Trust Standard Operating Procedure

University Hospitals Plymouth NHS Trust

Managing Safety Incidents Within the NHS Cervical Screening Programme

Issue Date	Review Date	Version
12 January 2018	12 January 2022	V1.2

Purpose

To define the pathway when there is concern or a screening cervical screening incident is suspected.

Who should read this document?

It is relevant to all healthcare staff involved in any part of the cervical screening process

Key Messages

Key Points:

Safety concerns and incidents in screening services need special attention because of the characteristics of screening.

Screening is a pathway not a test. Local screening services may span several clinical departments, organisations and geographical boundaries.

Health care providers should encourage their staff to report quality concerns and incidents so that action is taken to reduce risks and improve the service.

Core accountabilities	
Owner	Cervical Screening Provider Lead (HBPC)
Review	Cervical Screening Provider Lead (HBPC)
Ratification	Gynaecology Governance Steering Group Lead, Service Line Clinical Director, Clinical Lead
Dissemination	Gynaecology Governance Steering Group, Service Line Clinical Director, Clinical Lead, Histopathology Lead for Cervical Screening
Compliance	Cervical Screening Service PHNT
Links to other policies and procedures	

Version History		
V1.1		Initial document
V1.2		Trust logo updated

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

Standard Operating Procedure (SOP)

1 Introduction

Safety concerns and incidents in screening services need special attention because of the characteristics of screening.

Screening is a pathway not a test. Local screening services may span several clinical departments, organisations and geographical boundaries.

Health care providers should encourage their staff to report quality concerns and incidents so that action is taken to reduce risks and improve the service.

2 Key Definitions

2.1 HBPC - Hospital Based Programme Co-ordinator

2.2 Regional QA Team – NHS CSP Quality Assurance team, responsible for oversight of the entire programme across the region, spanning primary and secondary care.

2.3 BSCCP - British Society for Colposcopy and Cervical Pathology

2.4 NHS CSP – National Health Service Cervical Screening Programme

2.5 SQAS - Screening Quality Assurance South

2.6 SIAF – Screening Incident Assessment Form

2.7 SIT – Screening and Immunisation lead

2.8 STEIS – Strategic executive information systems

3 Regulatory Background

This document will be maintained by the author to reflect the most up to date national guidance as applicable, and/or the current research. The Gynae Governance Group is responsible for ensuring appropriate consultation on the review of this document.

4 Key Duties / Responsibilities

4.1 HBPC – senior staff member responsible for the over-sight of any incidents involving the cervical screening programme (lab and colposcopy), reporting directly to the Medical Director and the Regional QA team.

4.2 Regional QA Team – NHS CSP Quality Assurance team, responsible for oversight of the entire programme across the region, spanning primary and secondary care.

5 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of 5 years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Gynaecology Steering Governance Group and ratified by the Service Line Director

Non-significant amendments to this document may be made, under delegated authority from the HBPC, by the nominated author. These must be ratified by the Director and should be reported, retrospectively, to the Gynaecology Steering Governance Group.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades that are directly affected by the proposed changes.

5 Procedure to Follow

- Anyone with an immediate concern within the cervical screening programme should report this to the HBPC.
- Anyone who suspects a cervical screening incident has occurred should complete an internal incident report (DATIX) and inform the HBPC asap
- The HBPC will seek advice form the SQAS
- SIAF completed by the HBPC and incident classification agreed (complete within 5 days) www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

- Follow internal governance process if no further SQAS involvement
- In cases where serious incident declared – provider reports incident on STEIS within 2 working days and sets up incident panel (should include SIT and SQAS) See Appendix one
- 72 hour report produced

- Serious incident report produced and reviewed

6 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Cervical Screening Service Lead and ratified by the Gynaecology Governance Steering Group.

Non-significant amendments to this document may be made, under delegated authority from the Cervical Screening Service Lead, by the nominated author. These must be ratified by the Service line Director and should be reported, retrospectively, to the Gynaecology Governance Steering Group. Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

7 Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

8 Monitoring and Assurance

All incidents are routinely discussed at the Gynaecology Governance Steering Group quarterly meeting whereby dissemination of progress is reported. This in turn is reported to Trust Clinical Governance team.

An Annual report is presented by the HBPC to the Trust Board whereby

9 Reference Material

NHS England (2015) Serious Incident Framework
Serious incident framework | NHS Improvement

Public Health England (October 2015) *Managing Safety Incidents in NHS Screening Programmes*
www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

Public Health England. Screening incident assessment form
www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

NSC Managing Incidents in National NHS Screening Programmes)
http://www.screening.nhs.uk/incidents

Appendix	Appendix One

Screening Incident Assessment Form

SCREENING INCIDENT ASSESSMENT FORM

HOW TO USE THIS FORM

This form is to be used by providers of NHS Screening Programmes, Screening and Immunisation Teams and PHE's Screening Quality Assurance (QA) service to collect sufficient information to determine the severity of any screening incident and how it should be managed.

Please complete the form using the drop down boxes where provided or clicking into the grey boxes to add text.

TIMEFRAME FOR COMPLETION

It is expected that the form should be completed by all parties **within 5 days** of the incident being identified, with this achieved through early reporting, sharing of information and open discussion by all parties.

WHO SHOULD COMPLETE EACH SECTION?

SECTION 1: TO BE COMPLETED BY THE PROVIDER ORGANISATION (BLUE TABLE)

This is completed by the organisation investigating the suspected safety incident or serious incident. Normally this will be the provider in which the suspected incident has occurred. The form must be sent to the appropriate regional QA service and the local Screening and Immunisation Team by email within **3 working days**.

SECTION 2: TO BE COMPLETED BY REGIONAL QA SERVICE (ORANGE TABLE)

This is completed by the regional QA service and recommends the categorisation of the incident and how it should be managed. The form will be sent by QA to the provider organisation and the Screening and Immunisation Team. The form should be sent to the generic inbox for incidents where this is in place.

SECTION 3: TO BE COMPLETED BY NHS ENGLAND (GREEN TABLE)

This summarises the agreed categorisation of the incident, with this section completed by the Screening and Immunisation Team. The completed form is then sent back to the reporting organisation and regional QA by the end of day 5.

COMPLETION OF THE FORM

Fields with a * are considered the minimum information required and should be completed in all instances. The recording of information in all other areas of the form is not mandatory but is intended to support the risk assessment and QA recommendation, please try to enter as much information as possible and obtain any missing information during the fact finding period.

SECTION 1: TO BE COMPLETED BY THE PROVIDER ORGANISATION

1. DETAILS OF PERSON COMPLETING THIS FORM:		
*	**Name:**	
*	**Job Title:**	
*	**Email address:**	
	Telephone number:	

2. ORGANISATIONS INVOLVED:		
*	**Organisation/Department where incident has happened:**	
	Other organisations/departments involved:	
3. SCREENING PROGRAMME/S INVOLVED (Please tick) Where an incident involves more than one program please indicate the primary program where the incident occurred with a *		
*	**3.1 CANCER SCREENING**	
	Cervical Cytology Screening	☐
	Bowel Cancer Screening	☐
	Breast Cancer Screening	☐
*	**3.2 ADULT & YOUNG PERSON SCREENING**	
	AAA Screening	☐
	Diabetic Eye Screening	☐
*	**3.3 ANTENATAL & NEWBORN SCREENING**	
	Infectious Diseases in Pregnancy Screening	☐
	Fetal Anomaly Screening Programme	☐
	Sickle Cell & Thalassaemia	☐
	Newborn & Infant Physical examination	☐
	Newborn Infant Hearing Screening	☐
	Newborn Blood Spot Screening	☐

4. PERSON LEADING ON THE INVESTIGATION FOR THE PROVIDER:		
*	**Name:**	
*	**Job Title:**	
*	**Email address:**	
	Telephone:	
5. INCIDENT REFERENCE NUMBERS:		
*	**Provider incident number** (i.e. Datix)	
	STEIS number: (if a serious incident has been declared)	
6. DATES		
	Date incident occurred:	
*	**Date incident identified:**	Click here to enter a date.
*	**Date(s) notified to QA & NHS England:**	Click here to enter a date.
*	**Date this form completed:**	Click here to enter a date.
	Date Serious Incident declared: (if applicable)	Click here to enter a date.
7. DESCRIPTION OF THE INCIDENT: WHAT HAS HAPPENED? HOW WAS THE PROBLEM IDENTIFIED?		

8. INCIDENT DETAILS: (IF YOU ANSWER YES TO ANY QUESTIONS PLEASE GIVE DETAILS BELOW)		
	Relevant History: (previous incidents, is this an isolated event or has it happened previously, has it the potential to happen again)	
	Actual harm to individuals eligible for screening?	Please select
	Risk of harm to individuals eligible for screening?	Please select
	Estimate how many individuals are involved:	
	How long has this been going on?	
	Failure or misuse of equipment	Please select
	If equipment/medical device is involved has the suspect equipment been taken out of use pending further investigation/examination?	Please select
	If equipment/medical device is involved have the necessary external reporting regulations been followed, such as those from the Health & Safety Executive and MHRA?	Please select
	Failure or misuse of IT?	Please select
	Concern about professional competence of a member staff or team?	Please select
	Breach of confidentiality and/or data security?	Please select
	Is there actual harm or risk of harm to staff?	Please select
	Any other relevant information:	

9. ACTIONS TAKEN SO FAR:		
*	**What investigations have been undertaken so far:**	
	What immediate action has been taken to mitigate any risks identified?	
	What has been done to support the staff involved? (if applicable)	
	Has the practice of any trust/provider staff been investigated?	Please select
10. COMMUNICATIONS:		
	Have any internal communication actions been taken?	
	Who is the communications lead? (please include email address and/or telephone number)	
11. NOTIFICATION OF RELEVANT PARTIES:		
	Name of QA team member notified:	
	Date notified:	
	Name of screening and immunisation team member notified:	
	Date notified:	
	Any other agencies noted:	
	Name:	
	Date:	

SECTION 2: TO BE COMPLETED BY REGIONAL QA SERVICE

1. NAME OF QA SERVICE:		
*	**Name:**	
2. DETAILS OF PERSON COMPLETING THE FORM:		
*	**Name:**	
*	**Title:**	
*	**Email address:**	
	Telephone:	
3. DATE FORM COMPLETED:		
*	**Date:**	
4. IGI REFERENCE NUMBER:		
	Number:	
5. IMPLICATIONS FOR THE POPULATION ELIGIBLE FOR SCREENING: IF YOU ANSWER YES TO ANY QUESTIONS PLEASE GIVE DETAILS BELOW:		
	Is there the potential to affect a greater number of individuals than that identified? (Estimated number?)	Please select
	Is it likely that the problem could happen again?	Please select
	Is there a risk that it could happen in other screening programmes?	Please select
	Is there a systematic failure to comply with national guidelines or local screening protocols?	Please select
	If the problem continues is it likely that individuals eligible for screening or staff would suffer severe (permanent) harm or death?	Please select
	Has the practice of any trust/provider staff been investigated?	Please select
	What immediate steps have been taken to secure the safety of the programme?	

	What immediate steps have been taken for service users/eligible population directly involved in the incident (i.e. potentially harmed by the incident)?	
	Should the programme be suspended or restricted?	Please select
	Any other relevant information:	
6. COMMUNICATIONS:		
	Is it necessary to contact patients?	Please select
	What communications actions should be taken?	

7. RECOMMENDED QA CLASSIFICATION AND MANAGEMENT	
CLASSIFICATION	**TICK**
No concern – no further action required	☐
Problem still suspected, cause not yet identified, further investigation required	☐
Problem confirmed:	☐
-This can be managed internally (No further QA action required)	☐
- This should be managed as a screening safety incident (internal investigation and RCA)	☐
- This should be managed as a screening safety incident (multi-disciplinary/multi-organisation investigation panel and RCA)	☐
-This should be managed as a Serious Incident (declaration, concise or comprehensive or independent investigation)	☐

8. ANY FURTHER RECOMMENDATIONS:

SECTION 3 – TO BE COMPLETED BY SCREENING AND IMMUNISATION TEAM (embedded within responsible commissioner)

1. DETAILS OF PERSON COMPLETING THE FORM:		
*	**Name:**	
*	**Job Title:**	
*		

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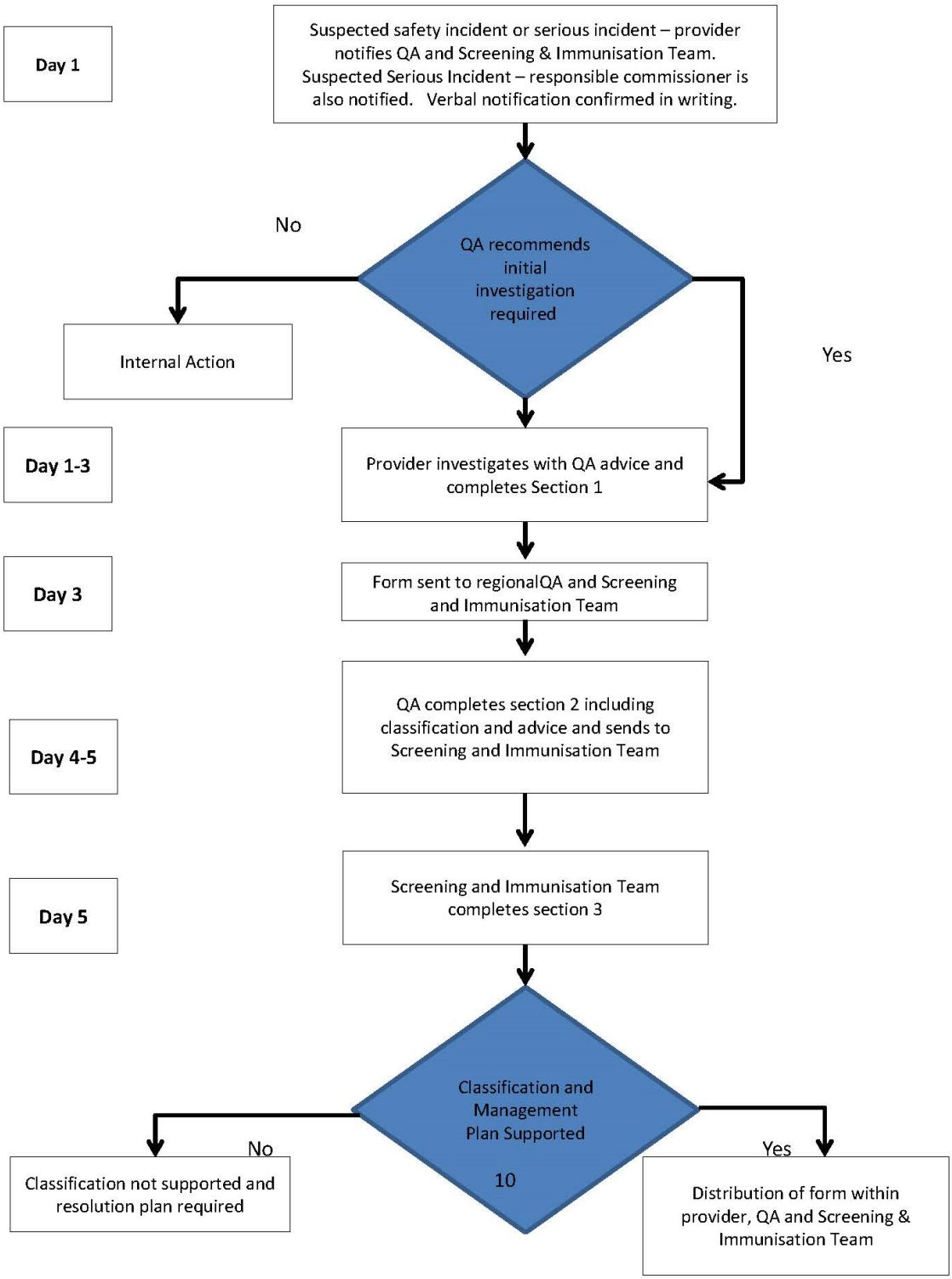
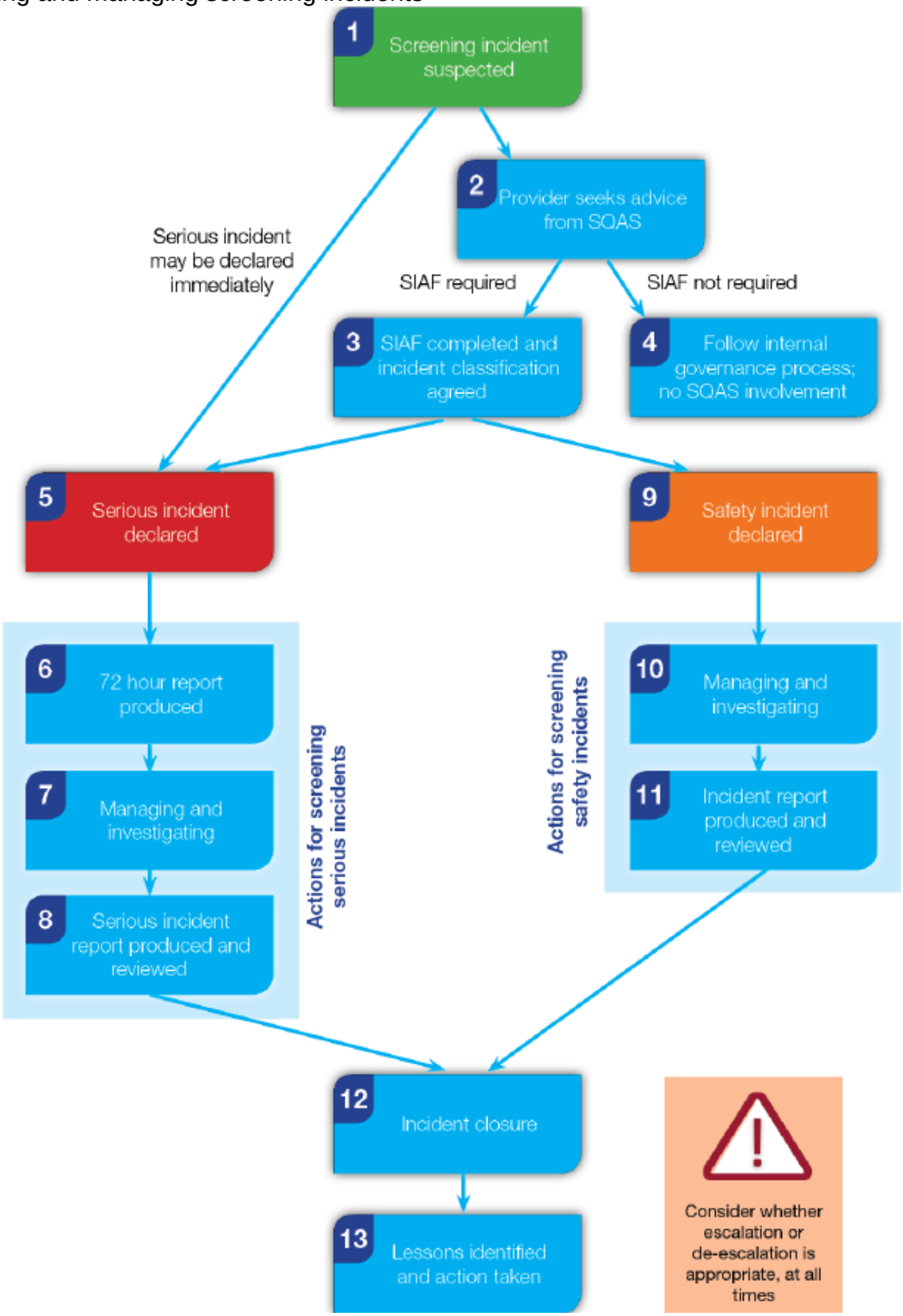
APPENDIX 1



1 of Screening Incident Assessment

Appendix	Appendix Two

Reporting and managing screening incidents



Notes to accompany reporting and managing screening incidents flowchart:

1. Screening incident suspected

2. Provider seeks advice from SQAS

A serious incident may be suspected but if there is insufficient evidence or a risk to declare a serious incident then ensure advice is sought.

3. SIAF completed and incident classification agreed

Aim to complete within 5 working days.

i. Provider details the facts in section 1 guided by SQAS (region).
ii. Provider registers suspected incident on national reporting and learning system (NRLS) or replacement (reference provided on SIAF).
iii. SQAS assesses and recommends a classification and handling to provider and SIT.
iv. SIT confirms classification and handling to provider and SQAS.

4. Follow internal governance process; no further SQAS involvement

This will also apply if a SIAF is completed and the classification is ‘not a screening incident’. If there is an incident but it is outside the screening pathway, the responsible commissioner is informed.

5. Serious incident declared

Provider reports serious incident on STEIS within 2 working days. Provider sets up incident panel (should include SIT and SQAS).

6. 72 hour report produced

7. Managing and investigating

Serious incident managed in accordance with agreed handling plan guided by SQAS (region). Changes to the handling plan and classification may be agreed by provider/SQAS (region) and SIT as more information is known.

8. Serious incident report produced and reviewed

Provider produces an incident report within 60 working days or alternative time period agreed with SQAS and SIT. SQAS and SIT comment on report. Aim is for all parties to agree the report within 20 working days.

9. Safety incident declared: If a final incident report is required then ensure the following actions are taken.

10. Managing and investigating

Safety incident managed in accordance with agreed handling plan guided by SQAS (region). Changes to the handling plan and classification may be agreed by provider/SQAS (region) and SIT as more information is known.

11. Incident report produced and reviewed

Provider produces an incident report within 60 working days or alternative time period agreed with SQAS and SIT. SQAS and SIT comment on report. Aim is for all parties to agree the report within 20 working days.

12. Incident closure

SQAS recommend incident for closure and responsible commissioner reviews and closes, governance for incomplete actions agreed, for example Programme Board monitoring

13. Lessons identified and action taken

SQAS records (region) lessons identified and disseminates eg national policy or guidance may need review.