Introduction

The purpose of this guidance and underpinning procedures is to inform staff how to prevent, handle and report ‘adverse events’ and to ensure that any adverse effects that do occur are managed and reported in an appropriate and timely manner and that all lessons are learned to ensure that a similar such event does not happen again.

Reporting adverse events will:

- inform risk management and contingency planning
- provide information to improve systems and processes
- enable prompt remedial action to be taken and prevent recurrence
- provide an opportunity to share learning from adverse events within the team
- assist decision-making, planning and future resource allocation
• provide information and reassurance to the Awarding Organisations (AO) that the Centre is committed to managing potential risks.

What is an ‘Adverse Effect’?

The following guidance has been taken from Ofqual’s General Conditions of Recognition September 2013 and concludes that:

An act, omission, event, incident or circumstance has an ‘adverse effect’ if it gives rise to prejudice to Learners or potential Learners, or adversely effects

• the ability of the Centre to undertake the development, delivery or award of qualifications

• the standards of qualifications which the Centre makes available or proposes to make available, or public confidence in qualifications

• there has been a failure in the delivery of an assessment which threatens Assessors’ ability to differentiate accurately and consistently between the levels of attainment demonstrated by Learners

• Centre being able to meet a published date for the issue of results or the award of a qualification

• Centre issuing incorrect results or certificates

• Centre identifying an incident of malpractice or maladministration, which could either invalidate the award of a qualification which it makes available or could affect Awarding Organisations

• Centre has (for any reason, whether inside or outside its control) incurred an increase in costs which it anticipates will result in an increase in its fees and therefore stop a Learner completing and obtaining certification

• Centre is named as a party in any criminal or civil proceedings or is subjected to a regulatory investigation or sanction by any AO, regulatory or government body

• A Senior Manager of the Centre is a party to criminal proceedings (other than minor driving offences), is subject to any action for disqualification as a company director, or is subject to disciplinary proceedings by any professional, regulatory or government body.

• A recognised Centre misleading Learners through statements, advertisements or promotions resulting in Learners being disadvantaged and not achieving a recognised qualification.

Prevention

As in the case of accidents, there may well have been a ‘near miss’ that happened some time in the past which, if analysed, and corrective action taken, may have prevented the later accident.
Similarly there may be ‘near misses’ or ‘close calls’ that have happened that, if analysed and corrective action taken, may prevent an adverse event from taking place.

Examples of this may be that a major mistake in an assessment spotted before certification or the loss of assessment materials that were subsequently found before the assessment.

In short the problem happened but it was caught before it could do any damage and have an adverse effect. Not all adverse effects can be prevented, however, having a culture where people are free to openly discuss ‘near misses’ in the organisation can help to reduce the risk if the ‘near misses’ are recorded, collected and analysed to reduce the risk of them happening again. Consequently we need to catch these near misses and we all have differing roles and responsibilities in averting and dealing with adverse events.

**Roles and Responsibilities**

**Centre Manager**

Has a responsibility to:

- promote a culture where it is acceptable and safe for all staff to report all adverse events, including near misses and where adverse events can be openly discussed
- ensure that there is a system in place to communicate ‘lessons learned’ across the Centre (i.e. briefings and minutes of meetings)
- ensure that an investigation appropriate to the level of risk has been undertaken
- Notify AOs/SFA/funding partners as appropriate

**Managers**

All Managers have a responsibility to:

- notify the Centre Manager immediately of any adverse event which they believe requires notification to a regulator promote a culture where it is acceptable and safe for staff to report all adverse events, including near misses and where adverse events can be openly discussed
- investigate and take action, when requested or required to do so, on all adverse events referred to them
- action is taken and all reasonable steps put in place to prevent reoccurrence of any adverse event
- ensure that lessons are learned and communicated following an adverse event

**All Staff**

Runway relies on staff to prevent (where possible) and notify their line manager promptly of any events or near miss to enable the Centre Manager to manage any adverse effects effectively.
All staff have a duty not to disclose any information regarding adverse events or investigations to any other person outside of Centre (such as social networking sites). Staff are reminded that inappropriate disclosure of information could lead to disciplinary action.

**Procedure for dealing with an Adverse Event**

Any near misses or actual adverse events should be reported to line managers in the first instance and then to the Centre Manager. Details of the adverse event should be emailed using the guidance below to ensure a complete picture of the adverse event is identified:

**What – what happened?**

- the qualifications, subjects, assessments, certificates affected
- the nature and cause of the incident (lost assessments/evidence, IT systems/software failure, lack of or errors in resources
- how the incident came to light

**Who – who is involved?**

- number of learners and/or staff/consultants affected
- whether learners and other stakeholders are aware of the incident
- the possible or actual impact on learners

**When – when did it happen?**

- Dates/times
- When may the effects be felt?

**Where – where did it happen?**

- location(s) including Centre or employer premises

**Why – why did it happen?**

- actions already taken or planned by the Centre to identify causes and effects and to mitigate adverse impact. It will also be useful to state the likelihood and impact of the adverse event identifying whether you believe the event is minor or could significantly impact the Centre, Learners or third parties

**The following risk rating structure provides some guidance**

1 **Minor** - could cause some embarrassment to the Centre if information came to light. Could result in non-compliance and may escalate if no action taken.

2 **Moderate** - the risk has already been identified and actions put in place however there has been one occurrence.
3 Significant - may impact a number of Learners and/or third parties and has the potential for reputational damage and AO/regulatory non-compliance.

Investigations Team

The Centre Manager in conjunction with the IQA team will organise for an investigation team to be put in place to establish and report on the facts of any adverse event that has been reported of a significant nature. If the adverse event involves suspected malpractice then investigation will be conducted in line with the Malpractice Policy.

The aim of this will be to:

- Confirm the facts, establish additional factors, circumstances and scale
- Confirm or identify the cause
- Obtain evidence
- Identify any patterns or trends
- Identify any changes to policy or procedure that need to be made by The Centre

There are certain principles that will be observed for conducting investigations:

- Confidentiality
- Rights of individuals to be accompanied
- Retention and storage of evidence and records
- Following an adverse event, the results of the lessons learnt will be disseminated to staff via their managers

Notification to AO/Regulatory Authorities

Mandatory Notification

There are some adverse events that need to be reported to the regulatory authorities if the Centre has cause to believe that it is, or likely to be, subject to:

- a material change in its governance structure or legal status
- a change of control
- a merger between it and another body, or
- any insolvency or bankruptcy proceedings

In addition the Centre must promptly notify the AO if it proposes to make available to a Learner another centre which can complete the delivery (learner transfer) made available.

The AO must also be notified of any events that have occurred outside of the UK which could have an adverse effect, for example, where the same or a similar qualification is taken in the UK or where the events could damage public confidence in the Centre.

Deciding on Notification
Each incident should be considered on a case by case basis using the following general principles:

- The scale of the event (how many learners has it affected?)
- The impact of the event (how serious has the impact been?)
- Has the event occurred in the Centre as opposed to it being at risk of occurring or from misleading information?
- Social Networking (the potential for the incident to gather momentum via social networking)
- The Centre Manager will apply their professional judgement in determining whether the AO needs to be notified of an incident
- Where there is doubt about whether to notify the AO in relation to a specific incident the decision should be to err on the side of caution and notify the AO

**Timing of Notifications**

If the event is to be notified to the AO it must be done promptly. When the Centre notifies the AO of an event, or as soon as possible afterward, the Centre will also inform on the steps that it has taken or intends to take to prevent the event having an adverse effect or to correct or mitigate that adverse effect if it occurs.

The Centre will not delay making a notification to the AO information that it has at the time and provide further information to the AO once it becomes available.

**Information to include when reporting an incident/event**

In the first instance the Centre Manager will telephone the regulatory authorities and follow up with a written summary of the incident event.

Where possible, initial notification of an event to the AO will include:

- the qualifications, subjects, units, assessments affected
- the number of Learners affected
- the nature and cause of the incident
- the possible or actual impact on Learners
- how the incident came to light
- whether other Centres/Learners/stakeholders are aware of the incident
- action plan detailing already taken or planned by the Centre to identify causes and effects, and to mitigate adverse impact.

**Awarding Organisation Response:**

It is likely that upon notification the AO will:
- consider whether the Centre has given sufficient assurance that they have/will take all necessary mitigating actions to protect the interests of learners
- confirm the timelines for any additional updates from the Centre with regard to any further investigation, implementation of mitigating actions, etc.
- seek assurance from the Centre that they have identified any actions required to prevent a repeat of the incident in future
- identify whether the incident is an isolated occurrence or has wider implications regarding the conduct of the Centre, or for other qualifications and awarding bodies, or
- simply acknowledge receipt of the notification and take no further action

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