Blackpool Teaching Hospitals
NHS Foundation Trust

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Title: **Prescribing, Supply and Use of Unlicensed Medicines**		**Version Number:** 4
		Status: Ratified
Target Audience: Trust Wide		**Divisional and Department:** Pharmacy
Author / Originator and Job Title: Angela Nelson, Assistant Director of Pharmacy – Support Services		**Risk Assessment:** Not Applicable
Replaces: Version 3 Prescribing, Supply and Use of Unlicensed Medicines CORP/PROC/312	**Description of amendments:** Updates to Responsibilities of prescriber, pharmacist, receipt of request process and removal of QC testing	
Validated (Technical Approval) by: Pharmacy Quality and Governance Committee Alastair Gibson, Director of Pharmacy Medicines Management Committee	**Validation Date:** 28/03/2018	**Which Principles of the NHS Constitution Apply?** Principle 1-4
Ratified (Management Approval) by: Medicines Management Committee	**Ratified Date:** 19/04/2018	**Issue Date:** 19/04/2018
Review dates and version numbers may alter if any significant changes are made		**Review Date:** 01/04/2021

Blackpool Teaching Hospitals NHS Foundation Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that they are not placed at a disadvantage over others. The Equality Impact Assessment Tool is designed to help you consider the needs and assess the impact of your policy in the final Appendix.

CONTENTS

1 PURPOSE

This procedure document describes the procedure for the procurement and use of unlicensed medicinal products (often called "specials"). These are unlicensed medicines, which have been specially prepared by the holder of a Manufacturers Specials Licence or imported in response to or in anticipation of the order of a doctor or dentist to meet the special needs of individual patients.

Unlicensed medicinal products must only be used when no pharmaceutically equivalent licensed product or suitable alternative licensed product is available for use at the time the patient requires it.

All unlicensed medicines used by the Trust are supplied by the Pharmacy Department and in accordance with this procedure.

This procedure does not cover products used outside their licensed indications (“off-label” use), investigational medicinal products (clinical trials materials), products extemporaneously dispensed within the Trust in response to a prescription, products prepared under section 9, 10 or 11 of the Medicines Act, non-medicines, medical devices, intermediate products, repackaged licensed products, or reconstituted Intravenous (IV) additives and CIVAS (central intravenous additive service) products.

2 TARGET AUDIENCE

This procedure applies to all staff working for, or managing patients under the care of, Blackpool Teaching Hospitals NHS Foundation Trust.

3 PROCEDURE

Unlicensed medicines should only be used where a licensed alternative is not available and pharmaceutical quality assurance has been demonstrated for both the procurement and use of such products.

The procedure covers the following categories:

- Medicines prepared by a manufacturer but not on sale in this country.
    - Such medicines may be awaiting the grant of a United Kingdom (UK) product licence, be undergoing clinical trial, be manufactured for export or may have been withdrawn from the UK market.
- Unlicensed medicines obtained from a hospital or a commercial supplier with a manufacturer’s “specials” licence.

Because unlicensed medicines have not been formally assessed through the licensing process for safety, quality and efficacy, the risks associated with their use cannot be presumed to have been evaluated. Harm that arises as a result of a product defect, i.e. the product is not of the quality or safety expected, may rest with the manufacturer of the product, provided all reasonable steps have been taken by the prescriber and the Pharmacy to ensure a product of appropriate quality and safety is supplied.

3.1 Responsibility and Role of Prescribers

Prescribers of unlicensed medicines carry their own responsibility and are professionally accountable for their judgement in doing so. Prescribers are responsible for the patient's welfare and in the event of adverse reactions he/she may be called upon to justify their actions.

The Prescriber must:

- Ensure the use of the unlicensed medicine is justified by the clinical condition of the patient.
- Ensure that records are kept.
- Ensure that incidents of patient reactions are recorded and reported to the Committee on Safety of Medicines via the Yellow Card Scheme and by the Trust's Electronic Incident Reporting Form.
- Ensure that where responsibility for ongoing care is to be transferred to the patient's general practitioner, that the general practitioner is informed of the unlicensed status of the medicine and that he or she is willing to accept clinical and legal responsibility for prescribing.
- The hospital doctor is responsible for continuing treatment if the general practitioner will not accept responsibility for continuing care.
- Responsible for the ongoing monitoring of the patient with regard to clinical safety.(Unless a Shred care agreement is in place)
- Subject to risk assessment, communicate with patients the implications of using the unlicensed medicine.

3.2 Responsibility and Role of Pharmacists

Pharmacists are responsible for ensuring that prescribers are always aware that a medicine they have requested is only available as an unlicensed product and must inform the prescriber of any clinical concerns identified in using the medication

Pharmacists will share responsibility as the purchaser of the product, particularly where this involves specifying the product to be purchased, or if their actions or omissions have contributed to the harm. Pharmacists are responsible for ensuring that the manufacturer holds the appropriate licence to manufacture and that the product complies with the product specification.

Pharmacists or other pharmacy staff who dispense or supply unlicensed medicines in response to prescriptions are professionally accountable for any harm caused by a defect in the medicine which is attributable to their own actions or omissions.

The Assistant Director of Pharmacy – Support Services is designated as having overall responsibility for controlling the procurement and supply of unlicensed medicines, the

“Designated Pharmacist”. However, Clinical Pharmacists will be involved in the decision making process.

When an unlicensed medicine is to be ordered for the first time their needs to be critical, evidence based evaluation for its use and the designated pharmacist has an important and responsible role in assessing the evidence and challenging use. The Pharmacist must also ensure that all the controls specified within this procedure are applied including the maintenance of appropriate records of use.

3.2.1 The Designated Pharmacist must:

- Ensure that written procedures to cover all aspects of the procurement and issue of unlicensed medicines are produced, authorised, and reviewed.
- Ensure that arrangements are in place to ensure that Prescribers are aware of the unlicensed status and accept the responsibility for the use of each unlicensed medicine.
- Ensure that arrangements are in place to make sure that unlicensed medicines are used only when an equivalent licensed product is unavailable
- Monitor and audit the handling of unlicensed medicines in the Pharmacy Department.
- Monitor the range and quantities of unlicensed medicines purchased, keeping a list of unlicensed medicines currently approved by the Trust.
- Refer and where appropriate report to the Drug and Therapeutics/Medicines Management Committee on the use of unlicensed medicines in the Trust.
- Communicate with MHRA and the prescriber to process any reports of adverse reactions
- Prepare specifications for unlicensed medicines in conjunction with Quality Control North West.
- Ensure that submissions for new products are submitted to Drug and Therapeutics Committee as appropriate
- “Authorise for Use” new products that are needed for urgent clinical use.
- Undertake a Risk based assessment to quarantine high risk unlicensed medicines from non-NHS suppliers on receipt within the Trust and undertakes quality assessments.
- Release all quarantined batches of unlicensed medicines for use within the Trust.
- Refer the request for approval to the D&T committee or chair of the D&T committee for One Off use approval. This is especially important for medicines that are deemed to be high risk
- Submit a copy of the completed request and risk assessment form to Quality Control North West.

3.2.2 Pharmacy Procurement Staff must:

- Ensure that the person making the request is authorised to do so.
- That the purchase of unlicensed medicines is in accordance with written procedures and that the Designated Pharmacist is aware of the purchase.
- Ensure any special requirements of supply are met.

Ensure that the medicine is quarantined on receipt as per written departmental procedures.

3.2.3 Pharmacy Procurement Staff must:

The clinical pharmacist, in conjunction with the designated pharmacist must:

- Ensure that the use of an unlicensed medicine is justified by the clinical circumstances and in line with published evidence and sound therapeutic argument
- Ensures that no licensed alternative product is available.
- Ensures that the prescriber is made fully aware of the clinical and legal implications of using the selected medicine.
- Ensures that the designated pharmacist is fully briefed on the pharmaceutical requirements of the product.

3.2.4 Pharmacy Supply and Dispensing

Pharmacy staff involved in the dispensing of unlicensed medicines must:

- Ensure that requests for unlicensed medicines are processed in accordance with Trust procedures
- Where appropriate communicate with patients the implications of using the unlicensed medicine.
- If appropriate, make arrangements for patients to have continuing supplies of treatment or provide the patient with details on how to obtain further supplies.

3.3 Patient Consent and Information

Health professionals must respect the right of patients, carers and parents to participate in discussions regarding the health care of the patient and to seek to ensure that decisions are properly informed.

No additional steps, beyond those taken when prescribing licensed medicines, are required to obtain the consent of patients and parents/carers for their use of unlicensed medicines.

Out patients or discharged patients should receive a generic patient Information Leaflet. This should explain why it is necessary to prescribe unlicensed medicines. This should

allay any concerns that patients or carers may have about unlicensed medicines. The leaflet may also give details on how to obtain further supplies.

3.4 Prescribers "Request and Risk Assessment Form for Unlicensed Medicines"

All requests for new medicines must be referred to the Senior Pharmacist- Medicines Information. Where appropriate, new requests will be considered by the Drug and Therapeutics (D & T) committee. Individual patient requests may be agreed without formal D&T approval but a One-Off Request and formal risk assessment must be undertaken. The D&T committee will be notified of all new requests for unlicensed medicines along with the results of the risk assessment.

All prescribers requesting the use of an unlicensed medicine will be asked to complete the "Request and Risk Assessment Form for Unlicensed Medicines (Appendix 1). The prescriber will be required to provide some evidence as to the benefits offered by the preparation together with a consideration of possible licensed alternatives. Any evidence of side effects, contraindications and precautions in use need to be detailed. The form must be returned to Assistant Director of Pharmacy – Support Services.

The completed "Request and Risk Assessment Form for Unlicensed Medicines" form, will be risk assessed with respect to clinical needs, alternative products, physical risks, labelling and the ability to procure a suitable product. The decision on whether the product can be used will be based upon this assessment. The prescriber will be notified regarding the outcome of the risk assessment. All issues regarding the procurement, cost, quarantine, testing and dispensing procedures will be discussed with the prescriber. Approval for funding of unlicensed medicines will have to be sought from the divisional financial manager. Ongoing costs for unlicensed medicines may remain within the Trust unless prior approval agreed by primary care.

3.5 Procurement Risk Assessment

The Designated Pharmacist must ensure that all procured medicines are of the correct quality for their intended use. They will assess the risk with respect to the source, license status of the medicine, product specification and quality information. Manufacturing or import licenses must be checked along with results of quality control audits. A full product specification must be drawn up for all medicines purchased.

The language used on the packaging must be determined along with details of who will supply the translation of the patient information leaflet and label.

An assessment of the supply chain must be carried out, and the ease with which further supplies will be obtained. The cost of the drug and any special funding needs are determined. Responsibility for continued supply needs to be identified.

The assessment process should take into account any issues raised by Quality Control North West. Orders for unlicensed medicines from non-NHS suppliers must include a request for a Certificate of Analysis.

Pharmacy is not permitted to import medicines directly. Unlicensed medicines may be obtained from:

- The holder of a Manufacturer's Specials Licence, either a commercial company or an NHS hospital.

Or

- By importation from the holder of a Wholesale Dealer's Licence (for importing from member states of the European Economic Area) or a Wholesale Dealer's Import Licence (for importing from outside the European Economic Area).

Procurement of unlicensed medicines is carried out in line with Regional Guidance. Products will be purchased, wherever possible, from manufacturers on the Regional "Specials manufacturers list", ensuring that the manufacturer holds the appropriate licence.

3.6 Receipts and Quality Assurance

Upon receipt, the unlicensed medicine and associated documentation will be formally checked. The checks will include the appearance of packaging, label details, checks on the certificate of analysis against current specifications. Pharmacy does not have the direct ability to test purchased medicines, therefore medicines that would require testing may not be suitable for use within the Trust.

The designated Pharmacist may liaise with Regional Quality Control North West to ensure the quality and share in the dissemination of stability data, product specifications and Certificates of analysis.

3.7 Issue and Dispensing

The medicine's overall risk will determine its use within the Trust and the restrictions placed on its dispensing. Low risk items may be stocked on wards and freely dispensed however high-risk items may only be dispensed against consultant prescriptions. The dispensing rules will be identified at the point of the request and will be drug specific. Pharmacy has a responsibility to maintain records on the receipt and issue of unlicensed medicines.

3.8 Adverse Drug Reactions and Defective Products

Adverse drug reactions and defective products must be handled and reported in the same way as licensed medicines. Doctors or pharmacists should report serious adverse drug reactions to the Medicines and Healthcare Regulatory Agency using the Yellow Card Scheme. Copies are available from the British National Formulary (BNF), Monthly Index of Medical Specialities (MIMS) and the intranet.

Suspected defects in unlicensed medicines are to be reported to the Pharmacy Department or the on-call pharmacist (out-of-hours) who will report them to Quality Control North West following the Regional Drug Defect Reporting procedure.

4 ATTACHMENTS	
Appendix Number	**Title**
1	Request and Risk Assessment Form for Unlicensed Medicine
2	Equality Impact Assessment Tool

5 PROCEDURAL DOCUMENT STORAGE (HARD AND ELECTRONIC COPIES)
Electronic Database for Procedural Documents
Held by Procedural Document and Leaflet Coordinator

6 LOCATIONS THIS DOCUMENT ISSUED TO		
Copy No	**Location**	**Date Issued**
1	Intranet	19/04/2018
2	Wards, Departments and Service	19/04/2018

7 OTHER RELEVANT / ASSOCIATED DOCUMENTS	
Unique Identifier	**Title and web links from the document library**
CORP/GUID/045	Management of Anaphylaxis in Adults http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-GUID-045.docx
CORP/POL/300	Medicine Policy http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-300.docx
CORP/PROC/185	Patient Identification Wristband http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-185.docx
CORP/PROC/301	Prescribing Medicines Zero Tolerance http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-301.docx
CORP/PROC/302	Controlled Drugs Safer Management of Controlled Drugs Procedure http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-302.docx
CORP/PROC/303	Intravenous Potassium Procedure http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-303.docx
CORP/PROC/310	Management of Medication Errors http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-310.docx
CORP/PROC/418	Hand Hygiene Procedure http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-418.doc
CORP/PROC/473	Performing and Aseptic Technique http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-473.docx
CORP/PROC/505	Aseptic Non Touch Technique (ANTT) In Intravenous Drug Administration http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-505.doc

7 OTHER RELEVANT / ASSOCIATED DOCUMENTS	
Unique Identifier	**Title and web links from the document library**
CORP/PROC/583	Safe Disposal of All Medicines Procedure http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-583.doc
CORP/PROC/312 Appendix 1	http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Attachments/Corp-Proc-312

8 SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS
References In Full
Crown. (1968). *Medicines Act 1968.* Available: http://www.legislation.gov.uk/ukpga/1968/67/contents
NHS Quality Control Northwest. *Quality Control Northwest.* Available: . https://www.qcnw.nhs.uk/welcome.php

9 CONSULTATION / ACKNOWLEDGEMENTS WITH STAFF, PEERS, PATIENTS AND THE PUBLIC		
Name	**Designation**	**Date Response Received**
	Pharmacy Quality and Governance Committee	March 2018
	Medicines Management Committee	April l2018

10 DEFINITIONS / GLOSSARY OF TERMS	
BNF	British National Formulary
Certificate of analysis	Certificate issued by a supplier of an unlicensed medicine giving details of analytical testing carried out and the results
CIVAS	Central intravenous additive service
D & T	Drug and Therapeutics
IV	Intravenous
Manufacturers Specials License	License issued by Medicines and Healthcare products Regulatory Agency to organisations wishing to place unlicensed medicines on the market in the UK
MIMS	Monthly Index of Medical Specialities

11 AUTHOR / DIVISIONAL / DIRECTORATE MANAGER APPROVAL			
Issued By	Angela Nelson	**Checked By**	Alastair Gibson
Job Title	Assistant Director of Pharmacy – Support Services	**Job Title**	Director of Pharmacy
Date	March 2018	**Date**	March 2018

APPENDIX 1: REQUEST AND RISK ASSESSMENT FOR UNLICENSED MEDICINES 2014

NHS
Blackpool Teaching Hospitals
NHS Foundation Trust

Request and Risk Assessment Form for Unlicensed Medicines 2014

This form should be completed by the prescriber in conjunction with a senior clinical pharmacist and the Trust Designated Pharmacist.

Before completing this form, you must have read the Trust Policy on the Prescribing, Use and Supply of Unlicensed Medicines (CORP/PROC/312) and must be aware of your responsibilities under this policy.

Please return the form to the Assistant Director of Pharmacy – Support Services

Page 1: Unlicensed Medicine Details

Product Name:.....
(International Non Proprietary Name)

Proprietary Name: .....
(if known)

Pharmaceutical Form .....

Strength: .....

Manufacturer: (if known).....

Indication: .....

Dose: .....

Frequency: .....

Route .....

Duration of Treatment:.....

Approx. no. of patients per annum.....

Why is an unlicensed Medicine being considered?

Pharmaceutically Equivalent Licensed product temporarily unobtainable*

Equivalent UK licensed product unavailable/unsuitable because.....

.....

.....

Other* Give details: .....

.....

.....

*Delete as appropriate
If 1, go to "Procurement Details" on page 3.

APPENDIX 1: REQUEST AND RISK ASSESSMENT FOR UNLICENSED MEDICINES 2014

Page 2: Clinical Evidence (To be completed by Prescriber)

Is there any evidence to support its use for the proposed indication? Yes / No

If not, is there any evidence to support its use for other indications? Yes / No

Is there evidence to support its proposed administration schedule (including dose, duration of treatment, concentration for parenteral products and route)? Yes / No

Is the active drug currently in a licensed product for use via the same route? Yes / No

Is the product licensed for the specified indication in an EU member state? Yes / No / Not known

Is the product licensed for the specified indication in a non-EU member state? Yes / No / Not known

Are other centres using this medicine? Yes / No. If so, name .....

.....

Summarise below the supporting evidence, list references and attach copies of references where available.

.....

What are the risks to the patient of not using this drug?

.....

What side effects or toxic effects have been reported?

Describe.....

Is any monitoring required? Yes / No

If so, describe .....

Are there any significant interactions? Yes / No

If so, describe .....

Is there patient information appropriate for intended use? Yes / No If so, attach.

Will there be any primary care implications? (e.g. need for a shared care protocol) Yes / No

If so, describe .....

Give details of contraindications and any other risks to the patient .....

.....

Precautions in use: .....

.....

Pharmaceutical Precautions: .....

Other Precautions:.....

APPENDIX 1: REQUEST AND RISK ASSESSMENT FOR UNLICENSED MEDICINES 2014

Page 3: Procurement Details (To be completed by Designated Pharmacist)

1. **Is the medicine to be obtained from**:
An NHS specials unit Y/N If yes, specify……and go to 6.

A commercial specials manufacturer	Y/N
A licensed importer	Y/N
A company which already has licensed products of the same active ingredient	Y/N
A licensed pharmaceutical wholesaler	Y/N

2. **Is a specification available?** Yes / No
If yes, attach a copy.
If no, then a full product specification will need to be drawn up in conjunction with Quality Control North West

3. **Is the product available "off the shelf"?** Yes / No

Manufacturer.....

4. **Is the manufacturer on the Manufacturer List given in the Quality Control North West Guidance Document GD 109?** Yes / No

5. **Is the manufacturer in the UK?** Yes / No

If no, complete questions 1 to 13 below:

1. Which country?: .....
2. Is this country within the EU? Yes / No
3. .If no, does this country have a mutual recognition agreement with the UK for the manufacture of medicinal products? Yes / No (If no seek QCNW Advice)
4. Importer: .....
5. Does the importer have a Wholesale Dealer Import Licence? Yes / No
6. What is the quoted importation time? .....
7. What quantity is to be imported? .....
8. What language is used on the label? .....
9. If not in English, is a translation available? Yes / No
10. Who will provide the translation? .....
11. Is an English Translation of the Patient Information Leaflet available? Yes / No
12. Who will provide the translation? .....
13. Are the English Translations Certified? Yes / No

If yes, by whom: .....

6. **Are there any problems associated with continuity of supply?** Yes / No

If so, describe .....

7. **What are the costs involved in obtaining this drug?** .....

8. **Issues raised by Quality Control North West** .....

.....

APPENDIX 1: REQUEST AND RISK ASSESSMENT FOR UNLICENSED MEDICINES 2014

Page 4: Details of Prescriber and Pharmacist Completing the Form

Form Completed by:

Pharmacist Name.....

Pharmacist Signature: ..... Date: .....

Prescriber Name: .....

Directorate/Speciality: .....

I have read the Trust Policy on the prescribing, use and supply of this unlicensed medicine and accept full responsibility for its use.

Signed: ..... Date: .....
(Consultant)

Outcome of Risk Assessment

Does Request need to be referred to Drug and Therapeutics? Yes / No

If no, give reasons .....

Drug and Therapeutics: Approval for use.

Is the medicine to be added to the formulary? Yes / No

Are there any restrictions on prescribing and use? Yes/No

If yes, please state.....

.....

Review Date: ..... Max 5 years)

Name .....

Signed..... Date: .....
Chairman of D&TCommittee(or Deputy)

Pharmacy Use

APPENDIX 2: EQUALITY IMPACT ASSESSMENT FORM

Department	Trust	**Service or Policy**	Policy	**Date Completed:**	19/03/2018

GROUPS TO BE CONSIDERED

Deprived communities, homeless, substance misusers, people who have a disability, learning disability, older people, children and families, young people, Lesbian Gay Bi-sexual or Transgender, minority ethnic communities, Gypsy/Roma/Travellers, women/men, parents, carers, staff, wider community, offenders.

EQUALITY PROTECTED CHARACTERISTICS TO BE CONSIDERED

Age, gender, disability, race, sexual orientation, gender identity (or reassignment), religion and belief, carers, Human Rights and social economic / deprivation.

QUESTION	**RESPONSE**		**IMPACT**	
	Issue	Action	Positive	Negative
What is the service, leaflet or policy development? What are its aims, who are the target audience?	Trust Policy			
Does the service, leaflet or policy/ development impact on community safety • Crime • Community cohesion	No			
Is there any evidence that groups who should benefit do not? I.e. equal opportunity monitoring of service users and/or staff. If none/insufficient local or national data available consider what information you need.	No			
Does the service, leaflet or development/ policy have a negative impact on any geographical or sub group of the population?	No			
How does the service, leaflet or policy/ development promote equality and diversity?	No			
Does the service, leaflet or policy/ development explicitly include a commitment to equality and diversity and meeting needs? How does it demonstrate its impact?	No			
Does the Organisation or service workforce reflect the local population? Do we employ people from disadvantaged groups	No			
Will the service, leaflet or policy/ development i. Improve economic social conditions in deprived areas ii. Use brown field sites iii. Improve public spaces including creation of green spaces?	No			
Does the service, leaflet or policy/ development promote equity of lifelong learning?	No			
Does the service, leaflet or policy/ development encourage healthy lifestyles and reduce risks to health?	No			
Does the service, leaflet or policy/ development impact on transport? What are the implications of this?	No			
Does the service, leaflet or policy/development impact on housing, housing needs, homelessness, or a person's ability to remain at home?	No			
Are there any groups for whom this policy/ service/leaflet would have an impact? Is it an adverse/negative impact? Does it or could it (or is the perception that it could exclude disadvantaged or marginalised groups?	No			
Does the policy/development promote access to services and facilities for any group in particular?	No			

APPENDIX 2: EQUALITY IMPACT ASSESSMENT FORM

Does the service, leaflet or policy/development impact on the environment • During development • At implementation?	No			

ACTION:			
Please identify if you are now required to carry out a Full Equality Analysis		**No**	**(Please delete as appropriate)**
Name of Author: **Signature of Author:**	**Angela Nelson**	**Date Signed:**	**19th March 2018**
Name of Lead Person: **Signature of Lead Person:**		**Date Signed:**	
Name of Manager: **Signature of Manager**		**Date Signed:**	