion
Absent	A response which implies a very high level of confidence in the result – should only be used where the assessment is comprehensive	USE for macroscopic findings eg ulceration, haemorrhage , necrosis, associated pathologies. Should not be used where review is across routine slides only and the outcome is based on those alone which means there is a possibility it may exist in sections not examined.
Not involved	A response which implies comprehensive assessment of a specific anatomical structure.	USE for margin status or evaluation of involvement of adjacent structures; assessment of lymph nodes.
Cannot be assessed	A response which implies that the specimen was not able to be assessed eg. due to sufficient quality or quantity.	USE for surgical margins
Not provided	A response which records that the information was not supplied eg by the requestor	USE for clinical information expected but not supplied by the requestor eg pre- operative results
Not applicable	A response which implies that the specimen supplied does not support assessment of this parameter.	Use as indicated.
Indeterminate	A response which implies that a clear result could not be reached but does not specify whether this is because it cannot be assessed or that the outcome is uncertain.	USE in cases where the level of granularity required by including both “uncertain” and “cannot be assessed” as options is onerous or not required by the circumstances.
Uncertain	While the specimen is of sufficient quality and quantity a clear result could not be reached.	
Present	A response used to record that an attribute has been found.	
Involved	A response which implies comprehensive assessment of a specific anatomical structure	USE for margin status or evaluation of involvement of adjacent structures; assessment of lymph nodes.
Submitted	A response used to record the presence of anatomical structures in the specimen eg lymph nodes, fallopian tubes etc	USE for recording anatomical structures in the specimen
Not submitted	A response used to record the absence of anatomical structures in the specimen eg lymph nodes, fallopian tubes etc	USE for recording the absence of anatomical structures in the specimen.
Positive	A response used to record that an attribute has been found.	USE for the assessment of cytology. Should not be used for the

Recommended Terms	Meaning/implications of use	Recommended use
		identification of histological findings – use Present or Involved (margins).
Negative	A response which implies a very high level of confidence in the result.	USE for the assessment of cytology. Should not be used for the identification of histological findings – use Not identified or Not involved (margins).

### Recommended response groupings\*

Group 1	Group 2	Group 3	Group 4	Group 5
Present	Involved	Present	Submitted	Not provided
Not identified	Not involved	Absent	Not submitted	
Cannot be assessed	Cannot be assessed	Cannot be assessed		
Uncertain	Uncertain	Not applicable		
	Indeterminate			
Indeterminate	Not applicable			
Use eg for microscopic findings: <ul style="list-style-type: none"> <li>• LVI</li> <li>• Perineural invasion</li> <li>• Metastatic spread</li> </ul>	Use for: <ul style="list-style-type: none"> <li>• Margins</li> <li>• Assessment of specific anatomical structures eg extent of invasion</li> <li>• Lymph nodes</li> </ul>	Use eg for macroscopic findings: <ul style="list-style-type: none"> <li>• Multiple lesions/multifocal tumours</li> <li>• Involvement of adjacent structures</li> <li>• Ulceration</li> <li>• Haemorrhage</li> <li>• Necrosis</li> <li>• Associated pathologies</li> </ul>	Use for recording the absence or presence of specific anatomical structures in the specimen eg <ul style="list-style-type: none"> <li>• Lymph nodes</li> <li>• Adjacent structures eg fallopian tubes</li> </ul>	Use for clinical information expected to be supplied by the requestor eg <ul style="list-style-type: none"> <li>• pre- operative results</li> <li>• treatment</li> </ul>

\*not all responses will be used in all use cases



### 3. GENERAL RULES FOR DATASET DEVELOPMENT

#### Including both macroscopic and microscopic elements of the same type e.g. tumour size

1. In developing a dataset where a measurement is taken macroscopically and then confirmed microscopically, the advice to authors is to include the measurement only once in the dataset and add a commentary indicating that this measurement reflects the final confirmed measurement.
2. Where both macroscopic and microscopic measurements are taken, the two measurements may be included in the report at the discretion of the reporting pathologist but must be clearly identified.
3. In the event that authors agree that it is necessary to include both a macroscopic and microscopic element such as the macroscopic and microscopic extent of invasion in the case of renal carcinoma for example, the word macroscopic and microscopic should prefix the appropriate element e.g. '*macroscopic* extent of invasion' and '*microscopic* extent of invasion' for clarity.