

OTHM Notification of Adverse Events Policy



1. Purpose

This policy sets out how OTHM identifies, manages, and reports events that could have an Adverse Effect on learners, centres, qualification standards, or public confidence.

It enables compliance with Ofqual's General Conditions of Recognition, especially:

- **B1:** Role of the Responsible Officer
- **B3:** Notification to Ofqual of Certain Events
- **A6–A8:** Risk management, incidents, malpractice and maladministration
- **D7:** Management of the withdrawal of qualifications

2. Scope

This policy applies to all OTHM regulated qualifications, assessments, centres, delivery partners, contractors, staff, senior officers, and any individual acting on behalf of OTHM.

3. Policy Statement

OTHM will:

- Identify and monitor all risks that could lead to an Adverse Effect.
- Take all reasonable steps to prevent adverse events.
- Respond promptly and effectively to any incident that could compromise qualification standards, delivery, assessment integrity, or public confidence.
- Notify Ofqual promptly when any event occurs, or may occur, which meets the threshold for notification under Condition B3.
- Maintain full, accurate, and timely communication with Ofqual throughout the management of an event.

4. Definitions

Adverse Effect

As defined by Ofqual, an event that has negatively affected, or could negatively affect:

- Accuracy of assessment results
- Standards of a qualification
- Delivery or award of a qualification
- Learners' ability to complete assessments or qualifications
- Public confidence in qualifications

Adverse Event

Any incident, situation, or set of circumstances that may cause or contribute to an Adverse Effect.

5. Examples of Notifiable Events

5.1 Assessment and Qualification Issues

- Substantial error in assessment materials.
- Loss, theft, or breach of confidentiality of assessment materials.
- Inability to supply assessment materials for scheduled assessments.
- Failure in assessment delivery affecting the ability to differentiate between levels of attainment.
- Issuing incorrect results or certificates.
- Inability to meet published results or certification timelines.

5.2 Malpractice and Maladministration

- Any suspected or actual malpractice or maladministration that could invalidate results or affect another awarding organisation.
- Systemic issues at a centre that could affect learners.

5.3 Organisational or Governance Issues

- Material change to governance or legal structure.
- Change of control or merger.
- Insolvency or bankruptcy proceedings.
- Significant increase in costs likely to result in a substantial fee rise.
- The awarding organisation being named in civil, criminal, or regulatory proceedings.
- Criminal proceedings, director disqualification, or disciplinary action involving a Senior Officer.

5.4 Centre-Related Events

- Centre closure, sudden cessation of delivery, or significant financial instability.
- Any event affecting a Centre's ability to deliver qualification requirements.

6. Proactive Controls and Preventative Measures

OTHM will maintain:

6.1 Risk Management (Condition A6)

- Controls designed to reduce the likelihood or severity of Adverse Events.
- Monitoring arrangements for centres and contractors, including Centre Quality Reviews and EQA activity (see Centre Risk Management Policy, Centre Sanctions Policy, Centre Quality Review Policy and Procedure).

6.2 Staff and Centre Awareness

- Mandatory training for relevant staff and associates on identifying and escalating potential Adverse Events.
- Clear guidance to centres on expected standards and how to report issues.

7. Procedure for Identifying and Reporting Adverse Events

Step 1: Identification

Any staff member, contractor, or centre must immediately report potential Adverse Events to the Head of QA and Accreditation.

Where identified as part of EQA or CQR activity, this may be reported via the appropriate report.

Malpractice and other centre-related issues are systematically reviewed as part of a weekly Quality Assurance meeting, chaired by the Head of Quality Assurance and Accreditation, to assess the need to escalate to the RO.

All relevant information and decision-making is recorded for audit.

Step 2: Initial Assessment

The Head QA and Accreditation will:

- Review all available information promptly.
- Determine whether the event meets the threshold for notification under Condition B3.
- Decide whether immediate mitigation is required.
- Record the issue in the Event Notifications log.
- Update / consult RO as required.

Step 3: Escalation and Internal Decision-Making

Where appropriate, the RO will involve:

- Senior Leadership Team
- Relevant operational teams
- Legal or compliance advisors
- Governing Body (for material governance or legal issues)

Where necessary, emergency decisions can be made by the RO to protect learners.

The RO will notify Ofqual promptly, even where full details are not yet available.

The initial notification will include:

- Description of the event
- How and when it was identified
- Known or potential impact on learners or qualification standards
- Immediate actions taken
- Planned next steps
- Timescales for further updates

Step 4: Ongoing Management

The RO and Head of QA and Accreditation will ensure:

- Regular updates are provided to Ofqual as the situation develops
- All actions are documented
- Root cause analysis is performed
- Remedial and preventative actions are implemented

Step 5: Closure

The RO will provide a final report to Ofqual, including:

- Full investigation findings
- Mitigation applied
- Long-term corrective measures
- Confirmation that risks have been addressed

8. Roles and Responsibilities

Responsible Officer (Condition B1)

- Acts as the authoritative point of contact with Ofqual.
- Oversees all regulatory reporting.
- Leads decision-making on adverse event notifications.
- Ensures accurate and timely information is provided to Ofqual.

Head of Quality Assurance and Accreditation

- Supports the RO with specialist input.
- Ensures appropriate internal resourcing to manage events.
- Leads day-to-day review of centre activity monitoring and escalates as required.

All Staff and Contractors

- Must promptly report any issue that may constitute an adverse event.
- Must cooperate fully with investigations as appropriate.

Centres

- Must immediately report incidents that could cause an Adverse Effect.
- Must cooperate with investigations and provide required information.

9. Record Keeping

OTHM will maintain:

- Incident Register entries for every reported event
- All correspondence with Ofqual
- Investigation reports and evidence
- Records of corrective actions

Records will be retained for a minimum of five years, or longer where required by regulation.

10. Regulatory References

- **B1:** Role of the Responsible Officer
- **B3:** Notification to Ofqual of Certain Events
- **A6 - A8:** Risk management, incidents, malpractice and maladministration
- **D6:** Management of the withdrawal of qualifications

11. Version Control

Policy Owner: Will Smith

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1.0	April 2020	
2.0	March 2025	Addition of adverse event in relation to a Centre.
3.0	December 2025	Full revision