Regulatory Enforcement Policy

Mental Health Commission

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1. Policy statement

The regulation of approved centres through a process of registration, inspection, monitoring and enforcement is one of the four key functions of the Mental Health Commission (MHC).

The MHC can take enforcement action in respect of any approved centre that fails to comply with legislative requirements. The aim of enforcement action is to address non-compliance and to ensure that all residents of approved centres are provided with safe care and treatment.

The MHC operates a responsive model of risk-based regulation based on the following principles:

- Proportionality;
- Accountability;
- Consistency;
- Transparency; and
- Targeting.

This document describes the process the MHC will follow when considering and issuing enforcement actions.

This document should be read in conjunction with the *Compliance and Ongoing Monitoring Policy (Ref MCH-RGP-008)*, *Risk Assessment and Rating Policy (Ref MHC-RGP-004), Regulatory Management Team Terms of Reference (Ref MHC-TOR-010)* and the *Enforcement Standard Operating Procedure.*

This document does not take precedence over the regulatory enforcement processes set out in the Mental Health Acts 2001-2018.

2. Definitions

2001 Act: The Mental Health Acts 2001-2018 (including any amendments made to that Act).
Annual regulatory inspection: The inspection of an approved centre carried out once a year pursuant to section 51(1)(a) of the Act.
Comprehensive Information System: the Mental Health Commission's online information management system.
Critical Risks: Serious incidents or events or levels of non-compliance which are defined as a "critical risk" in line with the *Risk Assessment and Rating Policy (Ref MHC-RGP-004).*
Director: Director of Regulation.
Focused inspection: An inspection that is undertaken to assess specific areas of concern howsoever arising.
Inspector: The Inspector of Mental Health Services. Any reference to the Inspector also applies to Assistant Inspectors to the extent that they are empowered to carry out the Inspector's duties.
Legislative requirements: Requirements set out in the Act and all regulations and rules made under the Act.
Register: The register of approved centres that is maintained by the MHC pursuant to the Act.
Registered Proprietor: As per Section 62 of the Act, the person whose name is entered in the register as the person carrying on the centre. Any reference to the Registered Proprietor in this policy will extend to any person nominated to receive or provide information on the Regsitered Propritor's behalf.
Regulations: S.I. No. 551/2006 The Mental Health Act 2001 (Approved Centres) Regulations 2006.

3. Responsibilities

- Regulatory Review Committee (RRC): Responsible for considering certain enforcement actions taken in respect of critical risks identified by the Regulatory Team. Relevant actions are outlined in Section 4.2.2.1.
- Director of Regulation: Member of the RRC. Primary responsibility for taking and monitoring enforcement actions where required. Issue statutory proposals.
- Head of Regulatory Practice and Standards: Member of the RRC. Coordinate case meetings and RRC meetings.
- Inspector of Mental Health services: Member of the RRC. Refer critical risk non-compliance from inspections. Provide reports and evidence from inspections undertaken. Undertake focused inspections, as necessary.
- Regulatory Team (Inspectorate and Standards and Quality Assurance division): Responsible for escalating critical risks to their head of division.
- General Counsel to the MHC (DSS): Member of the RRC. To orovide legal advice in relation to statutory enforcement measures and provide advice to the Chief Executive in respect of prosecution.
- Chief Executive: Decision maker in relation to representations made in respect of statutory proposals and prosecution.

4. Procedure

4.1 Enforcement model

Enforcement actions available to the MHC are set out in the pyramid below. Enforcement actions range from requiring a Corrective and Preventative Action plan (at the lower end of enforcement) to removing an approved centre from the register and/or pursuing prosecution.

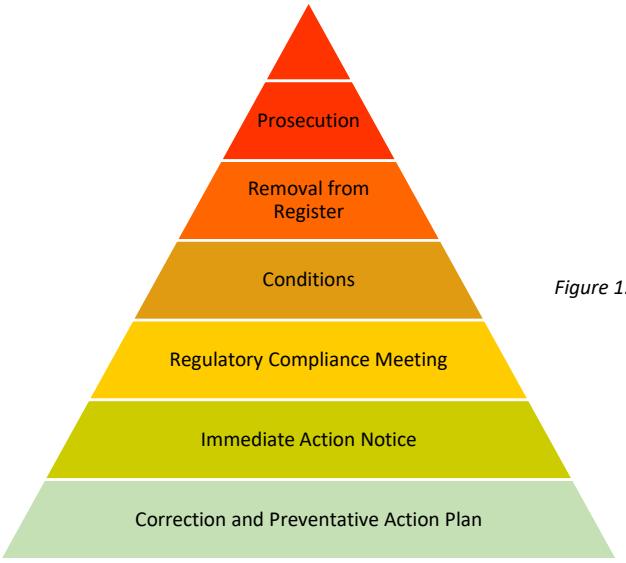


Figure 1.0 Enforcement model

The MHC recognises that incidents of non-compliance will occur from time to time and that these will vary in severity. Enforcement actions should be appropriate and proportionate to the incident. Before issuing an enforcement action, consideration should be given to:

- The nature of the non-compliance;
- Whether the non-compliance is ongoing or is a one-off incident;
- The level of risk presented to residents and staff;
- The capacity and likelihood that the approved centre will be able to comply with the enforcement action; and
- Any previous enforcement actions.

4.1.1 Escalation

In most cases, a Corrective and Preventative Action plan will be appropriate to address non-compliances in the first instance. If a serious incident is identified or if non-compliance continues then it may be appropriate to escalate to an Immediate Action Notice or another enforcement action.

Removing an approved centre from the register and pursuing prosecution are at the upper end of enforcement actions. In general, the MHC will only escalate enforcement to this level where non-compliance is serious, ongoing and has not been addressed through other enforcement actions.

There may be cases where removal from the register and/or prosecution is an appropriate action in the first instance. For example, where there is a serious and immediate risk to the safety, wellbeing or human rights of residents in an approved centre. This enforcement model is a guide and does not prevent the MHC from taking such actions that it deems necessary in appropriate cases.

4.2 Process

4.2.1 Case Meeting

Critical risks will generally be identified through the inspection process, compliance monitoring or by receipt of a Quality and Safety Notification. All critical risks should be referred to the Regulatory Management Team (RMT) through the relevant head of division (the Director or Inspector) within **1 working day** of identification/notification.

Within one working day of receiving the referral, the date for a case meeting must be agreed. This date must be within **2 working days** of the referral, or sooner if required. The case meeting must be coordinated by the Head of Regulatory Practice and Standards and attended by the Inspector, the Director and any other relevant person (i.e. Lead Inspector who made the referral or the Regulatory Manager).

At the case meeting, the critical risk will be discussed and the Director will consider and determine the appropriate enforcement action. The details of the case meeting and the decision made will be recorded as prescribed in the Enforcement Standard Operating Procedure (Enforcement SOP).

Any enforcement action agreed at the meeting will be issued to the approved centre's Registered Proprietor within **2 working days** of the case meeting. The Director is primarily responsible for issuing this correspondence and logging the action in line with the enforcement SOP. However, where a clinical issue is discussed, it may be appropriate for the Inspector to issue correspondence to the approved centre's Clinical Director or to require a meeting under section 51(2)(d) of the 2001 Act.

If it is agreed that further information is required from the approved centre or that another action is appropriate in the first instance (i.e. formally raising concerns with relevant stakeholders). Any agreed action will be taken as soon as possible and no later than **2 working days** after the case meeting. The Director is responsible for issuing this correspondence.

If it is agreed that a focused inspection is required, the Inspector (or an assistant inspector(s)) should undertake the inspection within 1 week of the case meeting (or as soon as is practicable). Where a focused inspection occurs beyond the **1 week** timeframe, the reason for this will be documented. Any ongoing critical risks will be referred to the relevant head of division (the Director or Inspector) and the Head of Regulatory Practice and Standards within **1 working day** of identification/notification.

4.2.2 Regulatory Review Committee

The RRC is a committee which is convened where consideration is being given to the actions set out in 4.2.2.1. The purpose of the RRC is to provide assurances and oversight to senior and relevant members of the Mental Health Commission in relation to certain enforcement actions taken in respect of critical risks.

The core membership of the RRC includes:

- Director of Regulation
- Inspector of Mental Health Services
- Head of Regulatory Practice and Standards
- General Counsel of MHC (DSS)

The RRC may invite any other person (i.e. or the lead inspector who made the referral) to the meeting.

Note: General Counsel for MHC (DSS) attends the RRC as part of their role as In-house Legal Advisor. Contributions made and minuted are not automatically covered by legal privilege, where matters are subject to legal privilege these shall be expressly noted and addressed. For further information, please refer to the Access to Legal Services Policy and Procedure (MHC-Legal-001).

4.2.2.1 RRC Process

The Regulatory Review Committee (RRC) will convene, where on foot of a case meeting the following enforcement actions are being considered:

- notice of proposal to refuse registration or remove a centre from the Register
- notice of decision to refuse registration or remove a centre from the Register
- recommendation for statutory enforcement action (i.e. prosecution)
- where appeals have been lodged with the District or Circuit Court

The RRC may also convene:

- In respect of high profile services where increased service risk could have national implications

A referral to the RRC will be made in line with the Enforcement SOP by the relevant head of division within **1 working day** of the case meeting. The RRC will meet within **3 working days** of the referral and will be coordinated by the Head of Regulatroy Practice and Standards.

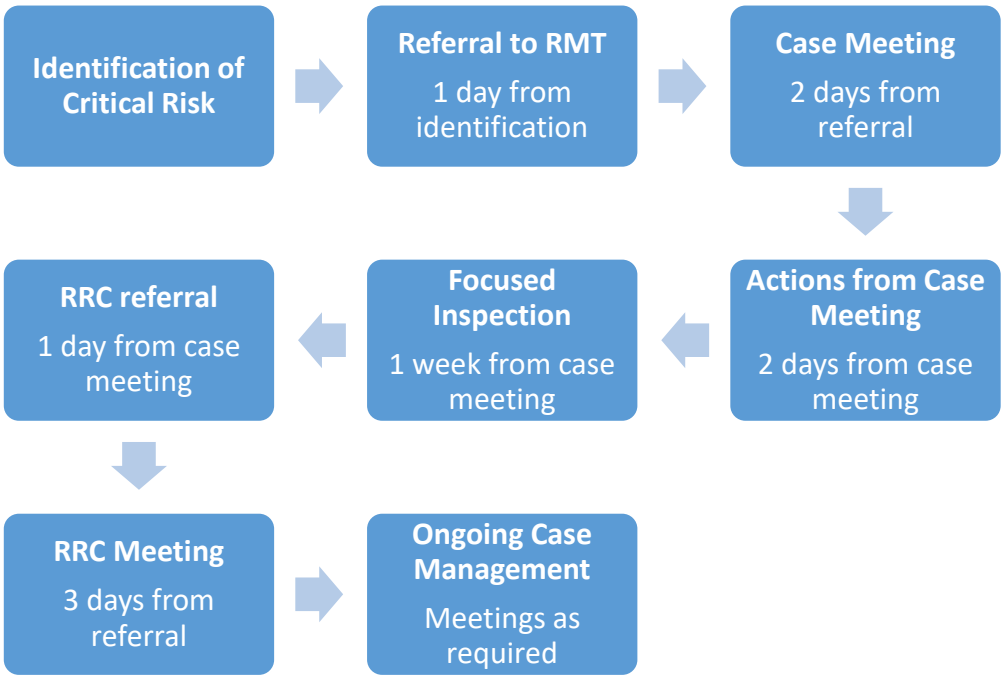
At the RRC, the relevant persons will present the details of the critical risk and actions taken to the RRC. The RRC may provide additional advices or recommendations for consideration by the Director.

The details of the RRC meeting will be recorded in line with the Enforcement SOP.

4.2.3 Ongoing Case Management

Subsequent case meetings or RRC meetings related to the management of an ongoing case will be convened as required. The details of these meetings and the decisions made will be recorded as prescribed in the Enforcement Standard Operating Procedure (Enforcement SOP). The record will chronologically document the management of the case. The relevant head of division will be responsible for the maintenance of the record.

4.2.4 Process map


Identification of Critical Risk
Referral to RMT
1 day from identification
Case Meeting
2 days from referral
Actions from Case Meeting
2 days from case meeting
Focused Inspection
1 week from case meeting
RRC referral
1 day from case meeting
RRC Meeting
3 days from referral
Ongoing Case Management
Meetings as required

4.3 Methods of information gathering

It is important that the MHC has access to relevant information when considering and issuing enforcement actions. Information gathered will also serve as evidence that the enforcement action was appropriate and proportionate.

Information will generally be gathered during the annual inspection process. Further relevant information may also be gathered through a focused inspection or by requesting specific information.

4.3.1 Focused inspection

The Director may request the Inspector to undertake a focused inspection of an approved centre to gather detailed evidence on the level of non-compliance and the level of risk. In general it will be appropriate to carry out a focused inspection prior to taking higher enforcement action such as closure or prosecution.

A focused inspection may also be undertaken to assess adherence to required action plans or conditions on the approved centre's registration.

The Inspector has the power to visit and inspect an approved centre at any time under section 51(2)(a) of the Act. A MHC staff member or an external advisor may accompany the Inspector on a focused inspection.

4.3.2 Request for information

The Director can request any information necessary to determine an approved centre's compliance with legislative requirements and to determine the approved centre's suitability for ongoing registration.

Requests can be made:

- Through the Inspector who has specific powers to request information, records and documents under section 51(2)(b) of the Act; or
- Through the Director in relation to any functions under Part 5 of the Act, pursuant to section 64(8) of the Act.

5. Enforcement actions

The following section sets out the primary enforcement actions which may be taken by the MHC. These are set out in order of severity and represent a standard enforcement escalation pathway.

5.1 Corrective and Preventative Action plan (CAPA)

A CAPA addresses the non-compliance and puts measures in place to prevent recurrence.

5.1.1 Process

The Director may request that the Registered Proprietor provide a CAPA in relation to:

- Non-compliance with legislative requirements identified during an annual inspection; and
- Any other enforcement action taken in line with this policy, which requires follow up enforcement and monitoring. For example, a CAPA may be requested following the issue of an Immediate Action Notice or the attachment of a registration condition.

5.1.2 Approval and ongoing monitoring

The process for accepting and monitoring CAPAs is detailed in *Compliance and Ongoing Monitoring Policy (Ref MCH-RGP-008).*

5.2 Immediate Action Notice

An Immediate Action Notice is a formal notice directing the Registered Proprietor to take immediate action to address a specific issue.

5.2.1 Process

Where the Director determines that an Immediate Action Notice is appropriate, the Director will send the Notice to the Registered Proprietor of an approved centre and any other such persons with responsibility for the service as appropriate.

The Registered Proprietor will be required to submit a response detailing the actions taken and timeframes to the Director. The time frame for response will be reflective of the immiedate risks identified. In most cases this will be **2-3 days** following the issusing of the Immediate Action Notice.

The Registered Proprietor shall be required to provide the MHC with evidence that the required action has been undertaken.

5.3 Regulatory Compliance Meeting

5.3.1 Process

The Director may request a Regulatory Compliance Meeting to discuss a serious incident/concern with representatives of the approved centre.

The request should specify who is expected at the meeting and may include the Registered Proprietor (or nominee), the Clinical Director and the senior manager(s) for the approved centre

and/or wider service, as necessary. The Director will send the request to all individuals who are expected at the meeting.

The Inspector may be invited to attend the Regulatory Compliance Meeting to discuss concerns and/or to validate the CAPA/evidence presented. However, the Inspector does not make any decisions about enforcement actions.

The meeting will be held at the MHC, or at another venue that the Director deems appropriate (e.g. videoconferencing may be used where required).

5.3.2 Addressing the serious incident/concern

The Director may request the following to be prepared and presented at the meeting:

- A detailed CAPA in relation to the serious incident/concern; and/or
- Evidence of any actions taken since the incident was identified; and/or
- A plan pursuant to a condition of registration.

At the end of the meeting and/or following the meeting the Director may request further information to be provided. The Director may either accept the approved centre's representations or initiate furhter enforcement actions.

5.4 Attach or amend registration conditions

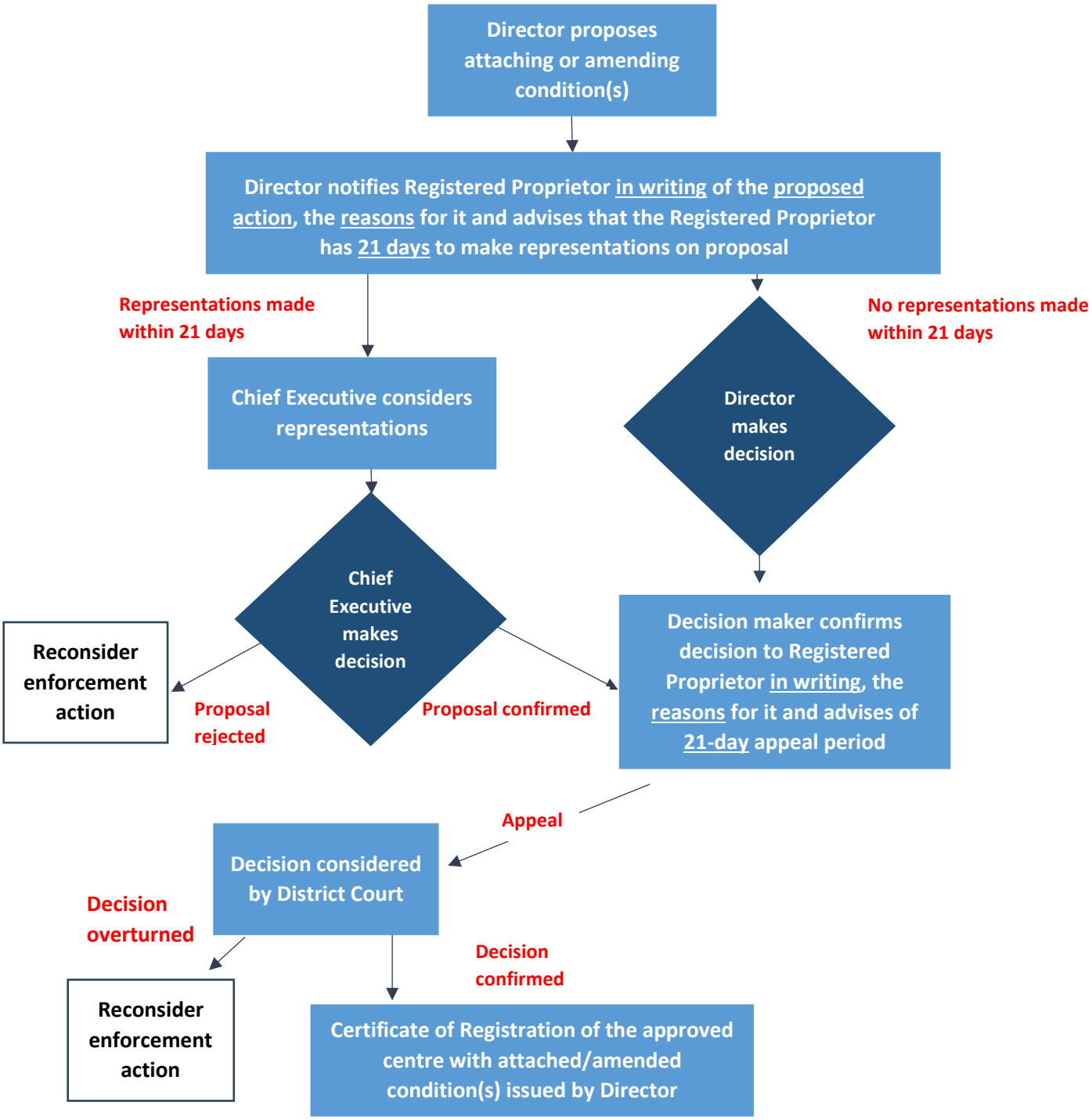
The MHC may attach or amend conditions to an approved centre's registration under section 64(6) of the Act. Examples of conditions that may be attached are listed in section 64(6)(b) of the Act.

The condition(s) attached to registration should aim to reduce the risk associated with the issue arising.

5.4.1 Process

The process for attaching, amending and revoking conditions is set out in the Act.

The following summary should be read in conjunction with sections 64(11) and (12) of the Act. Please note, where representations are made to the CE in respect of proposed conditions, correspondence must issue directly from the CE as decision maker.



Any proposal or decision issued by the Director will be copied to the Inspector and Chief Executive. Any decision made by the Chief Executive will be copied to the Inspector and Director.

5.4.2 Review of conditions

Conditions of registration shall be regularly monitored and formally reviewed after 12 months and following the annual regulatory inspection, or earlier as required.

If the approved centre has an existing condition on their registration, and the Director considers that the condition is no longer the most appropriate enforcement action, the Director may propose to amend or revoke the condition.

The legislative process for amending and revoking conditions must be followed in all cases.

5.5 Removing an approved centre from the register

The MHC may remove an approved centre from the register for the reasons set out in section 64(5)(b) of the Act. This includes situations where:

- The premises of the approved centre does not comply with the Regulations;
- The carrying on of the approved centre does not comply with the Regulations; or
- The Registered Proprietor has breached a condition of registration within the last 12 months.

The process for removing an approved centre from the register is set out in the 2001 Act and reflects the process for attaching, amending or revoking a condition of registration. This process is set out in 5.4.1 above and should be read in conjunction with sections 64(11) and (12) of the Act.

Removal from the register (in effect closure) should only be considered in the event of:

- Serious and ongoing non-compliance;
- A serious and immediate concern for the safety, health and wellbeing of residents; or
- An ongoing and serious breach of human rights.

5.6 Prosecution

The Act sets out a number of offences relating to approved centres. The table below sets out specific offences that may arise in the enforcement context.

Section	Offence	Liability
64(13)	Breaching a condition of registration	Registered Proprietor*
66(3)(a)	Failure of approved centre to comply with a provision of the Regulations	Registered Proprietor*
66(3)(b)	Refusing or failing to comply with a provision of the Regulations	Any person
69	Placing a resident under seclusion or mechanical restraint unnecessarily or Contravening a Rule made by the MHC providing for the use of seclusion and mechanical restraint	Any person

**Note that Registered Proprietor's nominee will not be liable in relation to any offence.*

The Chief Executive may decide to prosecute an offence after taking all relevant matters (including advice from General Counsel for MHC (DSS) and/or external legal advisors) into consideration.

Prosecution should only be considered in the event of:

- Serious and ongoing non-compliance;
- A serious and immediate concern for the safety, health and wellbeing of residents; or
- An ongoing and serious breach of human rights.

Proceedings must be instituted within 12 months of the offence.

5.6.1 Process

If the Director considers that prosecution is appropriate it will propose this enforcement action to the Chief Executive at an RRC meeting. Any proposal must set out the following:

- The specific incident or risk, and the date it occurred or was identified;
- The specific offence under the Act and evidence of that offence;
- The person or entity liable under the Act;
- Any enforcement actions taken to date and the results of that action(s); and
- Any legal advice sought.

If the Chief Executive agrees with the proposal to prosecute, they will communicate the decision to the Mental Health Commission members.

6. Change control

The following table details changes made to this policy.

Summary of changes		
Date	Description	Approved by
1 December 2017	Content reviewed. Role of RRC defined. Escalation pathway defined.	Patricia Gilheaney, Chief Executive
14 September 2018	Updated template and did a plain English review of content. Included further guidance on the enforcement model and the process. Removed detailed information contained elsewhere.	Senior Management Team
1 April 2019	Updated to reflect new business model (Regulatory Management Team) clarify criteria for serious enforcement and to correct minor errors.	Senior Management Team
21 December 2021	Content reviewed. Updated to reflect title changes. Updated to reflect a revised case meeting and RRC process. Updated formatting of process maps.	Regulatory Management Team
June 2023	No changes made. Policy considered up-to-date	RMT