Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Injectable Medicines Policy

This procedural document supersedes: PAT/MM 5 v.5 – Injectable Medicines Policy

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Executive Sponsor(s):	David Purdue – Chief Nurse
Author/reviewer: (this version)	Rachel Wilson – Deputy Chief Pharmacist Carol Scholey - Infection Prevention & Control Practitioner
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Amendment Form

Version	Date Issued	Brief Summary of Changes	Author
Version 6	June 2021	• Updated references • Removed obsolete clinical skills packages on accountability and syringe drivers • Added clinical skills package on anaphylaxis • Updated care groups to divisions • Removed working in new ways document • Updated resources in appendix 1 • Formatted into new template	Rachel Wilson & Carol Scholey
Version 5	January 2018	• Included Medicine as potential contaminant where PPE is indicated • Added restrictions on using multi-use vials for individual patients • Removed UCL Hospitals Injectable Medicines Administration Guide (3rd Edition) as a resource for information • Updated the titles of the infection control policies in section 4.2 & 12	John Bane & Carol Scholey
Version 4	December 2014	▪ Re-ordered into new APD format. ▪ Removal of duplicate information specified in other policies. ▪ Explicit statement added with respect to open and closed systems. ▪ Reference added regarding multiple use on single use medicines.	Roger Hancocks and Maurice Madeo
Version 3	September 2011	▪ Added contents page ▪ Reference is now made the Clinical Skills training packages rather than Scope packages. ▪ The responsibilities of person administering injectable medicines reflect the NMC Standards for Medicines Management. ▪ Checking of injection medicines refers to the updated policy PAT MM 1 Appendix IX. ▪ Section 7 Standard Preparation method now refers to CSTP IV Drug Therapy rather than describing it in detail again here ▪ Section 8 Education and training - Refers to the CSTP rather than provide details.	Roger Hancocks

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1 INTRODUCTION

This policy is written to minimise the risks associated with the administration of medicine by the injectable route. It should be used in conjunction with the Trust Clinical Skills Training Package for Intravenous Drug Therapy. Successful completion of the Clinical Skills Training package (CSTP) will ensure staff have the necessary skills to undertake IV medicines administration.

2 PURPOSE

The purpose of this policy is to describe how the Trust manages the risk associated with injectable medicines. It describes the roles and responsibilities of staff, preparation guidelines, and the risk assessments require to achieve this.

3 DUTIES AND RESPONSIBILITIES

3.1 The Prescriber

It is the responsibility of the prescriber to ensure that medicines are only administered by injection when no other route is suitable. This decision will be based upon:

- The availability or otherwise of other routes.
- The clinical condition of the patient requiring the need for an immediate effect or ability to reach therapeutic levels.
- The available formulations of the specific medicine required.

It is the responsibility of the prescriber to ensure that intravenous prescriptions are reviewed regularly, at least once every 24 hours, unless clinically indicated otherwise. The prescription must be changed to a less hazardous route at the earliest clinically appropriate opportunity.

Prescriptions for injectable medicines shall be written in accordance with the standards for prescribing as set out in section 5 of PAT/MM1 – Safe and Secure Handling Medicines Policy.

3.2 Persons Authorised to Administer

Injectable medicines shall be administered in accordance with the standards for administration as set out section 6 of PAT/MM1 – Safe and Secure Handling Medicines Policy.

Only persons who have demonstrated that they are competent to undertake administration of intravenous medicines may do so.

The Consultant is responsible for ensuring that only competent medical staff in their team undertake intravenous medicine administration and undergo regular re-assessment.

The nurse in charge of an area is responsible for ensuring that only competent nursing staff undertake intravenous medicine administration and undergo regular re-assessment. As a minimum, updates should be undertaken at least every three years where updating has not been identified earlier.

3.2 Persons Checking

Where the policy PAT/MM1 Safe and Secure Handling of Medicines requires the administration of an injectable medicine to be checked, they shall be checked in accordance with Appendix 4 of PAT/MM1 – Safe and Secure Handling of Medicines Policy.

The process of double checking involves two people working together, but staff should be aware that this can present dangers where staff prompt each other to reach the same conclusion.

3.3.1 Calculations

Calculations must be undertaken independently and the results compared by the two operators at the end.

There is a risk that if a person checks the working out of a calculation and they are not entirely confident in their maths ability they will confirm any error made.

4 PROCEDURE

4.1 PREPARATION GUIDELINES

Unless otherwise approved by the Drug and Therapeutics Committee medicines prepared for administration shall be administered immediately by the person who has prepared the medicine or in their presence.

Unless otherwise approved by the Drug and Therapeutics Committee medicines for injection in clinical areas must not be prepared in advance and stored for later administration.

Injections should only be prepared by healthcare staff who understand the risks involved and have been trained to use safe procedures.

The following information is intended as guidance where preparation is planned and is not necessarily applicable in an emergency situation. However, the procedure must be carried out in the safest manner possible regardless of the situation.

4.1.1 The Environment

All areas where IV medicines are administered should aim to have a designated area where preparation can take place.

The minimum standard for the preparation area shall be as follows:

- The area shall display the model instructions for the preparation of parenteral medicine.
- The work surfaces shall be easily cleaned and impervious to liquid
- Alcohol based hand rub shall be available.
- The area shall be situated away from sinks and windows, as these represent a microbiological risk. Where there is a window in the room it shall be closed when medicine preparation is being under taken.
- When preparing more than one product for administration the operator shall work in a systematic way to reduce the risk of error; preparing one product completely before commencing the next (starting with the flush first).

Before preparation the operator shall:

- Check the prescription to ensure they understand precisely what is required.
- Check the dose.
- Check the medicine has not already been given.
- Read and understand any relevant information leaflet concerning preparation, safety, handling, or reconstitution of the medicine being prepared.
- Assemble the appropriate materials.
- Prepare any relevant labels.
- Check that the components have not expired.
- Check that the components are physically compatible.
- Check that there are no therapeutic interactions with currently prescribed medicines or other contraindications.
- Check that the infusion solution is compatible with the infusion device.
- Check the integrity of the packaging of any components being used.

4.1.2 Infection Control

The hands of staff are the most common vehicle by which micro-organisms are transmitted between patients and are frequently implicated as the route of transmission in outbreaks of infection (EPIC 3, 2014).

This policy must be read in conjunction with Infection Control policies;

- PAT/IC 19 Standard Infection Prevention and Control Precautions Policy
- PAT/IC 5 Hand hygiene

Correct aseptic technique, the observation of standard precautions and the maintenance of product sterility are necessary to minimise the risk of cross infection.

a) Personal Protective Equipment (PPE)

Gloves and plastic aprons must be used to protect both the wearer and patient against contamination by medicines, blood, body fluids, and micro-organisms.

Non sterile gloves are adequate. Powdered, polythene, or vinyl gloves must not be used. Gloves and apron must be discarded after each procedure as non-infected waste.

b) Hand washing

Hands must be decontaminated before and after all procedures, and before putting on and after removing gloves. Hands must be washed in liquid soap when visibly soiled and must be dried with paper towels. In all cases before putting on gloves hands must be disinfected using alcohol based hand rub.

c) Swabbing

Before preparation all additive ports, ampoules and tops of vials must be disinfected using an approved alcoholic swab.

Tamper evident caps or metal covers that protect vials do not ensure sterility and must be removed before swabbing.

d) No Touch Technique

Medicines for injection shall be prepared using a 'No Touch' technique. This means being aware of, and avoiding touching the critical areas, such as needles, syringe tips, vial tops, infusion ports, additive ports and the necks of ampoules where greatest risk of contamination can occur.

e) Single and Multi-Use of Ampoules, Vials, and Infusion Bags

The majority of injectable medicines are intended for immediate use with a single patient. Only a small number of injectable medicines in vials, containing preservatives are intended for multiple use, for example **insulin** and some sodium **heparin** products. There are risks of contamination if single use injectable medicines are used multiple times with different patients. To mitigate this risk, multi-use vials like insulin should be reserved for one patient only and not shared between patients. On accessing the multi-use vial for the first time, a label should be applied to the product with the patients name and date of opening on it to ensure it is set aside for a single patient.

On no account should a single use injectable medicines be used for more than one patient, this is an unlicensed use that increases the risk of contamination, and patient harm. Failure to comply may result in disciplinary action for the individual.

Within a single procedure it is acceptable to withdraw from a single use vial or bag multiple doses, for a single patient provided a closed system is used. At the end of the procedure the remaining contents must be discarded. In all other circumstance when only a part of the

medication in a 'un-preserved' ampoule or vial is required, the remainder must be discarded; it must not be reserved for further patients nor retained for the same patient requiring a later dose

f) Administration Sets

In all cases the integrity of the packaging must be ascertained before use.

Set out below are the recommended maximum times before administration sets shall be changed. In all cases where contamination is suspected or the integrity of the product or system has been compromised the set shall be changed immediately. If a giving set is disconnected from a patient any remaining solution and giving set must be discarded. The administration and fluid balance charts must be annotated to record the fluid administered. Administration sets and unused fluids must be disposed of in accordance with the Trust Waste Management Policy CORP/ HSFS17.

Continuous Administration Sets

Primary and Secondary continuous administration sets shall be changed at least every 72 hours.
Primary sets which have been disconnected from the patient or secondary sets that have been disconnected from the primary must be discarded after use.

Intermittent Administration Sets

Primary intermittent administration sets shall be discarded after each use.

Parenteral Nutrition

Administration sets used to deliver parenteral nutrition must be changed every 24 hours using an aseptic non touch technique. Parenteral nutrition bags must not be re-spiked.

Blood and Whole Blood Components

The use of administration sets for blood and whole blood component must be done in accordance with Blood Transfusion Policy (PAT/T 81).

4.1.3 Open and Closed Systems

Notwithstanding the withdrawal of a single dose from an open ampoule, injectable medicines shall be prepared and administered using closed systems.

Under no circumstance should injectable medicines be decanted into **open gallipots** prior to drawing up and administration.

4.1.4 Labelling

a) Bolus medicines

Under no circumstances should an operator be in possession of more than **one** unlabelled syringe at any **one** time (NPSA 2007a). As bolus medications are given using a flush-medication-flush technique, even when only one IV medicine is being administered, the flush must be labelled so that the person administering them does not confuse the flush with the medication.

Prepare flush first and apply pre-printed label. Then prepare the product to be administered and write the medication name on a blank label (if no product-specific labels are available) and apply to the syringe as soon as the medicine is prepared.

As the purpose of the label here, is simply to identify contents of syringes that are given immediately after preparation, (unlike preparation for infusions), information such as diluent used etc. are not required.

b) Medicines for Infusion

Any intravenous product prepared by adding to an infusion bag shall be labelled. Standard labels are available. Where manufacturer's labels are used the following minimum information must be provided:

- Patient name
- Date of preparation
- Time of preparation
- Drug name
- The concentration (expressed as total mass of drug in total volume of infusion)
- The diluent name
- The expiry date and time (following preparation)
- The initial of the person preparing
- The initial of the person checking
- Other information may include
- Route
- Ward

Where a small volume infusion bag is used with a device that retains the vial of the medicine added to the bag, labelling is not mandatory, provided the infusion time is less than 30 minutes.

c) Documentation

It is recommended that complex calculations are documented in the clinical record for future reference.

The person administering the medication and the person checking the preparation and administration should make a record of the administration, as soon as possible after the event.

4.2 RISK ASSESSMENTS AND ASSURANCE

4.2.1 Ward and Departments

The Divisional Directors of Nursing shall ensure that the appropriate person (usually the nurse in charge) of each ward or department shall undertake an annual assurance audit of clinical practice (see Appendix 1). The audit will cover all practice in an area and not only those activities undertaken by nurses. The assurance document will be based upon the risk identified in the National Safety Patient Agency (NPSA) alert 20. It is the responsibility of the Divisional Clinical Governance Group to review the results obtained and mitigate any risks identified.

4.2.2 Medicines

The Medicine Information Pharmacist will risk assess injectable medicines which are new to the Trust. Injectable medicines shall be subject to risk assessment in accordance with the NPSA risk assessment tool. In addition account will be taken of the location the product is held and the frequency with which the operators use the product. Based upon these risk assessments the stocking of medicines may be restricted to specified areas.

As a mitigating factor clinical areas should have access to Medusa the Online Injectable Medicine Guide which contains monographs for injectable medicines.

The following medicines are always defined as high risk and shall **not** be manipulated outside the Pharmacy Department Specialised Dispensing Service.

- Parenteral Nutrition – Seals may be broken of dual and triple chamber bags but additions must not be made on the wards and departments.
- Cytotoxic Medicines – Shall be provided in a ready to use form.

4.2.3 Identification of High Risk Medicines to Users

Medicines deemed to be high risk will be identified to users.

The risk assessment will be based upon the NPSA Risk Assessment Tool score, likely area of use and familiarity of the operator with product and frequency of use. Therefore not all products which score as High Risk according to the NPSA alert will be identified as many will be used in specialist areas with competent users

The identified medicines are likely to be available in a number of non-specialist areas and would represent a risk if stock were transferred between wards and departments

These high risk medicines are identified on the Pharmacy stock control system and are labelled as follows:

This medicine has been assessed as HIGH RISK
If you are not familiar with its use, you must contact a pharmacist BEFORE ADMINISTERING this medicine

This medicine must not be supplied to another ward unless specifically authorised by a pharmacist

4.2.4 Non Stock

Some medicines are never held on wards or departments but are issued only following the authorisation of a pharmacist; the pharmacist will ensure that personnel on the ward or department understand how to administer the medicines correctly.

This is a dynamic list and the current list of non-stock medicines is held by pharmacy.

4.3 STANDARD PREPARATION METHODS

Where applicable always prepare and label the flush first.

Unless indicated in the manufacturer's literature standard preparation methods shall be used.

Standard preparation methods for preparing intravenous preparations are described in the Clinical Skill Training Package – Intravenous Drug Therapy

The nurse in charge or healthcare professional in charge of a department is responsible for ensuring that their staff are competent to administer injectable medicines described in their basic training. In the case of medical staff the consultant is responsible for their staff.

The following core Clinical Skills Training Packages apply to this policy:

- Intravenous Drug Therapy.
- Anaphylaxis

Only persons who have demonstrated that they are competent to undertake intravenous medicines administration may do so. The Consultant is responsible for ensuring that only competent medical staff in their team undertake intravenous medicine administration and undergo regular re-assessment.

The nurse in charge of an area is responsible for ensuring that only competent nursing staff undertake intravenous medicine administration and undergo regular re-assessment. As a minimum updates should be undertaken at least every three years where updating has not been identified earlier and every two years for anaphylaxis training.

The use of electronic infusion equipment shall only be undertaken by persons who have demonstrated they are competent to use them.

Only medical devices with luer connectors are to be used for preparation and administration of injections.

4.4 READY TO USE INJECTABLE MEDICINES

Where available the Trust, through the Drug and Therapeutics Committee, will consider the purchase of medicines in a ready to use form or will purchase devices that aid their preparation. The Drug and Therapeutic Committee will take into account the risks presented by the original preparation, benefit of the ready to use preparation, its licensed status, likely hood and consequences of untoward incidents

Ready to use in this context also means a liquid medicine in an ampoule of the correct concentration which only needs to be drawn up in a syringe prior to administration.

PATIENTS LACKING CAPACITY

Sometimes it will be necessary to provide care and treatment to patients who lack the capacity to make decisions related to the content of this policy. In these instances staff must treat the patient in accordance with the Mental Capacity Act 2005 (MCA 2005).

- A person lacking capacity should not be treated in a manner which can be seen as discriminatory.
- Any act done for, or any decision made on behalf of a patient who lacks capacity must be done, or made, in the persons Best Interest.
- Further information can be found in the MCA policy, and the Code of Practice, both available on the intranet.

There is no single definition of Best Interest. Best Interest is *determined on an individual basis. All factors relevant to the decision must be taken into account, family and friends should be consulted, and the decision should be in the Best interest of the individual. Please see S5 of the MCA code of practice for further information.*

5 TRAINING/SUPPORT

The following core Clinical Skills Training Packages apply to this policy:

- Intravenous Drug Therapy.
- Anaphylaxis

All areas where IV medicines are administered shall have available the following standard references:

- The BNF https://bnf.nice.org.uk/

- The up to date Summary of Product Characteristics, datasheet or manufacturers package information detailing as applicable ; instruction for reconstitution; compatibility with infusion fluids or other medicines; limits on the concentration of the final solution; stability; and administration rate.
- N.B. Technical information on preparation and administration of all licensed medicines can be found on-line at www.medicines.org.uk
- Medusa the Online Injectable Medicine Guide found at http://bit.ly/2mMhPY8

The use of electronic infusion equipment shall only be used by persons who have demonstrated they are competent to use them.

Please note: The Standard Learning Needs Analysis (LNA) – The training requirements of staff will be identified through a learning needs analysis. Role specific education will be delivered by the service lead.

6 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Compliance with policy	Divisional clinical governance teams	Ongoing monitoring	Datix reports reviewed by clinical governance groups
Annual assurance audit of practice	Appropriate person, usually the nurse in charge	Annually	Divisional clinical governance group
Competence of staff to undertake intravenous medicine administration	Nurse in charge or consultant	Ongoing	Observation of practice, monitoring of Datix and training records. Divisional teams

7 DEFINITIONS

Closed System

Packaging and presentation of an injectable medicine and/or procedures followed to prepare doses for use, which are designed to ensure the injection solution never comes in direct contact with the open air.

Open System

Packaging and presentation of an injectable medicine and/or procedures followed to prepare doses for use, which DO NOT prevent the injection solution from coming in direct contact with the open air. Exclude a single withdrawal of solution from an open ampoule.

8 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment for All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 2)

9 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

Blood Transfusion Policy; Blood Components, Blood Products and Transfusion Reactions – PAT/T 81
Hand Hygiene Policy – PAT/IC 5
Mental Capacity Act 2005 Policy and Procedure, including Deprivation of Liberty Safeguards (DoLS) - PAT/PA 19
Privacy and Dignity Policy - PAT/PA 28
Safe and Secure Handling of Medicines Policy Part A – PAT/MM 1
Standard Infection Prevention and Control Precautions Policy – PAT/IC 19
Waste Management Policy – CORP/HSFS 17A
Waste Management Manual – CORP/HSFS 17B

10 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) 2016).

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website:

https://www.dbth.nhs.uk/about-us/our-publications/uk-data-protection-legislation-eu-general-data-protection-regulation-gdpr/

11 REFERENCES

epic3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England. The Journal of Hospital Infection Volume 86, Supplement 1, Pages S1–S70, 2014.

Department of Constitutional Affairs
Mental Capacity Act (2005): Code of Practice, 2007 www.dca.gov.uk

NPSA. Patient Safety Alert 20 "Promoting the Safer Use of Injectable Medicines" 2007. https://www.sps.nhs.uk/articles/npsa-alert-promoting-safer-use-of-injection-medicines-npsa-20- 2007/

NPSA: (2007a) PROMOTING SAFER USE OF INJECTABLE MEDICINES: (A template standard operational procedure): National Patient Safety Agency

RCN: Medicines Management: An Overview for nursing, Royal College of Nursing London, 2020 www.rcn.org.uk

RCN: STANDARDS FOR INFUSION THERAPY, Royal College of Nursing London, 2016 www.rcn.org.uk

Royal Pharmaceutical Society (RPS) and Royal College of Nursing RCN)
Professional Guidance on the Administration of Medicines in Healthcare Settings, 2019 www.rpharms.com

Specialist Pharmacy Service. Multiple Use of Injectable Medicines in Clinical Areas – V2, 2020 https://www.sps.nhs.uk/wp-content/uploads/2019/12/Multiple-Use-of-Injectable-Medicines-in-Clinical-Areas-V2-February-2020.pdf

APPENDIX 1 – ASSURANCE AUDIT TEMPLATE

Assurance Statement	Guidance
The ward or department staff have sufficient written information or access to online information to ensure they can prepare injectable medicines safely	What Information do you have available on the ward? Is the Information up to date? Minimum suggested resources: BNF Summary of Product Characteristics Medusa the Online injectable Medicines Guide
The ward or department staff label injection syringes after preparation to distinguish between different bolus injections and flushes.	All syringes, including flushes and infusions, must be labelled immediately after preparation by the person who prepared them. The only exception to this situation is where preparation and bolus (push) administration is one uninterrupted process and the unlabelled product does not leave the hands of the person who prepared it. Only one unlabelled medicine must be handled any one time
The ward or department staff never decant injectable medicines from their original containers into open gallipots before drawing up the dose	Do you ever prepare anything when you open a product to the outside environment? Take tops off vials? Open an ampoule and withdraw multiple doses?
The ward or department staff never prepare more than a single dose of an injectable medicine from ampoule, vial or infusion (unless the product is specifically licensed for use in this way or it is used within a procedure for a single patient using a closed system)	Single use injection are not used for more than one patient Multiple doses are not withdrawn from open ampoules Single use vials are not stored for later use
The ward or department staff never prepare cytotoxic injectable medicines.	Cytotoxic medicines are supplied by the pharmacy in a ready to use form.
The ward or department staff never prepare or make additions to total parenteral nutrition solutions (TPN)	TPN solutions are supplied by the Pharmacy in a ready to use form. No addition are made to these bags on the ward
The ward or department staff never prepare or administer an infusion bag or syringe that is given over a period longer than 24 hours	Where additions have been made to bags or syringes for infusion, the maximum duration of infusion is 24 hours
The ward or department staff always consult the Pharmacy service to check stability where two or more active medicines are added to an infusion, unless there is local information available, e.g. the Palliative Care Handbook	When preparing syringe drivers that contain more than one medicine, how do you ensure the resulting mixture is stable?
The ward or department staff always have available an appropriate infusion pump or syringe driver to administer injectable medicines that require their rate of infusion to be controlled	

APPENDIX 2 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Division	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Injectable Medicines Policy	Trust Wide	Rachel Wilson	Existing	June 2021

1) Who is responsible for this policy? Dug and Therapeutics Committee

2) Describe the purpose of the service / function / policy / project/ strategy? To minimise the risks associated with the administration of intravenous medicines

3) Are there any associated objectives? CQC standards and national best practice guidelines

4) What factors contribute or detract from achieving intended outcomes? – Non-compliance with policy

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] –

6) Is there any scope for new measures which would promote equality? N/A

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	No	
b) Disability	No	
c) Gender	No	
d) Gender Reassignment	No	
e) Marriage/Civil Partnership	No	
f) Maternity/Pregnancy	No	
g) Race	No	
h) Religion/Belief	No	
i) Sexual Orientation	No	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form – see CORP/EMP 27.

Date for next review: June 2024

Checked by: Andrew Barker **Date: June 2021**