Audiology

Procedure

Document Control

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Supersedes:	2
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Target audience:	All Audiology staff
Lead Executive:	SLT
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Contents

1. Introduction

This Policy provides authors of Audiology documentation instruction on the general requirements for all audiology documentation, as well as specific instructions for the following document types:

- Policy
- Procedure
- Protocol
- Guidance
- SOP

This Policy also details steps in the approval, finalisation and implementation of documents as well as key measures in the control of documents (document control).

2. Executive Summary

This policy ensures that content, structure and formatting for policies, procedures, guidelines, protocols and SOPs is appropriate and consistent across the Audiology Service. This policy also outlines the process for document consultation and approval, version control and implementation, review and archiving. In summary:

- Audiology documents must adhere to content requirements and use the Audiology document template.
- Audiology documents must be approved by the Lead Executive or SLT prior to implementing as the current version in PDF format.
- Document version control must follow stipulated process.
- All current Audiology documents in PDF format must be accessible to all Audiology staff in a centralised document folder on the shared drive.
- An MS Excel spreadsheet detailing current & previous Audiology documents is available to view within the document folder on the shared drive. The spreadsheet is accessible to view by all Audiology staff, but locked for editing by document control team and SLT.
- MS word versions for all published Audiology documents are stored in a password protected archive folder on the shared drive for the purposes of review and revision when due.
- Archived Audiology documents in PDF format are stored in an archive file with limited access to prevent proliferation of out dated documentation or accidental use of superseded versions.

3. Procedure Statement

To comply with national recommended procedures and guidance, Audiology staff must meet the responsibilities of their individual roles as defined in Section 5 (Roles & Responsibilities), and must adhere to the practices defined in Section 6 and associated documents defined in Section 11 (References).

4. Definitions

Term	Definition
Policy	A framework for achieving mandatory service aims and objectives (see section 6.1.1).
Procedure	System-level actions required to achieve the aims and objectives of policies (section 6.1.2)
Protocol	Step-by-step instructions for actions associated with specific equipment (section 6.1.3).
Guidance	Recommended best practice; alternative procedural options may be appropriate where clinically justifiable (section 6.1.4).
SOP	'Standard operating procedure', step-by-step instructions to help staff carry out routine actions (section 6.1.5)

5. Roles and Responsibilities

5.1. Lead Executive

The lead executive is responsible for:

- Supporting author(s) with document content and providing constructive review and feedback in a timely manner during the document drafting stage.
- Approving the final draft versions content prior to its finalisation by document control.

5.2. Senior Leadership Team (SLT)

SLT are responsible for final approval of document contents applicable across the adult and paediatric diagnostic and rehabilitation services.

5.3. Document Control Team

The document control team are responsible for document implementation and control:

- Format-checking and PDF publishing of finalised documents on the shared drive.
- Updating the Audiology document spreadsheet & archiving superseded documents.
- Emailing staff to alert them of a new document and monitoring compliance with reading the document.
- Emailing lead executive and author(s) to alert them when review is due.

5.4. Document Author(s)

Authors are responsible for:

- Supporting the lead executive with document production/review and reporting on progress at agreed time points.
- Responding to feedback on draft documentation by the lead executive in a constructive and timely manner.

5.5. Audiology Staff

Audiology staff are responsible for:

- Reading, understanding and following this policy where it applies to their job role.
- Reading, understanding and following Audiology documents where they apply to their job role.
- Signing that they have read new documents as they are published via the agreed process.

6. Procedure

6.1. Content & Creation of Audiology Documents

All Audiology documents must be based on recognised best practice with an acknowledged evidence-base. The language and content should be concise, easily accessible to the intended audience, and be consistent across all Audiology documents. All documents must adhere to the document control policy laid out in the document 'Policy – Quality' along with the below.

The following are essential requirements for Audiology documents:

- Use the authorised Audiology document template.
- Be written in a clear and unambiguous way using appropriate language.
- Contain appropriate content for the document type (specified in the following sections).
- Specify document audience and responsibilities; including monitoring as appropriate (please see section 6.1.1)
- Be developed with the full involvement of relevant staff, patients and/or representative groups.
- Be compatible with NUH policy and organisational vision.
- Be compatible with published evidence, national policy and guidance where relevant.
- Be compatible with equality and diversity legislation and policy.
- Refer and cross reference to relevant local and national documents.

Hyperlinks may only be used where the full location of the 'referred to' document is also given. Broken hyperlinks should be reported to the document author.

6.1.1. Document intent & intended audience

Before writing or updating a document it is vital to consider what the overall intent of the document is. Details of what each document type should contain can be found later in this section. It is advised that consideration is given to this before writing the document.
It is also important to consider who the document's intended users will be. Taking time to consider this will ensure a more effective rollout of the document and better compliance with its contents. For example, detailing the documents intended audience as 'All Audiology Staff', when it is intended just for clinical staff working with Adults, will result in some staff being asked to read & understand the document where it is unnecessary. Additionally, newer documents should no longer use the terms 'NAS' & 'CHAC' but instead use 'Audiology', 'Adult Audiology' or 'Children's Audiology'.

6.1.1.1. Summary documents

When creating a document that summarises one or more Trust documents it is important to make the reader aware of where they can find the document in full. All summary documents must contain the following in their introduction:

This document is intended to support Audiology staff by providing a summary of the following key NUH document(s):

[Full NUH document title(s)]

For further information, please refer to these documents directly. Full reference details can be found in section 11 (references).
For the purposes of this document, unless otherwise stated, the guidance applies to all areas at Ropewalk House and Audiology at ENT, QMC.

Full reference details must be included in the reference section at the end of the document. Please note that this does not apply for Trust documents used only as reference.

6.1.2. Defining the lead executive

The lead executive for a document pertaining to a specific service within Audiology (i.e. paediatrics, adult rehabilitation or diagnostics) will be the Clinical Lead for that service. Where a document applies across the whole of Audiology, the lead executive will be the Head of Audiology and final document approval will be via SLT. Details of the individual and their role should be recorded on the documents front sheet.

6.1.3. Policy Content

A Policy should define a set of principles or ideas that inform subsequent documentation. Policy documents should be considered overarching frameworks that detail mandatory service aims and objectives. They should, where needed, guide the decision making and strategy required to achieve their (the policy's) goals.

6.1.4. Procedure Content

Procedures must document the mandatory actions required to achieve the aims and objectives set out in the Audiology policies. A procedure describes mandatory actions at a level applicable to the whole system, and therefore do not contain step-by-step instructions for actions associated with specific equipment or software (which are covered by protocols).

6.1.5. Protocol Content

Protocols are intended as a resource for staff using a particular piece of equipment or software, and therefore provide a step-by-step protocol for operation. The level of detail contained with a protocol should support self-directed learning or refresher training.

6.1.6. Guidance Content

Guidance documents detail activities or actions which are recommended as best practice with a supporting evidence base, but are not mandatory. Alternative activities or actions may be judged by staff to be appropriate and justifiable due to specific circumstances. Guidance documents may therefore contain procedural information, advice and recommendations not appropriate for a mandatory procedural document. Where deviation from the recommended guidance occurs, the specific reasons for doing so must be documented.

6.1.7. Standard Operating Procedure (SOP) Content

A Standard Operating Procedure should provide key details in how a particular goal is achieved; it should be clear and concise in the steps that are needed. A balance needs to be struck between

enough detail so nothing is missed and too much detail, where the reader is overwhelmed with information.

6.1.8. Other documents

In addition to written documents, various forms and templates may be in use throughout the service. These documents should be addressed on a case by case basis and their content decided accordingly. Each document should have a clear version number and review date. Should this not be possible, the reason should be recorded and communicated to Document Control who will manually record the details on the central documents database.

6.2. Document Review

All Audiology documents are allocated a review date, the standard for which is three years from implementation date. However, a review date may be planned for sooner, or brought forward by the lead executive and/or author, in order to maintain compliance with emerging or new clinical practice, new national or Trust guidance, and/or to maintain consistency with other local documentation. The Document Control team should be informed by lead executive or author(s) if a document is being reviewed early so that the Audiology document spreadsheet can be updated to reflect this.
Where a document is undergoing routine review, the author and lead executive should take into consideration:

- Relevant service review work, auditing and action plans
- Updated national guidance (e.g. BSA) and Trust policy
- Relevant research, emerging clinical practices and/or new clinical practices

As part of the document review, the author must ensure that any references are still current.

Documents will be updated to the current Audiology document template at the time of review.

The Document Control team monitor the Audiology document spreadsheet and inform a lead executive and author(s) when a document (for which they are responsible) has a review date in six months. This time frame should be sufficient for redrafting of the document, followed by the process of approval, document control and finalisation. The Document Control team will continue to monitor the documents in review and if a final draft has not been submitted for formatting three months prior to review date, a reminder email will be sent to lead executive and author(s).
Should a document become overdue, the Document control team will remind the lead executive and author once more, and raise a CAPA about the delay. This is so the matter can be investigated and appropriate action taken. This may result in a CAPA concession which will be recorded on the central documents database.

6.2.1. Retiring documents

During the document review process it may be decided that a document is no longer required and needs to be retired from circulation. Document Control must be informed of this decision, a record of which will made in document control spread sheet, after this all copies of the document will be moved from the shared area to a designated archive folder.

6.3. Document control

There are multiple steps in place to ensure that staff can only access the most up to date version of a document. These steps are applied throughout the document control process & their adherence sits with all parties involved in the creation, review & maintenance of documents.

6.3.1. Version Control

All Audiology documents, current or archived, are allocated a version number (which shall be an integer). Where a document replaces an earlier version, the version number is increased by one. Whilst in Draft, the document will retain its new version number followed by what version of the draft of this new document it is, for example should it be replacing version one of a document and is in its third draft version its title sheet & footer would read 'Version 2 Draft 3'. Draft versions of documents should be created in MS word & retain their 'Draft' watermark until removed by Document control. The intent of these controls is to ensure it is clear to staff when a document has not yet been finalised.

6.3.2. Finalisation of documents

When the content of a document has been authorised by the lead executive a member of the Document Control team will finalise it. This includes removing all draft notations (including the 'draft' watermark) and saving it as a PDF. This finalised document will be kept in a designated folder under document control. No copies should be made of this document. Any requirements to have it in other folders shall be covered by creating a link rather than a copy. This is intended to reduce proliferation of incorrect/outdated versions.

6.3.3. Archiving & control of previous and draft versions

When a documents content has been finalised & submitted to document control, all previous versions of the document will be moved from the shared area into a designated archive folder in line with the 'Issuing documentation following completion' SOP. This folder will sit outside of general staff access to help prevent proliferation of incorrect versions.
The final draft version of the document will be kept in MS Word format and stored in a designated draft documentation folder; this is to allow ease of update when its review is due. During the development process, document drafts should be maintained & updated within the document control folders on the shared drive. Draft versions should not be distributed or shared over e-mail.

6.3.4. Document Control Spreadsheet

A spreadsheet listing all current Audiology documents, including version number, author and review date and review progress is available to view by all staff on the shared drive in the Document control folder. Amendment of the spreadsheet is restricted to the document control team and SLT. This document also includes details of previous & retired versions of a document.

6.3.4.1. Non-local documents

In addition to locally created & maintained policy, documentation created at Trust & national level may be in use throughout the service. Consideration must be given to these documents & their details recorded on the document control sheet - If copies are saved at a local level. It is advised that wherever possible hyperlinks are used to access non-local documents, this is to ensure that the current version is used. However it is understood that local copies may be needed, if this is the case then they require appropriate document control. Where a document is saved, the source of it should be detailed in the file name, for example, a Health and safety policy downloaded from the

Trusts internet should be named 'NUH Policy – Health and safety'. This is to allow ease of identification of documents in circulation.

6.3.5. Communication and Ensuring Staff Readership

Audiology staff are made aware of new & updated documentation via email. It is a mandatory requirement that staff access and read Audiology documents where they apply to their job role. Staff are provided with a one month deadline for reading the new & reviewed documentation, for reviewed documentation this applies where there has been a change to the key contents of the document. The process of confirming and documenting this is detailed in the Audiology Procedure for Document Readership Assurance.

6.3.5.1. Launch schedule

To avoid overwhelming staff with excessive documents to read all at once, Documents will be launched according to a defined schedule. Documents that are completed will be issued in batches of up to five, every fortnight. The Lead executives of documents noted as completed will be asked to confirm their status prior to launch to allow them to be collated. This will allow better traceability of document launches whilst preventing staff receiving multiple notifications of documents 'as & when'.

The only exception to this will be for documents with a smaller target audience, typically this will be 'team specific' documentation. These documents can be launched in addition to those with larger readership groups; however consideration should be given to the overall quantity of documents Staff within the smaller target groups are being asked to read.

6.3.6. Hard copies

Hard copies are made of all locally created and maintained documents, this includes both written documentation such as policies & procedures as well as templates & forms.
These copies should be stored in folders that replicate the digital folder organisation for the digital versions found on the shared drive.
As with updates of the digital versions, the previous versions of these documents should be removed & replaced whenever a document is reviewed.
These copes are to be stored in a location designated by the document control team where access can be gained should a hard copy be required. The current location can be found detailed in the central documents database.

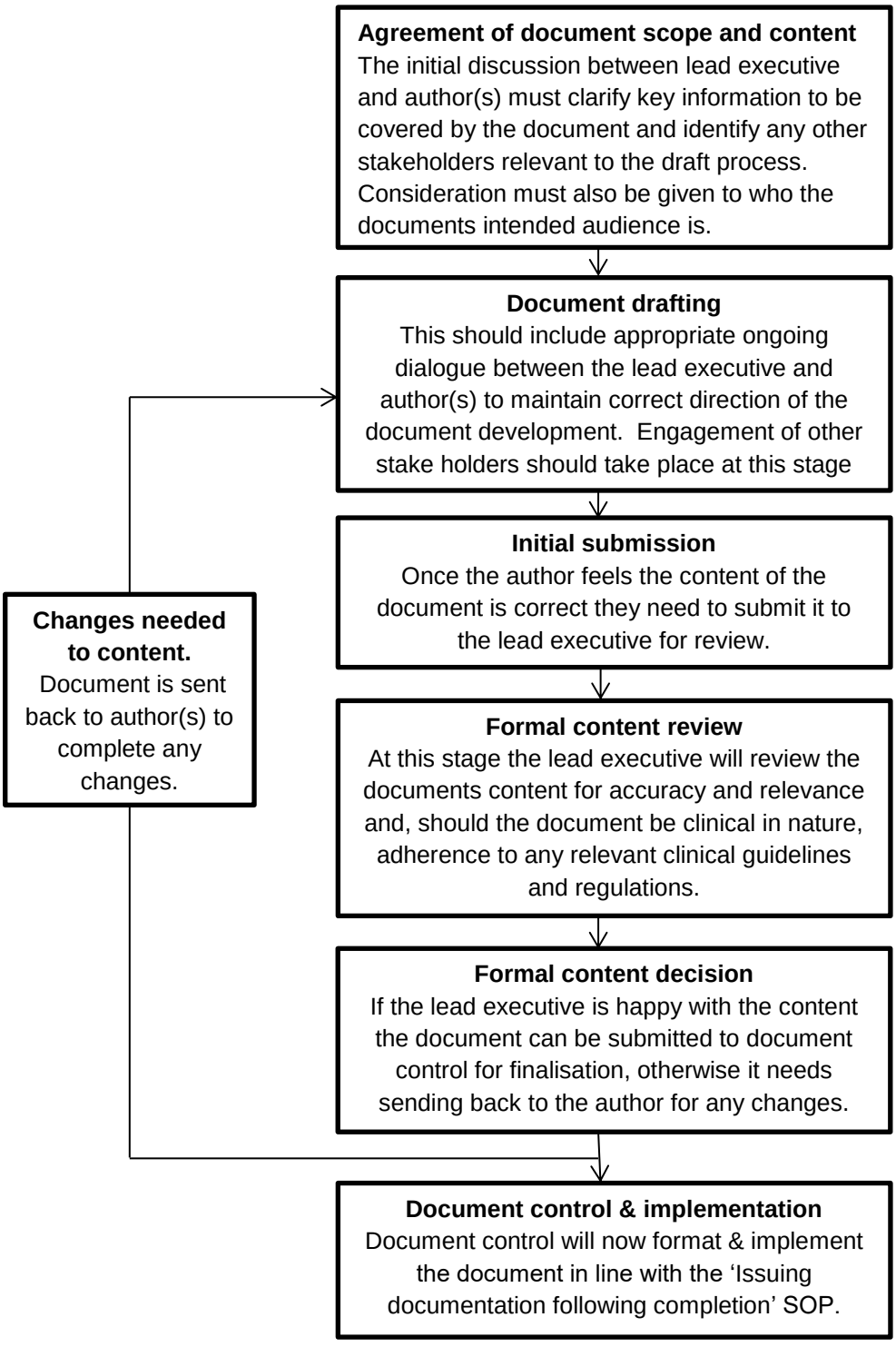
6.3.7. Quality monitoring

To ensure the overall quality of documentation within the Service, the SLT will conduct an annual audit of documentation.
This audit will take a sample of issued documentation and compare it to the final draft version; this is to ensure no changes have been made to the content between authorisation and issuing.
The audit will also check that only the authorised template is being used for documentation.

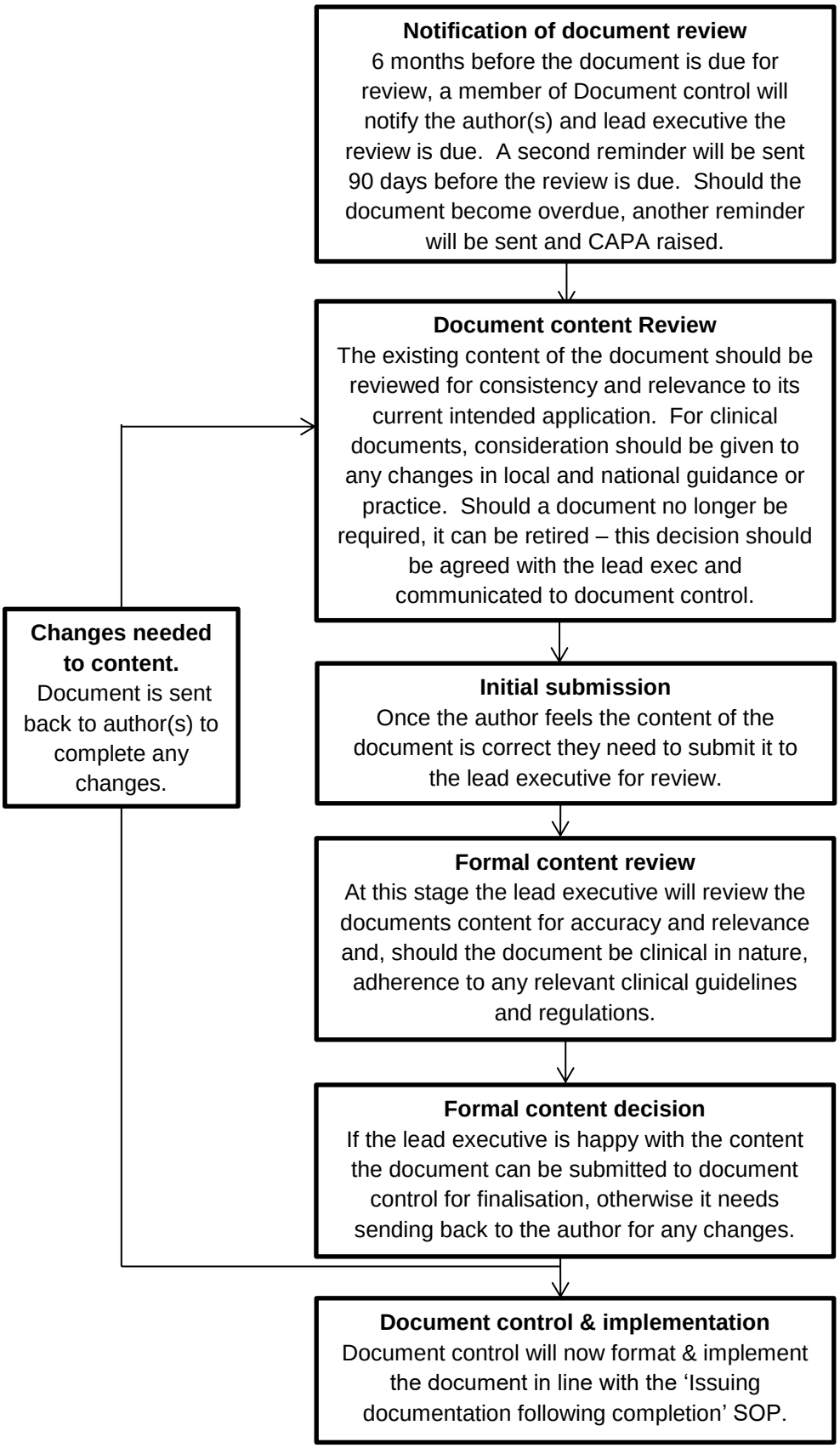
6.4. Document Generation, Approval and Control Processes overview.

Summaries for key stages in the process for document creation, approval and control process can be found in the following flow charts.

Process for creation of new documents



Process for Review of existing documents



6.5. Document readership assurance

6.5.1. Email Alerts

The document control team will send an email to Audiology staff when a new Audiology document version has been approved and is available on the shared drive. This includes Audiology, policies, procedures, protocols, guidance and any other documents requiring documented readership.

When possible, staff will be given a deadline to read and 'sign off' new document(s). Deadlines are generated to be reasonable in respect of staff workloads, risk presented by not reading a document and any external factors.

The E-mail will also indicate the required actions staff need to take for relevant documents. Care must be taken to make sure only the relevant teams read the required documents. For any documents that have had minor changes such as formatting or re-dating (i.e. no content change to the actual pro-forma), staff should be advised to refresh their knowledge of the document where possible but it is not compulsory.

6.5.2. Sign-Off Spreadsheet

The spreadsheet provides a facility for staff to confirm that they have read all Audiology documents relevant to their role.

When a new Audiology a new document becomes available it is added to the sign-off sheet, and listed against relevant staff for readership.

New staff names are added to the spreadsheet as they join, and they are provided with information on sign-off as part of the induction process.

The document control team monitor compliance with document readership. Readership is shared with the wider Quality team when relevant to CAPA or Datix incidents.

Records of former staff member's readership and readership of retired documents is archived within the readership assurance database.

7. Training and Implementation

7.1. Training

Training will be achieved through readership of this document.

7.2. Implementation

The document will be implemented by the document control team according to the document control process.

7.3. Resources

No additional resources are required.

8. Equality Impact Assessment (EQIA) Form

An equality impact assessment has been undertaken on this document and has not indicated that any additional considerations are necessary.

Q1. Date of Assessment: September 2021			
Q2. For the document and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the document or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups experience? i.e. are there any known health inequality or access issues to consider?**	**b) What is already in place in the document or its implementation to address any inequalities or barriers to access including under representation at clinics, screening**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of the document or its implementation being assessed:			
Race and Ethnicity	No issues identified		
Gender	No issues identified		
Age	No issues identified		
Religion	No issues identified		
Disability	No issues identified		
Sexuality	No issues identified		
Pregnancy and Maternity	No issues identified		
Gender Reassignment	No issues identified		
Marriage and Civil Partnership	No issues identified		
Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation)	No issues identified		

Q3. What consultation with protected characteristic groups inc. patient groups have you carried out? None			
Q4. What data or information did you use in support of this EQIA? None			
Q.5 As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments? None			
Q.6 What future actions needed to be undertaken to meet the needs and overcome barriers of the groups identified or to create confidence that the document and its implementation is not discriminating against any groups			
What	**By Whom**	**By When**	**Resources required**
Q7. Review date	Not applicable		

9. Values and Behaviours

The Trust's TEAM NUH Values and Behaviours describe the principals and beliefs of our people and show that 'we listen, we care'. The TEAM NUH Values and Behaviours have been considered in relation to this document.

Please rate each value from 1 – 3 (1 being not at all, 2 being affected and 3 being very affected)

Value	Score (1-3)
1. Polite and Respectful Whatever our role we are polite, welcoming and positive in the face of adversity, and are always respectful of people's individuality, privacy and dignity.	1
2. Communicate and Listen We take the time to listen, asking open questions, to hear what people say; and keep people informed of what's happening; providing smooth handovers.	1
3. Helpful and Kind All of us keep our 'eyes open' for (and don't 'avoid') people who need help; we take ownership of delivering the help and can be relied on.	1
4. Vigilant (patients are safe) Every one of us is vigilant across all aspects of safety, practices hand hygiene & demonstrates attention to detail for a clean and tidy environment everywhere.	1
5. On Stage (patients feel safe) We imagine anywhere that patients could see or hear us as a 'stage'. Whenever we are 'on stage' we look and behave professionally, acting as an ambassador for the Trust, so patients, families and carers feel safe, and are never unduly worried.	1
6. Speak Up (patients stay safe) We are confident to speak up if colleagues don't meet these standards, we are appreciative when they do, and are open to 'positive challenge' by colleagues	1
7. Informative We involve people as partners in their own care, helping them to be clear about their condition, choices, care plan and how they might feel. We answer their questions without jargon. We do the same when delivering services to colleagues.	1
8. Timely We appreciate that other people's time is valuable, and offer a responsive service, to keep waiting to a minimum, with convenient appointments, helping patients get better quicker and spend only appropriate time in hospital.	1

9. Compassionate We understand the important role that patients' and family's feelings play in helping them feel better. We are considerate of patients' pain, and compassionate, gentle and reassuring with patients and colleagues.	1
10. Accountable Take responsibility for our own actions and results	1
11. Best Use of Time and Resources Simplify processes and eliminate waste, while improving quality	1
12. Improve Our best gets better. Working in teams to innovate and to solve patient frustrations	1
TOTAL	12

10. Monitoring Matrix

Minimum requirement to be monitored	Responsible individual/ group/ committee	Process for monitoring e.g. audit	Frequency of monitoring	Responsible individual/ group/ committee for review of results	Responsible individual/ group/ committee for development of action plan	Responsible individual/ group/ committee for monitoring of action plan
Service evaluation/ monitoring audits	SLT All staff	Audits	Various	SLT CAPA team	SLT CAPA team	SLT CAPA team
Adverse Incident Surveillance	SLT AUDIOLOGY Clinical Governance Lead/CAPA team	Datix incidents/ CAPA reporting	Monthly	SLT AUDIOLOGY Clinical Governance Lead/ CAPA	SLT AUDIOLOGY Clinical Governance Lead/ CAPA	SLT AUDIOLOGY Clinical Governance Lead/ CAPA
Peer review	SLT All staff	Peer review	Various	SLT Line manager CAPA team	SLT Line manager CAPA team	SLT Line manager CAPA team

11. References

- Policy - Quality
- SOP - Issuing documentation following completion
- Central Documents Database
- Readership assurance database

12. Appendix

12.1. Issuing documents following completion

Please note this SOP is only relevant to those directly involved in control of documentation.

12.1.1. Final checks of a completed document

When the document author has completed their document a number of checks must be completed before it can be put into circulation. What follows is a check list to follow to ensure it is ready:

- Is the document on the standard authorised document template?
- Are all relevant details filled in on the title page? The author should be consulted for any missing information. Terms such as 'NAS' and 'CHAC' should be replaced with 'Audiology' and 'Paediatric Audiology' respectively.
- Is the footer complete? This should detail the document title followed by its document type, for example this document is listed as 'Issuing documentation following completion – SOP'. The Version number, issue date and review date should also match the information on the title sheet.
- Is the header on each page? On some older templates the NUH logo is missing from later pages
- Has the water mark been removed? Any water marks that say 'Draft' should be removed before the document is finalised.
- Are the EQIA and Values and Behaviours form, and monitoring matrix complete?
- Has the contents sheet been updated? There can be issues with the formatting within word on the contents page, so please ensure it has been updated & is correct before finalising the document.
- Check the general formatting of the document - are there any large gaps between text?
- Are there any obvious spelling mistakes? Whilst it is not the purpose of these checks to review the actual content of the document, it is worth checking through for any spelling mistakes that may have been missed.

12.1.2. Saving the document in its completed format.

Once the finale checks are completed the document can be saved ready for issue. The document should be saved as a PDF with the following name format '[document type] – [document name]', for example this document would be saved as 'Procedure – Document control'. There should be no additional information in this title such as version number or target audience.

The document should be saved within the Controlled documents folder in its relevant sub-folder.

When the document has been saved as a PDF it should be checked for any errors in the conversion process.

12.1.3. Preparing to issue the document

Now the document is finalised & saved in is final format the process of issuing it can begin. A shortcut to the document should be created and saved within the 'Launching' sub folder of 'controlled documents'. A New folder should be created using the date this action is carried out, any other documents launching at this time can have their shortcuts placed here too.

After this, the final draft of the document should be moved to the 'Drafts of launched documents' folder & the date of their eventual launch added to the document title.

12.1.4. Removing all previous versions

The share drives should now be cleared of all previous versions of the new document (save for the saved draft version mentioned above). Any versions which are found should be moved to the current designated archive location & replaced with links to the new document It is important that links are used rather than copies, this prevents proliferation of multiple versions & confusion as to what document should be in use. Archived documents should have their file name amended to include the date archived.

12.1.5. Creation of hard copy

A hard copy of the document should be created and filed in its designated location. For updates, the previous versions hard copy should subsequently be destroyed.

12.1.6. Updating the readership assurance database.

The individual steps in how to update the database are contained within it.

Once the database has been updated, the relevant team members can be e-mailed regarding the documents. This e-mail should detail any actions they need to take i.e. if they need to read the whole document or just be aware that there has been a minor update.

12.1.7. Update the Central Documents database

Now the document is launched, the Central documents database can be updated. This will include moving details of the previous document version to the 'previous' or 'retired' tabs (as relevant) and the updated document details moving into the 'current document' columns & any old information removing ready for its next update cycle.