

Guidance For Hospital Pharmacy Staff In NHS Grampian On The Safe Destruction Of Controlled Drugs

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Policy Statement:

It is the responsibility of all staff to ensure that they are working to the most up to date and relevant guideline, policies, protocols and procedures.

Version 4

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Executive Sign-Off

This document has been endorsed by the Medical Director, NHS Grampian

Signature:  _____

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| February 2024 | Update of title and hyperlink to NHS Grampian Policy for Safe management of CDs in Hospitals and Clinics. | Page 5, section 2. |
| February 2024 | Diagram updated to include new supplier of CD denaturing kits. Use of CD Denaturing kits in schedule 3 CD destruction. | Page 9. |
| February 2024 | Change supplier of CD Denaturing Kits Change spelling of PECOS Delete Denkit and changed paragraph describing use. | Appendix 2 |
| February 2024 | Updated hyperlinks throughout Guidance. | Throughout |
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Definitions

Controlled Drugs

The terms Controlled Drug (CD) and Controlled Drugs (CDs) refer to those in the Schedules of the Misuse of Drugs Act 2001 and subsequent regulations.

Note: Within NHS Grampian Schedule 3 Controlled Drugs may be treated in a stricter manner than legally required. Staff should consider any CD item which is stored in the CD cupboard and/or recorded in a CD register as a Schedule 2 with regards to disposal and recording in the register.

Throughout this document any reference to Schedule 2 will also include any Schedule 3 (i.e. Buprenorphine and Temazepam) treated by the supplying pharmacy as a Schedule 2 and will be referred to as Schedule 2*.

Authorised Witness

A person who has signed authorisation from the Accountable Officer NHS Grampian, to witness the destruction of stock Schedule 2 Controlled Drugs in community pharmacies, hospital pharmacies and GP practices. Within NHS Grampian this function is carried out by the CD team inspectors.

CD Denaturing Kit

A commercially available kit specifically designed for denaturing CDs taking account of health and safety risks. This is preferable for reasons of speed and efficiency particularly for small volumes and solid dosage forms.

Patient's Own Controlled Drugs No Longer Required

These are CDs that have been prescribed for, and dispensed to, a named patient but are no longer required and have been returned to the pharmacy, via the ward return system, for safe disposal.

Pharmacy Stock Controlled Drugs

These are CDs which have been obtained by the hospital pharmacy by ordering from a wholesaler or main pharmacy store.

Ward Stock Controlled Drugs

These are CDs which have been ordered by the ward area from pharmacy for administration to patients on the ward.

Waste Disposal Bin

A disposal bin specifically designated for storage and transport of waste medicinal products. Within NHS Grampian these are blue lidded blue bins labelled - “Medicinal waste products for yellow stream waste disposal” and are available through NHS Grampian facilities department.

Hospital Pharmacy

Throughout this document reference to hospital pharmacy includes pharmacy support services and/or dispensaries.

Guidance For Hospital Pharmacy Staff In NHS Grampian On The Safe Destruction Of Controlled Drugs

1. Purpose

This guidance has been produced for hospital pharmacy staff working within hospital pharmacies or at ward level who may be required to destroy CDs. This guidance covers stock CDs which are out of date (OOD) or no longer required by a pharmacy/ward/department and patient's own CDs which are no longer required. Adherence to this guidance will ensure that the destruction of these CDs is undertaken safely and in accordance with the requirements of the Misuse of Drugs Regulations 2001, new governance arrangements introduced in the Health Act 2006, subsequent Controlled Drugs (Supervision and Management and Use Regulations 2013 and relevant Waste Regulations).

2. Scope

This document provides guidance to individuals managing, undertaking and witnessing the destruction of stock Schedule 2 or Schedule 3 treated as Schedule 2 CDs (i.e. Buprenorphine and Temazepam) and patient's own CDs which are out of date/damaged or no longer required and assists managers who support these individuals in that duty in hospital pharmacies or community hospitals in NHS Grampian.

This document does not cover ward staff disposing of part used ampoules or dropped tablets of CDs at ward level or other aspects of CD management (e.g. ordering, receipt, transfer, etc). Refer to NHS Grampian Policy and Procedure for the Safe Management of Controlled Drugs in Hospitals and Clinics.

[NHSG Policy and Procedure For The Safe Management Of Controlled Drugs in Hospitals and Clinics](#)

This document does not cover the disposal of suspicious substances. Refer to NHS Grampian Procedure for Dealing with Suspicious Substances Found in the Possession of Patients, Visitors Or in NHS Grampian.

[Procedure For Dealing With Suspicious Substances Found In The Possession Of Patients, Visitors Or In NHS Grampian Premises](#)

3. Background

The Health Act 2006 introduced a statutory requirement for all NHS Boards to appoint an Accountable Officer (AO), with specific responsibility for the safe management of CDs within their Health Board. This responsibility includes providing arrangements for stock Schedule 2 CD destruction of and ensuring that any CD destruction procedures being applied are safe, legal and appropriate to the task.

Within NHS Grampian the Director of Pharmacy is the Accountable Officer (AO). The AO has in turn appointed a Controlled Drugs Team to assist with that function including the appointment of Authorised Witnesses (AW) to witness the destruction of CDs. Within NHS Grampian the role of AW is carried out by CD Team inspectors.

Schedule 2/3 stock CDs

Schedule 2 CDs are subject to safe custody requirements and denaturing and disposal in the presence of an AW. However, it is accepted practice within NHS Grampian hospitals that some Schedule 3 CDs (for reasons of control, audit and documentation) are treated by the supplying pharmacy as Schedule 2 and should therefore be included in the process of denaturing and disposal in the presence of an authorised witness (see [Definitions](#) page 3). This practice is supported by CEL 7 (2008), Safer Management of Controlled Drugs: A Guide to Good Practice in Secondary Care (Scotland).

Hospital pharmacy staff must make arrangements to contact NHS Grampian's Controlled Drugs Team to arrange destruction of any stock Schedule 2 CDs and Schedule 3 CDs handled by the supplying pharmacy as a Schedule 2 CD.

In addition Medicines, Ethics and Practice - the professional guide for pharmacists, published by the Royal Pharmaceutical Society, includes Home Office advice that all CDs in Schedules 2, 3 and 4 (part 1) should be denatured before disposal.

Hospital pharmacy staff must make safe and adequate arrangements for disposal of lower schedule stock CDs which may include denaturing if that department has resources and systems to support this, taking account of risk of diversion and safeguarding staff and patients.

Patient's own CDs

CEL 7(2008) allows patient's own CDs to be destroyed in hospital pharmacies/support services or in community hospital wards under the supervision of a pharmacist or registered pharmacy technician. Hospital pharmacy staff must have appropriate arrangements (equipment and Standard Operating Procedures) in place for ensuring the safe destruction and disposal of patient's own CDs.

4. Record Keeping

Having a clear audit trail is one of the key requirements of the current CD legislation. Records must be made of all transactions/movements of Schedule 2* CDs in and out of registers. Where possible all transactions/movements of CDs should be witnessed.

Stock CD Schedule 2*

On receipt of the Schedule 2* CD the receiving pharmacy department/support service must record the following details in the pharmacy department register to complete the audit trail:

- Date of entry of the CDs into the pharmacy register. This should normally be the day they were received either from the ward returning the OOD (out of date) stock or were identified by pharmacy staff as stock which was out of date.
- The name, quantity, strength and form of the CDs.
- The returning ward/department if applicable.
- The name and signature of the pharmacy personnel who entered the CDs into the register.
- At the time of destruction the date, name and signature of the person who carried out the destruction and the witness must be added.

Stock Schedule 3 or 4 part 1

There is no record keeping requirement for lower schedule CDs at time of destruction.

Patient's own Schedule 2*

Returned to pharmacy for destruction

- Patient's own Schedule 2* CDs no longer required or out of date CDs sent to pharmacy for destruction must be accompanied by appropriate ward documentation (e.g. patient own for destruction form).
- On arrival at pharmacy they must be recorded in a register or record book kept specifically for this purpose. There is no legally required format for this record book/register however best practice is a bound book: entries should be indelible, entries should not be erased but marked and corrected and an explanation made as for a CD register. A dispensary register with the columns amended to suit may be used for this purpose.

Details to be recorded include:

- Date of return of the CDs.
- The name, quantity, strength and form of the CDs.
- The role of the person who returned the CDs (if known).
- The name and signature of the person who received the CDs.
- The patient's name and address (if known) or ward.
- The name, position and signature of the person destroying the CDs.
- The name, position and signature of the person witnessing the destruction of the CDs.
- The date of the destruction.

These records should be retained for at least 7 years

<http://www.scotland.gov.uk/Publications/2012/01/10143104/7>

Schedule 2* patient's own CDs destroyed at ward level by pharmacy technician/pharmacist/CD Inspector

The following details must be recorded:

- Date of the destruction of the CDs.

- The quantity and strength of the CDs.
- The name, role and signature of the person who destroyed the CDs.
- The name, position and signature of the person witnessing the destruction of the CDs (normally the nurse in charge or an individual delegated by him/her with this responsibility).

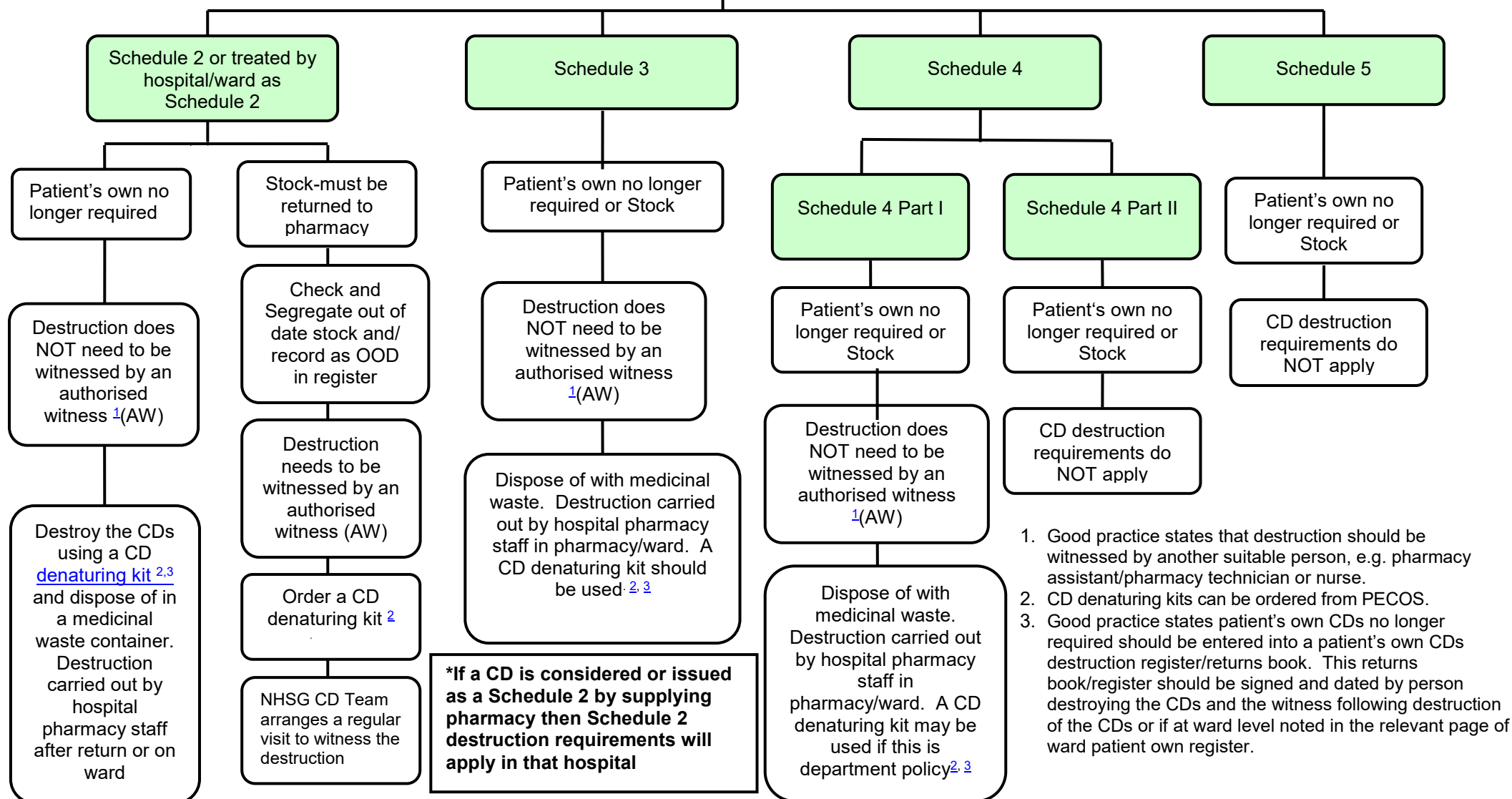
5. Destruction Process

Stock CDs and patient's own CDs requiring destruction must be dealt with differently as shown in the following flowchart:

Destruction of Controlled Drugs (CDs) in Hospital Pharmacies and Community Hospital Wards.

Destruction Of Controlled Drugs (CDs) In Hospital Pharmacies And Community Hospital Wards

Which Schedule does the CD belong to?



1. Good practice states that destruction should be witnessed by another suitable person, e.g. pharmacy assistant/pharmacy technician or nurse.
2. CD denaturing kits can be ordered from PECOS.
3. Good practice states patient's own CDs no longer required should be entered into a patient's own CDs destruction register/returns book. This returns book/register should be signed and dated by person destroying the CDs and the witness following destruction of the CDs or if at ward level noted in the relevant page of ward patient own register.

5.1 Stock Controlled Drugs

Stock Schedule 2* (out of date, no longer required or damaged CDs)

Stock Schedule 2* CDs which are out of date/damaged/no longer required must be returned to the onsite pharmacy department or ARI according to local hospital procedures.

Within NHS Grampian the CD team inspectors make regular scheduled CD visits to sites within NHS Grampian hospital pharmacies (ARI, RACH, RCH, and Dr Grays) to witness and participate in destruction of stock CDs. This arrangement does not apply to community hospitals.

- Within hospital pharmacies, on receipt, out of date stock CDs must be clearly marked as such and stored as CDs but segregated from in-date stock CDs. Such returned stock CDs must be assessed for return to stock or disposal (see note below).
- CDs for destruction should be entered into the register as soon as possible after receipt. Refer to [Section 4](#).
- Ensure a date for witnessed destruction is arranged at appropriate intervals in keeping with expected amounts of CDs for disposal.
- Arrange for a suitably sized denaturing kit and approved blue lidded blue bin labelled "Medicinal waste products for yellow stream waste disposal" to be available.
- For information on how to deal with broken ampoules/vials/oral liquids refer to [Appendix 1](#).

Note: No longer required CDs may be returned to stock if assessed as suitable and register adjusted accordingly. Only CDs supplied by an on-site dispensary can be returned to that on-site dispensary. All other CD returns, for re-issue, must be returned to ARI.

Stock Schedule 3 or 4 (Part I) CDs (out of date no longer required or damaged CDs)

- Destruction does not require to be witnessed by an AW and may be carried out by appropriately trained hospital pharmacy staff.
- Best practice would be to denature prior to disposal in a CD denaturing kit.
- Stock Schedule 3 and 4 (Part I) **must** be disposed of in a blue lidded blue bin labelled - "Medicinal waste products for yellow stream waste disposal".
- No record keeping is required; however destruction should be witnessed by another appropriately trained and delegated member of pharmacy staff if available.
- Within community hospitals stock Schedule 3 or 4 (Part 1) should be returned to the supplying pharmacy for destruction and disposal.
- Within some community hospitals areas, destruction and/or denaturing of stock Schedule 3 or 4 (Part I) may be carried out at ward level by a pharmacy technician and witnessed by a member of nursing staff. A record of this destruction should be made on form ZEP 101.

Record keeping - Refer to [Section 4](#).

5.2 Patient's own Controlled Drugs

In NHS Grampian destruction of patient's own CDs no longer required may be carried out after return to supplying pharmacy or at ward level in certain areas.

On occasion a patient may be admitted on prescribed cannabis products (e.g. Cannabis buds) if this product is not returned to the patient on discharge, then they should be returned to pharmacy for destruction. This should be treated as a Schedule 2 CD – patient return CD destruction as per [flowchart](#) (page 9).

General points

- Patient's own Controlled Drugs **must** not be reused or used for other patients.
- Patient's own Schedule 2* CDs no longer required, on receipt **must** be clearly marked as such and stored as CDs but segregated from stock CDs.
- These may be destroyed within the pharmacy department or at ward level, e.g. in community hospitals by appropriately trained pharmacist/pharmacy technician or CD Inspector.
- All patients' own Controlled Drugs which are to be destroyed must be accompanied by a Patient's Own Medicines for Destruction Form.
- Patient's own Controlled Drugs should be destroyed as soon as possible after receipt in pharmacy.
- All Schedule 2* CDs out of date/no longer required **must** be denatured before disposal in a blue lidded bin labelled - "medicinal waste products for yellow stream waste disposal".

Patient's own Schedule 2* out of date or damaged CDs sent to pharmacy department for disposal

- The record of the return should be made somewhere other than the main CD register. A hospital register may be adapted specifically for the purpose by altering the column heading appropriately or such returns book/register books are also available commercially.
- This patient's own Controlled Drugs returns register can also be used to record subsequent destruction details.
- Patient's own Controlled Drugs for destruction should be entered into the patient's own Controlled Drugs returns book/register at time of receipt.

Record keeping - Refer to [Section 4](#).

Patient's own Schedule 2* CDs destroyed at ward level by pharmacy technician/pharmacist/CD Inspector

- Schedule 2* patient's own CDs no longer required or which are out of date and destroyed at ward level will be recorded in the ward CD register under the appropriate page and patient name.
- The record of the destruction will be made in the ward CD register under the appropriate page for the patient and the CD to be destroyed.

Record keeping - Refer to [Section 4](#).

Schedule 3 or 4 (Part I) patient's own CDs

- These may be destroyed within the pharmacy department or at ward level, e.g. in community hospitals by the pharmacists/pharmacy technician.
- Schedule 3 or 4 (Part I) patient's own CDs do not require witnessed destruction by an AW.
- Schedule 3 or 4 (Part I) patient's own CDs should be denatured where possible.
- Destruction should be witnessed by another member of pharmacy/ward staff as for Schedule 2* patient's own CDs no longer required, though no record keeping is required.

6. Clinical Trials

The clinical trial protocol should stipulate their requirements for disposal of CDs. Clinical trial CDs must be destroyed in the same way as other CDs, however, this destruction may need to be carried out following the instructions of the trial sponsor. For example, the sponsor may wish to carry out an independent reconciliation prior to any destruction.

Clinical trial CDs returned by patients

The clinical trial protocol should stipulate requirements for handling of CDs returned by patients. Drug accountability records should be completed promptly when a patient returns the CD clinical trial medicine.

7. Equipment Required For CD Destruction

- CD denaturing kit(s) of a suitable size - Refer to [Appendix 2](#) - Kit selection for further information.
- PreGel® - if large volumes of liquids, 200mL or more are to be denatured.
- Blue lidded bin labelled - "Medicinal waste products for yellow stream waste disposal".
- Gloves, aprons, masks and safety glasses.
- Tablet crusher, mortar and pestle if required for PreGel® where grinding of tablets must take place before disposal.
- Needles/syringes as required.

7.1 Destruction process - CD Schedules 3 and 4 (Part I) Stock and CD Schedules 2, 3 and 4 (Part I) patient's own CDs

Further information on the destruction process can be found on [Welcome - Knowledge Hub \(khub.net\)](#) where the CDAO network Standard Operating Procedure (SOP) for Destruction of Controlled Drugs observed by an Authorised Witness is held.

This document is a nationally agreed resource for AWs and contains useful guidance and information on the CD destruction process.

- The area where CDs are to be destroyed should be well ventilated and away from any dispensing area.

- The person(s) destroying the CDs should wear protective clothing (glasses, gloves, apron and mask, etc) as appropriate.
- If the CD to be denatured is a large volume (e.g. over 200mL) these should be segregated and dealt with as for “PreGel®” below.
- Hospital pharmacies/Distribution services should use CD denaturing kits (refer to [Appendix 2](#) - Kit Selection for further information) in order to denature CDs.
- Patient’s own CD boxes/bottles should have labels removed and destroyed or otherwise obliterated at time of destruction, to preserve patient confidentiality.
- All empty containers, blisters, bottles, etc should be discarded into blue lidded blue bins labelled “Medicinal waste products for yellow stream waste disposal”. This is a waste management recommendation to ensure no trace of medicinal waste is ever disposed of as non medical waste.
- Destruction should be according to Standard Operating Procedures (SOPs) and instructions from manufacturer of denaturing kit. For further information refer to Kit Selection [Appendix 2](#).

CD Denaturing Kit

- Before use, denaturing kits should be shaken to loosen powder.
- All dry products should be added to the denaturing kit and mixed before liquids are added (to avoid contents gelling before all additions are completed).
- Liquid from ampoules/reconstituted ampoules/or from sachets/UDV’s/suppositories/syringes/mortar and pestle washing, etc can be gathered together before adding to denaturing kit.
- Each denaturing kit features a ‘fill to here’ line or specifies in writing how far to fill the container with CD products. Do not add items beyond that point as the remaining space is required for water to be added.
- An appropriate size (able to contain CD denaturing kit) blue lidded blue bin labelled “Medicinal waste products for yellow stream waste disposal” must be available.
- Filled CD denaturing kits which have been stored in the Controlled Drug cupboard for 24 hours must then be added to a medicinal waste product container labelled “Medicinal waste products for yellow stream waste disposal”.

Note - The kit contents will form a gel within a few minutes and may become warm initially (this is normal). It may take up to 24 hours for the inactivation process to complete.

PreGel®

- Large volumes of liquids may be added directly to the approved blue lidded blue waste bin labelled ‘Medicinal waste products for yellow stream waste disposal’.
- PreGel® should then be added until all liquid is absorbed.
- Once absorbed, i.e. denatured, the waste is no longer considered a CD and disposal is as for all medicinal waste.

References

Legislation

The Misuse of Drugs Act 1971.
The Misuse of Drugs (Safe Custody) Regulations 1973.
The Misuse of Drugs (Safe Custody) Regulations 2001.
Controlled Drugs (Supervision of Management and Use) Regulations 2006.
The Health Act 2006.
Controlled Drugs (Supervision and Management And Use) Regulations 2013.

National Guidance

Safer Management of Controlled Drugs HDL (2007) 12
https://www.scot.nhs.uk/sehd/mels/HDL2007_12.pdf

Safer Management of Controlled Drugs: A Guide to Good Practice in Secondary Care (Scotland) CEL 7 (2008)
http://www.sehd.scot.nhs.uk/mels/CEL2008_07.pdf

Controlled Drug regulations PSNC
<http://psnc.org.uk/contract-it/pharmacy-regulation/controlled-drug-regulations/>

A guide to the required standards of practice in the management of records for those who work within or under contract to NHS organisations in Scotland
<http://www.scotland.gov.uk/Publications/2012/01/10143104/0>

NHS Grampian Waste Management Policy [A-Z Local Policies & guidance \(scot.nhs.uk\)](#)

[Welcome - Knowledge Hub \(khub.net\)](#): SOP for Destruction of CDs observed by an Authorised Witness

Appendix 1 - Information on Dealing with Ampoules/Vials/Liquids Which Are Found To Be Broken or Broken Accidentally

Hospital dispensary/Distribution services stock

Note: When stock is received, sealed boxes should not be opened until they are required for use. A broken ampoule inside an apparently sealed container may go unnoticed for some time. If broken ampoules are identified at the time of receipt (because of damp packaging) refuse to receive and return to supplier.

Action to be taken if discovered during stock check or while putting stock away or accidental breakage or spillage

Where possible, the process of dealing with any spillage/breakage disposal should be witnessed.

Ampoules/vials containing liquid - where part of the box is fit for use:

- 1) Wear gloves and mask and glasses.
- 2) Carefully open box to inspect damage.
- 3) Remove broken ampoules/vials to blue lidded blue bin labelled "Medicinal waste products for yellow stream waste disposal". Add PreGel®.
- 4) Retain the part suitable for use with dispensary stock along with product information sheet.
- 5) Adjust register balance with note that stock was damaged and get a counter signature from witness.
- 6) Adjust computer stock. Add statement to explain why stock is being written-off.

Ampoules/vials containing liquid - where contents are unfit for use:

- 1) If on inspection box and contents are considered too damaged for issue or product insert is unusable then complete box and contents should be "bagged" and stock labelled "Do not use".
- 2) Stock should remain in the running balance and a note added to register in explanation.
- 3) Set aside for the attention of CD team Authorised Witness at next visit.

Liquids (normally oral liquids):

- 1) Wear gloves and protective equipment.
- 2) Depending on the extent of spillage or breakage add PreGel® to the areas where the breakage or spillage is to absorb all liquid.
- 3) Use paper towels to carefully gather broken glass and PreGel® to blue lidded blue bin labelled "Medicinal waste products for yellow stream waste disposal".
- 4) Adjust register balance with note that stock was damaged and get a counter signature from witness (if one has been present).
- 5) Adjust computer stock; add statement to explain why stock is being written off.
- 6) Ensure floor is thoroughly cleaned after spillage has been cleared as PreGel® may make floor slippery.

Appendix1 (continued)

Ampoules and vials containing powder:

- 1) These may be dealt with exactly as for ampoules and vials containing liquid.
- 2) Addition of PreGel® to medicinal waste container is only required if ampoules/vials have been rinsed out.

Appendix 2 – CD Destruction Kit Selection

For CD denaturing, commercial CD denaturing kits are the preferred option for reasons of speed, efficiency and health and safety. The choice of kit will depend on the CDs to be destroyed.

Recommended CD denaturing materials for use in NHS Grampian Hospitals are listed below and are available through PECOS.

Local SOPs must detail all methodology for using the kits.

Before using the CD denaturing kit read the instructions on the label. Solid dose formulations can be placed directly into most kits without first being ground or crushed. Twenty four hours must elapse before denaturing of the CDs is guaranteed. The used kit must be secured as a CD during that time (i.e. retained within a CD Cabinet). After 24 hours the used kit can be treated as pharmaceutical waste and should be placed into a blue lidded blue bin for collection by NHS Grampian.

A denaturing kit may not fit into the aperture of waste disposal bin (blue lidded) which has had the lid attached so ensure a blue lidded blue bin labelled Medicinal waste products for yellow stream waste disposal” is available.

Other Denaturing Kits

Denaturing kits are provided by a variety of suppliers. Care must be taken to read instruction carefully before use, in particular the requirements to open capsules, crush tablets.

PreGel®

This is the preferred option for large volumes of liquids (over 200mL). This is also the preferred option if large volumes have been accidentally spilt or damaged. PreGel® should be added to stabilise the volume of solution in the medicinal waste bin, i.e. until all the liquid has been absorbed onto the PreGel® and there is no remaining liquid. PreGel is available to order via PECOS.

ALL drugs will need to be ground and capsules opened if using PreGel®.