London Ambulance Service NHS
NHS Trust

Policy and Procedure for the Ordering, Storage, Use and Destruction of Controlled Drugs within the LAS

DOCUMENT PROFILE and CONTROL.

Purpose of the document: Provide all members of LAS staff with a policy and procedure, regarding the procurement, carriage, storage use and destruction of controlled drugs within the LAS.

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Sponsor Department: Medical Directorate

Author/Reviewer: Senior Clinical Adviser to the Medical Director. To be reviewed by June 2012.

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17/03/2010	1.1	Senior Clinical Adviser to the Medical Director	Reformatted. Added Introduction, scope, objectives, monitoring. Revised responsibilities. Revised appendix 1, added appendices 3 and 4. Re-written to include changes to carriage of morphine sulphate, and other controlled drugs by LAS staff, and the SOP for the destruction of out of date controlled drugs. Expanded incident reporting process and disposal of drugs at scene.
18/06/2005	0.1	Senior Clinical Adviser to the Medical Director	First draft

***Version Control Note:** All documents in development are indicated by minor versions i.e. 0.1; 0.2 etc. The first version of a document to be approved for release is given major version 1.0. Upon review the first version of a revised document is given the designation 1.1, the second 1.2 etc. until the revised version is approved, whereupon it becomes version 2.0. The system continues in numerical order each time a document is reviewed and approved.

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Links to Related documents or references providing additional information		
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OP 002	Procedure covering the issue & use of drugs by LAS Staff. (POMs)	Revised 27/09/2008
H&S 011	Incident reporting procedure	
	Misuse of Drugs Act 1985	
	Good practice in prescribing medicines – guidance for doctors (GMC; Sept 2008)	
	Misuse of Drugs Regulations 2001	
	The Joint Royal Colleges Ambulance Liaison Committee (JRCALC) in their National Clinical Guidelines for use in UK Ambulance Services	
	A guide to good practice in the management of controlled drugs in primary care 2009	
	Medicines Act 1968	
	Duthie Report 1998	
	Crown Report 1999	
	Health and Social Care Act 2001	
	Hazardous Waste (England and Wales) Regulations 2005	
	Health Act 2006	
	Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs 2007	

Document Status: This is a controlled record as are the document(s) to which it relates. Whilst all or any part of it may be printed, the electronic version maintained in P&P-File remains the controlled master copy. Any printed copies are not controlled nor substantive.

1. Introduction

The majority of this policy and procedure refers directly to the storage, administration and destruction of morphine sulphate injection for intravenous (IV), intramuscular (IM) or subcutaneous (SC) administration. This will be referred to as “morphine for injection”.

Where it needs to refer specifically to diazepam IV or rectal (PR) administration or morphine sulphate for oral administration that distinction will be made clear. These will be referred to as “diazepam” and “oral morphine” respectively.

The term “controlled drug” as used in this policy applies to the following drugs under their respective Schedules of the Misuse of Drugs Act 1985:

- Morphine sulphate injection – Schedule 2
- Diazepam (and thus diazemuls) – Schedule 4
- Morphine sulphate oral solution (10mg/ 5ml) (Oromorph) – Schedule 5

Morphine is a Class A Controlled Drug under schedule 2 of the Misuse of Drugs Act 1985, and is therefore subject to full controlled drug requirements relating to prescriptions, safe custody and the requirement to keep and register records.

Diazepam IV and PR, and morphine sulphate oral solution, by virtue of their respective places in Schedule 4 & 5 of the Misuse of Drugs Act 1985 are not subject to the same record keeping regulations as morphine sulphate injection. However they will be subject to the same destruction of unused pharmaceuticals procedure laid out in Appendix 2, and to the loss or theft actions detailed in this policy and procedure using the electronic form at Appendix 3. Further guidance on the storage and administration of diazepam and morphine sulphate oral solution is contained within OP 002 – Procedure covering the issue & use of drugs by LAS Staff (POMs).

The London Ambulance Service NHS Trust (LAS) allows the administration of morphine sulphate, morphine sulphate oral solution, diazepam for intravenous use and diazepam for rectal use to a patient by registered paramedics only. This is in accordance with the relevant group authorities issued under The Misuse of Drugs Regulations 2001. A registered paramedic is defined as a person whose name appears in the relevant part of the Register maintained by the Registrar of the Health Professions Council under the rules of Part III of the Health Professions Order 2001.

Medical practitioners registered with the General Medical Council (GMC) who are employees of the London Ambulance Service NHS Trust, (LAS Doctors), are also permitted, subject to the Medical Director’s discretion, to have access to LAS controlled drugs. Such doctors will abide by this policy in terms of the storage, signing in/ out whilst on duty only, and the destruction of unused amounts of controlled drugs. With respect to the indications, contraindications and doses they are expected to work within

their own scope of practice and professional judgement, and the advice of the GMC contained in *Good practice in prescribing medicines – guidance for doctors* (GMC; Sept 2008).

LAS registered paramedics must only draw controlled drugs for the duration of their shift period. Under no circumstances are these drugs to be retained whilst staff are off duty.

Guidance with regard to whom and at what dose morphine sulphate, morphine sulphate oral solution, diazepam for intravenous use and diazepam for rectal use may be administered is provided by The Joint Royal Colleges Ambulance Liaison Committee (JRCALC) in their National Clinical Guidelines for use in UK Ambulance Services. This guidance has been wholly adopted by the LAS.

The Misuse of Drugs Regulations 2001 defines those persons who are authorised to supply and possess controlled drugs while acting in their professional capacities, and describes the conditions under which these activities may be carried out. In these regulations consideration must be given to such activities as import, export, production, supply, possession, prescribing, audit and record keeping relevant to that particular drug.

The safe and secure handling of morphine sulphate within the LAS requires appropriate policies, procedures and quality assurance systems to be in place so that it is handled safely and securely, in accordance with legislative requirements and established best practice. This policy must be read in conjunction with the LAS Risk Management Framework.

The Accountable Officer, as required by the Department of Health in their guidance on the governance arrangements for controlled drugs, will be the Medical Director of the London Ambulance Service.

The person appointed by the Accountable Officer for the witnessing of the destruction of controlled drugs is the Corporate Logistics Manager.

2. Scope

This policy and procedure refers to all personnel legally authorised to possess and administer those controlled drugs used by the LAS. It relates to the daily operational management of all controlled drugs:

- Morphine sulphate injection
- Diazepam (and thus diazemuls)
- Morphine sulphate oral solution

All other issues relating to the storage, issue, administration and disposal of drugs by LAS staff is found in OP 002 – Procedure covering the issue & use of drugs by LAS Staff (POMs).

This policy and procedure does not cover the use of any controlled drug used by the Voluntary Aid Society staff, i.e., St. John Ambulance, British Red Cross, BASICS or private organisations subcontracted by the LAS.

This policy and procedure gives clear guidance on the record keeping, security and destruction of controlled drugs used by the LAS. For these areas it draws on the following guidelines or legislation:

- Misuse of Drugs Act 1985
- Misuse of Drugs Regulations 2001
- Medicines Act 1968
- Duthie Report 1998
- Crown Report 1999
- Health and Social Care Act 2001
- Hazardous Waste (England and Wales) Regulations 2005
- Health Act 2006
- Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures for Controlled Drugs 2007
- A guide to good practice in the management of controlled drugs in primary care 2009

3. Objectives

1. Defines which controlled drugs the LAS uses.

2. Gives guidance to staff on their responsibilities in relation to all aspects of controlled drugs.

3. Gives specific guidance on the actions to take if any controlled drug is lost / stolen or misplaced

4. Details the method by which unused controlled drugs are to be disposed of.

5. Details the procedure to be applied for destroying all out of date controlled drugs.

4. Responsibilities

All staff who are involved in the ordering, storage, carriage, use and administration of controlled drugs held by the LAS are under an explicit legal obligation to report any discrepancies, no matter how minor, as soon as possible to either an Ambulance Operations Manager (AOM), Duty Station Officer (DSO), Emergency Operations Centre (EOC), or other appropriate manager, in order that the matter can be quickly and thoroughly investigated. In addition all discrepancies must be recorded in the Station Occurrence Book.

IN ADDITION

If ANY drug in the possession of any person by virtue of their authority to store, carry or administer that drug is stolen or otherwise lost, the loss shall be reported by that person as soon as possible to EOC and then to the local police station. Thereafter, a full L.A.S. Loss / Theft report must be submitted to the AOM for full investigation. The AOM must also inform the Drug Licensing and Compliance Unit of the Home Office using the “Theft / Loss” form reproduced at Appendix 3, via the following e-mail link:- licensing_enquiry.aadu@homeoffice.gsi.gov.uk

The Medical Director, Assistant Director of Operations and the Corporate Logistics Manager must also be informed of any thefts or loss.

Further specific advice to staff is detailed below (Please also note Section 13 of this document).

There is also an exemplar sheet of a Controlled Drugs Register at Appendix 1.

4.1 Specific Responsibilities

The specific responsibilities for specific grades of staff are detailed below.

4.1.1 Registered Paramedics

The responsibilities of individual registered paramedics no matter what their rank / grade in the LAS in relation to controlled drugs are as follows:

- Receiving, checking, recording and storage of stock as appropriate;
- The safe and legal possession of any controlled drug that is in their possession as a result of their duties;
- Returning unused units to stock following shift completion and amending all balances accordingly;
- On occasion signing for the morphine sulphate received into stock and recording the event in the ambulance station's controlled drugs register;
- Recording the amounts of morphine sulphate issued from or returned to stock;
- Recording accurately in the patient's clinical record the amount of drug administered;
- Reporting adverse incidents involving controlled drugs, as soon as is possible to LAS management, and via the LA52 Untoward Incident reporting system;
- Safe disposal of any unused controlled drugs that remain in open units or syringes via the destruction system outlined in Appendix 2. This system is colloquially known as a "DOOP jar" or "DOOP System".

4.1.2 Ambulance Operations Managers

Only an AOM acting for the Complex for which they are responsible, can order morphine sulphate from the LAS Corporate Logistics Manager. However, AOMs may delegate this task to no more than five named registered paramedics /Team Leaders /DSOs /Administrative Staff per complex. These named individuals must be made known to the Corporate Logistics Manager. Record sheets that document the specimen signatures of all such personnel are available from the LAS Corporate Logistics Manager and once completed must be sent to the LAS Corporate Logistics Manager, and also placed in the personnel file of the relevant member of staff. If a member of staff moves from one station or Complex to another, consideration must be given by the

AOM as to whether they are removed from the Authorised Signatory Sheets for that Complex.

The responsibilities of individual AOMs in relation to morphine sulphate are as follows:

- Ordering morphine sulphate from LAS Corporate Logistics Manager;
- Regular auditing of station and authorised individuals record keeping;
- Checking and reconciling controlled drugs stocks and register accuracy, at least quarterly;
- Ensuring that any adverse incidents involving morphine sulphate are reported appropriately.
- Changing the keypad code for the controlled drugs safe every third payday from the previous change. The change is then to be notified by e-mail to the Corporate Logistics Manager.
- Ensuring that Duty Station Officers and Station Administration Staff who are not registered paramedics understand their role in assisting the AOM to ensure this policy is adhered to by all members of staff.

4.1.3 Assistant Director of Operations

The safe storage and maintenance of records / registers for controlled drugs within the Sector for which they are responsible will be audited, unannounced, on an annual basis by the Assistant Director of Operations, or a person delegated under their authority to carry out the audit.

4.1.4 Duty Station Officers and Team Leaders

Duty Station Officers and Team Leaders in addition to their duties specified above, if they are registered paramedics (section 4.1.1 & 4.1.2), are to assist the AOM in ensuring that Daily Audit Checks are carried out and that the general security of controlled drugs and observance of this policy is carried out by all grades of staff.

4.1.5 Accountable Officer

The Accountable Officer is responsible for the safe management and use of controlled drugs within the LAS.The full responsibilities of the Accountable Officer are placed in Appendix 4. of this document.

5. Definitions

5. Storage of Controlled Drugs on LAS premises

5.1 The law requires that there must be suitable and sufficient provision for safe and secure storage of controlled drugs on all LAS premises.

5.2 Currently the only controlled drug to be stored in a “controlled drug” safe on stations is morphine sulphate for IV, IM or SC use. Diazepam IV & PR, and morphine sulphate oral solution will be stored and issued via the paramedic drug packs and thus subject to OP 002 – Procedure covering the issue & use of drugs by LAS Staff (POMs).

5.3 Each Ambulance Station and the Logistics HQ will have a controlled drugs safe accessible only by an electronic keypad which has been sited on the advice of the LAS Estates Department.

5.4 The controlled drugs safe must only be opened by persons authorised by the LAS for legal reasons and the safe keeping of key codes is essential.

5.5 Currently the only persons allowed access to the controlled drugs safe are;

- Any person authorised by the Medical Director
- Registered Paramedics
- Duty Station Officers
- Team Leaders
- Ambulance Operations Managers – and those persons they have authorised locally so to do
- Assistant Directors of Operations
- Assistant Medical Directors
- Logistics Department personnel authorised by the Corporate Logistics Manager

5.6 The police may ultimately prosecute an individual or organisation where they consider that the regulations have not been complied with.

6. The Carriage of Morphine Sulphate in the possession of Registered Paramedics once signed out from a controlled drugs safe.

6.1 The law requires that there is acceptable provision for safe and secure storage of morphine sulphate on all vehicles in which controlled drugs are carried.

6.2 Morphine sulphate will only be carried in the receptacle detailed by the LAS. Currently this is a small belt pouch with a plastic ampoule holder provided individually to each registered paramedic by the LAS.

6.3 Morphine sulphate must not be placed / carried in any other holder / carriage device without the written permission of the LAS Accountable Officer.

6.4 Any controlled drug will only be prepared for use once its clinical need has been established. It must not be carried "pre-prepared" in any form.

6.5 If at any time the security of any controlled drug has been or could be compromised, the appropriate line-manager must be advised as soon as possible.

7. System for ordering and recording the storage and usage of morphine sulphate for injection in the LAS (General Information).

7.1 There is an absolute requirement in law that each unit of morphine sulphate for injection purchased by the LAS must be accounted for from the point of ordering to the point of administration to a patient, or disposal either as unused or as out of date.

7.2 The documents that the LAS will use to track the ordering, issue and usage of morphine sulphate will be:

- London Ambulance Service Controlled Drugs Order Book
- London Ambulance Service Controlled Drugs Register
- London Ambulance Service Assignment Record and Clinical Record Form
- London Ambulance Service Checked Correct Form
- London Ambulance Service Out of Date Controlled Drugs Form

7.3 The London Ambulance Service Controlled Drugs Order Book is a pre-printed order book that contains a two-part self carbonating form. This is the only form on which an order for morphine sulphate will be accepted at either the LAS Logistics Department, or at the pharmacy which supplies the LAS its drugs.

8. Station Controlled Drug Register

8.1 A separate controlled drugs register must be kept at each ambulance station for morphine sulphate that is received, stored and supplied to that station. This controlled drugs register will be kept in the controlled drugs safe.

8.2 Entries within the controlled drugs register must be made in indelible black biro or ink, and appear consecutively in date order.

8.3 All entries must be legible and made on the day of the transaction

8.4 No cancellation, obliteration or alteration of an entry will be made, and any corrections shall be made only by way of a marginal note.

8.5 Controlled drugs registers must be kept for two years from the last date of entry.

9. Witnessing Signatures in the Controlled Drug Register

9.1 When the unit(s) of morphine are signed out of the controlled drugs safe by paramedics, every effort must be made to obtain a witness to sign in the "Witnessed by …" column of the Controlled Drug Register.

9.2 On some occasions it is understandable and therefore acceptable that single responders may not be able to obtain a witness signature for the withdrawal or return of morphine. However the single responder should endeavour to obtain a witness signature at the earliest opportunity

9.3 It is acceptable for any member of staff such as Duty Station Officers, Emergency Medical Technicians and administration staff to witness to the withdrawal or return of morphine and sign in the appropriate place in the register. They are merely witnessing the signature of the paramedic withdrawing or returning the drug. (See also exemplar sheet at Appendix 1.)

10. Detailed guidance for requisitioning and receiving morphine sulphate into station stocks and usage

10.1 Requisition and Ordering of Drugs – Hospital Pharmacy

10.1.1 The Head of Procurement and Corporate Logistics Manager, in consultation with the supplying pharmacy, will be responsible for maintaining an ongoing review of the supply arrangements to ensure that they meet London Ambulance Service (LAS) needs and comply with current legislation. The corporate Logistics Manager will ensure that a register of all Logistics staff authorised to order, maintain, issue or transport morphine is produced and updated when necessary.

10.1.2 The Logistics Manager (Supply and Material Management or SMM) shall set a minimum / maximum stock level for morphine sulphate that can be regularly monitored. When stock reaches the agreed replenishment level, an order will be prepared for the supplying pharmacy.

10.1.3 All supplies of morphine will be ordered from the supplying pharmacy by the Logistics Manager (Supply and Material Management), or their designated deputy. The drugs will be ordered by means of an "Order for Controlled Drugs Record Book". This book will be maintained and stored at the designated LAS Storage and Distribution Centre. Used or completed books should be stored for a period of two years from the date of the last entry.

10.1.4 When completing the order book, the name of the drug preparation, strength and quantity should be entered in the appropriate boxes. The Logistics Manager (SMM) or the designated deputy should check that the details are correct, and then sign and date the numbered entry sheet (on line stating "Ordered by"). The order book should be taken to the supplying pharmacy.

10.1.5 When issuing the drugs, a designated person at the supplying pharmacy will sign the appropriate serial numbered sheet (on line stating "Supplied by"). The designated member of LAS Logistics Staff will then receive the drugs and confirm this by signing the appropriate serial numbered sheet (on line stating "Accepted for delivery"). The top (white copy) of the serial numbered sheet should be removed from the book and handed to the designated person at the hospital pharmacy. The second copy of the sheet (pink copy) should be left in the book. The drugs should then be secured in the lockable cabinet on the LAS delivery vehicle and returned to the Storage and Distribution Centre.

10.1.6 Should the supplying pharmacy not have sufficient stocks of morphine to fulfil the order, an amendment to the quantity requested on the serial numbered form should be made by the designated person at the pharmacy. This entry should be initialled and dated by that person and the designated Logistics staff.

10.1.7 When the drugs are returned to the Storage and Distribution Centre, the Logistics Manager (SMM), or their designated deputy, shall check that the drugs collected conform with the serial numbered sheet on the Order book. Account should be taken of any reduction in provision made by the Pharmacy as mentioned above. If the order has been correctly supplied, the sheet should be signed (on line stating "Received by"). If there are any discrepancies in the order supply, the Logistics Manager (SMM) or their designated deputy should immediately investigate the situation.

10.1.8 In addition to using the Order for Controlled drugs book, a requisition should also be raised on EROS. This should be authorised by the Logistics Manager (SMM) in the normal manner. When the order has been correctly delivered to

the store (or part delivered) the order should be receipted on EROS as soon as possible.

10.1.9 Morphine must only be ordered as outlined in this procedure. In particular, no member of staff is to replenish stocks from hospital sources.

10.2 Storage and Record Keeping

10.2.1 When an order has been delivered to the Storage and Distribution Centre, it should immediately be placed in the lockable storage cupboard by the Logistics Manager (SMM) or their designated deputy. The stock book held in the cupboard should be completed. The date, quantity of drug, serial number and expiry date should be recorded in the appropriate boxes. The stock level of the drug held should also be updated in the appropriate box. The Logistics Manager (SMM) or their designated deputy should witness that this action has been correctly carried out. The register should be retained for a period of two years from the date of the last entry

10.3 Ordering by Stations

10.3.1 Each main station will have an agreed minimum/ maximum stock level for morphine. When the stock reaches the replenishment level, an order should be raised.

10.3.2 Morphine will be ordered by main stations using their own “Order for Controlled Drugs” Book. A designated person on the station shall enter the station name on the serial numbered sheet in the book. They should then enter the strength and quantity required in the appropriate boxes on the sheet. The book will then be given to a designated member of the Logistics staff who will regularly call at the station.

10.3.3 The designated member of Logistics staff will take the record book back to the Storage and Distribution Centre and hand it to the Logistics Manager (SMM) or their designated deputy.

10.4 Issue of Stock from Storage and Distribution Facility

10.4.1 When an order is received from a main station, the Logistics Manager (SMM) or their designated deputy will draw the required amount of the drug from stock. The SMM will update the drug record book held in the lockable cabinet. The quantity drawn, serial number, and date should be recorded in the appropriate boxes. The stock level should then be adjusted to reflect the drugs withdrawn.

10.4.2 If there is not sufficient stock of the drug to fully meet the order requirement, the quantity requested on the serial numbered form will be amended by the Logistics

Manager (SMM) or their designated deputy. This amendment will be dated and initialled. When the designated member of the Logistics delivery staff takes possession of the order prior to delivery, this amendment should be explained to him and he should also be asked to sign and initial the serial numbered form.

10.4.3 When the Logistics Manager (SMM) has prepared the drug ready for deliver, they should sign and date the serial numbered page in the station record book (on line stating "Supplied by"). The order should then be secured in the lockable cabinet until the designated Logistics delivery driver is ready to collect it.

11. Delivery of Morphine by Logistical Staff

11.1 When starting their shift the designated Logistics staff should check with the Logistics Manager (SMM) or their designated deputy whether there are any morphine deliveries to be made. The member of staff will then be handed personally any such orders from the lockable cupboard.

11.2 When accepting the order from the SMM or their designated deputy, the designated member of Logistics staff should check the order is correctly drawn, checking if any reduction has had to be made as mentioned above. Any discrepancies should be discussed and resolved before the order is taken away for delivery. If the member of Logistics staff is content, they should sign and date the serial numbered sheet (on line stating "Accepted for delivery"), and place the order in the lockable cupboard on their delivery vehicle.

11.3 Morphine must be kept at all times in the lockable cupboard on the delivery vehicle. If the driver leaves the vehicle unattended for any period of time, they must ensure the drug storage cupboard and vehicle are locked at all times.

11.4 On arrival at the main station, the designated member of Logistics staff should remove the drug order from the cupboard and identify the designated member of station staff who is to receive the order. This should be a person authorised to order or check stocks of controlled drugs at a specific location whose name appears on the Controlled Drugs Authorised Signatories form.

11.5 When a designated person has been identified they should be asked to confirm that the delivery amount agrees with the order, taking account of any reductions made by the Storage and Distribution Centre. If agreed, they should sign and date the serial numbered form (on the line stating "Received by"). The top copy of the form (white) should be taken out of the book and retained by the designated member of Logistics staff. This should be returned to the Storage and Distribution Centre at the end of the shift. These forms must be retained for a period of two years.

11.6 If there are any discrepancies in the order delivery, the designated member of staff should inform the Logistics Manager (SMM) or their designated deputy and seek further instructions.

11.7 If it is not possible to locate a designated member of station staff, the order should not be left. The member of Logistics staff should make a note on the daily log sheet and return the order to the LM (SMM) or the designated deputy at the end of their shift. No undelivered orders should ever be left on a vehicle at the end of a shift.

11.8 The second copy of the serial numbered form (pink) should be left in the book when the book has been used and completed, it should be retained on the main station for a period of two years.

12. Audit

12.1 A daily audit of Morphine shall be carried out in the Storage and Distribution Centre. The Controlled Drugs Register should be checked against the stock held and reconciliation should be made. The "Order for Controlled Drugs" Books and serial numbered sheets retained from station books, and the Store based order books, should be checked against the stock records. The 'Controlled Drugs Checked Correct Record Form' should be completed on each occasion. This requires the date and time and the signature of the designated person checking to be entered. The quantity of drugs in the safe and the quantity recorded in the 'Controlled Drugs Register' should also be entered. The 'Controlled Drugs Checked Correct Form' should be kept for a period of two years from the last date entry.

12.2 If there are any discrepancies discovered, the Logistics Manager (SMM) or their designated deputy should investigate the situation immediately and suspend any further withdrawals of stock until the matter has been resolved. The Corporate Logistics Manager should also be advised of the situation.

12.3 When a stock audit is carried out, a line should be drawn under the last entry in the book. The date and findings of the audit should be recorded, and initialled by the auditor. A line should then be drawn under the audit entry for normal stock transactions to be resumed.

13. Daily Stock Check on Stations

13.1 The Ambulance Operations Manager will ensure that once in every 24 hour period for every station under their command, the Controlled Drug Record Book will be checked against the stock held in the controlled drug cupboard. The daily stock check needs to ensure that since the previous check, (dated and timed), all stock signed out has been signed back as either used or returned unused. This check will be recorded on the monthly Check Correction Sheet that will be held in

the controlled drug cupboard. Persons authorised by the AOM to perform this check must be detailed on the Authorised Signatories form.

13.2 This check should be carried out by the AOM or a member of his management/administrative team named on the Authorised Signatories List. Alternatively, the check may be carried out by a registered paramedic. The first paramedic to draw morphine sulphate from the controlled drugs cupboard after 07-00 hours each morning shall carry out an audit of the stock held. This process would be carried out in addition to the normal entry made on withdrawing.

13.3 The same audit procedure should be followed whether a manager or registered paramedic carries out the audit. The Controlled Drugs Register should be checked against the stock held and a reconciliation should be made. The Controlled Drugs Checked Correct Record Form should be completed on each occasion. This requires the date and time, name and the signature of the person checking to be entered. The quantity of drugs in the safe and the quantity recorded in the Controlled Drugs Register should also be entered.

13.4 Any discrepancies, no matter how minor, that are found during an audit must be reported as soon as possible to either an AOM/ DSO/ EOC or other appropriate manager, in order that the matter can be quickly and thoroughly investigated. In addition the Medical Director, the Assistant Director of Operations and the Corporate Logistics Manager must also be advised. All discrepancies must also be recorded in the Station Occurrence Book.

13.5 Once completed the Checked Correct Sheet will be stored for two years from completion in the AOM's Office.

13.6 When a stock audit is carried out a line should be drawn under the last entry in the book. The date and findings of the audit should be recorded, and initialled and dated by the auditor. A line should then be drawn under the audit entry for normal stock transactions to be resumed.

13.7 It is the responsibility of the AOM to ensure that robust arrangements are put in place to ensure the required audits are completed. This includes a process for ensuring that registered paramedics are carrying out the daily audit, should this option be taken up. Where this option is implemented, the AOM (or a member of their management/administrative team named on the authorised signatories list) must also carry out an audit of all Controlled Drugs Registers every five days. The process described in paragraph 8 above should be replicated. The auditor should check that registered paramedics have been completing daily audits as required. If any have not been undertaken, this should be reported to the AOM for investigation and action.

IN ADDITION

13.8 All staff who are involved in the ordering, storage, carriage, use and administration of morphine sulphate held by the LAS are under an explicit obligation to report any discrepancies, no matter how minor, as soon as possible to either an Ambulance Operations Manager (AOM), Duty Station Officer (DSO), Emergency Operations Centre (EOC), or other appropriate manager, in order that the matter can be quickly and thoroughly investigated. In addition all discrepancies must be recorded in the Station Occurrence Book.

13.9 If ANY drug in the possession of any person by virtue of their authority to store, carry or administer that drug is stolen or otherwise lost, the loss shall be reported by that person as soon as possible to EOC and then to the local police station. Thereafter, a full L.A.S. Loss / Theft report must be submitted to the AOM for full investigation. The AOM must also inform the Drug Licensing and Compliance Unit of the Home Office using the "Theft/ Loss" form reproduced at Appendix 3, via the following e-mail link: licensing_enquiry.aadu@homeoffice.gsi.gov.uk

13.10 The Medical Director, Assistant Director of Operations and the Corporate Logistics Manager must also be informed of any thefts or loss.

13.11 If a discrepancy is found the particular controlled cupboard must not have any more stock added to it, or taken from it until the matter has been fully investigated and resolved and with at least a person with the rank of Ambulance Operations Manager, given permission for it to be used again. All other controlled drug cupboards on the Complex should remain in operational use as normal. Should a controlled drug cupboard have to be 'locked out', staff can be allowed to sign morphine back in the normal manner. However, until the original problem is sorted out, the signing back must be supervised by a member of the Station Management Team, or someone nominated by the Ambulance Operations Manager if they so wish. An additional entry must be made in the Occurrence Book to this effect.

13.12 Morphine can be signed out from another station on the complex – but it will need to be signed back into the same Controlled Drugs Record Book register from which it was drawn.

13.13 If the discrepancy is discovered at a time when the member of staff is signing out morphine, and EOC contacts the station with a call to which that member of staff is required to attend, then the following procedure will be followed:

- Continue signing out the morphine they require, (up to the maximum of two units), in the "Stock Drawn" section in the normal manner. The figure placed in the "Stock Balance" column **must be the actual amount of stock that is physically in the controlled drug cupboard at that time**, then;

- Having completed the signing out process, draw a **single** line right across the page underneath that entry, then place their initials, the date and time at **both ends** of the line, then;

- If possible contact a member of Station Management on leaving the station, to inform them of the discrepancy;

- If there is no member of Station Management immediately available, then EOC must be contacted urgently via the radio or Crew Assist phone;

- EOC will then inform the appropriate AOM and Sec 13.11 above will apply.

13.14 If the discrepancy is discovered at a time when the member of staff is signing morphine back in, then the following procedure will be followed:

- Continue signing back in the morphine in the normal manner, completing all relevant details if morphine has been administered, or not as the case may be. The figure placed in the "Stock Balance" column **must be the actual amount of stock that is physically in the controlled drug cupboard at that time**, then;

- Having completed the signing in process, draw a **single** line right across the page underneath the last entry, then place their initials, the date and time at **both ends** of the line, then;

- If possible contact a member of Station Management on leaving the station, to inform them of the discrepancy;

- If there is no member of Station Management immediately available, then EOC should be contacted urgently via the reporting line, the radio or Crew Assist phone;

- EOC will then inform the appropriate AOM and Sec 13.11 above will apply.

14. Administration of any controlled drug to a patient – including disposal of unused amounts of controlled drugs at scene

14.1 As with any drug administered to a patient, the drug code, name, amount administered, number of doses, route, time and by whom administered must be recorded on patient's clinical record (LA4 / PRF).

14.2 In the case of diazepam and oral morphine the paramedic drug bag number must also be recorded in the "Drug Bag Code" boxes.

14.3 In the case of morphine for injection the controlled drugs register on the station from which it was drawn must be reconciled as soon as possible. The CAD Number and PRF number are to be recorded in the “PRF and CAD No” column.

14.4 Any unused amounts of morphine for injection, oral morphine or diazepam that were prepared for administration, but not actually given to a patient must be squirted onto a piece of tissue which is then placed into a sharps bin (all other “sharps” will be disposed of in the normal manner into the sharps bin as well).The disposal of all other drugs issued, administered, stored by the LAS is covered in OP/002.

14.5 The dosage actually administered to the patient (in mg), and the amount (in mg) that has been destroyed must both be recorded on the PRF. The amount administered will be documented in the “Fluid and Drug Administration” section of the PRF and the amount that has been destroyed recorded in the “free text” area of the PRF, or if used, on the Continuation sheet. Wherever possible a witness signature is to placed beside the entry recording the destroyed amount

14.6 On return to station the CD register must be completed ASAP and the amounts administered / destroyed recorded in the relevant section of the CD Register. (See exemplar at Appendix 1.).

15. Incident Reporting and Near Misses

15.1 Serious incidents must be verbally reported immediately, either directly to the Safety & Risk Department, or via Control.

15.2 Any adverse reaction to a drug administered by a member of staff, or any untoward event/ near miss that occurs as a result of drug administration is to be reported as soon as possible using the LA52 Incident Reporting form and following Health and Safety Incident Reporting Procedure (HS/011).

15.3 Duty Station Officers will grade the incident using the Trust’s Risk Matrix to establish the appropriate response and level of investigation required.

15.4 For Incidents classified as ‘High’ a root cause analysis will be undertaken by the appointed investigating officer.

15.5 Managers and Investigating Officers will feed back to individuals the lessons learned and monitor progress against action plans drawn up.

IMPLEMENTATION PLAN	
Intended Audience	Operational Staff
Dissemination	Available to all staff on the Pulse and to the public on the LAS website.
Communications	Revised Policy and Procedure to be announced in the RIB and a link provided to the document. Medical Directors Bulletin highlighting the main differences between this policy and the one it replaces.
Training	As part of paramedic education and training course. Locally via Team Leaders / Complex Trainers who will arrange short refresher training to take place during team meetings as required.
Monitoring	Individual paramedics will be monitored for adherence to this policy by CPI checks and Station Management Teams. Any problems identified will be referred to the Accountable Officer (Medical Director) and / or the Sector ADO as appropriate. The Accountable Officer (Medical Director) and the Senior Clinical Adviser to the Medical Director will monitor this policy in conjunction with the Local Intelligence Network (LIN) process of the Commissioning PCT (by way of the mandatory quarterly LIN reports), and by SCD6 – Drugs Directorate of the Metropolitan Police, who will liaise with the Senior Clinical Adviser regarding announced / unannounced audits / visits. The Trust Board will be informed of all activity / reports / action plans etc… in B. above via the Medical Director's Report submitted to the Trust Board at the earliest available opportunity.

Appendix 1

London Ambulance Service NHS Trust - Controlled Drug Register

NAME, FORM OF PREPARATION AND STRENGTH……Morphine Sulphate 10mg/1ml……..(Ampoule / ~~Unit / Box~~) Delete as Necessary

STOCK CHANGE

DRUG ADMINISTRATION / USAGE / WASTAGE

		C/FWD											
Amount		100			Authorised User Stock Change	Witness Signature for Change		PRF No. and CAD No	Quantity		Administered by	When used by single responder Callsign of other vehicle Witness signature for DRUG USED
OUT	IN	Running Total	Date	Req No	Printed Name & Signature	Printed Name & Signature			Administered	Wasted	Printed Name & Signature	Printed Name & Signature
	30	130	02/01/2010	357	P Joe Bloggs S *J Bloggs*	P A N Other S A N Other	**1**	PRF CAD			P S	P S
1		129	02/01/2010		P Frank Nurk S F Nurk	P Ivan Harvat S I Harvat	**2**	PRF 12345678 CAD 3211	7.5	2.5	P Frank Nurk S F Nurk	P Ivan Harvat S I Harvat
1		128	02/01/2010		P Frank Nurk S F Nurk	P Ivan Harvat S I Harvat	**3**	PRF CAD			P S	P S
	2	130	02/01/2010		P Billy Bodger S B Bodger	P Sam Splint S S Splint	**4**	PRF CAD			P S	P S
			/ /		P S	P S	**5**	PRF CAD			P S	P S
			/ /		P S	P S	**6**	PRF CAD			P S	P S
			/ /		P S	P S	**7**	PRF CAD			P S	P S

Appendix 2

Procedure for the Destruction of out of Date Pharmaceuticals

1. Out-of-Date Drugs

1.1 Out-of-date diazepam and oral morphine will be removed from circulation via the routine checking of returned paramedic drugs bag. All diazepam and oral morphine so removed will be placed into the "out of date" controlled drugs safe and the Out of Date Controlled Drugs Register updated accordingly.

1.2 The Corporate Logistics Manager or their designated deputy will monitor the expiry date of stocks of morphine for injection and advise stations when withdrawal is required of any 'out of date' stock. The designated person on a main station will also monitor expiry dates and notify the Corporate Logistics Manager or their deputy, that there are stocks of 'out of date' morphine to collect. The 'out of date' stock should be accompanied by a duplicated 'Out of Date Controlled Drugs Form'. The designated person on the main station should record the quantity of the out of date drug being returned, and sign and date the form (on the line stating: 'Drugs returned by: ').

1.3 On arrival at the station the designated member of Logistics staff should check with the designated member of station staff that the quantity being returned matches the amount identified on the form. If so, they should sign and date the form and place the morphine in the container provided. The out of date drugs should then be secured in the vehicle safe and returned to the Storage and Distribution Centre. A copy of the Out of Date drugs form should be retained by the station for a period of two years from date of the last entry.

1.4 When the out of date drugs are received in the store, the Logistics Manager (SMM), or their designated deputy, should check the out of date form in the presence of the designated member of Logistics staff and sign and date the form if the quantity listed is present, on the line stating 'Drugs Received by:' If the quantity listed is not present, an investigation should be immediately initiated. The out of date drugs form should be kept for a period of two years from the date of the last entry.

1.5 The out of date morphine should be stored in the Out of Date Controlled Drug Safe. An 'out of date' controlled drugs register should be kept in the safe. This should list the date, quantity, batch number, origin of the out of date stock, and date of disposal. When placing the out of date stock in

the Out of Date Controlled Drug Safe, the Logistics Manager (SMM), or their designated deputy, should complete the relevant details and witness the entry by signature. A daily audit of the register and a 'checked and correct form', should be completed for 'out of date' stock in the same way as for 'in date' stock. The register and forms should be kept for a period of two years from the date of the last entry.

2. Destruction of out of date controlled drugs

2.1 Under the Misuse of Drugs Regulations 2001, Regulation 27, those required to maintain a Controlled Drug Register are not allowed to destroy Schedule 1 – 4 controlled drugs that are either surplus or out of date, without that destruction being witnessed by an authorised person. The Accountable Officer is empowered to nominate individuals who are authorised to witness the destruction of these controlled drugs.

2.2 The Corporate Logistics Manager and The Audit Officer – Governance Development Unit] are the LAS Managers appointed by the LAS Accountable Officer to oversee and witness the destruction of all out of date controlled drugs held by the LAS. Destruction of out of date controlled drugs will occur at the discretion of the Corporate Logistics Manager, but in any event no less than every two months.

2.3 Any destruction day set is to ensure that **all** out of date controlled drugs since the last destruction is destroyed.

2.4 The Accountable Officer has also authorised any Assistant Medical Directors, the Senior Clinical Adviser to the Medical Director, any Clinical Adviser to the Medical Director to **assist** the Corporate Logistics Manager in the destruction of controlled drugs.

2.3 The Accountable Officer cannot witness the destruction of controlled drugs as they must remain independent from the day to day management of controlled drugs.

2.4 Once a date has been set for destruction of out date controlled drugs in accordance with 2.2 above the Corporate Logistics Manager ensure that, including themselves, there are lest two persons present to affect the destruction of the controlled drugs.

2.5 All destructions will take place at Deptford Logistics Depot.

2.6 This date is to be made known to the Senior Clinical Adviser to the Medical Director who will in turn inform SCD 6 Drugs Directorate of the Metropolitan Police and the Chairman of the Controlled Drugs Local

Intelligence Group (LIN) to which the LAS is currently a member at that time. The Senior Clinical Adviser will also ask CSD 6 and the LIN if they wish to be present at the destruction and inform the Corporate Logistics Manager accordingly.

2.7 On the appointed date the Corporate Logistics Manager will ascertain how many destruction of out of date pharmaceutical (DOOP) kits will be required, and draw said amount from a stock held at Deptford Logistics Depot.

2.8 All the out of date controlled drugs will be signed out of the Out of Date Controlled Drugs Safe and the Out of Date Controlled Drugs Register amended accordingly.

2.9 All the out of date controlled drugs will then be disposed of into the DOOP Kits and de-natured as per the manufacturer's instructions. Once the de-naturing process has taken effect the DOOP Kits will be disposed of via the LAS clinical waste disposal services.

2.10 Once the whole process has been completed the Corporate Logistics Manager will ensure that all the requisite entries in the Out of Date Controlled Drugs Register are completed correctly and all signatures witnessed.

2.11 The Senior Clinical Adviser to the Medical Director will, once informed by the Corporate Logistics Manager that 2.10 above has been done, inform SCD 6 and the LIN of the exact amount(s) drawn from the Out of Date Controlled Drugs Safe and the actual amount(s) destroyed. Any discrepancies must be accounted for and will be reported to the LIN via the quarterly LIN Occurrence Reporting procedure.

Appendix 3

Drugs Licensing & Compliance Unit
4th Floor Peel Building, 2 Marsham Street, London SW1P 4DF
Tel: 020 7035 0486/0487 Fax: 020 7035 6161
E-mail licensing enquiry.aadu@homeoffice.gsi.gov.uk
http://drugs.homeoffice.gov.uk/drugs-laws/licensing

Notification of Theft/Unaccounted Loss of Controlled Drugs

Name of Licensee:
Address of Licensee:
Home Office Ref No:
Named Contact Details:
Date of Theft/Loss:
Place of Theft/Loss (if different from above):
Details of Drugs Stolen/Lost:
Circumstances of Theft/Loss:
Action Taken:
Police Contact & Reference Number:

A full written report must be submitted to the address above when enquiries have been completed

Appendix 4

Responsibilities of the Accountable Officer

In discharging his responsibilities, an Accountable Officer must have regard to best practice in relation to the management and use of controlled drugs. The Accountable Officer must:

- Secure the safe and effective use and management of controlled drugs within local organisations subject to his/her oversight, i.e., the organisation and those with which it contracts.

- Appropriate systems for the safe management of controlled drugs must be established, operated and reviewed periodically.

- All arrangements must comply with relevant statutory requirements.

- Adequate and up-to-date standard operating procedures must be in place for the management and use of controlled drugs.

- Ensure that adequate destruction and disposal arrangements are made for controlled drugs.

- Appropriate arrangements for securing the safe destruction and disposal of controlled drugs must be established and operated.

- Ensure monitoring and auditing of the management and use of controlled drugs within the organisation and take action where necessary. The following must be in place:

    - Systems to alert the Accountable Officer to complaints or concerns involving the management of controlled drugs

    - An incident reporting system to capture untoward incidents involving the management or use of controlled drugs

- Arrangements for analysing and responding to untoward incidents involving the management or use of controlled drugs.

- Ensure that individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training. Arrangements must be in place for relevant individuals:

- o to receive information and, where appropriate, training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs

- o to be informed when any local standard operating procedures for controlled drugs are subsequently reviewed or amended.

- Monitor and audit the management and use of controlled drugs by relevant individuals, and to monitor and assess their performance. The Accountable Officer must, where appropriate, provide for the following

    - o Recording concerns raised in relation to the management or use of controlled drugs by a relevant individual

    - o Assessing and investigating concerns raised regarding the management or use of controlled drugs by a relevant individual

    - o Determining whether there are concerns in relation to the management or use of controlled drugs by a relevant individual which the designated body reasonably considers should be shared with a responsible body.

The Accountable Officer should be aware that unusually high usage of some CDs or unusually high numbers of breakages could indicate misuse.

- Maintain a record of concerns regarding relevant individuals. Such records may be paper-based or electronic. The Accountable Officer must:

    - o Establish and operate appropriate arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a relevant individual. This must include a system to ensure that access to such records is limited to the Accountable Officer, his staff and others who need to have access for the purposes of ensuring the safe management or use of controlled drugs.

    - o Ensure that adequate records are compiled, which must include (but not be limited to), as appropriate:

    - The date on which the concern was made known to the Accountable Officer;

    - Dates on which the matters that led to the concern took place;

    - Details regarding the nature of the concern;

    - Details of the relevant individual in relation to whom the concern was expressed;

- Details of the person who, or body which, made known the concern;

- The assessment of whether information in relation to the concern should be disclosed to another responsible body;

- If information regarding the concern is disclosed to another responsible body, the details of any such disclosure, including the name of the responsible body to which the disclosure was made and the nature of the information disclosed to the body.

• Assess and investigate concerns

  o Establish and operate appropriate arrangements for assessing and investigating concerns about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual.

  o Take appropriate action if there are well-founded concerns.

  o Establish and operate appropriate arrangements for ensuring that appropriate action is taken for the purposes of protecting patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a person who is, as regards designated body, a relevant individual, appear to be well-founded.

• Establish arrangements for sharing information

  o Establish and operate appropriate arrangements for ensuring the proper sharing of information, by his designated body with other responsible bodies regarding the management and use of controlled drugs.

  o Provide a quarterly report to the PCT Accountable Officer lead for the Local Intelligence Network.

  o Co-operate with other organisations including the Healthcare Commission, the Commission for Social Care Inspection, the NHS Business Service Authority and the police, as circumstances require.

• Participate in the Local Intelligence Network.