

Drug Checking Service Provider Licensing Handbook

Guidance for potential and current
drug and substance checking service
providers

2022

Citation: Ministry of Health. 2022. *Drug Checking Service Provider Licensing Handbook: Guidance for potential and current drug and substance checking service providers*. Wellington: Ministry of Health.

Published in April 2022 by the Ministry of Health
PO Box 5013, Wellington 6140, New Zealand

ISBN 978-1-99-110029-0 (online)
HP 8087



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Contents

Purpose statement	1
Introduction	2
Definitions	4
General application information	8
Applying for a licence	8
Penalties for breaching a licence or providing drug checking services without a licence	8
Applicant background information	9
Conflict of interest of the entity (applicant organisation) and any responsible persons of the applicant	9
Applicant suitability	10
Responsible persons	10
Suitability of the applicant	10
Convictions and non-compliance	11
Seriousness	11
Criminal record checking	12
Information required where there has been offending or non-compliance	13
Applicant suitability statement	14
Service delivery models	15
Target audiences, including equity and accessibility considerations	17
Workforce structure	18
Drug checking service provider functions	19
Provision of drug harm reduction advice with testing results	20
Testing	22
Calibration of equipment	23
Disposal of samples	23
Surrender of drugs to the police	24
Further testing	24
Loss or removal of drugs	24
Training	25
Additional information	26
Safe storage of samples	26

Transportation	28
Privacy	29
Data collection and storage of personal information	29
Record keeping and reporting	30
Record keeping	30
Reporting	31
Licensing decision	32
Decision to approve	32
Decision to decline	32
Licence renewal	33
Appeals	34
Suspension, or cancellation of licence	35
Surrender of licence by service provider	36
Complaints	37
Maintenance and monitoring	37
Monitoring schedule	39

Purpose statement

The purpose of this handbook is to provide information for both potential and current licensed drug and substance checking service providers. The handbook gives details on the application process, along with general information about the Drug Checking Licensing Scheme for drug checking service providers.

NB: Guidance for information to be included in the application submission appears in italics.

Introduction

Drug checking is a drug harm reduction service. Drug checking reduces some of the risks associated with drug consumption; it involves testing the composition of a drug to ascertain its likely composition. Drug checking services also provide people with advice on how to reduce risks and harms, and information that can help them make informed decisions about drug use. Drug checking services do not promote illicit drug use or claim that illicit drug use is safe.

The Ministry of Health's Drug Checking Licensing Scheme implements drug checking services in New Zealand. It:

- licenses new providers
- renews licences
- suspends, and cancels licences
- imposes, revokes and amends licence conditions
- manages appeals related to licensing decisions
- manages complaints
- monitors the compliance of drug checking service providers.

Under the scheme, for drug checking service providers to operate legally, the Director-General of Health must have licensed them. In terms of legislation, drug checking is regulated under amendments to the Misuse of Drugs Act 1975 (MoDA), along with the Psychoactive Substances Act 2013, the Medicines Act 1981, and the relevant regulations of those Acts.

The Drug and Substance Checking Legislation Act 2021 made relevant permanent amendments to the MoDA to implement the Drug Checking Licensing Scheme. It received Royal assent in November 2021, and can be viewed at:

<https://www.legislation.govt.nz/act/public/1975/0116/latest/DLM436101.html>.

The Government has also developed regulations to support the implementation of the Drug Checking Licensing Scheme. Applications for drug checking licences will be open once the regulations come into force, probably in the second quarter of 2022.

This new legislation replaces the Drug and Substance Checking Legislation Act 2020, which was temporary legislation. A transition period enables providers appointed at the date of repeal of the 2020 legislation to continue to deliver drug checking services under the same conditions as gazetted under that legislation.

If an appointed provider applies for a licence within one month after the regulations come into force, their appointment continues until the Director-General of Health (the Director-General)¹ makes a licensing decision on the applicant.

If a provider does not apply for a licence within one month of the regulations coming into force, their appointment will lapse.

The penalty for a person (or entity) undertaking drug checking without a licence is \$20,000.

All enquiries, application submission and supporting documentation are to be sent to: **drugcheckingadmin@health.govt.nz**.

¹ Where there is reference to the Director General of Health being satisfied of suitability related to convictions and non-compliance under Schedule 6 of the MoDA, the term Director-General also includes reference to the Minister of Health when applicable.

Definitions

Term	Definition
Accessibility	A measure of how easy services are to approach, reach, enter, speak with, use or understand.
Applicant	The individual or entity who is applying to become a drug checking service provider.
Conflict of interest	A situation in which a person (or potentially an organisation or other entity) is in a position to derive personal benefit from actions or decisions made in their official capacity.
Contactless and/or mail-in service delivery model	A service delivery model that facilitates fully contactless drug checking; that is, drug checkers have no face-to-face contact with the individual presenting the drug for checking.
Drug and substance	A drug, substance or any other material presented for checking. The terms 'drug' and 'substance' are interchangeable for the purposes of this handbook.
Drug checking service provider (or service provider)	An individual or entity licensed as a drug and substance checking service provider under clause 4 of Schedule 6 of the MoDA.
Entity	Includes: <ol style="list-style-type: none"> a. a body corporate b. a corporation sole c. in the case of a trust that has: <ol style="list-style-type: none"> i. only one trustee, the trustee acting in their capacity as trustee ii. more than one trustee, the trustees acting jointly in their capacity as trustees d. an unincorporated body (including a partnership).
Equity	The absence of avoidable or remediable differences among groups of people.
Existing service provider	A drug and substance checking service provider that: <ol style="list-style-type: none"> a. was appointed under old section 35DA of the Drug and Substance Checking Legislation Act 2020; and b. still held the appointment immediately before old section 35DA was repealed (by section 16 of the Drug and Substance Checking Legislation Act 2020).
Field event service delivery model	A service delivery model that involves a drug checking setup in a temporary location at an external event or festival (eg, a music festival).
Licence	A legal document giving the provider official permission to deliver drug checking services in New Zealand.
Loss (of drugs)	Unauthorised removal of drug or substances (eg, because of theft).

Term	Definition
Low-contact/drop-off service delivery model	A service delivery model that involves a drug checking setup entailing less contact (eg, an individual drops off samples for checking and comes back later to receive results face-to-face).
Mobile clinic service delivery model	A service delivery model that involves a drug checking set-up run out of a vehicle (eg, a van).
Non-compliance with the MoDA	<p>Any repeated or serious non-compliance offences under the MoDA, including activities that do not adhere to the requirements of the MoDA, including:</p> <ul style="list-style-type: none"> • offences against sections 6 to 13 of the Act – these sections cover involvement in the illicit drug trade, such as supplying, possessing, manufacturing, growing or importing illicit drugs (whether or not the person was convicted) • failure to comply with regulatory requirements relating to a licence or other permit under the Act, including a drug checking licence. Some (but not all) regulatory non-compliance is an offence under the MoDA or its regulations.
Offence	An act or omission that one may be prosecuted for and punished under the criminal law.
Other health services	<p>Health services as defined in section 2(1) of the Health and Disability Commissioner Act 2004 other than services carried out in the performance of a function specified in section 35DB of the MoDA. Such services include:</p> <ol style="list-style-type: none"> services to promote health services to protect health services to prevent disease or ill health treatment services nursing services rehabilitative services diagnostic services services provided to a person who has requested assisted dying under the End of Life Choice Act 2019, including psychotherapy and counselling services reproductive health services, including contraception services and advice, fertility services, sterilisation services and abortion services. <p>Note that health services may also include social type services.</p>
Personal information	Information about an identifiable individual (eg, name, contact details), as defined by section 7(1) of the Privacy Act 2020.
Residential premises	As defined in Residential Tenancies Act 1986, section 2(1), a residential premises means any premises used or intended for occupation by any person as a place of residence, whether or not the occupation or intended occupation for residential purposes is or would be unlawful.
Repeat offending/non-compliance	<ul style="list-style-type: none"> • Any significant (or serious) offence/non-compliance committed more than once. • Any less significant (non-serious) offending that is habitual or regular.

Term	Definition
Responsible person	<p>In relation to an entity that is, or is applying to be, a drug and substance checking service provider:</p> <ol style="list-style-type: none"> a. a director, partner or trustee of the entity b. if the entity does not have directors, partners or trustees, a person who acts in relation to the entity in the same or a similar fashion as a director, partner or trustee would were the entity a company, partnership or trust.
Satellite/pop-up clinic service delivery model	<p>A service delivery model that involves a drug checking setup at a location that is not the provider's permanent location and not a field event (eg, a short-term rented location in a city where the provider does not have a permanent location).</p>
Seriousness (of drug offences and regulatory non-compliance)	<p>Seriousness of drug offences is determined by consideration of the following:</p> <ul style="list-style-type: none"> • the usual justice system response to an offence • the likely impact of the offending on other people, and the scale of the likely impact • the extent to which the offending calls into question the character or judgement of the offender. <p>Seriousness of regulatory non-compliance is determined by consideration of the following:</p> <ul style="list-style-type: none"> • the actual and potential impact of the non-compliance • whether the non-compliance was technical (eg, providing information late or in the wrong format) • whether the relevant regulatory Ministry officials regards the non-compliance as serious.
Static clinic/commercial premises service delivery model	<p>A service delivery model that involves a drug checking setup at a location that is the provider's permanent location. This will usually be the provider's office or other location regularly used for drug checking.</p>
Suitable applicant	<p>An applicant is suitable if the Director-General or the Minister (as the case may be) is satisfied that:</p> <ol style="list-style-type: none"> a. the applicant will comply with the MoDA, its regulations and the applicant's licence conditions; and b. there is no other reason why the applicant would not be suitable, with consideration to: <ol style="list-style-type: none"> i. conviction of an offence against the MoDA, the Psychoactive Substances Act 2013 or the Medicines Act 1981 (or any regulations made under any of those Acts); or ii. a crime involving dishonesty (as defined in section 2(1) of the Crimes Act 1961); and iii. whether there has been a serious or repeated failure by the applicant (and, if the applicant is an entity, any responsible person) to comply with any requirement of the MoDA or its regulations; and iv. any evidence provided by the applicant about their suitability; and v. any other matter that the Director-General or the Minister considers relevant.

Term	Definition
Term of licence	The licence is for a maximum term of three years. This term may be shorter at the discretion of the Director-General.
Worker	A person who carries out work in any capacity for a drug checking service provider, including work as: <ul style="list-style-type: none"> <li data-bbox="632 407 810 439">a. an employee <li data-bbox="632 448 986 479">b. a contractor or subcontractor <li data-bbox="632 488 1353 548">c. a volunteer (a person who carries out work on a voluntary basis, whether or not they receive out-of-pocket expenses).

General application information

Organisations or individuals may apply for licensing if they consider they meet the requirements of the relevant Acts, their regulations and the suitability requirements outlined in this handbook.

Applicants must demonstrate how they meet (or intend to meet) the functions of a drug checking service provider as specified in the MoDA.

Applying for a licence

Download the Drug Checking licensing application form available on the Ministry of Health drug checking webpage under 'published documents', complete this and submit it with supporting documentation to drugcheckingadmin@health.govt.nz.

There are no application fees.

Penalties for breaching a licence or providing drug checking services without a licence

If there is a breach of any terms or condition of licence, the offender is liable for a fine of up to \$5,000, and the licence may be cancelled.

Providing drug checking services without a licence is an offence and the offender may incur a fine up to \$20,000.

Applicant background information

The Ministry requests certain information to obtain an insight into the applicant's background, their reasons for wanting to be licensed as a drug checking service provider, their previous experience in harm reduction or drug checking services and any other supporting information.

Provide a summary (maximum 300 words) of background information, including:

- *a general statement about the applicant*
- *previous drug checking experience or related work*
- *why the applicant is applying to become a drug checking service provider.*

Conflict of interest of the entity (applicant organisation) and any responsible persons of the applicant

A conflict of interest arises when something that is in one person's (or organisation's) best interests is not in the best interests of another. Conflict of interest may be actual or perceived.

It is preferable to declare potential conflicts of interest, to ensure they can be managed if necessary.

In the drug checking context, an example of a conflict of interest is a financial interest in a drug-related service or providing a service that promotes an abstinence-only approach to drug usage.

The Ministry directly asks applicants about potential conflicts of interest, but it also seeks broader information on other activities an applicant undertakes; this will help to determine further potential conflicts of interest, as well as the suitability of the applicant as a licensed provider.

If the applicant is an entity, outline any activities (other than drug checking) that it will carry out, or is likely to carry out, during the term of the licence.

State any potential conflict of interest the applicant or any responsible person may have in providing drug checking services.

Applicant suitability

Responsible persons

For the purposes of the application to be licensed as a drug checking service provider, a responsible person includes a director, partner or trustee of the applicant entity.

If the entity does not have directors, partners or trustees, a person who acts in relation to the entity in the same or a similar way as a director, partner or trustee is a responsible person.

If the applicant is an individual person, that person is the responsible person.

Provide certified identification documentation for each responsible person that comprises at least one of the following:

- *New Zealand driver's licence*
- *Passport*
- *Birth certificate.*

Include any other names the responsible person(s) has previously been known by.

Suitability of the applicant

The legislation requires the Director-General to be satisfied as to the suitability of the applicant and any responsible person of the applicant. An applicant or any responsible person will be suitable if the Director-General is satisfied that:

- the applicant will comply with the MoDA, its regulations and the applicant's licence conditions, and
- there is no other reason why the applicant would not be suitable (see below).

The licensing process assesses the suitability of the applicant and responsible persons.

Unsuitability of a responsible person does not automatically mean that the applicant cannot be licensed. For example, the Ministry may still consider a particular applicant to be suitable, on the condition that the unsuitable responsible person is not involved with drug checking.

Convictions and non-compliance

In determining suitability, the Director-General must consider any relevant convictions (as defined in the legislation) and any serious or repeated non-compliance with the MoDA.

The Minister of Health's approval is required where an applicant, or any responsible person of the applicant:

- has been convicted of an offence under the MoDA or its regulations, or
- has had a licence under that Act revoked due to non-compliance or
- was a responsible person for another entity that has been convicted of a MoDA offence or had a licence revoked.

Seriousness

The Director-General will consider the seriousness and relevance of the offending or non-compliance, and the amount of time which has elapsed since it occurred, on a case-by-case basis.

The Director-General will determine the seriousness of drug offences by considering the following:

- the usual justice system response to an offence
- the likely impact of the offending on other people, and the scale of the likely impact
- the extent to which the offending calls into question the character or judgement of the offender.

The Director-General will determine the seriousness of regulatory non-compliance by considering the following:

- the actual and potential impact of the non-compliance
- whether or not the non-compliance was technical (eg, providing information late or in the wrong format)
- whether the relevant regulatory Ministry officials regard the non-compliance as serious.

See 'Definitions' for further information.

Criminal record checking

Each responsible person must provide a criminal record check, dated no earlier than three months before the application submission date.

You can apply free of charge for a criminal record check: see <https://www.justice.govt.nz/criminal-records/get-your-own/#tips>.

Note that a criminal record check is different from a police vetting check. See <https://www.justice.govt.nz/criminal-records/police-clearance/> for terminology. The Ministry may request additional information at any time, if required.

Provide a full copy of the results of a criminal record for each responsible person.

Where an applicant is an entity, include a criminal record check for every director, trustee or partner.

Where an applicant does not have directors, trustees or partners, include a criminal record check for everyone acting in a similar role.

Where an applicant is one person, include a criminal record check for that person.

Information required where there has been offending or non-compliance

Additional information is required to be submitted where an applicant, or any responsible person of the applicant, has a relevant conviction or history of non-compliance (as stated above).

We require the applicant to declare all offending both with and without conviction to provide an equitable application process for anyone applying. Any non-compliance needs to be noted regardless of conviction. Any instance of non-compliance will be assessed on a case-by-case basis.

The following information is required to be declared where there has been responsible persons offending or non-compliance:

- *any conviction of an offence against:*
 - *the MoDA*
 - *the Psychoactive Substances Act 2013*
 - *the Medicines Act 1981*
 - *any regulations made under any of those Acts*
- *any crime involving dishonesty (as defined in section 2(1) of the Crimes Act 1961)*
- *any pending court hearings/trial/sentencing*
- *whether the person has ever seriously or repeatedly failed to comply with any requirement of the MoDA or its regulations (whether or not a conviction resulted)*
- *whether any responsible person of the applicant, while a responsible person for a different entity, was ever seriously or repeatedly non-compliant with the MoDA (whether or not a conviction resulted)*
- *any overseas convictions equivalent to the relevant convictions listed above.*

For each offence or non-compliance (with or without conviction), state the length of time since the conviction or non-compliance.

Non-compliance of the MoDA also includes instances in which licences or permits held under the MoDA were revoked or cancelled, including when a responsible person worked for another entity.

For each responsible person, state:

- *whether they have held (or currently hold) any other licences or permits under the MoDA (name these)*
- *whether any licences or permits they have held under the MoDA, for this or any other entity, have ever been revoked or cancelled, and the reasons for this and whether they were a responsible person of the entity at the time.*

Applicant suitability statement

Where a responsible person has a relevant MoDA conviction or non-compliance, the applicant must submit a statement explaining why they are suitable to hold a licence. The Director-General will assess this statement on a case-by-case basis to determine suitability.

Suitability statements may include information on the following factors:

- the nature of the offending or non-compliance, including its seriousness and relevance to drug checking
- the length of time since the offending or non-compliance
- the name of any licences or permits revoked or cancelled, or compliance issues, the reasons for the revocations or cancellations and the time since any revocation or cancellation has occurred
- the extent of the person's awareness of and involvement in the offending or non-compliance, and what they did do prevent or stop it
- the role the responsible person will play in the drug checking service (eg, the person may be a director of the entity, but not involved in the drug checking service provision itself)
- the reason the person has for becoming involved in drug checking services and the provision of drug harm reduction advice
- an assurance that the person will comply with the legislation, regulations and licensing conditions.

Where a responsible person has a relevant MoDA conviction or non-compliance, the applicant must submit a statement explaining why they are suitable to hold a licence. The Director-General will assess this statement on a case-by-case basis to determine suitability.

This statement should be a maximum of 500 words.

Service delivery models

Applicants need to prove to the Director-General that their service model will enable them to carry out their functions to an appropriate standard, complying with the legislation and any conditions of licensing.

Applicants must be able to demonstrate that their service complies with current best practice principles. These principles pertain to identification of the composition of drugs, use of up-to-date drug libraries and provision of the best possible drug harm reduction advice.

The service model must comply with the legislation, regulations, licensing requirements and conditions of licensing. For example, drug checking service providers must not perform any of their functions from residential premises (see section 35DB of the MoDA).

In identifying their service delivery models, applicants must specify the following:

- service delivery type (eg, field events, static clinics)
- location (eg, national, regional)
- target audiences, taking health inequities considerations into account (eg, Māori, rainbow communities, youth, people experiencing homelessness, rural populations, urban populations)
- frequency (eg, regular clinics, seasonal events)
- any other relevant aspects, such as accessibility (eg, wheelchair access).

Current service delivery models include:

- field events, such as summer festivals
- static clinics/commercial premises
- satellite/pop-up clinics.

These service models primarily target youth and the young adult demographic. The Ministry anticipates that drug checking services will increase to become more equitably accessible across the country, including through other service models such as fully contactless and mail-in services. Currently, such models require further Ministry and stakeholder exploration.

The Ministry may restrict an applicant's licensing conditions to the specific service type(s) they select in their application.

Currently, drug checking services may only use certain Ministry-approved technology and testing methods. Information on approved technology and testing methods can be found at <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/drug-checking>.

Where an applicant wants to use a testing method that is not on the approved list, they should follow the instructions on the drug checking webpage to submit a new method for approval.

Applicants must outline the service delivery models they propose in their submission, and licences will only apply to the specified models.

Once licensed, providers must notify the Ministry in writing if they wish to change or extend their model(s). The Ministry will assess such requests on a case-by-case basis. If it approves a request, it may, where necessary, officially amend the service provider's conditions of license.

Please identify all service delivery models you wish to deliver.

State the applicant's experience with each selected service delivery model as specified.

For each service delivery model specified, include evidence of your competence or plan to achieve competence, to deliver that model. This may include building experience under the supervision of another experienced approved or licensed drug checking organisation.

Target audiences, including equity and accessibility considerations

Equity and accessibility are key considerations for the Ministry of Health. To this end, the MoDA regulations require all drug checking licence holders to have demonstrated they have taken reasonable steps to provide equitable services and maximise accessibility. A key principle of the licensing system is that the system should enable a wide variety of approaches at a range of locations.

Over time, the Ministry plans to extend drug checking services to increase access among particular groups experiencing health inequities, such as Māori, people with disabilities, rainbow communities, homeless populations and people experiencing substance dependence.

Applicants must outline the ways in which their service will take equity and accessibility into account.

As examples, methods of increasing equitable access include providing resources in other languages and providing targeted resources for people with disabilities. We acknowledge that resource limitations may affect services' ability to implement such measures, but note that, where possible, services should aim to improve equity and accessibility considerations over time.

The Ministry takes into consideration cost, licence holder capability and the accessibility limitations of the particular location where drug checking will be provided.

The Ministry will not restrict licences according to the target audiences and equity and accessibility considerations specified in the application. Rather, the Director-General will use this information to gauge the intentions of the applicant.

Describe the steps you have taken to improve inequity or improve or maintain accessibility (where practical), in terms of:

- *location (eg, national, regional)*
- *primary target audiences, taking health inequities into account (eg, Māori, rainbow communities, youth, people experiencing homelessness, rural populations, urban populations)*
- *frequency (eg, regular clinics, seasonal events)*
- *technology and testing methods (see testing section below).*

Note any accessibility and/or equity considerations which are being considered, for example:

- *wheelchair access*
- *information provided in visual form (for deaf and hard of hearing clients)*
- *information provided in audio form (for blind and low vision clients)*
- *information provided in additional languages (eg, te reo)*
- *any other relevant considerations such as improving or maintaining accessibility and equity.*

Workforce structure

To determine whether an applicant's service model is appropriate and fit for purpose, we ask applicants to demonstrate how they will deliver services for each service model, including in terms of workforce structure.

When possible (taking into account resourcing limitations), applicants should take equity and accessibility considerations into account when planning workforce structure. A more diverse workforce allows greater ability to provide effective services to a more diverse client base (in terms of ethnicity, gender, disability and so on).

Applicants should clearly articulate the process they will follow when escalating potential issues to organisational leadership or other agencies (eg, the police or Drug Information and Alerts Aotearoa New Zealand (DIANZ),² including what factors would trigger escalation to whom and when.

Please provide the following information for each service delivery model you use, or intend to use:

- *workforce structure (volunteer, employed or both)*
- *worker numbers during drug checking, including minimum number of workers for each service delivery model*
- *roles workers hold (eg, supervision, leadership, drug testers, harm reduction workers, 'welcome' worker, etc)*
- *supervision and leadership in place*
- *training or qualifications (eg, applicable science degree) required for each role.*

Outline processes for escalation to organisational leadership or other (eg, organisation supervisor, police/DIANZ), should issues arise and what factors would trigger escalation to whom and when.

² A function of the National Drug Intelligence Bureau, which is a joint agency made up of representatives of the Ministry of Health, New Zealand Police and New Zealand Customs Service.

Drug checking service provider functions

Drug checking service provider functions include the following:

- Harm reduction advice: Provide accurate and appropriate harm reduction advice about particular substances, to help individuals make informed decisions. Partnering with another organisation to provide this function may be appropriate.
- Drug checking testing: Test any drug that an individual presents for checking, within the capabilities of testing technology available.
- Results of testing: Advise individuals about the outcome of the testing.
- Sample return: Return the drug to the individual, as appropriate.
- Sample disposal: Dispose of any sample used in testing.
- Disposal (or arrangement of disposal) of surrendered drug: Dispose (or arrange for the disposal of) any drug surrendered by an individual for disposal.
- Further testing: Arrange for a sample of a drug to be tested by an approved laboratory where applicable.
- Training: Train (or arrange for the training of) the service provider's workers to perform the functions specified in section 35DB (a)–(g) (including by using, for training purposes, drugs that have been surrendered for disposal).

Provision of drug harm reduction advice with testing results

The Director-General of Health may only issue a licence if satisfied the applicant will provide accurate and appropriate harm reduction advice. Failure to provide harm reduction advice is a breach of a drug checking service provider's licence conditions.

Drug checking service providers must provide anyone who receives test results for a particular drug with information and advice relating to harm reduction for that drug, specific to the person, their circumstances and the drug identified. They should also explain limitations to results provided (eg, there may have been other drugs within the substance that have not been detected in the test result).

If testing does not indicate the likely identity of the drug but the provider has a reasonable idea of what it may be, the provider can provide advice on the drug that they think it is alongside advice on consumption of a drug of an unknown identity.

If testing does not indicate the likely identity of the drug, and the provider does not know what it is likely to be, the provider must provide general harm reduction advice.

A service provider does not breach their licence conditions if, despite reasonable efforts being made to give the advice, the individual refuses to receive it.

Providers must present test results in a way that makes it difficult for drug manufacturers (or dealers) to promote their products. They must present information in a way that the person receiving the results can understand. For example, a generic pamphlet on MDMA would meet this requirement, as would a handwritten note specifying the drug name, but a printout of a spectrometer result would not, as interpreting such a printout requires substantial knowledge and training.

Drug checking service providers must ensure that, to the extent their resourcing allows, they consider equity when providing harm reduction advice (eg, by offering information in different languages, such as te reo).

Harm reduction advice must be accurate and appropriate. This means:

- it should be based on the best information available to the provider
- it should be tailored to the persons, their circumstances and the drug tested, as far as is reasonably practical
- it should not stigmatise a person or their actions, or express a moral judgement
- it should not consist of advice merely not to consume a drug (such advice may be included as a recommendation, alongside harm reduction advice).

Advice must specify:

- if the test indicates the likely identity of the drug, the harms associated with that drug
- if the test does not indicate the likely identity of the drug, but the service provider considers that they are able to form a view on its likely identity:
 - the harms associated with that drug
 - the harms associated with taking a drug of an unknown identity
- where the test does not indicate the likely identity of the drug, the harms associated with taking a drug of an unknown identity
- how drug harms could be reduced or avoided.

The provision of inaccurate or inappropriate advice creates a significant risk, in that it may:

- give users of the drug checking service a false sense of security or
- undermine the credibility of drug checking services in general.

Drug checking services must cover the provision of harm reduction advice in training of workers, both at induction and on an ongoing basis.

Describe the process you use to advise an individual of the outcome of the testing of a drug or substance for each different service model.

Describe your delivery of accurate and appropriate harm reduction advice, and how you will update this advice to ensure it is current.

Describe your past experience in providing drug harm reduction advice.

Describe the procedures workers in your service follow for the provision of drug harm reduction advice.

Provide examples of harm reduction resources available through your service, including:

- *specific drug/substance harm reduction resources*
- *harm reduction advice associated with particular drugs/substances identified*
- *harm reduction advice associated with taking unknown substances*
- *other information sources, noting how they would be utilised.*

Testing

Applicants should use a range of testing methodologies and equipment to carry out comprehensive, high-quality drug checking activities in line with best practice. When drug checking is provided, it is expected that services have access to equipment and testing methodologies from the approved methods list to ensure a comprehensive, quality service is delivered for people presenting drugs for testing. This includes access to current drug libraries associated with each specific spectrometer.

Reagent testing as a stand-alone service does not meet the intent of the legislation with regard to providing a high-quality drug checking service (with the exception of fentanyl test strips or Ehrlich's test for LSD reagent testing, for example). The use of reagent testing alone may increase a person's risk of serious harm. A reagent test may identify a single drug (eg, MDMA) when a substance also contains a drug of greater risk (eg, eutylone).

The Ministry of Health's drug checking webpage lists current approved technologies and testing methods: see <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/drug-checking>.

If an applicant or licensed provider wishes to use a method not on the approved list, they will need to satisfy the Director-General that the method is fit for its intended purpose. (Follow the instructions on the Ministry's drug checking webpage to submit a new method for approval.)

The Director-General may restrict an applicant's licensing conditions according to the technology and testing methods specified.

Please provide the following information:

- *all testing methods that your service will use*
- *if spectrometers are loaned, where they are loaned from (eg, ESR or other agencies)*
- *which drug libraries you will use, and how they will be kept up to date*
- *whether/how reagent testing will be used*
- *testing limitations for all methodologies to be used*
- *risks and mitigation strategies associated with limitations of the technology (eg, machinery malfunction, stand-alone reagent testing)*
- *experience with all technologies to be used*
- *examples of the procedures workers will follow for the testing of a drug for each testing methodology.*

Calibration of equipment

Providers may need to use illicit drugs to calibrate their testing equipment. This is considered a function of testing, and possession of these drugs for this purpose is permitted. Providers must keep records of any drugs used for calibration, and make appropriate storage arrangements (see 'Safe storage of samples' below).

Where an applicant has held or holds an import licence under the MoDA for calibration or training purposes, this must be declared in the application. Applicants can apply for such a licence through Medicines Control (Medsafe) within the Ministry of Health.

Please provide the following information:

- *whether drugs will be used to calibrate equipment (if yes, state what type of calibration samples will be used and how these are suitable for accurate calibration)*
- *what type of calibration samples will be used (eg, legal laboratory samples or surrendered illicit drugs)*
- *arrangements for the safe storage and recording of drugs held by applicants for the purpose of calibration of equipment*
- *whether an import licence under the MoDA has been held, is held or will be sought for controlled drugs.*

Disposal of samples

Disposal (or arrangement for the disposal) of drugs is a mandatory function of a drug checking service provider. Providers will need to dispose samples:

- used in testing
- surrendered by an individual for disposal
- used in training
- drugs being transported for disposal at a later date.

Service providers must keep records of any drug that is or has been in their possession for the purpose of disposal, with the exception of recording disposal of drugs on site at the time of testing (eg, by dropping it in a jar of bleach).

Please provide details of the procedure you will use for disposal of samples:

- *used in testing*
- *surrendered for disposal*
- *used in training*
- *drugs being transported for disposal at a later date.*

Surrender of drugs to the police

When surrendering drugs to the police, service providers must adhere to a process that follows police procedures.

Describe the procedure you will use to surrender a drug or substance to the police.

Further testing

Where a drug requires further testing to determine its composition, or if initial testing identifies that it is a drug of concern or an unknown drug, or when specifically requested by the National Drug Intelligence Bureau (NDIB), providers must arrange for further testing at an approved laboratory.³

Service providers must maintain records for each drug they have in their possession for the purpose of arranging testing by an approved laboratory. Records must specify when the sample was provided to the laboratory, how and to which laboratory it was provided.

The service provider must demonstrate knowledge and understanding of the required processes (as specified by NDIB/DIANZ and ESR) for packaging, transportation to the approved laboratory, reporting and notification, and follow those processes when necessary.

Provide evidence of your knowledge of NDIB/DIANZ and ESR transportation/courier requirements to enable further testing of a drug or substance, including in terms of:

- *packaging*
- *reporting*
- *notification.*

Loss or removal of drugs

Section 35DDH of the MoDA requires providers to report lost or unauthorised removal of drugs.

When a provider becomes aware of a loss or unauthorised removal, they must report it:

- immediately to the police⁴ and
- as soon as is reasonably practicable (before the end of the following month) to the Director-General via the drug checking email inbox.

Describe the procedure you will follow after the loss or unauthorised removal of a drug.

³ New Zealand's approved laboratory is the Institute of Environmental Science and Research (ESR).

⁴ Online report to the Police non-emergency 105 website: <https://www.police.govt.nz/use-105> or call ten five (105) available 24 hours a day, 7 days a week.

Training

The Director-General may only issue a licence if satisfied that the training of drug checking workers is appropriate.

Service providers must ensure that everyone carrying out drug checking functions is appropriately trained for the tasks they undertake. Training workers across different roles will allow for greater workforce flexibility, but is not a requirement. In the context of workforce training, the Ministry recommends collaboration with other drug checking service providers. Training should take into consideration how services will be delivered to clients of different backgrounds (in terms of culture, gender and so on).

Providers must specifically train their workers to perform the functions specified in section 35DB of the MoDA, relevant to the workers role in drug checking.

In making licensing decisions, the Director-General will consider the extent of training provided, including what resources are available and whether competencies are measured before workers undertake certain functions, and what mechanisms are in place for mentoring and supervision to support workers.

Please provide details on the training you offer or arrange for including:

- *the delivery of harm reduction advice*
- *use of technology and testing methodologies, including calibration, interpretation and use of drug libraries*
- *providing test results to individuals*
- *returning drugs to individuals*
- *safely sending drugs for further testing*
- *safely disposing of drugs or arranging for their disposal*
- *surrendering drugs to the police*
- *use of drugs for training purposes*
- *safe storage and transportation of drugs*
- *data collection, recording and reporting requirements.*

Include information on how worker understanding and competencies are assessed following training and any mentoring or supervision is in place (including collaboration with other experienced drug checking providers), whilst a worker is maintaining competence.

Provide examples of the training programme and resources.

Describe processes to maintain safe use and storage of drugs or substances if used for training purposes.

Specify examples of the names of drugs and/or substances to be used for training purposes.

Specify examples of how training will take into consideration providing services to individuals from different backgrounds (cultures, genders, disabilities, etc).

Additional information

Safe storage of samples

The following guidance reflects best practice for safe storage acknowledged in New Zealand and overseas. It is designed to meet New Zealand regulatory requirements and apply in a range of contexts including regular static clinics (eg, provider's permanent office), events held in the field (eg, festivals) and pop-up clinics (eg, temporary location to deliver a clinic).

The safe storage of drugs entails rigorous measures to prevent drugs from being stolen or lost, while recognising the practical issues providers face, particularly in the field.

Amendment to the Misuse of Drugs Regulations exempts drug checking service providers from certain storage requirements (such as the requirement to store drugs in a metal or concrete safe that is securely fixed to a building), since these are impractical for most drug checking providers delivering services in a temporary or field setting. However, secure safe storage remains a requirement under section 35DDG of the MoDA.

A service provider must securely store all controlled drugs or substances when:

- holding and transporting them prior to further testing at an approved laboratory
- holding and transporting them prior to disposal (other than for those disposed of at the time of drug checking)
- surrendering them to the police
- using them for training purposes
- using them in the calibration of equipment.

The following principles apply to the safe storage of drugs and substances:

- Packaging and labelling: Samples are placed in a suitable specimen bag for storage, labelled with:
 - the sample ID/number that aligns with more detailed information recorded in the hard copy or electronic register
 - the date the sample was retained
 - the location at which the sample was retained
 - the name of the person who accepted the sample
 - the reason for possession and storage.
- Lockable storage: Samples are secured in a lockbox (eg, a locked cupboard, cabinet or safe), specific to the service delivery model (eg, a transportable lockbox in the field and a non-movable safe in an office or static clinic).

- **Restriction from unauthorised access:** The lockbox is not accessible to unauthorised persons, and it is secure when unattended. The mechanism to unlock the lockbox is held by authorised personnel only.
- **Discretion:** The lockbox is not visible to unauthorised people. If it is visible, its purpose is not identifiable.
- **Maintenance of drug and/or substance register:** The names of those authorised to access the lockbox are documented, and a register (hard copy or electronic) of all drug and/or substance possession activity (including for training purposes) is kept, adhering to the following principles.
 - The register is held securely, either electronically or in hard copy (if in hard copy, the register is held in a lockbox that is separate from the lockbox used to store drugs).
 - Each sample is logged separately (to ensure it can be tracked independently) in the register with the following details:
 - sample ID/number of any drug or substance added to or removed from the lockbox
 - name (if known) of any drug or substance added to or removed from the lockbox
 - date and time of any addition or removal from the lockbox
 - name and signature of the worker adding or removing the drug or substance from the lockbox
 - reason for holding the drug or substance.

This registers will hold a current record of all drugs and substances held by a drug checking service provider at any given time. In the context of field events or pop-up clinics, providers must maintain an interim register and store it securely, then update the master register as soon as practical afterwards. Providers must maintain document control for interim and master registers, to ensure obsolete register information is not used in error.

The Ministry require that no worker of a drug checking service provider can leave the lockbox unattended unless they have taken all reasonable steps against unlawful removal.

Licence conditions may state specific storage requirements that vary from those outlined above.

Transportation

The principles specified in the previous safe storage section also apply to transportation of drugs or substances.

In transporting drugs or substances via courier to an approved laboratory for further testing, or surrendering them to the police, providers must follow relevant ESR and NDIB/DIANZ protocols, including in terms of informing those agencies that a sample is being sent.

Where providers send samples of drugs and substances to ESR or NDIB/DIANZ, they must be tracked. Further transportation safety measures are required for liquids and known dangerous substances.

Providers should ensure that labelling and descriptors on the package do not reveal its contents.

Please provide the following information about your procedures for safe storage:

- *how drugs and substances will be stored safely:*
 - *in all service delivery settings*
 - *when being transported*
- *the processes you will follow in the event of unauthorised loss or removal of a controlled drug or psychoactive substance.*

Privacy

Providers must be aware of the Privacy Act 2020 and know how to prevent privacy breaches. They must be able to demonstrate how they will comply with the information privacy principles contained in the Privacy Act.

Drug checking service providers will not collect or hold personal information (eg, names or contact details) in the course of service delivery unless the service also provides other health-related services (such as acute care services, mental health or drug addiction services). If this is the case, the provider must collect and store that information independently from the drug checking service.

Privacy considerations should be included in training and worker service agreements. Providers should be aware of the need to address behaviours such as casual discussion (gossiping), should explicitly prohibit the photographing, recording or filming of service users in any context, and should take steps to minimise the potential accidental identification of people from their demographic information.

Identify potential risks to the privacy of service users and outline how you will mitigate these risks.

State whether your service collects personal information for the purposes of other health-related services and outline the processes you follow to keep that information separate from drug checking service provision.

Data collection and storage of personal information

Applicants need to demonstrate how they will comply with legislative requirements relating to the collection of personal information (see 35DDE of the MoDA). Service providers must not:

- require individuals to disclose demographic information (such as their age, gender, ethnicity or cultural background) as a condition of providing service
- collect, maintain, use, or disclose any individual's personal information.

A drug checking service may collect anonymous demographic information (eg, for the purposes of general service outcome reporting and trends). However, it cannot require a person who presents for drug checking to provide this information.

Service providers should collect data for recording and reporting as required by the legislation and their particular licensing conditions (see 'Record keeping and reporting' below).

Describe what processes you have in place for data collection and data storage.

Record keeping and reporting

Record keeping

Under section 35DDJ of the MoDA, service providers must keep a record of:

- the number of tests they carry out
- the number of individuals they advise of test results
- for each drug or substance that the service provider tests and returns to the individual who submitted it:
 - the purported identity (if known) of the drug or substance
 - the test result
- for each drug or substance that the service provider has in their possession for the purpose of disposal or arranging testing by an approved laboratory:
 - the purported identity (if known) of the drug or substance
 - if the drug or substance has been tested by the service provider:
 - the test result
 - the weight of the drug or substance
 - whichever of the following applies:
 - ⌘ if the drug or substance is disposed of by the service provider, how and when it was disposed of
 - ⌘ if the drug or substance is provided to another person for disposal, when, how and to whom it was provided:
 - ⌘ if the drug or substance is provided to an approved laboratory for testing, when, how and to which laboratory it was provided
- for each drug or substance that the service provider has in their possession for the purpose of training:
 - the identity of the drug or substance, as indicated by testing performed by the service provider or an approved laboratory
 - the weight of the drug or substance
 - if the drug or substance is destroyed while being used for training, how and when that occurred.

The service provider must retain each record for the period prescribed by regulations under the MoDA.

Information that must be kept for 12 months includes:

- any data required to be reported to the Director-General or the NDIB (12 months after the date on which the data was sent)
- any drug or substance in the possession of the licence holder, and the purpose for possession (12 months after the licence holder ceased to have any of the drug or substance in its possession)
- where legislation does not specify a time period.

Information that must be sent to the Director-General within 60 days (unless a different period of time is specified in writing) includes, where providers have surrendered their licence, any records or information they were required to collect/maintain that has not already been sent to the Director-General and/or the NDIB.⁵

Describe how your record keeping processes will comply with the rules set out in the MoDA.

Reporting

Drug Information and Alerts Aotearoa New Zealand collects and analyses data on illicit drugs, including data from drug checking service providers.

Section 35DDI of MoDA requires all drug checking service providers to report data to the Director General and NDIB/DIANZ on:

- test results and
- the number of people provided with results to the Director-General and to DIANZ

Section 35DDH of MoDA requires all drug checking service providers to report data to the Director General and the police on:

- loss or removal of a drug or substance.

Providers must collect data for recording and reporting as required by the legislation, their specific licensing conditions.

Outline legislative reporting requirements.

⁵ The former provider should not be required to keep any records or information which has been sent to the Director-General and/or the NDIB.

Licensing decision

The Director-General will assess applications for licences, then make a decision either approving or declining a licence.

Decision to approve

After a decision to approve a licence, the Director-General will inform the provider and publish a notice in the *Gazette*. The notice includes conditions of licence.

The Director-General may impose, amend or revoke licence conditions by written notice to a service provider at any time.

A licence issued to a particular service provider is not transferable.

A licence remains in force until the close of the third anniversary of the date on which it was issued. The Director-General may specify a shorter period for the licence.

Decision to decline

If the Director-General is not satisfied of the applicant's suitability, they must decline the application and notify the applicant of the decision and the reasons for the decision.

Where the Director-General declines a licence or renewal of a licence, the applicant or licence holder has the right to a review (ie, an appeal) of the decision. A review is undertaken through the appeals process (see 'Appeals' below).

Licence renewal

MoDA regulations state if an application to renew a licence is made no earlier than 90 days before and no later than 30 before the expiry of a licence, the licence will continue in force until a decision is made on the licence renewal.

The Director-General will base the decision to renew a licence on assessment of any matters that have changed since the original licence was granted; the licence holder's record of compliance; and any other relevant information, including maintenance and monitoring activities.

Service providers may apply for a renewal of licence by filling out a 'Renewal of licence' application form (available at <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/drug-checking>). They should email this form, with supporting documents, to: drugcheckingadmin@health.govt.nz.

Appeals

Providers may lodge an appeal on a licensing decision (where a licence or renewal application is declined, suspended or cancelled or a condition is imposed, amended or revoked) by completing the 'Review of decisions – appeals' form (available at <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/drug-checking>) within 14 days of receiving the decision.

Providers can submit the completed form by emailing it to drugcheckingadmin@health.govt.nz.

The Director-General will appoint a Ministry official who was not involved in the original licensing decision to conduct the appeal review. The reviewer will make a recommendation to the Director-General, who must then confirm their original decision or make a new decision.

While an appeal from an existing licence holder is under consideration, the licence holder may not carry out any drug checking functions without the express permission of the Director-General.

Suspension, or cancellation of licence

The Director-General may suspend or cancel a licence if they believe that:

- the licence holder has breached the terms or conditions of their licence
- the licence holder provided false information in their licence application
- a licence holder, partner or director, after being licensed, has been convicted of an offence against the MoDA or any of its regulations, the Psychoactive Substances Act or the Medicines Act, or a crime involving dishonesty as defined in section 2(1) of the Crimes Act.

Surrender of licence by service provider

Where a service provider's licence is cancelled or the service provider no longer performs any of the functions of a service provider, the provider must surrender their licence by giving written notice to the Director-General. A *Gazette* notice will then be published repealing the licence.

Complaints

Where the Ministry receives complaints about a particular drug checking service provider, it will include those complaints in its monitoring of the service's performance (see 'Maintenance and monitoring' below). As the licensing authority, the Ministry will receive, investigate and act on complaints as a core component of the Ministry's regulatory role.

Members of the public and service users must be able to easily and anonymously make complaints and provide feedback about drug checking service providers. To this end, a complaint form is published on the Ministry's drug checking webpage: see <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/drug-checking>. Alternatively, people can email complaints to drugcheckingadmin@health.govt.nz, or make complaints anonymously via telephone to the Ministry on **0800 855 066**.

Service providers must cooperate fully with any inquiry relating to a complaint about their service.

Maintenance and monitoring

The Ministry is responsible for the maintenance and monitoring of drug checking service providers' performance to ensure compliance with the MoDA legislation and licence conditions.

Under the legislation, individual licence conditions and any other requirements specified by the Director-General, maintenance and monitoring activities may include the following.

Maintenance

- Recording requirements as legislated
- Reporting requirements as legislated
- Any additional maintenance activities required by the Drug Checking Licensing Scheme

Monitoring

- Audit
- Non-compliance progressing monitoring
- Self-declaration activities
- Any additional maintenance activities required by the Drug Checking Licensing Scheme

The purpose of monitoring is to assess licensed providers' compliance with the Act, its regulations and licensing conditions. Through monitoring, the Ministry can support providers to deliver services at an appropriate standard, enable verification of suitability and continue to provide services.

The maintenance and monitoring framework includes core requirements under the Act, regulations and specific conditions of licence, alongside any additional risk-based issues identified.

While there is a structured monitoring schedule (see below), the Ministry may at any time request that a licensed drug checking service provider demonstrate compliance with the Act, its regulations, licensing conditions and any other relevant conditions. An authorised person from the Ministry can access sites where service providers perform any of the functions specified in section 35DB of the MoDA.

An authorised person who accesses a service provider's site for the purposes of assessment must make all reasonable efforts to avoid disrupting the service provider in its performance of any of the functions specified in section 35D of the MoDA. They must not enter a part of the site where an individual is presenting a drug for checking or being advised of the results of testing (unless the individual gives their express permission for them to do so).

Unannounced or short-notice inspections or audits may occur where the Ministry has a concern related to performance (including complaints or information received regarding potential breaches of the Act, its regulations or licensing conditions, or concerns with the provider's continued suitability).

Where the Ministry identifies a breach of the Act, its regulations, licensing conditions or any other relevant condition, the Director-General will decide whether to suspend, or cancel a licence, and may impose, revoke or amend licence conditions.

Monitoring schedule

In the initial licence period (three-year duration or less), the Ministry may undertake:

- a minimum of an annual audit throughout the first audit licence cycle
- non-compliance progress monitoring.

In subsequent licence periods (after first renewal of licence), the Ministry may undertake:

- a performance and risk-based approach
- reception of an annual self-declaration from the provider of its continued compliance with the Act, its regulations and licensing conditions
- mid-point audit and/or surveillance activity in the second year of licensing (ie, 12–24 months after renewal of licence)
- non-compliance progress monitoring.