

HTA Board meeting, 26 June 2025

Agenda item	3.3 – Evidential Compliance Assessments (ECA) trialled in the PM sector during 2024-25
For information or decision?	Information
Decision making to date?	N/A
Recommendation	The HTA Board is asked to note and comment by exception on the approach
Which strategic risks are relevant?	Risk 1: Operational
Strategic objective	Approach to Regulation
Core operations / Change activity	Core operations
Business Plan item	Regulation – fulfilling our licensing, inspection, incident management and approvals functions, providing technical advice and superintending compliance across the sector, including responding to the Fuller Independent inquiry and engaging with a review of our implementation of the Duty to Report regulations
Committee oversight?	N/A
Finance and resource implications	Business resource to implement the changes through revised processes
Timescales	N/A
Communication(s) (internal/external stakeholders)	As described in the paper
Identified legislative implications	N/A

Evidential Compliance Assessments (ECA) trialled in the PM sector during 2024-25

Purpose

1. To update the Board on a new regulatory approach to risk assessment, Evidential Compliance Assessments (ECA's), trialled in the post-mortem sector.
2. We aim to further trial this approach in other sectors as part of a strategy of refining our approach to regulation, through innovation and continuous improvement to enhance evidence-based assurance practices and compliance processes.

Ask

3. The Board is asked to **note** progress as we seek to improve our risk assessment of certain licenced establishments.

Background

4. The HTA has been robustly strengthening its approach to probing and assessing compliance with key standards relating to security, governance and quality in the Post Mortem (PM) sector by developing new tools aimed at enhancing the focus on best practice and being clear with establishments what is required to meet HTA standards.
5. As mentioned in previous sector risk papers to ARAC, the top risk factors in the PM sector which can lead to a negative impact on the dignity of the deceased are:
 - security,
 - capacity,
 - misidentification/traceability issues, and
 - a disconnect between documented processes and operational reality.
6. Security has been an increasing area of concern and emphasis over recent years. The issue was highlighted as an area of risk by the Fuller Independent Inquiry (Phase 1 report), reflecting the difficulty of regulating a complex system with multiple underlying causes for shortfalls (such as available mortuary capacity, training, maintenance and upkeep of premises).

HTA 19-25

7. The trial considered a programme of assurance-focused activities based on HTA standards in critical areas. It involved direct communication with licenced establishments in the sector on their operational practices.
8. The immediate response has seen an increase in the number of reported incidents, specifically in the 'near-miss' category, suggesting growing awareness of security issues at an establishment level and the importance of ongoing monitoring and reporting:

Financial Year	Total	Incident	Near Miss
2023/24	38	14	20
2024/25	87	26	48

Approach

9. In March and April 2024 the HTA delivered mandatory awareness sessions¹ by webinar on security and access-related standards for 158 DIs of establishments licensed under the PM sector.² These sessions covered the licensing standards relevant to mortuary security (themes identified in reported incidents as HTARIs and inspection shortfalls as part of the inspection process) to ensure DI awareness of the HTA standards in critical areas with known risks.
10. Following this, all relevant PM licensed establishments were required, through their obligations to provide the HTA with information under the Standard Conditions of licenses, to submit an ECA (**Annex I**) specifically evidencing compliance to standards GQ1(a), GQ2(a), GQ6(c), PFE1(d), PFE1(e), which cover oversight and governance of security and access of the mortuary.
11. Communication with the sector was maintained during the exercise via direct emails and through the HTA newsletter, setting out the overall approach and conditions for completing the mandatory assessment component including follow-up actions to meet compliance in the event the establishment was assessed as non-compliant.

Assessment

12. 158 assessments were returned. The review process categorised assessment returns as 'compliant', 'compliant with advice and guidance', or 'non-compliant':

¹ [Security DI presentation.pptx](#)

² Whilst there were 160 licences, this activity was not considered relevant to two licensed establishments, whose activities did not entail storage of whole bodies.

HTA 19-25

- 31 establishments were found to be compliant;
 - 79 establishments were found to be compliant with advice & guidance and;
 - 48 establishments were found to be not compliant.
13. Establishments were informed of the outcome of their assessment and expected next steps. For those categorised as non-compliant, a programme of active engagement was immediately initiated and progressed through three pathways:
- if the establishment had an existing Corrective & Preventative Action (CAPA) plan open, follow-up was through the CAPA management process;
 - if the establishment was already scheduled for an inspection in 2024/25, that inspection would go ahead as planned; or
 - if neither was the case, the establishment was fast-tracked for a focused inspection (8 establishments) against the standards relevant to the ECA and any identified potential shortfalls.
14. The ECA programme was completed by the end of 2024/25, with all establishments involved being assessed and inspected. An overview of this targeted assessment is available in a recently posted HTA blog³.
15. Development and delivery of the programme utilised notable staff resource internally, absorbed within core business, which was recorded and logged against the different aspects of the process.
16. Preparation and desk based evidential review of each assessment (by the team of 5 Regulation Managers) took place before a final case review with the Head of Regulation. The process also incorporated a moderation mechanism to ensure consistency. Delivery of the core ECA process took approximately 28 resource days from April to September 2024, on top of scheduled core business and before any follow-up activity, including the additional targeted inspections. Subsequently, resource was also utilised to develop and finalise a SOP, that can be utilised and further adapted for any future ECA programme.

Outcomes

17. The overall approach incorporated a range of methods to enable the HTA to critically assess compliance with HTA standards in specific risk areas,

³ [Strengthening regulatory oversight: Evidential Compliance Assessments in mortuary regulation | Human Tissue Authority](#)

including preparatory communication to all DIs by newsletter and email, mandatory webinars, the issue and assessment of ECA's and subsequently an unannounced inspection programme.

18. The ECA's in particular were a key mechanism for raising awareness of critical risks and standards around security and access to mortuaries, reinforcing the role and responsibility of the DI and licensed establishments in responding to those areas of risk.
19. As a compliance programme, it firmly placed responsibility on licensed establishments and DIs to evidence how they met a focused sub-set of Standards in an intense and coordinated programme of activity across the whole sector in a short period of time. This of itself helped raise the profile of these risks, and how to better manage them, across the sector.
20. As an assessment tool, it provided assurance of compliance (for those who were compliant) and enabled effective identification of non-compliance, for which further intervention could be targeted. This enabled the HTA to have effective oversight on key areas of risk.
21. ECAs and the related processes have been received well by establishments and have been acknowledged as a driver for implementation of improved security measures in response to the outcomes and findings of the assessments, with some DI's indicating that findings have been used to support funding requests or upgrades to existing security systems.
22. We have found the ECA methodology described to be a very useful addition to our regulatory tools.

Next Steps

23. Following the conclusion of the ECA programme, the HTA implemented an unannounced inspection programme, between September 2024 and March 2025; an evaluation is now underway but given the positive responses from staff and the sector, this approach has been extended into the 2025/26 inspection programme.
24. The ongoing Innovation in Inspection project provides an opportunity to continue to review and evaluate our use of assessment tools, such as ECAs, as part of the HTA's evolving response to regulatory risk. Whilst the ECA work informally utilised learning from other sectors, future work will more formally consider how learning can be shared with and from other regulators.

HTA 19-25

25. The level of input would likely be proportionately fairly similar if the exercise were repeated in another sector. Going forward the resource requirements for future use of the ECAs will be fully considered within the business planning process.
26. An additional factor being considered is to trial the thematic use of ECA's in a focused area of risk, possibly in another sector, which could be again covering on security standards or targeting a completely different risk area, such as consent; options will be considered through business planning for 26/27.

Recommendation

27. The Board is asked to **note** progress as we seek to improve our risk assessment of certain licenced establishments.

Annex I

Evidential Compliance Assessment – Mortuary Security & Access

The HTA recently provided presentations regarding mortuary security and access for Designated Individuals (DIs) in the Post Mortem (PM) sector. The presentations covered the licensing standards relevant to mortuary security, themes identified in reported incidents and inspection shortfalls, and the HTA's expectations in meeting the licensing standards relevant to mortuary security.

This Evidential Compliance Assessment (ECA) form is for completion by the DI responsible for the establishments PM sector licence. Completing this assessment and submitting the requested documentation is a requirement under the standard licensing conditions for PM sector licences.

The HTA will review the information provided to assess your establishment's compliance with the PM sector licensing standards relating to mortuary security. The information and any documentation provided must be correct and up to date to ensure accurate assessment of your establishment. Further evidence may be required after the information has been submitted and may be reviewed in more detail as part of a Virtual Regulatory Assessment (VRA), site visit inspection, or other form of regulatory assessment, to provide assurance of compliance.

Please refer to the [‘Mortuary security presentation for Designated Individuals’](#) slides distributed to all DIs following the presentations.

Please answer under each of the following questions in as much detail as possible, for each site covered by your licence.

Licence number:

Main site name:

1) How is the mortuary accessed by staff (*check applicable box*)?

- ☐ Key
- ☐ Swipe card
- ☐ Key and swipe card
- ☐ Other (please provide further information):
.....

2) Who authorises staff access and how?

3) Where keys and/or a swipe card for the mortuary are held centrally e.g. for porters to use, how is access/use of the keys/swipe card managed?

4) If keys are used:

HTA 19-25

- i) how many keys are in circulation?
 - ii) how frequently are key holders reviewed?
 - iii) what is the process in place to have keys cut?
- 5) How is access to the mortuary stopped e.g. when staff leave?
- 6) How are all persons who access the mortuary documented?
- 7) Where staff access the mortuary with others e.g. porters admitting bodies in pairs, is the access of all staff documented?
- 8) i) How do contractors/external engineers undertaking work in the mortuary gain access?
- ii) How are they supervised/monitored?
- iii) Do they access the mortuary out of hours to carry out work?
- 9) i) If CCTV is in use, where are cameras located (*select each dropdown*)?
- Mortuary entrances/exits **Choose an item.**
 - Mortuary external areas e.g. car park **Choose an item.**
 - Covering external body store units **Choose an item.**
 - Covering temporary body store units **Choose an item.**
 - Body store(s) **Choose an item.**
 - Covering fridge/freezer bank doors **Choose an item.**
 - PM room **Choose an item.**
 - Viewing room **Choose an item.**
 - Public/reception areas **Choose an item.**
 - Other (please provide further information) **Choose an item.:**
-
- No CCTV in place **Choose an item.**
- ii) Where do CCTV images feed to?
- iii) Who has access to and monitors the CCTV?
- iv) How long is mortuary CCTV footage retained for?

10) Which internal areas of the mortuary are secured out of hours and how?

Area	Secured?			How?			
	Yes	No	N/A	Key	Swipe	Coded door lock	Other

HTA 19-25

PM Room(s)							
Body store(s)							
Fridge/freezer bank doors							
Mortuary office(s)							
Changing rooms							
Other:							

Where 'Area Other' and 'How Other' have been selected please provide further information here:

.....

11)i) Are doors (including fire exits) and windows regularly checked for any issues including potential security issues e.g. damage, wear and tear, faulty mechanisms/magnetic locks?

ii) Who is responsible for these checks?

iii) How are findings actioned?

Please complete the following table for those persons who have access to the mortuary (do not provide the names of specific people):

Job role	How many	Purpose	How is access documented?
<i>e.g. Porter</i>	10	<i>Admission of hospital bodies, facilitate access to contracted funeral director to admit community bodies, out of hours viewings.</i>	<i>Visitor log Body admission paperwork</i>

Satellite site 1 name:

1) How is the mortuary accessed by staff (*check applicable box*)?

- ☐ Key
- ☐ Swipe card
- ☐ Key and swipe card
- ☐ Other (please provide further information):

-
- 2) Who authorises staff access and how?
 - 3) Where keys and/or a swipe card for the mortuary are held centrally e.g. for porters to use, how is access/use of the keys/swipe card managed?
 - 4) If keys are used:
 - i) how many keys are in circulation?
 - ii) how frequently are key holders reviewed?
 - iii) what is the process in place to have keys cut?
 - 5) How is access to the mortuary stopped e.g. when staff leave?
 - 6) How are all persons who access the mortuary documented?
 - 7) Where staff access the mortuary with others e.g. porters admitting bodies in pairs, is the access of all staff documented?
 - 8) i) How do contractors/external engineers undertaking work in the mortuary gain access?

ii) How are they supervised/monitored?

iii) Do they access the mortuary out of hours to carry out work?
 - 9) i) If CCTV is in use, where are cameras located (*select each dropdown*)?
 - Mortuary entrances/exits **Choose an item.**
 - Mortuary external areas e.g. car park **Choose an item.**
 - Covering external body store units **Choose an item.**
 - Covering temporary body store units **Choose an item.**
 - Body store(s) **Choose an item.**
 - Covering fridge/freezer bank doors **Choose an item.**
 - PM room **Choose an item.**
 - Viewing room **Choose an item.**
 - Public/reception areas **Choose an item.**
 - Other (please provide further information) **Choose an item.:**

.....

 - No CCTV in place **Choose an item.**
 - ii) Where do CCTV images feed to?
 - iii) Who has access to and monitors the CCTV?

HTA 19-25

iv) How long is mortuary CCTV retained for?

10) Which internal areas of the mortuary are secured out of hours and how?

Area	Secured?			How?			
	Yes	No	N/A	Key	Swipe	Coded door lock	Other
PM Room(s)							
Body store(s)							
Fridge/freezer bank doors							
Mortuary office(s)							
Changing rooms							
Other:							

Where 'Area Other' and 'How Other' have been selected please provide further information here:

11)i) Are doors (including fire exits) and windows regularly checked for any issues including potential security issues e.g. damage, wear and tear, faulty mechanisms/magnetic locks?

ii) Who is responsible for these checks?

iii) How are findings actioned?

Please complete the following table for those persons who have access to the mortuary (do not provide the names of specific people):

Job role	How many	Purpose	How is access documented?
e.g. Porter	10	Admission of hospital bodies, facilitate access to contracted funeral director to admit community bodies, out of hours viewings.	Visitor log Body admission paperwork

Satellite site 2 name:

1) How is the mortuary accessed by staff (check applicable box)?

HTA meeting papers are not policy documents.

Draft policies may be subject to revision following the HTA Board meeting

HTA 19-25

- ☐ Key
- ☐ Swipe card
- ☐ Key and swipe card
- ☐ Other (please provide further information):
-

- 2) Who authorises staff access and how?
- 3) Where keys and/or a swipe card for the mortuary are held centrally e.g. for porters to use, how is access/use of the keys/swipe card managed?
- 4) If keys are used:
 - i) how many keys are in circulation?
 - ii) how frequently are key holders reviewed?
 - iii) what is the process in place to have keys cut?
- 5) How is access to the mortuary stopped e.g. when staff leave?
- 6) How are all persons who access the mortuary documented?
- 7) Where staff access the mortuary with others e.g. porters admitting bodies in pairs, is the access of all staff documented?
- 8) i) How do contractors/external engineers undertaking work in the mortuary gain access?

ii) How are they supervised/monitored?

iii) Do they access the mortuary out of hours to carry out work?
- 9) i) If CCTV is in use, where are cameras located (*select each dropdown*)?
 - Mortuary entrances/exits **Choose an item.**
 - Mortuary external areas e.g. car park **Choose an item.**
 - Covering external body store units **Choose an item.**
 - Covering temporary body store units **Choose an item.**
 - Body store(s) **Choose an item.**
 - Covering fridge/freezer bank doors **Choose an item.**
 - PM room **Choose an item.**
 - Viewing room **Choose an item.**
 - Public/reception areas **Choose an item.**
 - Other (please provide further information) **Choose an item.:**
 -
 - No CCTV in place **Choose an item.**

ii) Where do CCTV images feed to?

iii) Who has access to and monitors the CCTV?

iv) How long is mortuary CCTV retained for?

10) Which internal areas of the mortuary are secured out of hours and how?

Area	Secured?			How?			
	Yes	No	N/A	Key	Swipe	Coded door lock	Other
PM Room(s)							
Body store(s)							
Fridge/freezer bank doors							
Mortuary office(s)							
Changing rooms							
Other:							

Where 'Area Other' and 'How Other' have been selected please provide further information here:

.....

11)i) Are doors (including fire exits) and windows regularly checked for any issues including potential security issues e.g. damage, wear and tear, faulty mechanisms/magnetic locks?

ii) Who is responsible for these checks?

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Please complete the following table for those persons who have access to the mortuary (do not provide the names of specific people):

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Where your establishment has more than two satellite sites, please copy and paste the questions and tables for each site.

Please see the following list of documentation required for submission via the SharePoint link provided:

- **Mortuary security SOP (for each site, if applicable) and/or other SOPs that include relevant security considerations**
- **Lone working SOP (for each site, if applicable)**
- **Mortuary security risk assessment (for each site, if applicable)**
- **Lone working risk assessment (for each site, if applicable)**
- **The last 3 mortuary security/access audits (for each site, if applicable)**

Declaration by Designated Individual

As the person with legal responsibility and under whose supervision licensed activities are authorised to be carried out, I certify that:

- a. suitable practices are used in undertaking licensed activities;**
- b. persons working under the licence are suitable;**
- c. the conditions of the licence are complied with; and,**
- d. the information provided in this form and the requested documentation is correct, accurate and up to date to the best of my knowledge.**

Name:

Date: