



Home Office

## Forensic Analysis and Reference Standards- Licensing Factsheet

This factsheet provides information on the situations where a Controlled Drug Licence may be needed by those undertaking forensic analytical work, or handling reference standards. It is intended as a resource for existing licensees and prospective licensees who need to apply for a licence.

**Important Note: This is intended as general guidance only it is not legal advice. Anyone in doubt should seek their own independent legal advice to ensure they are compliant with any relevant legislation.**

### What is 'forensic' work?

Neither the Misuse of Drugs Act 1971, nor the Misuse of Drugs Regulations (MDR) 2001 define 'forensic' analysis. The relevant definition within the Oxford English Dictionary is in the following terms:

#### **forensic**

**A** *adjective*. 1. Of, pertaining to, or used in a court of law, now spec, in relation to the detection of crime.

2. Of, pertaining to, or employing forensic medicine.

**B.** *noun*. 1. ....

2. Forensic science (esp. as the designation of a department, laboratory, etc.). *colloq*

### I undertake or want to undertake forensic analysis- do I need a licence?

**It is highly likely that a Home Office licence is needed.**

Regulation 6(7)(e) of the MDR 2001 provides that:

*(6) Notwithstanding the provisions of section 5(1) of the Act, any of the persons so specified may have any controlled drug in his possession.*

*(7) The persons referred to in paragraphs (5) and (6) are .... (e) a person engaged in the work of any laboratory to which the drug has been sent for forensic examination when acting in the course of his duty as a person so engaged;*

However, the person would only be able to handle those samples for analysis, where those samples have been provided (brought to) them, by another person, for the purposes of forensic analysis. Circumstances will vary but generally an individual could not collect, possess and undertake forensic analysis of those samples without a Home Office licence.

Where reference standards are used in the course of analysis, possession of those standards for the purposes of analysis would not come within the scope of this provision. This applies irrespective of whether those standards are 'consumed' in the course of the analysis.

**Where a reference standard is not an exempted product, as defined by Regulation 2 of the MDR 2001, it is therefore highly likely a licence is needed, to enable lawful possession of 'reference standards', when used in such analysis.**

Are there any exemptions to the need for licensing to possess reference standards?

**Yes, but these are limited-** Regulation 2 of the MDR 2001 provides that a product is exempt from control (licensing) where it meets the definition of an 'exempted product'.

The MDR 2001 outlines as follows:

*"exempt product" means a preparation or other product consisting of one or more*

*component parts, any of which contains a controlled drug, where—*

*(a) the preparation or other product is not designed for administration of the controlled*

*drug to a human being or animal;*

*(b) the controlled drug in any component part is packaged in such a form, or in*

*combination with other active or inert substances in such a manner, that it cannot be*

*recovered by readily applicable means or in a yield which constitutes a risk to health; and*

*(c) no one component part of the product or preparation contains more than one*

*milligram of the controlled drug or one microgram in the case of lysergide or any*

*other N-alkyl derivative of lysergamide;*

This definition could apply to some reference standards, but all three limbs of the definition must be satisfied.

In the course of my work, I 'produce' new reference standards from ones I hold. Does that mean I need a 'production' licence?

## **Potentially.**

'Production', as an activity for the purposes of the MDR 2001, which is held to mean the creation of ne substance (containing a controlled drug) from another, even if the molecular structure of the controlled drug element is unchanged. Hence, 'dilution' of the drug content of a solution would usually be considered a 'production' activity and need to be licensed as such.

### What about toxicology, pathology, or other types of analytical testing work?

The provision in respect of samples sent to a person for the purposes of forensic analysis referred to above (Regulation 6(7)(e)) does not apply to other (non-forensic) analytical work, **so it is highly likely a Home Office licence would be needed.**

Whilst it is possible that a sample under test may come to be an 'exempted product' as defined by Regulation 2 of the MDR 2001, unless this is known at the point of possession, this cannot be relied upon. Furthermore, there is likely to be a licensing need for any reference samples held as outlined above.

### What about laboratory services conducted by police force employees?

Regulation 6(7)(a) of the MDR 2001 means that 'constable' may possess controlled drugs, in limited circumstances, when acting in their capacity as such. However, we do not consider this provision would extend to someone holding the office of a constable undertaking forensic analytical work.

Furthermore, any authority afforded to constables does not extend to civilian employees of the police. So, any police employees conducting forensic analysis, or organisation providing such services within a police building would likely need a Home Office Controlled Drug licence to lawfully carry out this work.

### Does a licence issued restrict me to certain types of analytical work?

No, once granted a generally licence enables the lawful holder to undertake the licensed activities (e.g. possess, supply, produce controlled drugs) with the drug schedules covered by that licence (e.g. drugs listed in Schedule 2 to the Misuse of Drugs Regulations 2001). It is not, as a general rule, issued for individual drugs or specific purposes.

There will be some exceptions to this, but any limitations are clearly stated on the licence. As a general rule, if a licence enables you to undertake forensic analysis in respect of certain drug schedules, you would be able to conduct other types of analysis for those schedules and activities covered- e.g. toxicology, biochemistry services, other analytical work so long as it is consistent with that individuals duties.

### How do I apply?

- Online, via the Home Office Drugs Licensing website:  
<https://eforms.homeoffice.gov.uk/outreach/DrugsConsole.ofml>
- We do not accept applications by post or e-mail.

### What is the process for making a licence application?

We have produced a downloadable application guide to help you complete the application, available at:

<https://www.gov.uk/controlled-drugs-licences-fees-and-returns#applying-for-a-licence-companies>

In summary, you need to

- Obtain an 'iCasework web app' login
- Apply for your enhanced DBS check using the links available on the Home Office website, ensuring the Home Office is noted as the relevant body.
- Provide payment details for the licence fee, when contacted by the Home Office (see How do I pay a fee? below)
- Fully complete and submit the application form via the web portal
- Record and retain your application reference number

### Is there a fee payable?

- Yes, there is a fee payable for the issue of a licence. Fee levels have been calculated on a full-cost recovery basis and will be periodically reviewed.
- A 'new' licence, issued to a person for the first time is subject to a variable fee structure in recognition of the differing level of complexity associated with these types of applications. The fees vary from £3,133 (possess licence) to £4,178 (possess and produce preparations). This includes a mandatory compliance visit to your premises.
- Licences are valid for one year from the point of issue.
- The fee structure at the point of renewal for existing licensees is considerably lower, ranging from £326 to £1,371 if a compliance visit is required. All applications are subject to a risk-based consideration and triage, and we expect to visit those renewing licences, approximately every 3-5 years.

### How do I pay a fee?

- Payment information must be provided to enable the application to be submitted, but payment is not taken at that stage.
- Assuming your application is approved in principle, we will issue you an invoice by email for immediate payment via our Shared Service Centre.
- Licences will not be issued without payment being received.
- If you undertake activities with controlled drugs for which a licence is required before paying for, and receiving your licence, you will be doing so unlawfully.

### Do I need to have a DBS check?

Yes. Satisfactory completion of an enhanced DBS check has been a requirement applicable to all Controlled Drug and Precursor Chemical licence applicants.

- A fee is payable for an enhanced DBS check.
- Applications must be made via Security Watchdog (part of Capita PLC), and the Home Office Drugs Licensing must be noted as the Registered Body. If this process is not followed, any check completed elsewhere is not transferable.
- Generally speaking, we will not ask you to obtain a further enhanced DBS check, where you obtained one for the purposes of drug licensing, within the last three years.
- A DBS application must have been lodged before you submit your application for a licence.

### When shall I apply?

Early application is encouraged.

Please allow up to 16 weeks for us to contact you to arrange a compliance visit, if one is required.

Please note:

- All first time licensees, new sites and upgrades are visited as an integral part of the consideration process and before the issue of a licence
- 'Renewal'/ amendment/ further or additional licence applications may receive a visit, before the issue of new licences- we will make a risk-assessed decision whether to visit. On average, we aim to visit each site once every 3-5 years
- Applications are only considered complete where all component parts of an application are correct and present i.e DBS completed, and all further information requested has been received etc.
- If there is a delay because we have asked for more information regarding your application, it will take longer than 16 weeks to contact you to book a compliance visit

Licences will not be issued until such time as the fee payment is received and time should be allowed for this process.

### Contacts- Home Office- Drugs Licensing & Compliance:

**Please use our dedicated enquiry e-mail in the first instance**

[dflu.dom@homeoffice.gov.uk](mailto:dflu.dom@homeoffice.gov.uk)

**Duty Compliance Officer-** Our number can be found on the Drugs Licensing web page on [www.gov.uk/guidance/controlled-drugs-domestic-licences](http://www.gov.uk/guidance/controlled-drugs-domestic-licences)