National Institute for Health and Clinical Excellence

Health Technology Appraisal

Intensity modulated radiotherapy for treatment of specific cancers[1]

Response to consultee and commentator comments on the draft scope

Comment 1: the draft remit

Section	Consultees	Comments	Action
Appropriateness	Elekta	The topic is appropriate to the needs of the radiotherapy community. However, it should be noted that IMRT is NOT a new treatment procedure and has been undertaken by numerous radiotherapy centres around the UK.	Comment noted
	Accuray	In light of NHS investment strategy to improve radiotherapy services in England and Wales, it is appropriate that modern radiotherapy and radiosurgery technologies are appraised by NICE. However, IMRT is only one of a number of modern approaches to increasing the accuracy and efficacy of radiotherapy, and we believe the remit should be expanded to include other technologies such as stereotactic radiosurgery systems. This will ensure that the NHS is fully informed of the evidence supporting all the alternative technologies rather than just IMRT.	Radiosurgery does not fall within the remit of this appraisal.
	Institute of Cancer Research	We support the appraisal of IMRT as it is expensive in both capital and running costs	Comment noted.

[1] The draft remit was changed to separate the original remit into three different topics; head and neck, breast and prostate cancer.

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	Mouth Cancer Foundation	Yes, This represents a significant change from standard radiation techniques, which deliver uniform radiation doses to the targets and to the noninvolved tissue residing in proximity to the targets. The critical structures that may potentially be spared using IMRT include the optic nerves, spinal cord, and brain stem. Sparing these structures would allow safer delivery of radiation and the potential for radiation dose escalation, which would not be possible using standard techniques. In addition, IMRT may allow sparing of the parotid glands, thus reducing severe radiation-induced xerostomia.	Comment noted.
	Institute of Physics & Engineering in Medicine (IPEM)	The remit is appropriate	Comment noted.
	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	It is appropriate	Comment noted.
Wording	Elekta	The wording seems appropriate to the case.	Comment noted.

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	Accuray	In the light of our comments above, we suggest the remit is redefined as: 'Innovative radiotherapy technologies, including intensity modulated radiotherapy and stereotactic radiosurgery for specific cancers'.	Radiosurgery does not fall within the remit of the technology appraisal
	Institute of Cancer Research	IMRT is distinct from on-line imaging, though this is an important asociated QA technology. The main technologies relate to beam delivery systems (such as "step-and-shoot" or dynamic MLC, and to the requirement for Inverse Planning)	Comment noted.
	IPEM	The wording is appropriate.	Comment noted.
	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	Yes, the wording is appropriate	Comment noted.
Timing Issues	Elekta	We feel that the proposed appraisal is relatively urgent as many centres would like to be using IMRT but do not due to time and complexity issues.	Comment noted.
	Accuray	The timing is appropriate.	Comment noted.
	Institute of Cancer Research	There are many published articles on IMRT but few randomised trials	Comment noted.

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	Mouth Cancer Foundation	Yes, the sooner we can reduce the side effects of irradiation treatments the better for patients who live with the long term side effects forever.	Comment noted.
	IPEM	The appraisal is not urgent. IMRT is an established technology, but there is still little phase III evidence to determine the most appropriate clinical use for IMRT. The majority of published work concentrates on improvements to the dose distribution without long term follow up for a group or patients with an appropriate control arm.	The Institute has now received formal referral to appraise IMRT for three indications as three separate Multiple Technology Appraisals (http://www.nice.org.uk/niceMedia/pdf/TAP.pdf). Consultees are now invited to make submissions, and an Assessment Group will prepare a protocol for their own assessment. A Consultee Information meeting will be held at which all consultees and commentators are invited to raise any issues related to the evidence. .
	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	There is no perceived urgency and there are concerns that at present there is insufficient level 1 evidence available for a meaningful appraisal.	See above.

Section	Consultees	Comments	Action
Additional comments on the draft remit	IPEM	The technology is important, but there is a lack of evidence of clinical effectiveness. UK based IMRT trials have been established for head & neck, breast and prostate and are ongoing. The NHS should support further research to improve the evidence base for the effective use of IMRT.	Comment noted – please see response above. Candidate topics for future research can be identified during a technology appraisal on the basis of evidence gaps identified by the systematic review and cost-effectiveness analysis – see the Guide the Methods of Technology Appraisal section 5.9.11 http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf)
	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	Three RCTs are close to completion which may significantly enhance the database: the Cambridge breast trial, PARSPORT in head & neck and a trial in cervix from India. It would be important to have this data available to any appraisal. The main focus at present should be to support and encourage research to develop the necessary data base for an evidence based decision.	The Institute has now received formal referral to appraise IMRT for three indications as three separate Multiple Technology Appraisals (http://www.nice.org.uk/niceMedia/pdf/TAP.pdf). Consultees are now invited to make submissions, and an Assessment Group will prepare a protocol for their own assessment. A Consultee Information meeting will be held at which all consultees and commentators are invited to raise any issues related to the evidence. Candidate topics for future research can be identified during a technology appraisal on the basis of evidence gaps identified by the systematic review and cost-effectiveness analysis – see the Guide the Methods of Technology Appraisal section 5.9.11 http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf)

Comment 2: the draft scope

Section	Consultees	Comments	Action
Background information	Elekta	IMRT can be utilised for any anatomical site and malignant condition. It can also be utilised for benign conditions (Pituitary Gland for example) as the intention is to minimise dose to the surrounding normal tissue whilst modulating the dose to the tumour to increase effectiveness.	Comment noted
	Accuray	Yes it is correct, but the scope of the appraisal should be modified to cover innovative radiotherapy including IMRT and stereotactic radiosurgery	Stereotactic radiosurgery is not within the referred remit of this appraisal.
	Institute of Cancer Research	There are less common, but compelling indications where the capacity to shape the high dose envelope with a concavity around a critical normal structure is important, eg skull base tumours.	Following consultation on the draft scope of this appraisal, the Institute has now received formal referral to appraise IMRT for head and neck cancer, prostate cancer, and breast cancer.
	Mouth Cancer Foundation	Sufficient	Comment noted
	IPEM	The background information overstates the ability of both IMRT and 3D conformal radiotherapy as they cannot completely spare or avoid irradiating surrounding normal tissue. IMRT can be used to create steep gradients to reduce the dose received by normal tissue located close to the disease, and this may be achieved by an increased volume of the patient receiving lower doses of radiation. Total body irradiation should not be considered as it is an experimental treatment with unproven clinical effectiveness.	Comments noted - the scope has been modified, including more emphasis on adverse effects associated with irradiation.

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The technology/ intervention	Elekta	Focus should also be made on the technology to plan the treatments as well as to deliver. Although mentioned, planning systems are usually separate to the linear accelerator and are supplied by a number of manufacturers. Elekta supplies two planning solutions for IMRT in the form of PrecisePlan and Ergo++. It is important to note that the imaging equipment does not "allow" for the movement of the body, but will visualise it and provide the user with the ability to account for any discrepancies highlighted. Immobilisation of the patient is a priority in establishing excellent IMRT techniques. The imaging mentioned in the "Hi-Art" system utilises a Megavoltage Beam to obtain the images. This gives significantly higher doses to the patient than can be found with the Elekta Synergy Kilovoltage 3-Dimensional imaging. It is also of worth note that Elekta are the only manufacturer of a fully functional kilovotage 3 dimensional imaging system. Other IMRT systems are in use throughout the UK and this includes the Elekta Precise and Synergy equipment which has been available to do IMRT since 1998. This is being taken forward to administer VMAT (Volumetric Intensity Modulated Arc Therapy). This involves gantry arcs being used along with other dynamic components to modulate doses and produce even better treatments than standard IMRT.	Comments noted. The scope has been amended where appropriate.
	Accuray	This statement is correct in its definition of IMRT. However, other technologies such as stereotactic radiosurgery (SRS) offer comparable treatment capabilities utilising multiple beamlets of radiation to single or multiple targets.	Radiosurgery is not within the remit of this technology appraisal.
	Institute of Cancer Research	Yes; the great majority of centres use an MLC with a linear accelerator.	Comment noted.
	Mouth Cancer Foundation	The Hi-ART system allows online imaging and should theoretically provide more accurate irradiation of the tumour shape as it changes in response to treatment. This isn't made clear.	Comment noted.

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	IPEM	There is some confusion in the text between IMRT and image-guided radiotherapy equipment. IMRT can be delivered by any linear accelerator with an MLC as long as the appropriate software has been enabled. The major manufacturers of linear accelerators are Varian, Siemens and Elekta. The recent wave of machines purchased by the Department of Health was all capable of IMRT treatments. The machines mentioned in the technology section, i.e. Elekta Synergy and Varian OBI, are image-guided linear accelerators with enhanced imaging capabilities. Although there may be an improvement to IMRT from these enhanced capabilities, IMRT treatments can be adequately performed on a linear accelerator without them. In addition, the software to enable the physician to determine the dose and distribution of radiation is not necessarily supplied by the linear accelerator manufacturer as third party companies also produce treatment planning software for this purpose. By alluding to the importance of imaging to target radiation the appraisal could easily shift from an evaluation of IMRT to that of IGRT, a technology that is still in its infancy. Also, the accuracy of targeting the radiation is achieved by compensating for the movement of the body structures, not by allowing it, i.e. the body structures move irrespective of how the radiation is targeted. The discussion of the technology focuses on inverse planned IMRT. An alternative is for forward planned IMRT producing simpler IMRT treatments. This is particularly appropriate for breast IMRT treatments. The discussion regarding tomotherapy is incorrect as there is a system now available within the NHS, as well as one in the private sector.	Comments noted. The scope has been amended where appropriate.

Section	Consultees	Comments	Action
	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	No; both the description of IMRT and 3D conformal radiotherapy are inaccurate. It is also noted that there is no mention of the Cyberknife, a further innovation in conformal radiation delivery, but again where level 1 evidence for efficacy or superiority is lacking.	The scope has been amended where appropriate. The Cyberknife technology is not within the remit of this technology appraisal. The remit is limited to intensity modified radiotherapy.
Population	Elekta	It should be a clinical decision as to who will receive IMRT. The usual constraints are fitness (ability to lie still and flat for example), and curative/palliative intent (stage/grade of tumour). Benefit to such sites as suggested need to be addressed by looking at critical structure proximity and possible outcomes of the treatment.	The population is defined in the final scope as people for whom radiotherapy is appropriate.
	Accuray	It should be acknowledged that certain technologies allow the possibility of treating additional patient populations. CyberKnife, for example, can treat cancers that cannot be safely treated with all IMRTs such as intracranial tumours, spine tumours (primary and metastatic) and lung tumours (primary and metastatic).	Following consultation on the draft scope of this appraisal, the Institute has now received formal referral to appraise IMRT for head and neck cancer, prostate cancer, and breast cancer.
	Institute of Cancer Research	Agree	Comment noted.
	Mouth Cancer Foundation	Yes, head and neck cancer patients are a population who suffer long term side effects of radiotherapy to the salivary glands. Patients with nasopharyngeal and maxillary sinus cancer planned using IMRT have significant reduction of the dose to the optic nerves, below what would be delivered with standard techniques and would be associated with a risk of damage. This should translate into safer radiation courses for these patients.	Comment noted.
	IPEM	The population is appropriately defined.	Comment noted.

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	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	The particular issues which can be best dealt with with an IMRT solution are: dose to tumour and normal tissues as outlined above. It may be better to focus on these generic issues. At present it is correct to say that the major clinical interest is in the treatment of prostate and head and neck cancer. However there is also a potential role in mesothelioma, pelvic malignancies, sarcoma, paraspinal tumours, liver metastases, hypatocellular carcinoma and other rare tumours. These orphan diseases will not be ameable to randomised clinical trials.	Following consultation on the draft scope of this appraisal, the Institute has now received formal referral to appraise IMRT for head and neck cancer, prostate cancer, and breast cancer.
Comparators	Elekta	The comparators seem realistic as most centres in the UK are utilising Conformal on a day to day basis. Conformal treatment could in theory be described as "best alternative care".	Comment noted.
	Accuray	The standard treatment for radiotherapy within the NHS is 3D CRT. CyberKnife can also deliver 3D CRT treatment. IMRT is utilises 2D treatment capability. Best alternative care can be surgery in the cases of intracranial tumours, spine tumours (primary and metastatic) and lung tumours (primary and metastatic). We therefore believe surgery should be included as a comparator for certain tumours.	Comments noted. At the scoping workshop, 3D CRT was identified as the appropriate comparator. In the appraisal for prostate cancer, surgery is also a comparator.
	Institute of Cancer Research	OK – Conformal RT	Comment noted.
	Mouth Cancer Foundation	IMRT is a significant step to improving the quality of life. The standard radiation techniques,are the comparators but for head and neck cancer patients , they should be considered 'second best' alternative care.	Comment noted.
	IPEM	3D conformal radiotherapy is the standard treatment within the NHS.	Comment noted.

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	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	The correct comparator is 3D conformal radiotherapy which is the standard of care in the NHS as stated in the scope. In certain sites the use of brachytherapy should also be included in the comparator, in particular cervix, uterus, prostate and breast.	Comments noted. At the scoping workshop, 3D CRT was identified as the appropriate comparator. In the appraisal for prostate cancer, surgery is also a comparator
Outcomes	Elekta	We believe that they will.	Comment noted.
	Accuray	These are all important outcomes. It is also important to note that some technologies may lead to cost saving relative to others. This is also an important outcome in these cases.	Comment noted. Resource use and costs will be considered in the economic analysis.
	Institute of Cancer Research	Some estimate of benefit can be derived from theoratical dose distribution studies also	Comment noted. The remit is to appraise clinical and cost effectiveness, and the most relevant outcomes to achieve this have been listed in the scope. However, if Consultees or the Assessment Group consider data from theoretical dose distribution studies to be relevant, this may be included in submissions and Assessment Report. A Consultee Information meeting will be held at which all consultees and commentators are invited to raise any issues related to the evidence.
	Mouth Cancer Foundation	The outcome measures must include the cost of the need for a high standad of oral hygiene when a dry mouth is produced by irradiation of the saliva glands.(cost of time brusjhing teeth frequently, using a fluoride mouth wash, fluride gel) and the cost of 'radiation caries' (restorations, extractions, social disgigurement),	Comment noted. Resource use and costs will be considered in the economic analysis.
	IPEM	The outcomes are correctly stated, but there is likely to be insufficient evidence in the literature at present.	Comment noted.

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	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	The outcomes are correctly stated in the draft scope but expert opinion is that it is unlikely that there will be much useful data at present in the literature. What there is will be evidence of relatively low level on the SIGN grading system.	The Institute has now received formal referral to appraise IMRT for three indications as three separate Multiple Technology Appraisals (http://www.nice.org.uk/niceMedia/pdf/TAP.pdf). Consultees are now invited to make submissions, and an Assessment Group will prepare a protocol for their own assessment. A Consultee Information meeting will be held at which all consultees and commentators are invited to raise any issues related to the evidence.
Economic analysis	Elekta	These appear to be adequate methods of evaluating cost effectiveness.	Comment noted.
	Accuray	These are all appropriate.	Comment noted.
	Institute of Cancer Research	OK	Comment noted.
	Mouth Cancer Foundation	Life long complications for survivors	Comment noted. The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.
	IPEM	The lack of good clinical evidence on the benefits of IMRT at the present time makes the time horizon difficult to define. At least 5 years follow up from good quality randomized studies are required to allow a comparison with the standard treatments. The economic benefits to the NHS of IMRT may not easily be measurable. IMRT requires greater expertise and time in defining treatment volumes and creating suitable treatment plans and verifying that the plans are accurate compared to standard treatments. This can be offset by a reduced treatment time particularly for head & neck treatments. However resource savings on treatment cannot easily be transferred to treatment design and verification due to the different skills required.	Comments noted. The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Resource use and costs (including those required for specialist staff) will be considered in the economic analysis. For further information, see the Guide the Methods of Technology Appraisal http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf)

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	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	The time horizon should be for a minimum of 5 years follow up. Such data are unlikely to be available in large quanitities and in addition those that are will be single arm case report studies rather than randomised trials. One of the roles which the NHS could usefully fulfill is adding to the evidence base for this technology. It should be remembered that the set up costs for any new technology is substantial. Costs per case will fall if its use becomes commoner. Recent experience is Europe is that delivery time is now no longer than for conformal RT. The issue is the planning process. It should also look at the impact of IMRT on other tretament capacities in a department and the effect of diverting scarce staff resources from 'routine' work.	Comments noted. The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Resource use and costs will be considered in the economic analysis. For further information, see the Guide the Methods of Technology Appraisal http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf)
Other Considerations	Elekta	One key issue that appears to be missing is Quality Assurance (QA). Before an IMRT treatment is delivered to the patient the physics team in the centre will effectively make a dry run of the treatment and measure the expected dose to the patient. This is becoming less with Elekta IMRT equipment as people have gained confidence that the systems deliver as planned. It is a time consuming process and would have an effect on staffing levels, cost effectiveness and time constraints (usually performed out of clinical hours) Treatment times do increase with IMRT so focus needs to be made to look at staffing levels, patient throughput etc. Ultimately will have a large bearing on cost effectiveness. Machine reliability needs looking into as well. There is scope with these complex machines to have some down time. There is a constant need within the health care sector to meet targets. We also believe that when looking at this down time that the statistics from all manufacturers are scrutinised and not taken at face value.	Comments noted. The scope has been amended where appropriate. Guidance on the approach to be used in appraising IMRT can be found in the Guide the Methods of Technology Appraisal section 5.9.11 http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf)
	Accuray	The examination of subgroups is of particular importance, specifically subgroups in which only particular technologies are appropriate.	Comment noted. If evidence allows, the appraisal will seek to identify subgroups of individuals for whom the technology is particularly clinically and cost-effective.
	Mouth Cancer Foundation	None	

Section	Consultees	Comments	Action
	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	It is unlikely that currently available evidence will permit assessment of the other considerations identified in the draft scope.	Comment noted.
Questions for consultation	Elekta	It should be a clinical decision as to the highest priority patients for IMRT. However, as previously mentioned, the most benefit will be seen from areas of treatment where surrounding highly critical structures can be avoided. Components for appraisal should be Planning systems, QA procedures, Delivery equipment, delivery times and effectiveness. Within the UK, Elekta Precise and Synergy systems are being utilised for IMRT.	Comment noted. Following consultation on the draft scope of this appraisal, the Institute has now received formal referral to appraise IMRT for head and neck cancer, prostate cancer, and breast cancer.
	Accuray	The cancers that should be considered are also Intracranial tumours, spine tumours (primary and metastatic), lung tumours (primary and metastatic).	Comment noted. Following consultation on the draft scope of this appraisal, the Institute has now received formal referral to appraise IMRT for head and neck cancer, prostate cancer, and breast cancer.
	Institute of Cancer Research	Agree with priorities, followed by breast cancer where randomised trial evidence is available and simplified :class solution" planning can save considerable resources . Multileaf collimator generated IMRT is the most common in the NHS	Comment noted. Following consultation on the draft scope of this appraisal, the Institute has now received formal referral to appraise IMRT for head and neck cancer, prostate cancer, and breast cancer.
	Mouth Cancer Foundation	Will the provision of IMRT for head and neck cancer patients affect waiting times for radiotherapy for treatment as more time is required in plannning it?	Comment noted. Resource use and costs will be considered in the economic analysis.

Section	Consultees	Comments	Action
	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	We agree that the current areas of particular clinical interest are prostate cancer and head and neck members. However few high quality data are yet available . We have identified other areas to be considered. As alluded to below, under additional comments, the author of this scope is under a fundamental misapprehension about the nature of IMRT. It can be an extended role for a standard linear accelerator in use by the NHS, depending on having a fully equiped machine with additional software and adequate staff to run the machine and plan the patients treatments. TomoTherapy is a particular solution but there is only one machine currently installed in the NHS. No cyber knife is installed in the UK in any setting.	Comment noted. The scope has been amended accordingly. Resource use and costs will be considered in the economic analysis. These would be expected to include specialist staff time and any software required.
Additional comments on the draft scope.	IPEM	The draft scope in its current form does not exhibit a full understanding of the technology involved in IMRT and in places confuses IMRT with image-guided radiotherapy, a much less mature technology currently being introduced into clinical practice in the UK. There are several problems with the description of the technology and the basis of IMRT as solely involving inverse planned treatments. The adoption of IMRT across the UK has been varied due to the changing demands placed on staff from its introduction and a lack of guidance on safe practice. IPEM have addressed the specific issue of commissioning of IMRT equipment and a report is to be published in the near future. This type of guidance may enable departments to increase the use of IMRT within the NHS and help to provide evidence of its effectiveness. Finally, it should be stressed that the lack of randomized clinical trials means that the use of IMRT does not currently have a strong evidence base. Without a strong evidence base the evaluation will be of limited value.	The scope has been amended accordingly. Inclusion of the IPEM report on commissioning of IMRT equipment referred to here may be a helpful inclusion if IPEM make a consultee submission. Consultees are now invited to make submissions, and an Assessment Group will subsequently prepare an Assessment Report. A Consultee Information meeting will be held at which all consultees and commentators are invited to raise any issues related to the evidence.

Section	Consultees	Comments	Action
	NCRI Radiotherapy CSG, Royal College of Radiologists, Royal College of Physicians, Joint Collegiate Council for Oncology, Association of Cancer Physicians	This draft scope as it stands is fundamentally flawed in that it reveals poor understanding of the technology and conflates on page 2 image guided radiotherapy with intensity modulated radiotherapy. The scope gives a reasonable definition of what intensity modulated radiotherapy is and describes inverse planning adequately. It does not address the issue of forward planned IMRT which can be considered as field in field boost therapy. This is particularly important for the radiotherapy of breast cancer where there are two major trials in the UK. This is an important application of IMRT but does not require the sophistication of inverse planned treatment nor the outlining of mutliple targets and organs at risk.The draft scope takes no cognisance of the workload issues in IMRT particularly for outlining targets and organs at risk as alluded to above. In addition there is physics time for planning and then the extensive quality assurance of the plan before it is delivered to the patient. Treatment delivery also takes longer. TomoTherapy raises different issues as less physics time is required for planning and it is claimed that radiographer staffing can be reduced. These claims are unverified, certainly in NHS practice. Intensity modulated radiotherapy is incorrectly viewed as a different product manufactured by a range of manufacturers. The workhorses of radiotherapy are linear accelerators and worldwide these are produced by Varian, Seimens and Electa. These devices are now routinely equiped with multi leaf collinators (MLC) and electronic portal imaging devices (EPIDS). These are the fundamental equipment required to deliver intensity modulated radiotherapy. However additional software must be purchased with the machine and there is a significant workload implication as alluded to above. This latter fact has been a major obstacle in the introduction of this technology into the NHS. It is hoped that these problems can be overcome as a recent wave of machines purchased by the Department of Health are fully IMRT capable and indeed IGRT capable (not the subject of this draft scope).	The scope has been amended accordingly. Please see responses above.

Section	Consultees	Comments	Action
		There is further confusion in this scope because of the TomoTherapy Hi-Artmachine. This is manufactured by TomoTherapy Inc and is a device similar to a CT scanner in which the radiation source rotates around the patient. About 100 of these devices are installed worldwide, there are now 2 in the UK, one in the private sector and one in the NHS. A second device is due to be commissioned by the NHS shortly. It is designed for IMRT combined with IGRT. It also comes with a sophisticated treatment planning package. The cyber knife is another complex device which is essentially a linear accelerator mounted on a robotically controlled arm which can treat the patient for multiple directions thus giving IMRT controlled by an IGRT system. None are available in the United Kingdom.	

Comment 4: Regulatory issues

Section	Consultees	Comments	Action
Remit	Elekta	Yes	
	Accuray	The marketing authorisation in the remit is limited to IMRT. The recommendation is to broaden the marketing authorisation to such as the CyberKnife (see below) where it is not specific to a technology such as MLC.	
Current or proposed marketing authorisation	Elekta	Step and Shoot IMRT where OAR (Organs at Risk) are in close proximity to the tumour [confidential information removed]	
	Accuray	It is intended to provide treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumours and conditions anywhere in the body when radiation treatment is indicated. It is intended to provide treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumours and conditions anywhere in the body when radiation treatment is indicated. CE Mark Class IIb	

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

Royal College of Nursing
Welsh Assembly Government
Department of Health
McMillan Cancer Support – not participating in appraisal