

SOP Guidelines for producers and other licensees

- **Purpose** of SOP and its status (e.g. would failure to follow it be a disciplinary offence?) should be stated at the top of the document.
Purposes may include procedures for delivery, dispatch, handling and storage of cd's. During production storage should include in process material. May also include recruitment policy (cd store and other sensitive areas) staff searches, cctv monitoring as well as tape management, key access and procedures, entry/exit procedures to main warehouse and cd store, alarm activations, hostage situations.
- The **scope** of the particular SOP should be stated (eg covers all matters relating to cd's)
- Some procedures may be subject to separate SOPs of their own eg. booking in, despatch, stock checks & QA sampling. There should also be a separate SOP covering emergency procedures such as fire, unauthorised entry, personal attack etc.
- It should be clearly stated who within the company has overall **responsibility** for cd's and who for operational matters (may be the same person) The post having responsibility for each must be clearly stated.
- If there is a security officer/manager or other security personnel on site their roles, duties and responsibilities must be clearly defined.

1. Orders and arrangements for receipt of cd's (to be agreed with suppliers)

- 1.1 It should be clearly stated who may place orders for cd raw materials/finished goods & under what authority
- 1.2 There should be an agreed form(at) for ordering, preferably a single cd order form
- 1.3 A second named postholder should check/authorise orders
- 1.4 Manual alterations to printed orders should not be allowed, except in the most stringent of circumstances
- 1.5 There must be a proper record kept of orders (paper and/or computer)
- 1.6 Records of orders and confirmation of receipt of goods by customers should be checked or audited at agreed intervals
- 1.7 In the case of all or significant orders, suppliers should be made aware of identity of personnel who may order cd's and the form of the orders
- 1.8 An agreement should be made with suppliers over delivery arrangements for cd's and this should be adhered to unless revised
- 1.9 Receiving company to know details of delivery i.e. time, vehicle, personnel & contents (for large deliveries particularly)

2. Acceptance of deliveries & procedures on receipt

- 2.1 There should be agreed procedure for receipt of deliveries of cd raw material & delivery vehicles brought on to site (eg checking drivers' bona fides, unloading vehicles behind closed doors by authorised personnel only).

- 2.2 There should be agreed procedures (including physical security) for returns and deliveries/dispatches of other cd's (eg through goods in not Reception)
- 2.3 There should be a visual check made of goods before acceptance and before delivery is signed for
- 2.4 Drums/containers must be check weighed at earliest opportunity, gross weights recorded and checked against tare record.
- 2.5 There should be an agreed procedure for delivering goods to secure storage
- 2.6 If discrepancies are discovered there must be a clear and agreed procedure for reporting these to responsible person within the company, to the supplier & to the Home Office Drugs Inspectorate within a specified time.

3. Procedures for accepting orders and cd dispatch

- 3.1 The bona fides and/or licensed status of customers must be confirmed before any order for cd's is accepted. The latter is particularly important for suppliers of Schedule 1 (para 1b &1c compounds) cd's
- 3.2 Cd's should remain in the cd store or other agreed secure receptacle until ready for dispatch
- 3.3 Cd's should not be released to a delivery driver except in accordance with an official order form
- 3.4 There should be a separate SOP for storage and delivery of cd's from delivery vehicle
- 3.5 This SOP should include clear instruction that deliveries should be signed for by authorised person before being left

4. QC

- 4.1 SOP/agreed procedure for who has authority to break seals, take QC samples and re-seal containers. Certain QC staff may need to be on list of personnel authorised to enter cd store
- 4.2 Removal of sampling material by QC staff should be undertaken in the presence of another member of that section
- 4.3 Samples should be recorded in an agreed manner (record kept in cd store & QC lab)
- 4.4 QC should have its own SOPs covering all their work including secure storage facilities
- 4.5 QC will be involved at other stages, including production. SOPs should take account of this. All QC practices will be covered by GLP.

5. CD Store (may be subject to separate SOP covering all aspects such as entry/exit and alarm procedures)

- 5.1 If there is a cd store, those having access to it should be listed in an annex to the SOP (not necessarily including managers). Access should be strictly limited to essential personnel only
- 5.2 Certain unauthorised persons (visitors/contractors/HO inspectors) may be allowed access but must be accompanied by an authorised person, who should not leave the visitor unsupervised at any time
- 5.3 Those allowed accompanied access (HO inspectors/police etc) should be listed and the circumstances under which they are allowed access should be stated. Warrant cards/ID must be shown where appropriate.

- 5.4 Under no circumstances should staff, visitors, or contractors be allowed to take bags, cases etc into the cd store
- 5.5 Persons authorised to hold keys to cd store should be listed in separate annex along with secure location for keys when not in use
- 5.6 There should be a set procedure for handing over keys and returning same
- 5.7 The Cd Store alarm(s) should always be set when the store is unoccupied
- 5.8 It may be appropriate, for high security stores, to record entries (time, date & personnel) to the store
- 5.9 Upon entry to the cd store the alarm must be turned off immediately
- 5.10 The circumstances under which the cd store may be opened and remain opened with alarms unset should be set out
- 5.11 If there is a grill or day gate the circumstances under which it may be open should be set out
- 5.12 If cctv is installed covering cd store it should be switched on at all times
- 5.13 It must be clearly set out who has responsibility for checking cctv monitors
- 5.14 Outside contact and procedures in emergency situations must be clearly understood by all concerned

6. Recruitment policy

- 6.1 Licensees may wish to set up or take advantage of local arrangements with police to vet prospective employees, particularly those working in sensitive areas. Such employees may be asked to obtain a personal CRO check from the police
- 6.2 All references from prospective employees should be taken up by Security Officer/Manager or other manager
- 6.3 Personnel selected for cd store duties should have been with company for a minimum period of time (12 months or more)
- 6.4 All new recruits should be asked to sign an agreement authorising personal searches and searches of their means of transport (where applicable) by approved company personnel (see also para 9). The company may wish to consider the use of random drug testing for employees working with controlled drugs
- 6.5 Particular care needs to be taken in the recruitment and use of agency staff. The licensee will wish to satisfy themselves of the agency's bona fides, as well as its procedures for vetting potential candidates.

6.1 is a particularly sensitive and fluid area at present and may present some difficulties

7. Production and packing runs

- 7.1 Posts with authority to start a production run should be clearly stated and understood by all company employees
- 7.2 There should be agreed procedures for taking cd raw material to production suite, taking into account SOPs on deliveries/secure storage etc
- 7.3 There should be agreed reconciliation procedures to accord with GMP
- 7.4 If cd material is ever left unattended outside the cd store during production process there should be agreed physical security for this
- 7.5 There should be reasonably secure facilities for storage of rejected amps/tabs or other containers on the production/packing lines

- 7.6 At the end of each working day any waste or leftover cd material should be secured and removed to the cd store
- 7.7 All finished cd packs should be removed to the cd store at the end of each working day
- 7.8 There should be agreed procedures (with authorised witness?) for destruction of waste material
- 7.9 Finished packs should be reconciled with raw/base material used, in accordance with GMP

8. Emergency procedures

- 8.1 These should cover fire, flood, illness and attack
- 8.2 People who work inside the cd store, for whatever periods, should understand all emergency procedures
- 8.3 Normal advice in hostage situations is to do whatever the hostage taker asks. We have sought Police guidance as to whether hostages need to bear anything else in mind
- 8.4 Panic buttons/hidden alarms should normally not be used if under armed threat.

9. Staff searches

- 9.1 Staff searches should be undertaken by authorised personnel and must be regular but random (except in special circumstances)
- 9.2 All staff, visitors and contractors must be warned that they will be required to empty their pockets immediately on leaving the cd store
- 9.3 A record of search will be signed by both the searcher and the searchee and stored in a secure place
- 9.4 The checking of all documentation will take place outside the cd store prior to entry

10. CCTV monitoring and tape management

- 10.1 During weekdays cctv tapes will be changed every 24 hours. At the weekend the tapes will be changed every 72 hours (to be varied by agreement) A check should be made at each change that the timer on the recorder is set correctly.
- 10.2 The licensee will wish to consider who, and how often reference to activity on security television screens is monitored.
- 10.3 During weekdays the previous day's tape(s) will be reviewed. At weekends the tapes will be reviewed after 72 hours. Any abnormality should be reported to the Security Manager/Officer or Ops Manager
- 10.4 Used tapes should be dated and archived in a secure cabinet somewhere on site
- 10.5 Each tape should be kept for a period of at least 31 days before being re-used
- 10.6 When a tape reaches the end of its useful life it should be wiped clean and destroyed after not less than 31 days from when it was last used

11. Alarm activations

11.1 Fire Alarm

- 11.1.1 Upon activation of the fire alarm a siren will sound (?throughout the warehouse)
- 11.1.2 All staff must then, unless otherwise notified, congregate at the authorised meeting points
- 11.1.3 The cd store should be locked shut before cd staff proceed to the meeting point provided that this is not a threat to personal safety
- 11.1.4 The fire alarm should, if applicable, notify the Intruder Alarm Monitoring Station or CCTV Monitoring Station. Procedures should be in place to notify the fire brigade or the police, as appropriate

11.2 Intruder Alarms

- 11.2.1 In the event of an activation the Intruder Alarm Monitoring Station (IAMS) should be alerted automatically (whistles and bells optional)
- 11.2.2 If appropriate, the IAMS will contact the CCTV Monitoring Station (CCTVMS) for assistance in establishing whether there is an identifiable threat. If a threat can be identified the CCTVMS should call the police
- 11.2.3 In the absence of a CCTVMS the IAMS should notify the appropriate responsible person within the company and accompany him/her onto site.
- 11.2.4 In the event of any identified threat to staff, the police should be called by dialling 999.

11.3 Personal attack alarms (where used)

- 11.3.1 Arrangements for response to these will vary and should be checked with the company's security personnel
- 11.3.2 One system in use is that upon activation a message is relayed automatically to the IAMS who immediately call the police, the company's responsible person and the CCTVMS (where applicable)

12. Security Officer's/Manager's responsibilities

- Assuming that the company in question has a security officer, duties will vary considerably between different locations. The duties below are some that relate to one of our licensees and are offered as an example
- 12.1 To ensure that all those dealing with cd's are able to identify them (eg a list of cd products is available in Goods In)
- 12.2 To ensure that members of staff handling cd's are well known to the company and considered appropriate persons for handling such products
- 12.3 To ensure that, once received, all cd's are taken immediately to a cd store after visual checking (bulk supplies) or detailed verification (This may not always be appropriate)
- 12.4 To make immediate enquiries with suppliers and/or carriers into shortages/overages/damages/delays in cd deliveries
- 12.5 To report any thefts/losses to Home Office Drugs Inspectorate in accordance with the terms of their licence
- 12.6 To ensure that, under no circumstances, are staff, visitors or contractors

- allowed to take bags, cases etc into the cd store.
- 12.7 To direct staff/visitor searches in accordance with SOP on searches
 - 12.8 To ensure that any alarm system covering cd's is in full working order and that police/security company response to activations is commensurate with the risk
 - 12.9 To ensure that the SOP on CCTV procedures is complied with
 - 12.10 To ensure that the SOP on key security is complied with
 - 12.11 To ensure that any references provided by cd store personnel are taken up and are satisfactory
 - 12.12 To arrange destruction of damaged or out of date cd's with an authorised witness present.

The witness may be the HO Inspector or a person within the company authorised to witness destructions under The Misuse of Drugs Regulations 2001.

A method of destruction will need to be agreed in advance with the HO Inspector and may range from adulteration of small amounts to incineration for larger ones.

A written record in an agreed format must be produced of materials destroyed.

- 12.13 To amend cd stock records as necessary (?with HO approval)
- 12.14 To ensure that cd stock checks are carried out according to company policy

13. CD Operatives responsibilities

- This may also vary according to licensed premises but not as much as security personnel
- 13.1 Immediate checking of all incoming against supplier's delivery note to ensure correct goods in satisfactory condition have been received
 - 13.2 To bring to the immediate attention of Security Manager/Officer or Ops Manager any discrepancy or signs of tampering found in a delivery or any delivery of cd's that has not been ordered.
 - 13.3 Immediately (or at least within 24 hours) update the records system(s)
 - 13.4 Undertake stock checks in accordance with company policy

14. Client/customer responsibilities

- 14.1 To ensure cd's are not delivered outside agreed procedures
- 14.2 In the case of large or particularly sensitive cd deliveries, to advise Security Officer/Manager of date, time and means of delivery
- 14.3 To ensure that delivery is as per order when it is dispatched