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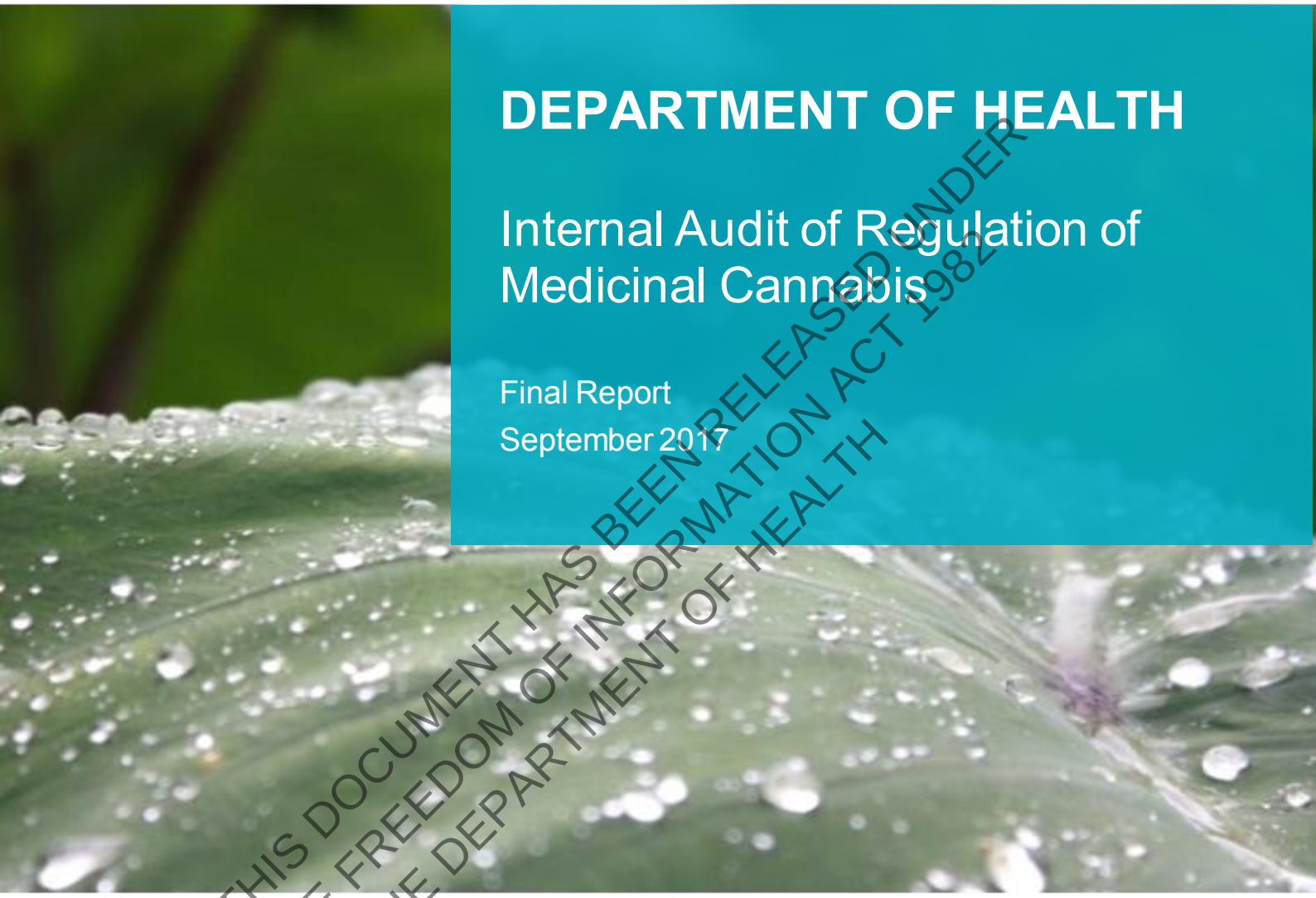

DEPARTMENT OF HEALTH

Internal Audit of Regulation of Medicinal Cannabis

Final Report
September 2017

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Timeline

Milestone	Dates
Entry Interview	21 July 2017
Approved Audit Plan	11 August 2017
Commence Fieldwork	14 August 2017
Completion of Fieldwork	1 September 2017
Draft Report	18 September 2017
Final Report including Management Comments	28 September 2017
Final report provided to the Audit Committee	October 2017
Completion of the Audit Satisfaction Survey	October 2017

Sign-Off

I acknowledge the findings and recommendations enclosed in this report and undertake to have the agreed actions completed within the identified time frame.

……

Adj Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

……

Mark Harrison
Managing Director
Protiviti

Contents

1. Executive Summary

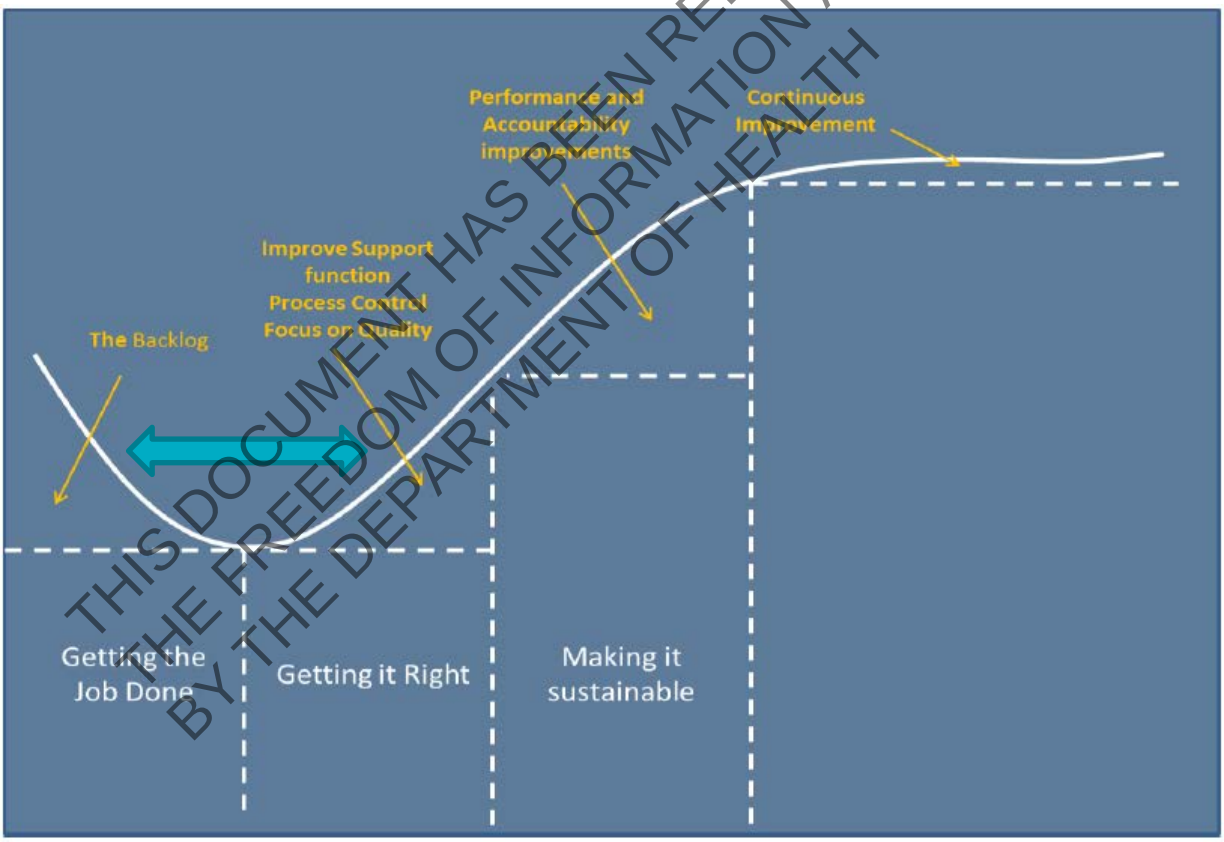
The *Narcotic Drugs Act 1967 (the Act)* and Regulations, administered by the Office of Drug Control (ODC) within the Department, establishes a licence and permit scheme (the scheme) to regulate the cultivation, production and manufacture of medicinal cannabis.

The Medicinal Cannabis Section (MCS) in the Office of Drug Control (ODC) issues two types of licences related to production – a medicinal cannabis licence authorising cultivation and production, and a cannabis research licence authorising cultivation and / or production for research purposes. As at 17 August 2017 eight medicinal cannabis licences (commercial cultivation and production) and five cannabis research licences had been issued under the scheme.

The MCS team currently consists of a Director, three Executive Level staff (ELs) and three Australian Public Service level (APS) staff. Since establishment, MCS has been focussed on establishing the necessary infrastructure to receive and assess applications (including developing the regulations and regulatory guidance for industry prior to October 2016, and since then developing checklists for assessment and making forms available for industry).

New regulatory regimes, such as the scheme, typically follow a maturity profile over time reflected in the below diagram. Through this internal audit we have considered the scheme against this maturity profile.

Diagram 1: Common Maturity Profile of New Regulatory Regimes



An internal audit of the regulation of medicinal cannabis was included on the 2017-18 Internal Audit Program.

1.1 Overall Assessment

Against the maturity model outlined on the previous page, MCS' management of the scheme can be defined as the "getting it right" stage. There are a number of initiatives that have been or are being introduced that have moved it to this level (including quality assurance over decisions and development of draft standard operating procedures). In this report, we have designed our recommendations around requirements to move to a more sustainable state.

We have made the following assessments relating to the objectives below.

Objective	Assessment
Assess the adequacy of the framework[1] for processing and managing licence applications for medicinal cannabis	MCS development and rollout of the framework for management of the scheme has been a product of pragmatism and the need for expediency at the time it was established. The primary focus of the initial set up of the scheme was to establish processes consistent with the legislative framework and the essential infrastructure to receive and process applications. In this regard, it has achieved what was intended (in the immediate term) and there are approved licences and permits that allow for the cultivation and production of medicinal cannabis in Australia. Accordingly, the framework for processing and managing licence applications is at a low level of maturity, which is not uncommon for new schemes.
Assess whether regulatory activity and resources are aligned with regulatory risks	A risk assessment for introducing the scheme was developed at commencement. While the direction of resources has not necessarily followed the higher risks in that assessment, resources have been directed at high priorities to get applications processed (the "getting it done" maturity level). With 80% of MCS resources directed at application processing, and with a backlog existing for processing of applications, it is clear that the resource allocation model is not sustainable. Market engagement, permit assessment, compliance activities, etc. will all need to be undertaken which will need a re-balancing of resource allocation. While it is possible that some re-balancing will occur naturally (when the current backlog of applications is addressed), a defined plan to improve that allocation will be beneficial. The recommendations in this report will go some way to support that re-balancing of resourcing.

1.2 Summary of Findings and Recommendations

The following recommendations have been made to improve the maturity of the MCS regulatory framework over the intermediate and long term.

The risk ratings associated with the recommendations reflect the assessment of consequence and likelihood of the related risk exposure of the finding using the Department's Risk Management Matrix and definitions included in **Attachment A**.

[1] The definition of regulatory management framework used for the purpose of this internal audit is included in section 2 of this report.

Finding	Recommendation	Risk Rating
Finding 1: Resource allocation is unsustainable	The Department should define the resourcing required for scheme management beyond application assessment over the coming 1-2 years (with a focus on regulatory risk and medium-term outcomes). ODC should then establish a plan for reducing required effort on application assessment to the extent necessary (potentially using some or all of the options identified in this report), and implement the reforms accordingly.	High
Finding 2: Limited performance reporting and monitoring	The MCS should: ▪ establish a simple regular report of key measures against regulatory and process objectives (and consequent targets against each measure) that can be used by management to drive activities and initiatives.	Medium
Finding 3: Processes are not standardised and there is a high reliance on a few key individuals	The MCS should: ▪ finalise SOPs for assessing applications and conducting compliance activities; ▪ refine the application checklist, based on lessons learned from previous applications, that establishes some priorities and provides guidance on the more important (or judgemental) aspects of the application assessment; ▪ establish structures around the on-the-job guidance that defines minimum and maximum guidance to be provided and key processes and capabilities that need to be covered and demonstrated; and ▪ establish a lessons learned component of MCS team meetings to ensure lessons are shared amongst all team members.	Medium
Finding 4: Manual case management tool subject to error	The MCS should leverage off other case management systems in the Department to implement simple (but tailored) case management system to manage applications, permits and compliance activity.	Medium

1.3 Management Comments

Management agrees with and accepts the commentary and recommendations in this report with some caveats.

The current resource allocation for the medicinal cannabis section within the Office of Drug Control was put in place in 2016 prior to any applications being received, and when there was no on-the ground experience of the requirements of the application assessment process.

For context, the initial sensitivity analysis in the external report commissioned on "Modelling the cost of the Medicinal Cannabis Scheme" prior to the commencement of the Scheme, considered a range of between 1 to 20 cultivators under the scheme. However, as of late September 2017 ODC has received over 110 applications, with over 50 licences under assessment, and 13 (plus an additional 6 manufacture licences which will need to be encompassed by the emerging compliance and inspection elements of the scheme) already granted.

Similarly, the complexity of assessment processes is substantially higher than originally envisaged. For example, liaison with all law enforcement agencies across Australia is time consuming and

complex, although it has been very important e.g. in several cases where assessments have uncovered connections to organised crime, and in two recent instances, directors have been formally removed from organisational involvement. It should also be emphasised that the application assessment times are at the mercy of receipt of information from law enforcement agencies and the response times from other state agencies and the applicants themselves.

As presented, the audit recommendations potentially introduce other risks to the integrity of the scheme under current resource parameters, as shifting focus onto proposed activity under the recommendations will necessarily require a down-grading of effort in other areas. The Department will need to carefully consider the extent of its risk appetite for such resource realignment and how that will impact existing relationships with law enforcement and other state and territory regulatory entities.

1.4 Restriction of Use

This report is intended solely for use by the Department of Health, and should not be distributed to any third party without the consent of Protiviti, which will not be unreasonably withheld. This document is not to be used for any other purpose, except as required by law, without our prior express consent.

2. Background, Objective, Scope and Approach

2.1 Background

Regulatory Frameworks and Maturity

Regulation has become a critical feature of contemporary economies and societies. As the OECD points out, regulation "underpins markets, protects the rights and safety of citizens, and their property, and assists the efficient and equitable delivery of goods and services."[2] Poorly-implemented regulation imposes unnecessary burden upon businesses and the community. Where regimes are unnecessarily complex, duplicative or implemented poorly, the flow-on effects are felt by both the regulated community and the regulator.

Around the world, there is growing recognition of a regulatory craft and the need for regulatory maturity. Regulators are developing a greater understanding principles and approaches to regulation that are more likely to achieve the desired outcome, reduce impacts on regulated communities and maintain the trust of the community. This requires a deep understanding of the regulated communities and their operating context.

Effective regulatory arrangements (and regulators) demonstrate the following characteristics:

- understands its operating environment and strives for continuous improvement;
- understands the complexity of regulation and strives to undertake its mandate in the most efficient and effective manner possible;
- embeds the principles of regulatory best practice in all of its activities;
- has clearly defined objectives and a defined regulatory philosophy and approach;
- has a strong culture and leadership;
- builds and maintains a regulatory toolbox of a range of incentives and disincentives to achieve desired outcomes;
- has a problem-solving approach that utilises the best tools for the job at least cost;
- manages risk effectively;
- has a well-trained workforce;
- has the right businesses systems and processes to function efficiently and effectively;
- is a consistent and proactive two-way engager with stakeholders;
- is flexible and agile; and
- organises resources around problems and tasks rather than the traditional model of simply allocating tasks to particular work areas.

The ANAO has defined that a framework for managing regulatory performance[3] should focus on:

1. defining regulatory outcomes and administrative priorities;
2. a risk-based approach to regulatory administration;
3. effective stakeholder relationships;
4. effective information management;

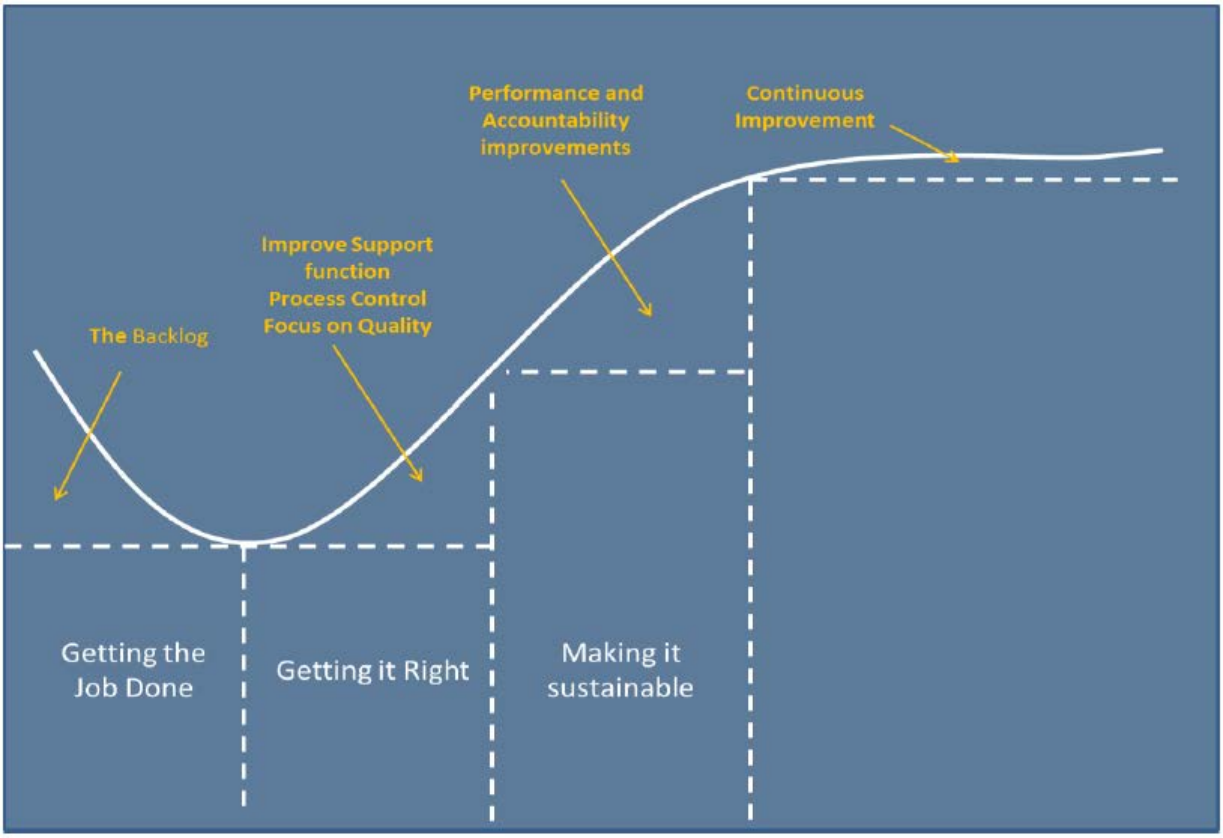
[2] OECD (2011). *Regulatory policy and governance: Supporting economic growth and serving the public interest*, http://www.oecd.org/gov/regulatory-policy/regulatorypolicyandgovernancesupportingeconomicgrowthandservingthepublicinterest.htm

[3] ANAO *Administering Regulation: Achieving the Risk Balance* (2014).

5. transparency and accountability;
6. managing regulatory capability; and
7. Measuring, reporting and reviewing regulatory performance.

New regulatory regimes, such as the scheme, typically follow a maturity profile over time reflected in the diagram below. Through this internal audit we have considered the scheme against this maturity profile.

Diagram 1: Common Maturity Profile of New Regulatory Regimes



Medicinal Cannabis Regulation

The Department of Health (the Department) leads Australia's development of health policies, undertakes the administration and delivery of health programmes, and ensures the effective regulation of health products and services to support improved health outcomes for all Australians. In delivering this organisational objective, the Department has the function to apply appropriate levels of regulation to ensure the safety of Australians alongside timely access to new health products and services.

The *Narcotic Drugs Act 1967* (the Act) and associated Regulations, administered by the Office of Drug Control (ODC) within the Department, establishes a licence and permit scheme (the scheme) to regulate the cultivation, production and manufacture of medicinal cannabis.

While the import, export and manufacture of cannabinoids had been regulated by the Act for many years, it was only in February 2016 that the *Narcotic Drugs Amendment Act 2016* was passed to enable the cultivation of cannabis for medicinal and related scientific purposes and MCS needed to be ready to receive applications by October 2016 (i.e. nine months allowed for implementation).

The ODC issues three general types of licences relating to medicinal cannabis products – a medicinal cannabis licence authorising cultivation and production, a cannabis research licence authorising cultivation and or production for research purposes, and a manufacturing licence authorising the

manufacture of a medicinal cannabis product. A permit which sets out the type and amount of cannabis that can be grown and / or the amount of medicinal cannabis products that may be produced is required prior to any cannabis cultivating activity. For the licence to manufacture medicinal cannabis products, manufacturers must additionally obtain a Good Manufacturing Practice (GMP) licence from the Therapeutic Goods Administration (TGA) before applying for a permit to manufacture.

The Scheme's Regulatory Processes

At a simplified level, key aspects of the application process are:

Diagram 2: MCS application processes

Following the granting of a licence, applicants are required to lodge permit requests in a similar fashion to obtain permission for levels of production. Variation requests to licences or permits also follow a similar process. At the date of this audit, only one licence holder has completed the permit application process.

The MCS is in the process of setting up an inspectorate function, which includes two types of inspections that are conducted in relation to the medicinal cannabis scheme.

- application inspections (conducted to physically validate that the information provided in an application for a licence or permit is correct); and
- monitoring inspections (conducted to verify compliance with the Act, these may be conducted in the following manners: announced, unannounced, follow-up or desktop).

The MCS Regulatory Priorities

As at August 2016, the critical priorities identified for the MCS (in the risk register presented to the Medicinal Cannabis Program Board) related to:

- completing the detail of the legislative and regulatory basis of the Scheme (undertaken by the ODC to develop the instructions for legislative draft);
- engaging with industry and the public (undertaken through website construction);
- alignment with state and territory regulatory practices (undertaken through working groups and Single Point of Contact in jurisdictions); and
- establishing the cost recovery arrangements (captured through Cost Recovery Implementation Statement).

However, the risk profile has changed over time. Discussions with management have identified that the key emerging risks relate to building maturity of industry and updating the regulatory framework.

There are limited planned mitigation strategies to address these and instead there is a reliance on key individuals within the ODC to monitor this.

Additionally, the latest risk assessment in March 2017, identified the highest risks to the medicinal cannabis scheme more broadly relate to patient access and prescribing practitioner education. Discussions with management identified that the current key risks specific to the MCS relate to workload and resources not being aligned and the lack of appropriate skills to administer the scheme.

2.2 Objective

The objective of this internal audit was to assess the adequacy of the framework for processing and managing licence applications for medicinal cannabis, including whether regulatory activity and resources are aligned with regulatory risks.

2.3 Scope

The scope of the internal audit included:

1. assessment of whether regulatory activities and resources are aligned with regulatory risks; and
2. review of established governance and systems used to assess applications for two types of licences relating to medicinal cannabis products – the medicinal cannabis (cultivation and production) licence and the cannabis research (cultivation and production) licence, with a view to identifying lessons learned.

2.4 Scope Limitations

The scope of this internal audit did not include:

- any legal advice in relation to the issue of licences relating to medicinal cannabis products;
- assurance of the ODC processes related to security checks. As this internal audit was limited to reviewing the processes for licence issue for medicinal cannabis products and overarching governance arrangements;
- review of the processes relating to import or export licences or manufacturing licences, as this internal audit only focused on medicinal cannabis (cultivation and production) and cannabis research (cultivation and production) licences;
- a review of TGA methods and processes to issue GMP licences or TGA's role in patient access; or
- consultation with external stakeholders.

The assessments made during this internal audit have been provided in good faith and in the belief that such statements and opinions are not false or misleading. Due to the limited duration of the internal audit, Protiviti has relied on information that was provided by the Department. Protiviti does not express an opinion as to whether the information supplied is accurate and no warranty of accuracy or reliability will be given. Furthermore, we have not implied and it should not be construed that we have verified the information provided to us, or that our enquiries could reveal any matter that a more extensive examination might disclose.

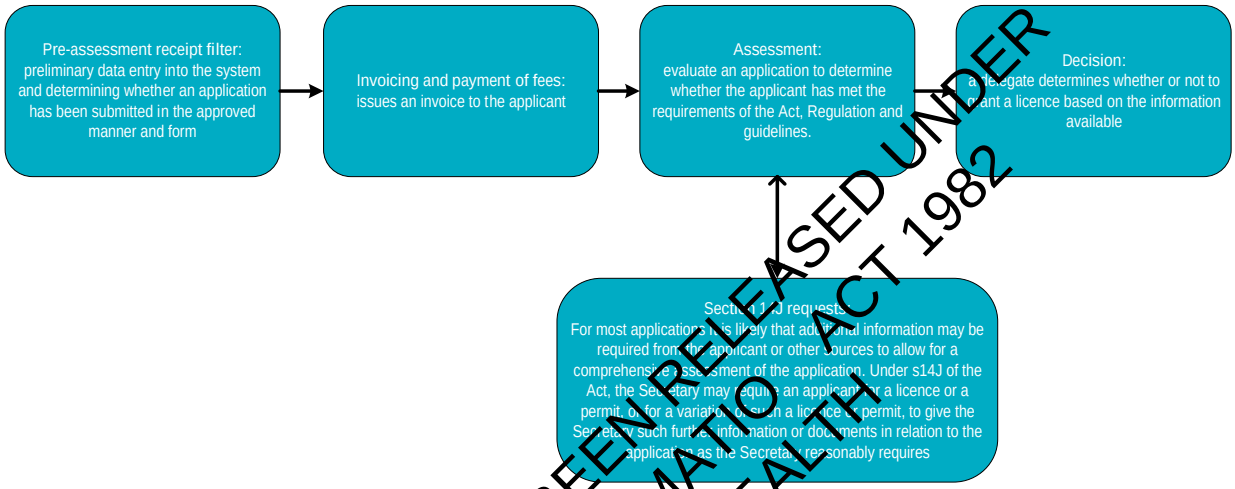
The Department is responsible for maintaining an effective internal control structure. The purpose of the internal audit was to assist management in discharging this obligation. Due to the inherent limitations in any internal control structure, it is possible that errors or irregularities might have occurred and have not been detected. Further, the overall control environment within which the reviewed control procedures operate has not been audited.

Please note that an internal audit is not designed to detect all weaknesses in control procedures as

the audit is not performed continuously throughout the period and the tests performed were conducted on a sample basis. Any projection of the evaluation of the control procedures to future periods is subject to the risk that the procedures may become inadequate because of changes in conditions, or that the degree of compliance with them may deteriorate.

Considerable professional judgement is required in determining the overall assessment. Accordingly, others could evaluate the results differently and draw different conclusions.

Diagram 2: MCS application processes



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- establishing the cost recovery arrangements (captured through Cost Recovery Implementation Statement).

However, the risk profile has changed over time. Discussions with management have identified that the key emerging risks relate to building maturity of industry and updating the regulatory framework.

3. Finding and Recommendations

3.1 Positive Practices

We identified that the MCS has taken a number of steps to establish an effective regulatory scheme for medicinal cannabis, including the following:

Engagement with jurisdictional representatives

The State and Territory Cultivation and Production Working Group representatives, and Advisory Council member that were consulted were complimentary of the support provided by ODC management. They were also complimentary of the efficiency with which consultative processes were established in the context of the scheme.

Focus on lessons learnt

Management of the MCS is aware of the necessary improvements to the MCS going forward. Accordingly, using licence applications to date, the ODC has compiled data on further information that is frequently requested from applicants. This data can be used to streamline the application processing procedure by improving the information available to industry, enhancing the clarity of the licence application forms, and / or enabling the creation of useful information request letter templates.

3.2 Finding 1: Resource Allocation is Unsustainable

Currently, 80% of MCS staff activities are focussed on assessing applications. Given the expanse of responsibilities in managing a regulatory scheme, this is unsustainable.

Discussion

Currently, 80% of MCS staff activities (see Attachment B for full breakdown) are focussed on assessing applications.[4] The focus of time and effort on assessing applications is a sound and necessary direction of effort in the current circumstances of a new scheme, where there was a desire from the Government to establish a supply of medicinal cannabis.

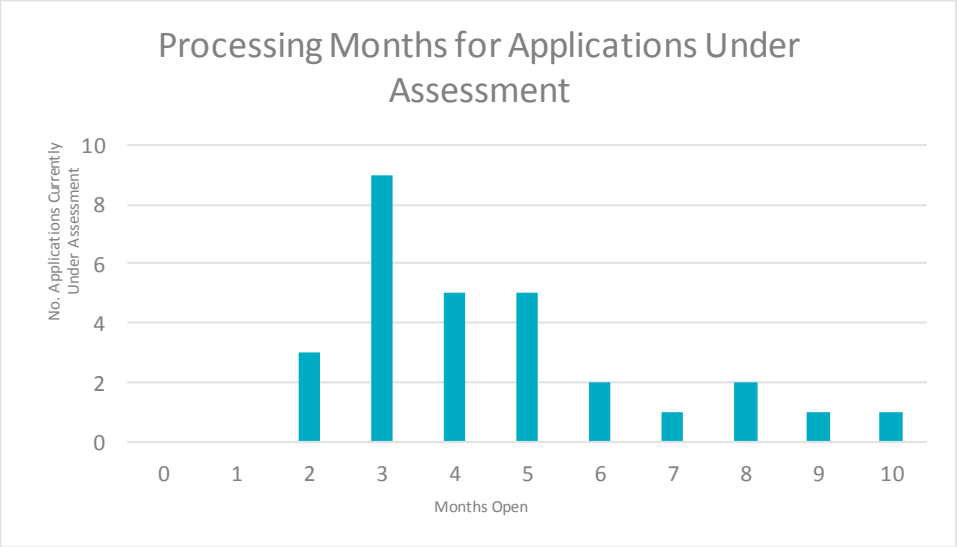
The internal audit was advised that time spent on application assessment is extended due to applications being received not having sufficient information to allow for a complete and robust assessment as required under the Act and Regulations. MCS staff consulted identified obtaining additional information (through the issue of s14J requests for additional information) to make the application decision-ready can represent up to 50% of the time required on assessing applications. As an indicator of the magnitude of requirement for additional information, the MCS had issued 815 questions on 30 applications. This 14J process has contributed to a backlog in processing.

Of the applications under assessment:

- 19 are awaiting 14J responses not yet due (with response dates up to 4 November 2017);
- five are currently being assessed; and
- five are pending assessment (there is backlog to 24 July 2017).

The diagram on the following page illustrates the processing months for applications under assessment as at 17 August 2017.

[4] MCS does not maintain a time recording system and so these estimates are based on representations by team members and have been validated by MCS management.



The above diagram shows that one application had been open for 10 months. While this is a developing industry (i.e. in its first year of operation) it is expected that there is a lesser quality of application resulting in application decision making requiring more staff, and resulting in a backlog.

It is likely that there will be further pressure on the limited resources in the future with the commencement of compliance inspections, permit application processing, regulatory adjustments, and a forecast reduction in staff as a result of Department-wide funding allocation reductions. MCS management has identified a number of emerging priorities for the team, including establishing controlled business processing (discussed further in Finding 2), building maturity of industry and updating the regulatory framework.

To deliver on expected functions and emerging priorities, there needs to be a clear plan on how it can reduce the need to invest so much time in application assessment.

In considering how other regulatory regimes have addressed this issue in the past, MCS has a number of options (some of which can be applied together):

- **Educate sector participants** through guidance on the Department's expectations for decision-ready applications. This can minimise the amount of work required to address issues in applications. This could include updating Guidelines to industry as necessary to reflect lessons learnt over the past twelve months. (The current Guidelines were last updated in October 2016);
- **Measure, report and respond to amount of time taken to assess application**s through utilising of a time recording and "clock management" system that allows data regarding the amount of time being taken to be more clearly understood. This will allow for more active management and response where individual applications are taking too long to assess.
- **Transferring the burden of poor, incomplete or insufficient applications back to sector participants** through rejecting applications that do not meet minimum thresholds. This would need to be applied with guidance, and in a consistent and transparent manner to avoid criticism.
- **Impose variable cost for assessing applications**, and in that way imposing a form of financial implication on sector participants for applications that require additional work or multiple clarifications from applicants. Such a cost could be built into the cost recovery model.
- **Set expectations that application assessment will take longer** and therefore dedicate fewer resources to application assessment.

MCS has advised that a project is underway to analyse s14J requests, to identify the common themes in applications requiring additional information, in order to establish a 'commonly asked questions' factsheet as additional guidance. This will likely go some way to reduce the need for disproportionate resources being dedicated to application assessment.

It is also possible that, as the regulated entities understand the department's expectations from applications, that applications will improve over time.

The marginal impact on required resources (and application backlog) of each of the above initiatives will be variable and will emerge over time. Accordingly, it is possible that a program of new initiatives to support improved applications being submitted may need to be introduced over time.

Risk Exposure

MCS may not be able to effectively implement all of its roles in managing the scheme in the future within current resource constraints.

Recommendation 1	
Risk Rating	High (Consequence: Major. Likelihood: Possible)
The Department should define the resourcing required for scheme management beyond application assessment over the coming 1-2 years (with a focus on regulatory risk and medium-term outcomes). ODC should then establish a plan for reducing required effort on application assessment to the extent necessary (potentially using some or all of the options identified in this report), and implement the reforms accordingly.	
Management Comments	
The recommendation is Accepted in Part only. Given the present financial situation of the Department it is unlikely that the effort in closely mapping the resourcing required would lead to an increase in resources for the medicinal cannabis program. There will be the ability to reduce effort on *some* of the applications through reforms to work processes such as identifying common s14J issues, and more clearly communicating requirements to applicants. The suggested mechanisms under the discussion above will be reviewed and a plan developed. In doing so, it will be necessary to make policy decisions around the altered treatment of assessments and manage the reality that reduced effort on assessment and the shifting of the burden of 'getting over the line' back to industry will significantly disadvantage later entrants into the industry. Importantly, given the end result that the number of compliance inspections, and/or the level of rigour put into application assessment must necessarily fall under any rebalancing, there is a heightened risk of criminal diversion and criminal infiltration of the medicinal cannabis scheme. Note also that this audit finding is being made without the reality of the full workload of the inspectorate being in place. As applications and permits come on line, no amount of process refinement around application assessment will be able to completely address the resource pressure of that additional but critical activity under current resource levels. It should also be noted that current levels of Commonwealth Government funding for the medicinal cannabis scheme is only 10% of that of individual states such as NSW and Victoria.	
Accountable Position	Agreed Completion Date
Assistant Secretary, Office of Drug Control	• Assurance 1 (Plan in place): 01 DEC 2017 • Assurance 2 (reporting on allocations): 30 JUN 2018

Assurance

The following will provide assurance that the risk has been managed:

- a documented plan for reduction of effort directed to application assessment
- management reporting of actual allocation of resources between the various responsibilities in the management of the scheme, showing a more balanced allocation consistent with the documented plan.

3.3 Finding 2: Limited performance reporting and monitoring

Performance reporting and monitoring is largely activity focussed and driven by the Minister and Departmental Executive expectations for information, and not designed as a monitoring and driving tool for improved performance.

Discussion

The *Public Governance, Performance and Accountability Act 2013*, and the Australian Government's Regulator Performance Framework[5], establish an environment where regulatory functions should be subject to effective performance management. This is especially true for regulatory regimes that are high profile, or are subject to tight resource constraints.

Essential components of good performance management are:

- performance targets established and agreed related to regulatory outcomes;
- accurate data against which to measure actual results against targets; and
- simple, targeted, informative and timely reporting which provides data and analysis of performance against targets.

Management and Ministerial reporting is point in time reporting on application numbers and licences granted. , In general, what is being reported is reactive to the requests of stakeholders, including the Minister.

In this regard, it is noted that MCS has access to data which can support effective performance management.

In the early days of any scheme, it can be difficult to define what information is necessary; and against key outcomes what are sensible targets. However, with a year of experience, the MCS is in a position to establish sound performance measures and targets that the management can use to guide the function and the scheme.

It is important to note that performance measures can be quantitative and qualitative, and performance reporting does not need to be voluminous. However it can be very powerful for senior executives (especially where they do not have daily line-of-sight of operations) to monitor and guide the function and priorities.

Management reporting could include:

- actual time spent on applications (so that limited resources can be managed in line with Finding 1);
- performance against service standards (which may include elapsed time of application with MCS vs with the applicant);
- issues from inspectorate activities (and how this impacts scheme priorities such as safety of supply);
- exchange of information between state organisations;
- number of complaints; and/or
- market impacts.

Risk Exposure

Absence of effective performance reporting and management may result in poor performance against expectations not being identified until it is unrecoverable. Further, there is an increased possibility that opportunities to improve performance are missed.

[5] It is noted that the scheme is not subject to the Regulator Performance Framework, however for the purpose of this report we note that many of the principles can be applied effectively to the scheme.

Recommendation 2	
Risk Rating	Medium (Consequence: Moderate. Likelihood: Possible)
The MCS should: ▪ establish a simple regular report of key measures against regulatory and process objectives (and consequent targets against each measure) that can be used by management to drive activities and initiatives.	
Management Comments	
Recommendation: Accepted in Part only. The proposed Assurance measures are agreed to the extent that the performance reporting will be limited and that target timeframes will exclude issues outside MCS's control, such as the time taken by law enforcement agencies or by applicants to respond to requests for information. The recommendation is agreed in part, noting that given very limited resources, the emphasis will be on management reporting directly aimed at increasing the efficiency of the scheme to better manage resource allocation. Other reporting will remain reactive in nature. It would seem sensible to combine this management reporting with that discussing resource allocation under recommendation 1. Consequently the completion dates have been aligned.	
Accountable Position	Agreed Completion Date
Assistant Secretary, Office of Drug Control	30 JUN 2018

Assurance

The following will provide assurance that the risk has been managed:

- an example performance report (including actual performance against relevant targets and suitable analysis) is developed and discussed with the Executive
- an example performance report that shows the scheme is meeting (or has actions to meet) agreed performance measures.

3.4 Finding 3: Processes are not standardised and there is high reliance on a few key individuals

As is often the case in the early stages of a new regulatory regime that has been implemented rapidly, there are no standard operating procedures (SOPs) for key aspect of the scheme management, and training for new staff relies on "on-the-job" guidance.

Discussion

The *Narcotic Drugs Amendment Act 2016* was passed in February 2016 in preparation for operation in October 2016. Consequently, the priorities during the period from October 2016 to mid-2017 have been about assessing applications to establish a base level of medicinal cannabis supply.

The operating model has relied on experienced staff establishing assessment and other processes and working with other staff to support their application. There are limited SOPs, however MCS has established a checklist to assist staff in assessing applications (containing over 70 criteria), with the focus being on individuals working together to collectively learn the processes.

This has resulted in a high dependency on key individuals, particularly with regard to exercise of judgement

by senior staff on risks associated with applications.

The MCS is currently preparing SOPs, which will be an important development in ensuring processes are repeatable and less reliant on individuals. Internal audit notes that effective SOPs do not need to be lengthy (and excessive length can often reduce effectiveness). However, they need to provide sufficient information to be useful, repeatable and targeted at key risks or areas of judgement.

In an environment where there is limited formal guidance, teams necessarily rely on training and support. In the MCS environment, the current focus is on-the-job guidance and support from senior personnel (further emphasising the reliance on limited key personnel). The current on-the-job guidance is unstructured with limited control to ensure that all key processes and skills are covered within a reasonable timeframe.

Risk Exposure

If certain key personnel leave the MCS under the current circumstances, there would be significant gap in capability and knowledge, increasing the likelihood of delayed or incorrect regulatory decision making.

Recommendation 3	
Risk Rating	Medium (Consequence: Moderate. Likelihood: Unlikely)
The MCS should: ▪ finalise SOPs for assessing applications and conducting compliance activities; ▪ refine the application checklist, based on lessons learned from previous applications, that establishes some priorities and provides guidance on the more important (or judgemental) aspects of the application assessment; ▪ establish structures around the on-the-job guidance that defines minimum and maximum guidance to be provided and key processes and capabilities that need to be covered and demonstrated; and ▪ establish a lessons learned component of MCS team meetings to ensure lessons are shared amongst all team members.	
Management Comments	

Recommendation 3	
First recommendation: Accepted Second recommendation: Accepted Third recommendation: Accepted in Part only Fourth recommendation: Accepted Part 1: SOPs for assessing applications and conducting compliance activities are an agreed and necessary element of maintaining the capability of the Section. Such SOPs will be designed along principles rather than as necessarily prescriptive procedural documents where appropriate. To that end, MCS envisages 'practice statements' being in place for the broad activities of "assessing applications" and "conducting compliance" generally, with procedural documents in place as necessary under those broader documents. For example, there might be a procedural document for sampling and testing under a wider practice statement on inspections. Part 2: Agreed. Part 3: The discussion preceding this recommendation suggests that where more formal guidance is in place there is less reliance on on-the-job guidance. To that end, structured control points for key processes will be specified in formal guidance documents requiring structured intervention – signing off on inspection plans, internal review of negative decisions etc. The suggestion that minimum and maximum levels of guidance should be provided is not relevant where the formal documentation is relied upon. Part 4: MCS is establishing post-inspection feedback as a standing item to team meetings. Note that the development of such documentation is already partly in place, and to some extent this will be a case of collation and refinement of existing process maps etc. Regardless, there remains a substantial amount of work to undertake and this will again raise other risks (including greater delays in reviewing applications) as resources are reallocated to meet the recommendation.	
Accountable Position	Agreed Completion Date
Assistant Secretary, Office of Drug Control	• Assurance 1 (SOPs and a revised checklist are in place): 30 JUN 2018 • Assurance 2 (staff confidence): 30 JUN 2018 • Assurance 2 (reporting on KPIs): 30 JUN 2018

Assurance

The following will provide assurance that the risk has been managed:

- a set of SOPs and a revised checklist are in place and being applied;
- consultation/survey with staff result in confidence that they are adequately informed and guided in their responsibilities; and
- key performance indicators for the scheme indicate timely and accurate completion of scheme management responsibilities.

3.5 Finding 4: Manual case management tool subject to error

The current Microsoft Excel tools being used to manage tracking of applications and permits does not exhibit usual controls to manage loss of data, erroneous data entry, streamlined reporting and decision support tools that would be expected from a tailored case management system.

Discussion

The case management systems is currently based in excel. While a manual system such as excel can be appropriate for a case load of 100+ cases, we note that there have been challenges encountered in the use of the current database, including loss of data.

We understand that the MCS is in the process of exploring other case management systems and we support this. In this regard, we note that the Department uses a range of regulatory (and other) case management systems, and to the extent possible MCS should look to leverage an existing system and licence for its purpose.

The benefits of a tailored case management system:

- allows for greater (and easier) visibility of all cases (applications), their status, who is responsible for them and where there are issues or delays;
- generally supports more efficient data entry;
- reduces risk of lost application data or loss of control of cases when spreadsheets are corrupted, changed or lost;
- can have built in checks to support accurate data entry;
- can support workflow that allows the application to be efficiently transitioned between team members as required; and
- generally has built-in reporting capability allowing for commonly used reports to be generated quickly and reliably.

Risk Exposure

Poor case management (through use of poor technology support) can result in lost data and delays or poor decision making in connection with applications, permits or other regulatory matters.

Recommendation 4	
Risk Rating	Medium (Consequence: Moderate. Likelihood: Unlikely)
The MCS should leverage off other case management systems in the Department to implement simple (but tailored) case management system to manage applications, permits and compliance activity.	
Management Comments	
The recommendation is Accepted – subject to separate departmental funding ODC supports the principle behind this recommendation but notes that it can only agree to carry out this recommendation if separate funding is made available through the Department's IT capital financing processes or otherwise. MCS has made significant progress in working with the Department's IT development areas to: • construct a bespoke system (phase 1 quoted at $750,000 for 'phase 1' and not progressed), • replicate the existing Microsoft Dynamics in use (minimum cost with 'tailoring for purpose' quoted at ROM $500,000), and • leverage the existing EPS solution for case management (initial estimates ROM $500,000). Of these, replicating and tailoring the existing Microsoft Dynamics system seems most appropriate, but the last such tailoring project (for people management purposes in HR) cost approximately $500,000 to make 'fit for purpose'. No internally available solutions appear to exist which could simply be cloned and tailored without additional resources.	
Accountable Position	Agreed Completion Date

Recommendation 4	
Assistant Secretary, Office of Drug Control	Subject to funding: 30 June 2018

Assurance

The following will provide assurance that the risk has been managed:

- an implemented, tailored case management system which has replaced the spreadsheets currently being used to manage all MCS activities.

4. Observations

During the internal audit we identified the following observations that the Department should be aware of and consider in its endeavours to continuously improve and develop its management of the scheme.

4.1 Observation 1: Cost recovery

The MCS has implemented the Department of Finance guidelines regarding recovering costs for regulatory services. The Medicinal Cannabis Program Costing Model was last revised in July 2016. The Cost Recovery Implementation Statement contains estimates of staff time per application – 25 hours for licence applications, 9 hours for permit applications and variations, and 19 hours for variations to licences.

It is known that this does not reflect current actual cost to undertake applications and permits assessment, with actual levels of time being much higher. Consequently, the Commonwealth is under-recovering current costs (noting that the cost recovery revenue goes to Consolidated Revenue, and is not hypothecated to the Department, so this would have no impact on the levels of available funding).

MCS is of the view that actual times will reduce to be closer to existing estimates for cost recovery. It will be appropriate to monitor this, and if actual cost levels (in a steady state environment), then a revised Cost Recovery Impact Statement may be appropriate to ensure ongoing compliance with the *Cost Recovery Guidelines of the Commonwealth*.

Attachment A: Risk Rating Definitions

This internal audit report includes a range of findings and observations. The risk exposure of these findings and observations have been identified based on the internal audit work performed. A risk rating associated with the findings has been determined based on an assessment of the consequence and likelihood of the related risk exposure of the finding. We have used the Department Risk Assessment Matrix at **Diagram 3**.

Opportunities have been identified to address each finding / observation. **Diagram 4** provides an outline of the expected management response to, and monitoring of, recommendations. This has also been taken from the Department's Risk Management Framework.

Diagram 3: Risk Assessment Matrix

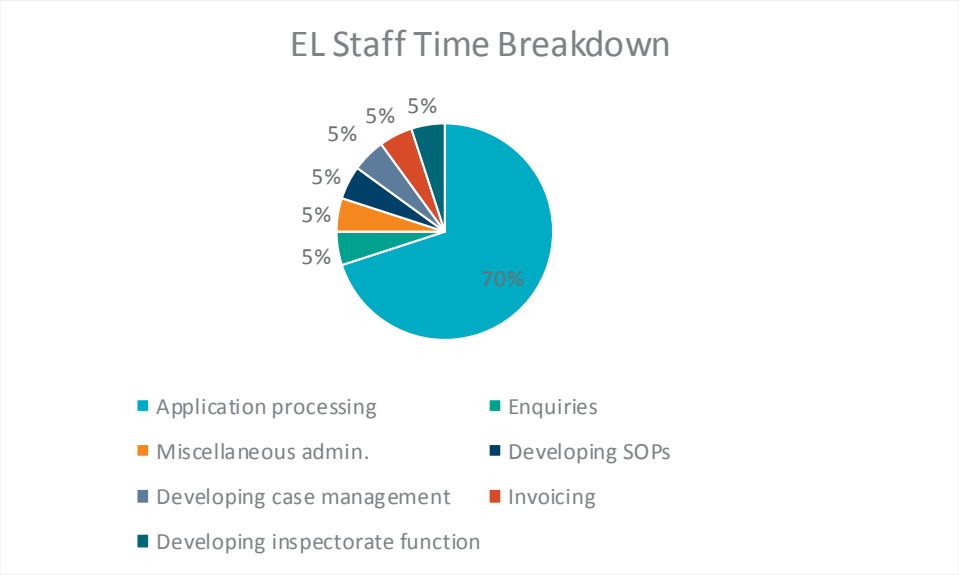
Australian Government Department of Health		RISK ASSESSMENT MATRIX				
		Likelihood →				
Date Approved:		Rare	Unlikely	Possible	Likely	Almost Certain
	General description of Consequences	Exceptional circumstances only	Not expected to occur	Could occur at some time	Will probably occur in most circumstances	Expected in most circumstances
Consequence ↑	Would stop achievement of functional goals/objectives — Severe	High	High	Extreme	Extreme	Extreme
	Would threaten functional goals/objective(s) — Major	Medium	Medium	High	High	Extreme
	Requires significant adjustment to overall function to achieve objective(s) — Moderate	Medium	Medium	Medium	High	High
	Would threaten an element of the function and would require some adjustment to achieve objective(s) — Minor	Low	Medium	Medium	Medium	High
↓	Lower consequence to achievement of objectives. — Insignificant	Low	Low	Low	Medium	Medium

Diagram 4: Transparency and accountability requirements

Rating	Risk Tolerance Table – Action Required
Extreme	Must be given immediate senior management attention. Risk assessment and approved plan, including treatments, must be undertaken.
High	Must have considerable management attention to reduce risk to as low as reasonably possible. Risk assessment and approved plan, including treatments, must be undertaken.
Medium	Risk should be managed and monitored. Risk assessment and approved plan required. If contracts are working effectiveness than additional treatments are optional.
Low	Risk should be managed and risk and controls monitored.

Attachment B: Additional Analysis

The below diagram illustrated the breakdown of MCS EL staff time as provided by staff representation, and averaged across the three staff members.



The below diagram illustrated the breakdown of MCS APS staff time as provided by staff representation, and averaged across the three staff members.