NHS Newborn Blood Spot Screening Programme: laboratory quality assurance evidence requirements

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
1,2,3	Introductory sections - As ISO 15189		
4.	**MANAGEMENT REQUIREMENTS**		
4.1	**Organisation and management**		
4.1.1.3d	**Treatment of human specimens**	The laboratory must handle blood spots according to the Code of Practice for the Retention and Storage of Residual Newborn Blood Spots.	Policy / SoP for retention and storage of blood spots
4.1.1.4	**Laboratory director**	The newborn screening laboratory must have a named clinical lead and management structure for screening. The clinical lead must be the Newborn Screening Director. The clinical lead must be a Fellow of the Royal College of Pathologists.	Job description for named clinical lead and any other screening staff. Organogram showing screening roles and links to accountability / responsibility / governance structure within organisation

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
4.1.2.1	**Management responsibility**	The laboratory must have a viable contingency plan for screening, to continue the provision of newborn blood spot screening in the event of any failures to the laboratory service.	Business continuity plan / Emergency plan / Business contingency standard operating procedure or policy Evidence that this plan has been tested
4.1.2.1	**Management responsibility**	The laboratory must participate in the cross-organisational and multi-disciplinary arrangements for the governance, management, communication and development of the screening pathway. This must include: • having clear communication arrangements with users and commissioners of the service, midwifery, GPs, health visiting, child health records and treatments services • sharing information on laboratory screening performance, quality indicators and incidents	Agenda / minutes / terms of reference / performance reports / incident outcome reports / action plans
4.2.	**Quality management system**		
4.2.1	**General requirements**	The laboratory quality management system must incorporate all the laboratory requirements for newborn bloodspot screening. The laboratory must have documented standard operating procedures for the following processes, agreed with relevant services, for how screening specimens are monitored and managed. These must include identified responsibilities and failsafe arrangements. • receiving and processing specimens to enable matching these against the	All standard operating procedures for newborn blood spot screening undertaken within the laboratory

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
		cohort of babies for whom screening has been offered and accepted • identifying and recording un-labeled or mislabeled specimens, and specimens unsuitable for analysis, and requesting and receiving repeat specimens • making sure screen positive results are received by clinical services • having an escalation process for where screening is incomplete	
4.3.	**Document control**		
4.3	**Document Control**	The screening laboratory must make sure that all documents required by the quality management system, including documents of external origin are controlled to make sure that there is no unintended use of obsolete documents. The following documents are expected to be controlled, as external documents, as a minimum: • NHS England. Serious Incident Framework • NHS Screening Programmes. Managing Safety Incidents in NHS Screening Programmes • NHS service specification for newborn blood spot screening • NHS service specification for SCT • NHS NBS Screening Programme. Cystic fibrosis: screening laboratory handbook • NHS NBS Screening Programme. Congenital hypothyroidism: screening	Screenshots / evidence of listed documents within QMS

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
		laboratory handbook • NHS NBS Screening Programme. Laboratory guide for inherited metabolic diseases • NHS SCT Screening Programme. Handbook for newborn laboratories • NHS NBS Screening Programme. Failsafe procedures • NHS NBS Screening Programme. Standards • NHS SCT Screening Programme. Standards • NHS Screening Programmes. Key Performance Indicators (KPIs): submission guidance and data definitions • NHS NBS Screening Programme. Code of Practice for the Retention and Storage of Residual Newborn Blood Spots • NHS Numbers for Newborn Screening: Output Based Specification for the Blood Spot Card Label • NHS NBS Screening Programme. Guidelines for Newborn Blood Spot Sampling • NHS NBS Screening Programme. Newborn Blood Spot Status Codes	
4.4.	**Service agreements**		
4.4.1	**Establishment of service agreements**	The laboratory must have documented signed and dated agreements and a risk assessed protocol that sets out the responsibilities and working arrangements for screening specimens sent to other laboratories.	Service level agreements / risk assessment protocols / send away procedure

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
		For NBS the agreements must include arrangements for: • confirming specimen receipt • meeting laboratory turnaround times • making sure that results of the investigations are returned to the referring laboratory • making an initial clinical referral for screen positive babies These laboratories must be ISO 15189 accredited (or CPA accredited and working to ISO 15189), and participate in ISO 17043 accredited EQA schemes.	document / data sharing agreements
4.5	Examination by referral laboratories - As ISO 15189		
4.6	External services & supplies - As ISO 15189		
4.7	Advisory services - As ISO 15189		
4.8	Resolution of complaints - As ISO 15189		
4.9	**Non-conformities**		
	Identification and control of non-conformities	The laboratory must make sure that the management of the identification and control of non-conformities includes a review process for screening-related non-conformities.	Incident management / non-conformity policy demonstrating link to local, NHS and PHE frameworks for screening incidents.

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
		Screening non-conformities must be reviewed, managed and reported according to local, NHS and PHE frameworks for screening incidents, in particular the NHS England Serious Incident Framework and NHS Screening Programmes Managing Safety Incidents in NHS Screening Programmes.	
4.10	Corrective action – As ISO 15189		
4.11	Preventive action - As ISO 15189		
4.12	Continual improvement - As ISO 15189		
4.13	**Control of records**		
4.13.d	**Record of specimen receipt**	The laboratory must use the nationally agreed status code for blood spot screening specimen receipt. NHS Numbers for Newborn Screening: output based specification for the blood spot card label.	
4.14	**Evaluation and audit**		
4.14.1	**General**	The laboratory must have a documented evaluation and audit programme to assess performance against screening standards and quality indicators, in line with NBS Programme requirements. This must include audit of all the quality indicators in 4.14.7.	NBS related audits. Audit programme. Minutes of meetings that audit is presented at and any associated action plans.
4.14.3	**Assessment of user feedback**	The laboratory must make sure that there are arrangements for communicating with laboratory service users in the screening pathway and	Service user surveys / feedback analysis / action plans.

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
		acting upon their feedback. The user group should reflect the communication pathways and multi-disciplinary team working in the NBS screening pathway.	
4.14.5	**Internal audit**	The laboratory must undertake an annual vertical audit of the screening pathway, from arrival of the specimen at the laboratory to receipt of screen positive results by clinical services. The audit must be of a randomly selected positive specimen.	Vertical audit. Associated action plans. Minutes of meetings that audit is presented at and any associated action plans.
4.14.6	**Risk management**	The laboratory must have a documented risk management policy for the laboratory aspects of the screening programme describing the steps in the testing pathway where errors could occur and the procedures taken to minimise the risk of the error occurring. This must be part of an overall risk management policy for the whole of the screening programme, and include the laboratory interaction with other services in the screening pathway.	Risk management policy.
4.14.6	**Risk management**	The laboratory must upload results to the national newborn blood spot failsafe solution within one working day of reporting.	SoP for results upload Data sharing agreement
4.14.7	**Quality indicators**	The laboratory must comply with requirements for meeting and reporting NBS standards and key performance indicators. Collection of data to measure performance against programme standards must be reported annually to the programme by the mid July at the latest. Key	KPI and annual data submissions

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
		Performance Indicators (KPIs) must be reported quarterly between 2/3 months of each quarter end. The laboratory must: • meet NBS Standard 9 ‘Timely processing of CHT and IMD (excluding HCU) screen positive samples’. The proportion of CHT and IMD (excluding HCU) screen positive results available and clinical referral initiated within 3 working days of sample receipt by the screening laboratory • submit data for NBS Standard 3 ‘Barcoded NHS number label is included on the blood spot card’ to support maternity reporting • submit data for NBS Standard 4 ‘Timely sample collection’ to support maternity reporting • submit data for NBS Standard 5 ‘Timely receipt of a sample in the newborn screening laboratory’ to support maternity reporting • submit data for NBS Standard 6 ‘Quality of the blood spot sample’ to support maternity reporting • submit data for Standard 11 ‘Timely entry into clinical care’ to support clinical care reporting • submit data on SCT screen positive babies to the National Congenital Anomalies and Rare Diseases Register	
4.15	**Management review**		
4.15.1	**General**	The laboratory must include newborn screening as part of its management review of the quality management system.	Management review document

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
			Minutes of meetings where review presented and ratified for sign off.
5.	**TECHNICAL REQUIREMENTS**		
5.1	Personnel - As ISO 15189		
5.2	Accommodation & environment - As ISO 15189		
5.3	Equipment, reagents & consumables - As ISO 15189		
5.4	**Pre-examination processes**		
5.4.3a.	**Request form information**	The laboratory must use paper or electronic data request fields which are compliant with the minimum data fields required for the Programme. The laboratory must use the standard NBS card (or equivalent) as approved and reviewed by the NHS NBS Programme Blood Spot Advisory Group. Where consent is declined, the information currently must be handwritten on the card, as there is no specific field for recording 'declines'.	Request form (scanned paper copy or screenshot of electronic request).
5.4.4	**Primary specimen collection and reporting**	Blood sampling guidelines (pre collection and collection) are nationally determined.	

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
5.4.6.b	**Criteria for acceptance / rejection**	The laboratory must use the nationally defined acceptance and rejection criteria for blood spot specimens.	Local dissemination of national criteria, staff competency logs, education update sessions.
5.5	**Examination processes**		
5.5.1	**Selection, verification and validation of exam processes**	Screening laboratories must define and use clear cut-off values to classify screen positive results. These will typically be those within the nationally agreed screening protocols for testing set out in the appendices within the NBS laboratory handbooks. • QC material for newborn screening • Sickle cell and thalassaemia screening action values for tandem mass spectrometry	Test meets requirements detailed in laboratory handbook.
5.6	**Ensuring quality of examination results**		
5.6.3	**Inter-laboratory comparisons**	The laboratory must participate in ISO 17043 accredited EQA schemes, and must be prepared to share their data on EQA performance to the PHE QA Services and NHS Screening Programmes.	EQA performance data reports
5.7	**Post-examination processes**		
5.7.2	**Storage, retention and disposal of**	The laboratory must store, retain and dispose of blood spots in line with the Code of Practice for the Retention and Storage of Residual Newborn Blood Spots, including the separation of demographic information from the dried blood spot specimen.	SoP for retention and storage of samples

ISO 15189	ISO Requirement	NHS newborn blood spot screening: laboratory quality assurance requirements	Examples of evidence to be assessed
	clinical specimens		
5.8	**Reporting results**		
5.8.3	**Report content**	The laboratory must use the newborn screening results status codes and sub-codes for reporting results to child health records departments and the national newborn blood spot failsafe solution**.** Where hard copy reports are issued these should include the following information; identification of the laboratory that issued the report; identification of conditions screened for; patient identification including NHS number and date of birth; date of sample collection; specific comment when screening is declined; relevant status codes and sub-codes; other comments consistent with laboratory handbooks; date and time of report. (This will differ from the ISO 15189 data reporting requirements)	Scanned / screenshot copy of report
5.9	Release of results - As ISO 15189		
5.10	Information management - As ISO 15189		