Invitations to Tender: Review of Inspections Project

Introduction

The Human Tissue Authority (HTA) is to commission a number of consultants to assist it in carrying out a review of its inspection process.

The HTA's primary goal is to protect public and professional confidence in the safe and ethical use of human tissue.

The HTA is the national independent regulator for organisations that remove, store and use tissue for research, medical treatment, post-mortem examination, teaching and display in public. We also give approval for organ and bone marrow donations from living people. With the interests of the public and those we regulate at the centre of our work, we aim to maintain confidence by ensuring that human tissue is used safely and ethically, with proper consent.

Established under the Human Tissue Act 2004, we are an Executive Non-Departmental Public Body sponsored by the Department of Health and Social Care. The Authority's Chair and Board are appointed by the Secretary of State for Health. The Chair and half of the Board are lay, with the remainder being professionals drawn from some of the groups who are affected by the legislation. The Authority is supported by an Executive team of 50 staff.

HTA core values

The HTA's values are our shared beliefs about behaviours that are key to how we deliver against our objectives. Our values help us achieve our vision and strategy, shape the way we deliver our regulatory functions and are integral to the way we interact with each other, professional stakeholders and the public.

Our values:

- **Professionalism** – the high standards we apply in the conduct of our individual and collective responsibilities.
- **Respect** – a proper regard for the abilities and perspectives of others.
- **Expertise** – the skills, knowledge and experience we apply for the benefit of our stakeholders and each other.
- **Agility** – rapid and positive response to changes in the internal and external environment without losing momentum.

Background

The HTA licences a wide range of establishments to carry out activities involving human tissue as set out in human tissue legislation, including our founding legislation, the Human Tissue Act 2004 and related regulations. More information about the HTA is available on our website: https://www.hta.gov.uk/

Inspection is one of the HTA's core regulatory processes, although is not a statutory obligation except in the "Human Application" sector (the use of human tissue for treatment).

The scope of the Review of Inspections Project is set out in the document attached at **Annex A**. This project is a core strategic objective of the HTA for 2022/23. More detail on the planned workstreams, for which tenders are invited, is set out below.

Workstreams for which invitation are sought

1. Desktop research and HTA staff engagement: Evidence-based review and evaluation of former and current ("as is") inspection delivery model as part of HTAs regulatory activities

Deliverables

- Review approach and operating model of the inspection regime.
- Map and describe the process of inspections and the scheduling process
- Review working inspection models of other regulatory bodies
- **Deliver** an 'options' report detailing how HTA can best organise and undertake inspections to ensure consistency, quality, efficiency and resilience.

Anticipated not to exceed 16 days. Assessment criteria to be confirmed pre-award of contract. SRO sign-off on deliverables required.

2. Review of how the use of technology and data could be improved to support the HTA's approach to inspection, from risk assessment to delivery and follow-up of inspection

Deliverables

- Identify technological tools to enhance delivery of inspections and recommend mechanisms to support and deliver remote visual inspections
- Outline best use of professional expertise in a virtual setting
- Recommend how the use of data could support 'other' assessment techniques and help set priorities for inspection time-tabling, considering type/complexity of inspection and committed RM resource
- Propose how HTA can work cooperatively and share resources with other health regulators, safely/legally, through data sharing on inspections
- **Deliver** a proposal report outlining options for making better use of technology to support and streamline inspections**.**

Anticipated not to exceed 14 days. Assessment criteria to be confirmed pre-award of contract. SRO sign-off on deliverables required.

3. Systems review, including internal and external stakeholder engagement, to develop options for "to be" future models to develop and enhance the HTA's approach to inspection:

Deliverables

- Scope out the potential application of evidenced/proposed new processes, use of technology, mechanisms to support inspection work through the optimisation of current/enhanced resources, drawing upon evidence collated and recommendations submitted as part of workstream 1 and 2
- Consider alternative approaches to structuring activity; the logistical side of delivery and the standard staffing model employed across different types of inspections; reflecting on evidence gathered from workstream 1 and 2 and differentiating between generic and non-routine inspections
- Recommend mechanisms to support continuous improvement
- Undertake interviews with HTA staff managing/delivering regulatory activities and the senior management team; present draft proposals for enhancing the inspection regime, and consider and integrate responses for the final recommendation report.
- **Deliver** a final evidence-based report detailing: recommended tools to enhance inspection work; mechanisms to support continuous improvement; options for diversifying delivery models options, supporting and underpinned by input via stakeholder engagement.

Anticipated not to exceed 15 days. Assessment criteria to be confirmed pre-award of contract. SRO sign-off on deliverables required.

4. Scope and deliver a regulatory "delivery time study": systematic analysis of the time and resource demands on Regulation Directorate staff to provide management information to improve data available for business planning for inspection-related activity:

Workstream 4 is indirectly linked to the Review of Inspections scope as set out in Annex A.

The HTA is conscious of its aims to maximise effectiveness and efficiency in its regulatory operations, including inspection.

The HTA has a matrix resource model for Regulation Managers (RMs), the frontline staff who carry out the inspection function. RMs often inspect across several sectors and their role is much broader than inspection, with RMs carrying out a wide range of core regulatory functions. This is broadly achieved through informal means, including extensive and effective engagement across the Regulation Directorate to ensure effective allocation of resource to deliver the inspection programme.

At times, the HTA experiences significant demands from non-routine elements of its regulatory workload. It would benefit from better data about delivery time for core regulatory functions carried out by RMs to assist its planning.

This would enable the HTA to further develop its planning methodology in a way that reflects the complexity of HTA's regulatory functions, with many variables affecting the volumes and time each may take.

An exercise to understand the delivery landscape more fully, in terms of types of activity and the time these require, would provide clearer insight for the planning process, support resourcing discussions and ensure sufficient capacity to deliver core business.

Deliverables

- Scope a proportionate "delivery time study" to meet the high level requirements set out above
- Undertake a "delivery time study"
- Provide an analysis of the delivery time study
- **Deliver** a written report summarising the methodology and findings of the delivery time study and giving recommendations for future action

Anticipated not to exceed 8 days. Assessment criteria to be confirmed pre-award of contract. SRO sign-off on deliverables required.

Approach to procurement

The HTA is seeking tenders from suitably qualified and experienced consultants to undertake these workstreams.

The HTA has project resource to manage and coordinate the activity being undertaken under this project, which is being undertaken under the oversight of the Director of Regulation as Senior Responsible Owner.

The HTA's ambition is to procure a number of independent consultants, working in parallel to facilitate rapid progress. This approach should also ensure that each consultant has suitable and relevant knowledge, skills and experience for the workstream they are delivering.

Quotes are sought for both or either of these deliverables.

Successful consultants appointed to undertake work on this project are expected to quickly establish constructive working relationships with the business to ensure effective coordination of activities with staff who will be contributing to this work or who will be asked to have input as well as with fellow consultants, where relevant.

Challenging delivery timescales:
Consultants wishing to tender for this work should be prepared to start and deliver quickly. The HTA expects consultants to be available from early to mid-Autumn 2022, with deliverables accomplished by early in Quarter 4 (January to March 2023).

The HTA will want to consider actions it may undertake in 2023/24 to take forward any recommendations it adopts from this work. Hence, rapid progress is needed on

this project to enable future phases to be incorporated into the HTA's business planning for 2023/24 during Quarter 4 of 2022/23.

Skills and capabilities required:

- Expertise in developing regulatory operational policy, ideally but not essentially within a related or relevant regulatory context
- Robust knowledge of the UK regulatory framework, ideally but not essentially within a related or relevant regulatory context
- Experience in developing and/or contributing to the development of regulatory strategy, ideally but not essentially within a related or relevant regulatory context
- Experience of stakeholder engagement in regulatory policy development, ideally but not essentially within a related or relevant regulatory context
- Excellent communication skills to interact with a variety of stakeholder within the public sector
- Flexibility to deliver work in line with timescales and phases involving varying demands over the delivery period

Quoting for this work

Please contact Dee Noonan (Project Manager) if you wish to discuss this work.

Any bid should briefly set out how you meet the contractor specification, what approach you would propose to take and give details and the basis of your quote, being clear as to whether VAT needs to be added.

Bids will be assessed in line with HTA procurement policy, with contracts awarded to those considered best able to meet the requirements of the work and who offer best value for money.

Contractual and appointment details will be finalised with successful bidders once they have been identified.

Successful bidders should ideally be available to start in November 2022.

Bids should therefore be submitted as soon as possible and by 9am on Monday 10 October 2022 at the latest, to:

Dee Noonan, Project Manager, Human Tissue Authority

Dee.Noonan@hta.gov.uk

(Dee can also be contacted by phone on: 020 7269 1949)

Dee can also be contacted to discuss any further information that may be needed about this project or to arrange to speak to the SRO, Nicolette Harrison, Director of Regulation.

Annex A

Systems Review: Using inspections most effectively to ensure regulatory compliance across sectors regulated by the Human Tissue Authority (HTA)

Introduction

The Human Tissue Authority (HTA) is a regulator tasked with superintending compliance with the Human Tissue Act 2004 (HT Act). The HTA was created in 2005 following events in the 1990s that revealed a culture in hospitals of removing and retaining human organs and tissue without consent. The legislation that established the HTA not only addressed this issue but also updated and brought together other laws relating to human tissue and organs. (The HTA is not the only regulator for human tissue, for example the HFEA regulates the use of gametes and embryos.)

The HTA was created by Parliament as an executive non-departmental public body (otherwise known as an "arms'-length body") of the Department of Health & Social Care and has a Board of lay and professional members appointed by government.

Much of the work of the HTA is under the remit of the HT Act and related regulations, including regulations that implemented EU Directives concerning the quality and safety of human tissue used for human application and the use of organs for transplantation.

The HTA regulates organisations that remove, store and use human tissue, cells and organs for research, medical treatment, post-mortem examination, education and training, and display in public. The Authority also gives approval for organ and bone marrow donations from living people.

The interests of the public and those we regulate are central to the HTA’s work. The HTA builds on the confidence people have in our regulation by ensuring that human tissue and organs are used safely and ethically, and with proper consent. There are many different types of human cells and tissue, including skin, body parts, organs, and bone.

Bodies, organs, tissue and cells can be used for many purposes including:

- Treating patients with particular medical conditions.

- Transplanting into people whose organs have failed.
- Treating patients who have blood disorders like leukaemia with stem cells.
- Researching causes and treatments for illnesses, such as cancer or diseases of the brain and nervous system.
- Teaching students about the human body and training to develop the skills of surgeons.
- Display in public, such as exhibitions and museums.
- Finding out through post-mortem examination why someone has died, including examining their organs and tissue samples to determine the cause of death.

More background information about the HTA can be could at www.hta.gov.uk

How does HTA regulate at present?

The Regulation Directorate of HTA fulfils the HTA's core regulatory functions. Led by the Director of Regulation, 4 Heads of Regulation, each with one or two sector specialisms, between them manage a Licensing team, a Living Organ Donation Team, and approximately 18 Regulation Managers (RMs) who carry out a range of core regulatory functions, including inspection. The HTA uses the term "Regulation Manager" to reflect the breadth of this role, with RMs not just carrying out inspections but also dealing with enquiries (from the public or technical enquiries), manage the HTA's response to incidents reported to the HTA by licensed establishments, carry out licence approvals (including changes to licences) and various other statutory approvals, depending on sector. They also support wider organisational priorities and engagement with stakeholders, which can be on technical working groups.

Many RMs work across multiple sectors. The HTA's current sectors are Post-Mortem, Public Display, Research, Anatomy, Human Application, and Organ Donation and Transplantation. Whilst inspection-related activity is only one of a number of duties undertaken by

RMs, that is the primary focus of this project; to aid the HTA in understanding how the current inspection regime can be improved to be more effective at a system level and more efficient at an operational level.

The HTA has a number of other projects to which it is committed during 2022/23, to aid it in becoming more risk-based, proportionate and efficient, including by making better use of technology, as it develops and moves towards a new Target Operating Model comprising the following 5 elements:

- Licensing
- Data & Intelligence
- Assessment – Inspections etc
- Authoritative Voice
- Corrective Action

This assignment focuses on the third of these elements, namely, the assessment activity of the HTA. See **Annex B** for background to the model.

The HTA also has a legal obligation to carry out site visit inspections of premises licensed for Human Application not less than once every 2 years. There is no legal obligation to undertake inspections in other sectors and the HTA has not set out an expected inspection cycle. The number of licence-holders in each sector is summarised in **Annex C**.

Inspections may be carried out by one or two RMs, with the number and pattern varying according to sector, the HTA's assessment of risk and the nature of the inspection.

Pre-Covid, the HTA carried out up to 180 inspections a year, although immediately prior to Covid19 had reduced that to 140-160 a year in recognition of a reduction in RM resource (used to be 20 RMs) and to free-up RM resource to for other business priorities, including the HTA's Development Programme.

The management team are open to new ways of performing their regulatory duties and have an ongoing focus on continuing improvement. Virtual Regulatory Assessments (VRAs) were developed and introduced during 2020/21 and 2021/22, partly in response to the restrictions of the Covid-19 pandemic, when site visits were halted for a period, but also as part of a strategic desire to make better use of technology, improve efficiency and increase regulatory reach. Whilst site visits are now fully resumed, VRAs also embedded in the delivery model for inspections.

In 2022/23, the HTA target for inspections has increased to around 210 on the basis that a mixture of different approaches will be trialled more widely to increase effectiveness and efficiency. This will increase the coverage of those establishments touched but on a more proportionate basis.

A number of internal audits over the past few years have focused on inspection and other core regulatory processes. Those reports will form useful background material for consultants appointed to this project.

Feedback on HTA Inspections

Feedback from those regulated by HTA has generally been very positive. A Savanta ComRes survey in 2020, ahead of the Covid pandemic showed that, overall, respondents were positive about their knowledge, understanding, interactions with, and experience of, the HTA. For example, the HTA scored positively in a number of key areas including:

- Knowledge – 96%
- Confidence in regulation – 94%
- Favourability towards HTA – 87%
- HTA is effective in fulfilling its regulatory responsibilities – 90%

Potential Areas for Improvement – Several questions were included in the survey to gauge the perceived impact of potential future developments in the HTA's approach and operating model. Respondents were positive about the introduction of a "streamlined regulatory model" / "relationship manager" (81% positive). With the HTA's aim to be a right-touch, proportionate regulator, and engaging its authoritative voice to good effect, it is in line with the strategic aim of using the minimum necessary direct intervention to achieve compliance and improvement.

The next most favoured option for potential future change was "Shorter, more focused inspections". This ties in, conceptually, with "more unannounced inspections" being the least positively received (29%) and some criticism of the HTA's responsiveness to enquiries. The concept of more focused inspection links to our work - accelerated somewhat during the COVID-19 lockdown period - exploring how the HTA might conduct and undertake remote, regulatory activity and oversight.

Deliverables

The HTA has been making changes to how it undertakes inspections of the establishments it licences. It is recognised the Authority is on a journey of improvement and the HTA is now seeking to contract suitably qualified technical assistance to advise on how to make further improvements to the inspection regime.

The appointed consultants will have extensive experience of regulatory tools and approaches, and be able to draw upon relevant experience in the health sector and the life sciences to command confidence in their work.

Further detail of the four lots and the deliverables for each are set out in the invitation to tender.

Taken together with any relevant internal activity, the consultants working on this project will assist the HTA by making recommendations for enhancing the approach to inspection to increase reach, effectiveness and efficiency without losing quality.

In carrying out this work, it will be important for the appointed consultants to engage with and take views from HTA staff involved in delivering and managing the regulatory activities, as well the Senior Management Team.

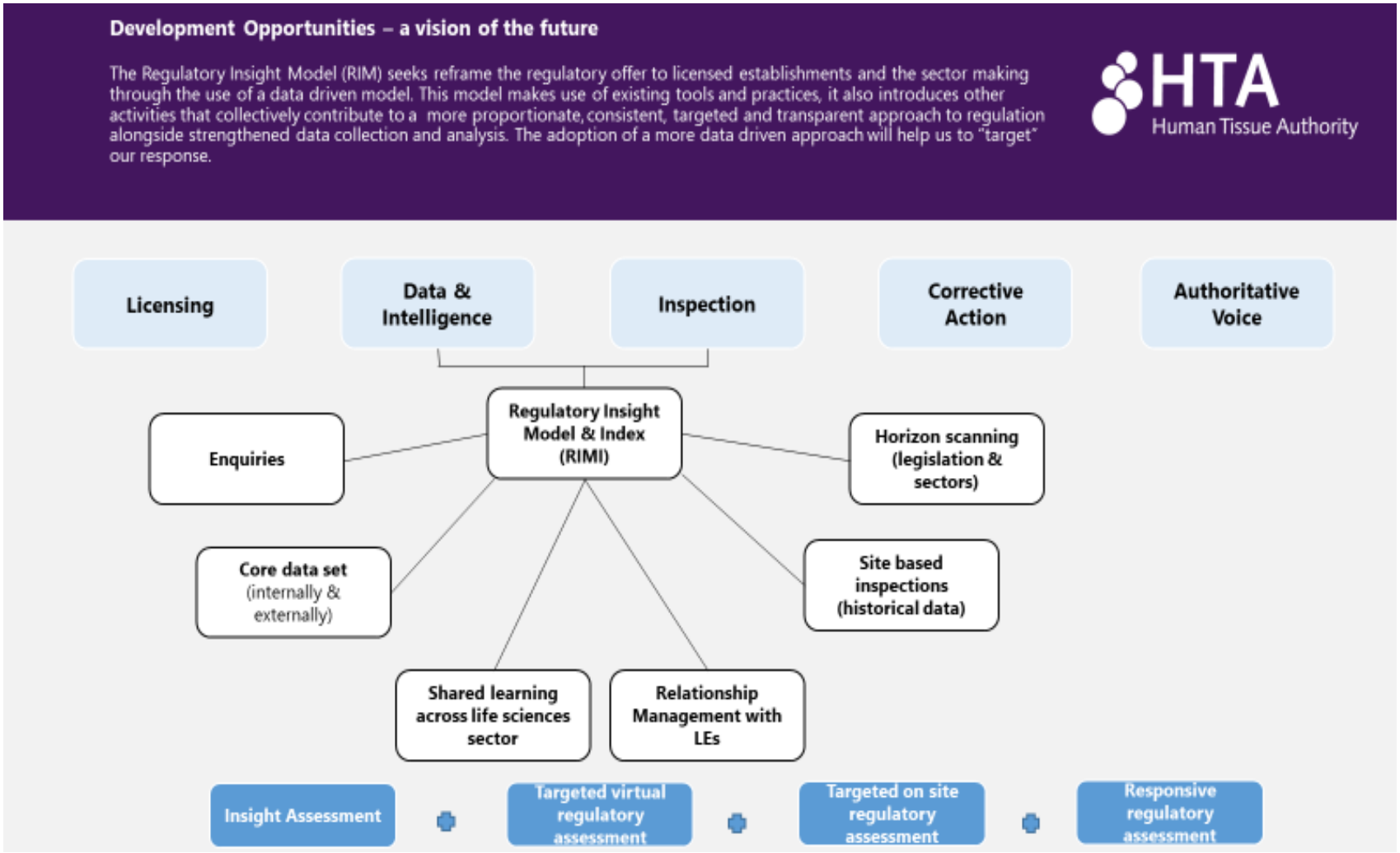
Key illustrative questions and themes for consideration that have informed the development of the workstreams are set out below:

1. How can the HTA look beyond its current delivery model to be more risk-based, for example by using a greater range of solutions (full inspections, partial or themed inspections etc)
2. How might the HTA's approach to inspection change as it develops an approach to segmentation of its licensed establishments
3. How could the HTA develop a generic model of the time spent on inspection covers and other core regulatory functions carried out by RMs, to inform resource planning and management
4. What areas not currently covered in our approach to inspection might be considered for inclusion or alternatively may be considered not to be necessary, to streamline reports and inspection time
5. What performance metrics might be most helpful to gauging performance in any revised approach
6. How could the HTA maximise the use of remote assessments or other assessment techniques to enable the best use of finite professional expertise, drawing upon the actions and experiences of other regulators
7. How might improved technology (both kit and tools) enhance our delivery of inspections

8. How might VRAs be extended to incorporate effective remote visual inspections of premises, facilities and equipment (VRAs currently being focused on discussion with establishments and paperwork sharing and review)
9. How might the HTA use other assessment techniques (including third-party data and other intelligence) to support and enhance the regulatory assessment process and enable best use to be made of finite professional expertise
10. How might the HTA work more co-operatively with other health regulators to share resources, whether that be data on inspections or actual inspection activity
11. What is the potential for more multi-skilling of RMs
12. What parameters might be developed to improve consistency and effectiveness of resource planning for different types and complexity of inspection
13. What different options might there be for the structuring the management of our regulatory activity, which is currently sector-focused approach
14. What other options might there be for structuring the people resource applied to inspection, for example the balance between specialist and generalist resource and depth of specialism required, or greater use of support resource
15. How can we maximise the benefits of remote assessments
16. How could we realise the potential of collaboration and joint working with other regulators or accreditation bodies

Separate from this project, the HTA is also undertaking work in parallel to develop our approach to segmentation by developing a data-driven risk engine to improve our overall risk assessment process and help us to determine how to deploy the right mix of different regulatory tools.

Annex B – Outline of the Target Operating Model, with Inspections being the third element



Annex C

How many establishments have HTA licences

- Total: 612 main sites + 330 satellites (totalling 942)
- Anatomy: 44 main sites + 13 satellites (totalling 57)
- Research: 183 main sites + 165 satellites (totalling 348)
- Post Mortem & Removal: 183 main sites + 77 satellites (totalling 260)
- Public Display: 14 main sites + 5 satellites (totalling 19)
- HA: 152 main sites + 70 satellites (totalling 222)
- ODT: 36 organisations

Number of new licence applications (since April 2019)

- Total: 99 of which 24 in 2019-20; 39 in 2020-21; 36 in 2021-22
- Anatomy: 1 in 2019-20; 2 in 2020-21; 3 in 2021-22
- Research: 12 in 2019-20; 8 in 2020-21; 12 in 2021-22
- Post Mortem & Removal: 5 in 2019-20; 16 in 2020-21; 2 in 2021-22
- Public Display: N/A
- HA: 6 in 2019-20; 12 in 2020-21; 19 in 2021-22
- ODT: 1 in 2020-21

How many inspections do the RMs do each month?

The pre-Covid19 expectation was that RMs would lead an inspection and support another each month. Sometimes supports are less (as HTA doesn't routinely use 2 inspectors for VRAs and there are some hybrid inspections – it's on a case-by-case basis whereas, previously, the assumption was that every inspection would have a lead and support) but most RMs will be involved once or twice a month across lead and support roles. Sometimes a third is required but this is the exception to the rule and generally only happens due to non-routines, CAPA follow ups, LAAVs (which are normally carried out by a single RM) etc.

How many RMs are cross sector trained? Are any RMs trained in all areas?

See breakdown below of the RM cadre from March 2022.

Please note that this is based on sectors that RMs routinely inspect in, rather than being ‘trained in’, as that training and their last inspection may be some years ago, and they are no longer routinely utilised for certain inspections:

# Sectors	5	4	3	2	1	Total
# RMs	1	1	4	2	10	18 RMs