Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing Quality Branch

MQB - Standard Operating Procedure (SOP)			
SOP 1.6	Internal Audits		
Process Owner	Assistant Secretary, MQB	Authorised by	Director, Quality Risk and Case Management
Date Issued	25 November 2015	Version #	1.4

Proposed changes to this MQB QMS Document must be initiated through the following document change proposal form: R15/888418

Purpose

Internal audits are performed in order to monitor the implementation and continuing compliance of the Quality Management System and to identify potential improvements. This procedure details the internal audit process within the MQB.

Responsibility

Quality Risk and Case Management Director and Quality Manager	To prepare the annual internal audit schedule To ensure internal audits are performed as per the Internal Audit Schedule and by staff that work outside the audited area To manage the internal audit program and report on it To maintain records related to internal audits To communicate internal audits outputs To drive the completion of tasks relating to internal audits, including reporting data analysis, management of CAPA as required and trending for Branch Management To assist in performing internal audits as required To maintain TRIM container/s of internal audits To prepare and present internal audit briefings to the MQB Branch Head and MQB Management team where required.
Assistant Secretary	To ensure provision of resources is allocated to internal audits. To intermittently review progress and effectiveness of the internal audit program.
MQB Directors	To ensure provision of resources is allocated to internal audits To make staff available for performing internal audits, or attend internal audits received
All MQB Staff	To be available to perform or participate in internal audits in accordance with the internal audit schedule To contribute to timely corrective and preventive action completion

Process

	Step	Reference
1.	At the start of each financial year, the Quality Risk and Case Management section drafts an internal audit schedule that meets the following criteria: • Covers upcoming financial year • Ensures at least one internal audit is performed per Section/ Team per year. (MDSAP activities must be included in this review) • Ensures key QMS areas are audited at least once every year and all elements of the QMS are audited at least once every two years • Clearly outlines when an internal audit shall take place • Ensures that internal auditors are trained in MQB Internal auditing processes • Ensures that internal auditors do not audit work in which they have been involved • Is flexible enough to ensure that aspects of the system identified at any management meeting for investigation could be audited in a timeframe such that they can be reported on within 3 months • Incorporates a risk based approach to internal audits • In addition to a risk based approach a smaller number of areas of critical concerns for the Financial Year will be subject to a deep dive review (internal audit with a limited scope focused on a particular area of concern) and this will be reflected in the internal audit schedule. These activities are often in synergy with quality control activities in other areas of the QMS, eg witnessed inspections in training **Note:** all MQB staff could be involved in performing an internal audit. Upon drafting the internal audit schedule, the QRCM section considers the roles, capabilities and expertise of staff involved in performing the internal audit to be appropriate for the intended scope.	PIC/S PI002-3 ISO 17021 R14/774813 MQB Risk Assessment and analysis
2.	The QRCM Section tables the schedule for discussion and approval in the MQB management meeting at the beginning of the financial year. This may be done prior to all details being available. Once approved, the QRCM section ensures the document is kept updated when further detail becomes available. The QRCM section sends an all-MQB staff email to advice about the schedule and/or provides a TRIM link to audit reference..	
3.	Internal audits may focus on aspects such as: • Compliance with MQB policies, procedures and work instructions • Compliance with TGA and Departmental policies and procedures • Compliance with therapeutic goods legal framework • Compliance with APS framework • Alignment with the relevant external standards the MQB QMS intends to adhere to: • Follow up of any external audits received by MQB	Form 1.6.a – Internal audit Schedule

	Step	Reference
	• Follow up of from previous internal audits • Qualification and training • Inspection program	PIC/S PI002-3 ISO 17021
4.	There may be circumstances where non-scheduled internal audits may be performed in the timeframe. This may occur for example where there are significant changes to procedures or as a directive from the QRCM Section. This will ensure any recommended actions required can proceed including ensuring effective implementation.	
5.	The QRCM Section notifies the auditor/s and their supervisor as well as the audited area/s about the upcoming audit, giving sufficient time for preparation, travel arrangements etc.	
6.	The auditor/s complete Section 1 of the Internal audit record and may develop an internal audit checklist, providing the auditor/s with a guide to the aspects of the system that will be audited, using the aspects mentioned in step 2 as guidance. The auditees are not provided the details within the checklist.	FORM 1.6.b, section 1
7.	The auditor/s advise staff of the purpose and objectives of the internal audit, before proceeding with the internal audit.	FORM 1.6.b, section 1
8.	The auditor/s issue an internal audit/deep dive report within 5 working days of the conclusion of the internal audit. The report should highlight areas of good practice as well as areas for development. For areas of good practice, enter N/A in the column 'Recommendations'	FORM 1.6.b,
9.	The auditor/s save the record in the relevant TRIM internal audits container, forwarding the TRIM link to the QSM as well as the Manager responsible for the area audited. Log the non-conformities in the Issue and CAPA log.	**Issue and CAPA Log 2015-2020** R15/100842
10.	The Manager responsible for the area and QRCM Section discuss the identified Issues, observations, recommendations and Opportunities for improvement and manage them in accordance with the Issue and CAPA Management SOP.	R13/20865 SOP 1.4 - MQB Issue and CAPA Management.
11.	A report including briefing on the findings of an internal audit or a deep dive review is to be submitted to the MQB management within two weeks from the date of the completion of the internal audit/deep dive review. The briefing should include a reference to the Issues raised as part of the Internal Audit report or the Internal Audits Briefing Report. Any findings that require immediate attention shall be communicated to the MQB Management directly upon identification. Any adverse findings related to MDSAP activities must also be communicated to the MDSAP Quality Manager by the Australian MDSAP representative and within the same timeframe.	

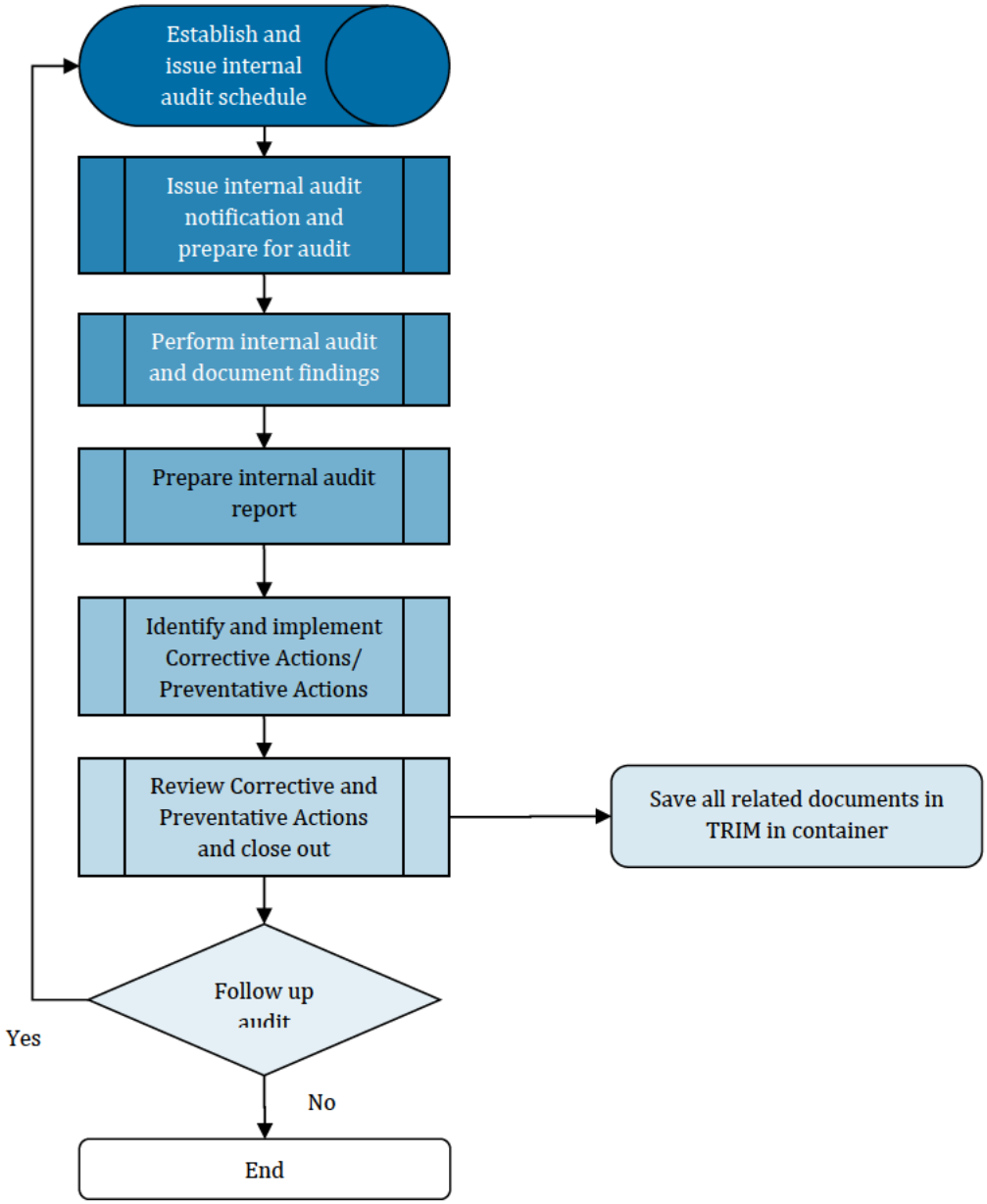
	Step	Reference
12.	The Manager responsible for the area audited or the person to whom the responsibility of the implementation of a particular CAPA has been assigned drives the implementation of CAPA actions by the agreed completion dates. Note: the Quality Manager assumes the role of the CAPA investigator where appropriate.	
13.	Where deemed necessary, a follow-up audit may be conducted to ensure that corrective action has been implemented and is effective. Where the QRCM Section, the auditor/s and the manager of the audited area agree a follow up audit is required, the QRCM Section adds it to the internal audit schedule. Subsequently, it is processed as a new internal audit as per this procedure.	
14.	Upon completion and close out of all items, the QRCM Section closes out the internal audit by: • Setting the TRIM workflow for the auditor/s and the Manager to e-sign in TRIM • Verifying whether all documents relevant to the internal audit have been migrated to the TRIM internal audits container that relates to that year • Recording the close out date in the internal audit schedule	

Version history

Version	Description of change	Author/s	Effective date
V1.0	New Format. Supersedes B1.05	s47F [redacted]	8 August 2014

Version	Description of change	Author/s	Effective date
V1.1	Minor amendments to reflect new structure	s47F [redacted]	5 September 2014
V1.2	Alignment with Department of Health business structure Changes to reflect the implementation of the new Non-conformance management and CAPA procedure Changes to the frequency to internal auditing	s47F [redacted]	2 February 2015
V1.3	Inclusion of internal audit briefing requirements Amendment of Quality Management Section to Quality Risk and Case Management (QRCM)	s47F [redacted]	10 July 2015
V1.4	Amendment of the SOP to include a link to the Document Change Proposal Form Inclusion of the requirement that internal auditors are trained in MQB Internal auditing processes	s47F [redacted]	25/11/2015

Simplified flow chart



MQB Internal Audit Log

Internal Audit Date	Section Audited	Scope	Inspectors	TRIM	Status	Date Report Issued	Date Response Received	Date Closed	Comments
s22									
November 2019	Inspections	Close Out Process	s47F	E19-686054	Closed	2/01/2020	17/02/2020	17/02/2020	
s22									
November 2021	Inspections	Training	s47F	E23-335856	Conducted	3/12/2021	16/01/2024		
November 2022	Inspections	Inspections Process		E23-533983	Closed	14/12/2022	18/04/2023	18/04/2023	
s22									s22 s22
April 2024	Inspections	Inspection Data Entry	s47F	E23-340375	Conducted	27/05/2024			Conducted 30 April, report issued 27 May.
s22						s22 s22			

Australian Government
Department of Health
Therapeutic Goods Administration

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Internal Audit:

Inspector Training, 29 - 30 November 2021

TRIM container: E21-411637

Background:

This internal audit is part of the overall internal audit program within MQB. The Section / Business unit of focus will be the Inspection section. The last recorded internal audit was November 2019. The extended period between internal audits have been at direct cause of the COVID-19 pandemic.

Scope:

The intention of this audit is to review the close out process:

- The Training of Inspectors
  - Compliance with the relevant documents (SOP's / WI / Templates) and MIS database
  - Record Keeping / Documentation
  - Review of IT database and recording of information – MIS and TRIM
- Review of open CAPA's from the November 2019 internal audit
- Post implementation review of CAPA (D20-321230) from the EU Audit December 2019.

Internal Auditors:

s47F [redacted]

Other personnel may also be engaged for this process. This may include personnel from the inspection section.

Method:

Review of the below against the key documents:

- A selection of inspection training forms / status / documentation from TRIM or other sources.
- Review of SOP's, Work Instructions, Forms etc relevant to the training program for inspectors.
- Review of CAPA's generated from previous internal audit in November 2019 and EU Audit 2019.

Key Documents:

- R13/946652 – MQB Training Program
- Forms 2.1.1a – Form 2.1.1f; Form 2.1.1h – Form 2.1.1i; Form 2.1.1m, Form 2.1.1n
- D21-2118901 – Undertaking a Witness Inspection
- D19-6571038 – MQB New Starter Induction
- D18-10963655 – Inspector competency spreadsheet.
- D21-2484205 – MQB Induction Checklist

Findings/Proposed Actions

There are numerous potential actions and they depend on findings. These actions need to be considered case-by-case and some should only be considered as consequences of previous actions. Actions which are frequently appropriate include:

- Follow the internal Issues and CAPA process for the management of findings.
- Conduct a thorough review of the issue "deep dive" and document the findings in Table 1: Additional Investigation "deep dive" findings.
- Present findings to the MQB Branch Management with classification as follows:
    - **Nonconformity (NC):** Non-fulfilment of a requirement (ISO 9000:2005)
    - **Recommendation (R):** Is an opportunity identified for continuous improvement of the TGA QMS during internal and external audits but do not include or recommend specific solutions (ISO 17021: 2011, 9.1.10.)
    - **Observation (O):** A statement of fact made in an audit team's report that something was found during the audit that doesn't rise to the level of nonconformity (no objective evidence of nonconformity, doesn't require a corrective action) but which, if left alone, could result in a future audit finding. Sometimes referred to as an "opportunity for improvement". (ISO definitions)
    - **Continual Improvement (CI):** Recurring activity to increase the ability to fulfil requirements. (ISO 9000:2005)

Implications for MQB QMS

Any Corrective Actions or improvements identified will be managed via MQBs Quality Management System.

Document Change Proposal

Proposed changes to this MQB QMS Document must be initiated through the following document change proposal form: R15/184929

Version history

Version	Description of change	Author/s	Effective date
V1.0	New Document, supersedes FB1.05a	s47F [redacted]	18 July 2014
V1.1	Minor title changes to reflect new structure	s47F [redacted]	5 September 2014
V1.2	Alignment with Department of Health business structure Remove Section 3: Internal audit response as NC/CAPA Procedure introduced Update Section 2: Internal audit report to include Process/QMS Document and classifications of NC/O/R/OFI	s47F [redacted]	2 February 2015
V1.3	Inclusion of link to Document Change Proposal Form Included briefing information and reference to the findings of a deep dive and/or the need to undertake a DD review (to align with changes to the IA SOP)	s47F [redacted]	28 July 2015

Table 1. Internal audit (IA) findings

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Classification (NC, R, O, CI)	Response	Due Date
1	SOP 2.1 MQB Training Program	Reference to Specialist Initial Training	R!5/157397	Has not be updated for long time. Remove reference and link to Inspector's training matrix R14/ 830929	O	It is acknowledged that the SOP has not been recently updated. The SOP will be revised to clarify items raised as part of the Internal Inspection and to implement some planned clarifications to the process to improve training operations.	End April, 2022
2	Training Files - s47F [redacted]	Inspector's training records are maintained and current	Form 2.1.1.b is used as a guide for Inspectors during initial training	No Form 2.1.1.b was available for s47F	O	Due to some inherent anomalies in the content of the Training Forms and application defined in the SOP, s47F (and other Inspectors) had incorrectly completed information in the additional Manufacturing Type form so as to include relevant observed/training Inspection details/Feedback. It is acknowledged that the application of different forms, the detail required to be included and the management of the process requires revision to improve clarity and flexibility in the conduct & recording of Training in the Inspectorate. It is recommended that the process be simplified so that recording is simpler and the form	End April 2022

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Classification (NC, R, O, CI)	Response	Due Date
						allows for flexibility of initial training and additional Manufacturing type training as each should record the same information. As such the SOP and associated Forms will be revised and re-published with input from the Inspectorate. It is also intended to transfer the Training records and associated records to SharePoint to allow more flexible access to relevant Inspector Training Records. Current repository in TRIM restricts easy access to records due to other sensitive information contained within the current restricted staff folders.	
			Additional manufacturing type training records are maintained on FORM 2.1.1d	No form 2.1.1d was available / completed for s47F for any manufacturing types	NC	Review and remediation of s47F training records in alignment with the SOP be resolved in the interim, prior to new process adoption	End March 2022
			E19-529130, Form 2.1.1c (05/08/2019) It is stated that s4 will undergo a witness inspection before going out on his own	Please confirm that this has occurred or alternative please confirm that s has not conducted further inspection for Blood Donor Centres	O		

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Classification (NC, R, O, CI)	Response	Due Date
			D19-5811416 (Form 2.1.1c (20/3/2019) s4 was assessed as competent in the following manufacturing types, but it is not reflected in MIS or competency spreadsheet API-Biotech ; API – Non-sterile; API-Classic Fermentation; Testing- Biotech	MIS or Competency spreadsheet not updated to reflect s4 training	NC	Competency Spreadsheet and MIS competencies to be reviewed and aligned. TL's to review current status for each team member and remediate any discrepancies. Training records to support this alignment to be verified as complete.	11 April 2022 (allowed for next Office week to resolve any issues with inspection team)
3	Training Files – s47F s47F	SOP2.1 MQB Training Program The RPL process is conducted upon commencement with the relevant supervisor. Any RPL's assigned are documented and the rationale will be recorded. The training plan may be abridged according to the documented RPL.	s47F has not conducted any inspections to date since his return in Q3 2021 but is assigned to inspection without any training records / plan available.	No evidence of the required training plan for s47F based on his RPL is available	O	s47F Training plan based on review of RPL to be recorded (either as separate doc or within Training records) s47F was observed for the first 3 inspections and record completed????	11 April 2022

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Classification (NC, R, O, CI)	Response	Due Date
4	Training Files - s47F	SOP 2.1 MQB Training Program Form 2.1.1.a should be signed and approved	Form 2.1.1a not completed by inspector or approver	Form not completed – signed or dated by inspector or approver	O	s47F Training records to be reviewed and remediated in alignment with the SOP	11 April 2022
		All forms	Form 2.1.1.i Inspection of s2 2 conducted in July 2020 remain incomplete	s47F was the second inspector on this inspection. This document remains open with no outcome. Please provide clarification on whether this should be complete as part of s47F training	O	As above	As above
			The majority of forms are incomplete (i)Form 2.1.1i NSW Health (ii) Form 2.1.1d Cell Therapies & QIMR (biological class iv) (iii) Form 2.1.1d 4 manufacturers (testing)- no trainers / assessor provided recommendation,	(i)No feedback has been documented in these forms (ii) Form is incomplete Clarify if s4 has conducted Biological Class IV (iii) Form is incomplete Inspection conducted in May 2019 has no recommendation or assessment provided	NC	As above	As above

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Classification (NC, R, O, CI)	Response	Due Date
				Clarify if s47F has conducted inspections of Testing labs?			
5	Training Files – s47F s47F	SOP 2.1 MQB Training Program ..manufacturing type is approved the Quality Manager records the competence on the Compiled Inspector Competence Spread sheet. Full competence is also recorded against staff profile in MIS	s47F s undergoing training and has participated in inspections in different capacities.	From his training records s47F is not signed off on any manufacturing type. In MIS the staff profile for s47F indicates he is trained in Blood processing; blood collection; blood etc. s47F s not nominated in the competency spreadsheet	NC	s47F raining records to be reviewed and remediated in alignment with the SOP	11 April 2022
6	Training Competency	SOP 2.1 MQB Training Program ..manufacturing type is approved the Quality Manager records the competence on the Compiled Inspector Competence Spread sheet. Full competence is also recorded against staff profile in MIS	The current competency Form 2.1.1e was last updated in 4/2020.	s47F as conducted numerous inspections since he commenced in the Branch. This is not reflected in the competency spreadsheet. A draft spreadsheet D19-6361653 is being used. This is not a controlled document.	NC	s47F raining records to be reviewed and remediated in alignment with the SOP and Competency Spreadsheet to be updated as above	11 April 2022

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Classification (NC, R, O, CI)	Response	Due Date
			A draft spreadsheet is being used D19-6361653 (Version 3.0)	A draft spreadsheet has been updated that does not align to the current spreadsheet. The following are 3 examples; s47F has been removed from Class II human tissue s47F is "F' for one competency against 4 in the current spreasheet. MIS shows she has more than 1 'F' s47F is "F' on the current spreadsheet for Medicinal Products – Sterile. The draft version this is absent	NC	As above	11 April 2022
7	Witness Inspections	Post Implementation Review of CAPA 200303 (D20-321230) WI 2.1.4 Form 2.1.1n Form 2.1.1m SOP 2.1	WI 2.1.4 "..the record will be reviewed by MQBs Quality Manager and the record finalised"	No Witness Inspection forms have been reviewed by Quality Manager.	O	SOP to be updated to remove QA Manager approval as there is no requirement (and/or role) for MQB QA Manager and the process adds no value to the process as initial inspection training currently does not require QA Manager review and approval	End April 2022

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Classification (NC, R, O, CI)	Response	Due Date
			Witness inspections conducted s47F s22 s47F s22	Forms fo s47F equire sign off by assessor and team leader / delegate	O	Forms to be finalised	11 April 2022
			SOP 2.1 ..Witness inspections are aimed to be conducted every three years for each inspector	No evidence is available to indicate that these witness inspections have been carried out	O	Witness Inspection records are contained within each Inspectors Training Folder. Witness inspections were postponed due to the impact of COVID and transition to remote inspection. Witness Inspection SOP be to be revised in alignment with Training SOP	End April 2022
			SOP2.1 "..The witness observes the performance of the nominated inspector whilst on site and completes Form 2.1.1h or Form 2.1.1i"	WI 2.1.4 FORM 2.1.1.m - **D21-2118668** is referenced as the form to complete for witness inspections	R	As above – due to COVID, onsite inspections have been postponed. SOP to be revised to provide for remote witness assessment.	End April 2022
8	Internal Audit Documentation		It is noted that the submission of documents requested were hampered due to the various reason, This impacted on the ability to review training files as part of this Internal Audit	Reviewing documentation was not ideal as the training files we not easy to access. QM should have access to these documents.	R	It is acknowledged that the SOP has not been recently updated. The SOP will be revised to clarify items raised as part of the Internal Inspection and to implement some planned clarifications to the process to improve training operations.	End April 2022

Name	s47F [redacted]		
Signature		Date	03 December 2021

Australian Government
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Internal Audit:

Inspectorate 2022 - 2023

TRIM Container: E22-607350

Background

This internal audit is part of the overall internal audit program. The section of focus will be the Inspections section.

Scope:

The intention of this audit is to review the application processes:

- Sample up to 5 Inspections – different types will be chosen
- Compliance with the relevant documents (SOP's / WI)
- Record Keeping / Documentation
- Review of IT database and recording of information – MIS and TRIM
- Training records

Internal Auditors:

- Primary: s47F [redacted], Clearances Section
- Secondary: s47F [redacted], Manufacturers Assessment Support Section

Method:

Review of the below against the key documents:

- Randomly select up to 5 inspections then use the applications to review:
- SOP's, Work Instructions, Forms, etc
- Roles and training record for the staff involved
- Position description for the staff involved
- MIS, TRIM databases and other record management systems

Key Documents:

- R13/943168 – Internal Audit
- R13/946652 – MQB Training Program
- All relevant SOPs/WIs:
  - R12/618875 – SOP 5.2 Inspection Preparation and Planning
  - R12/640998 – SOP 5.3 Conducting an Inspection
  - R12/676280 – SOP 5.4 Inspection Review, Close Out and Completion

Findings/Proposed Actions

There are numerous potential actions and they depend on findings. These actions need to be considered case-by-case and some should only be considered as consequences of previous actions. Actions which are frequently appropriate include:

- Follow the internal Issues and CAPA process for the management of findings.
- Conduct a thorough review of the issue "deep dive" and document the findings in Table 1: Additional Investigation "deep dive" findings.
- Present findings to the MQB Branch Management with classification as follows:
    - **Nonconformity (NC):** Non-fulfilment of a requirement (ISO 9000:2005)
    - **Recommendation (R):** Is an opportunity identified for continuous improvement of the TGA QMS during internal and external audits but do not include or recommend specific solutions (ISO 17021: 2011, 9.1.10.)
    - **Observation (O):** A statement of fact made in an audit team's report that something was found during the audit that doesn't rise to the level of nonconformity (no objective evidence of nonconformity, doesn't require a corrective action) but which, if left alone, could result in a future audit finding. Sometimes referred to as an "opportunity for improvement". (ISO definitions)
    - **Continual Improvement (CI):** Recurring activity to increase the ability to fulfil requirements. (ISO 9000:2005)

Record of internal audit finding

For each inspection reviewed indicate if the QMS processes were followed.

Element	Inspection 1	Inspection 2	Inspection 3	Inspection 4	Inspection 5
Processes followed					
Records saved in TRIM					
Records saved in MIS					
Record of training for staff					
Position description for staff					

Element	Inspection 1	Inspection 2	Inspection 3	Inspection 4	Inspection 5
Comments					

Implications for MQB QMS

Any Corrective Actions or improvements identified will be managed via MQBs Quality Management System

Document Change Proposal

Proposed changes to this MQB QMS Document must be initiated through the following document change proposal form: R15/184929

Version history

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V1.2	Alignment with Department of Health business structure Remove Section 3: Internal audit response as NC/CAPA Procedure introduced Update Section 2: Internal audit report to include Process/QMS Document and classifications of NC/O/R/OFI	s47F [redacted]	2 February 2015
V1.3	Inclusion of link to Document Change Proposal Form Included briefing information and reference to the findings of a deep dive and/or the need to undertake a DD review (to align with changes to the IA SOP)	s47F [redacted]	28 July 2015

Table 1. Internal audit (IA)/ Deep Dive (DD) review findings

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
1a	Conducting an Inspection s22 [redacted] s22 [redacted] SOP 5.3 ver 3.2	Process in relation to inspection notes to be compliant with the SOP	SOP 5.3 under step 13 requires '... The inspection team members record all relevant observations and evidence sighted for later use when writing the report and as a record of evidence....'	No notes saved in TRIM by the inspector, and no records of observations saved in TRIM can be seen as a record of evidence in support of writing up the report.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
1b		Post Inspection Letter (PIL)	The SOP 5.3 under step 25 requires '...A PDF version of the PIL,	The word version of PIL (D22-5717324) was not e-signed for peer review (only	The SOP 5.3 will be revised to streamline the steps where possible.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			created after the Word version was finalised and e-signed in TRIM…The email to the manufacturer is also saved in the relevant TRIM container…'	reviewer's initial was noted on the title of the document), was not made final. There were still tracked changes in it.	A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
2a	Inspection Preparation and Planning s22 [redacted] s22 [redacted]	Announcement letter	2(a)i. Step 12 requires 'Emails the announcement letter… Files the email in TRIM..' 2(a)ii. Step 11 requires 'The lead inspector to save	2(a)i. No email found in TRIM under 'Pre-Inspection Preparation (Inspectors)' TRIM inspection container 2(a)ii. The inspection announcement letter found in 'Pre-Inspection	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.2. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
	SOP 5.2 ver 3.1		inspection announcement letter in to the 'Pre-Inspection Preparation (Inspectors)' TRIM inspection container and e-signs it in TRIM... ..Declares the document 'Final' in TRIM only after the review of the WHS by the DI and including whether it will be a remote, onsite or hybrid and eSigned by DI and LI...'	Preparation (Inspectors)' TRIM inspection container, however it was not e-signed by the LI in TRIM, and was not made Final.	and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
2b	SOP 5.2 ver 3.1 WI 5.1.9 ver 1	MIS 'Assign & Schedule Audit Task'	2(b)i. The SOP 5.2 under step 13 requires 'complete the MI 'Assign & Schedule Audit Task' following the WI 5.1.9...' The WI 5.1.9 under step 6 of complete the	2(b)i. The MIS Task – Assign & Schedule Audit assigned to was not updated according to the WI. The entry to the Assigned to was entered 'Inspectors'	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.2. This is planned for week 5 June 2023

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			Assign & Schedule Task section requires '...complete the "Assigned To" field by clicking on the twisty, then type in 'Audit Completion – Medicines' or 'Audit Completion – BT&CT'...' 2(b)ii. SOP 5.2 requires the inspection announcement letter (step 10 &11) to be sent out first, and then complete the MIS 'Assign & Schedule Audit' task after sending out the letter (step 13)	2(b)ii. The MIS Task – Assign & Schedule Audit the actual end date 8/6/2022 which was entered earlier than the inspection announcement letter signature date 9/6/2022, indicating the MIS task was completed prior to the sending out the letter.	In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
2c	WI 5.3.1	Inspecting a BT&CT manufacturer, no	WI 5.3.1 is still in draft.	Only copy of the WI 5.3.1 (R16/769929) is currently still in draft. The MQB	WI 5.3.1 will be reviewed and updated and released by end of June 2023.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
		current effective WI in place		Quality Manual master index also indicates there is no version release date for the current draft to become effective.	
2b	Conducting an Inspection s22 [redacted] s22 [redacted] SOP 5.3 ver 3.2	Inspection attendance sheet	SOP 5.3 under step 9 requires '....The manufacturer representative are asked to complete the inspection attendance sheet...'	The only Inspection attendance sheet saved in TRIM (D22-5699255) was left blank	A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
2c		Inspection notes & records of observations	SOP 5.3 under step 13 requires '... The inspection team members record all relevant observations and evidence sighted	No notes saved in TRIM by the inspector, and no records of observations saved in TRIM can be seen as a record of evidence in	The SOP will be reviewed and revised to streamline the steps where possible.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			for later use when writing the report and as a record of evidence….'	support of writing up the report.	A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
2d		Post Inspection Letter (PIL)	SOP 5.3 under step 25 requires '…A PDF version of the PIL, created after the word version was finalised and esigned in TRIM… ….The email to the manufacturer is also saved into the relevant TRIM container….'	The PIL was esigned, however was not made final. There was no email about the issuance of PIL to the manufacturer saved in TRIM.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
					processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
2e	Inspection Review, Close Out and Completion s22 [redacted] s22 [redacted] SOP 5.4 ver 3.3	Close out record	2Ii. SOP 5.4 under step 5 requires '...Lead Inspector saves e-copies of the responses provided by the manufacturer in the relevant TRM container...' Step 8 requires '... The Lead Inspector 'finalises' and e-signs the reviewed response document in TRIM...'	2Ii. No email correspondence saved TRIM indicating the close out record saved in TRIM was an actual response provided by the manufacturer. There were 2 close out records saved in TRIM, however neither of them were e-signed, nor made final.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.4. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
2f	SOP 5.3 ver 3.2	Inspection record	2(f)1. SOP 5.4 under step 9 requires '...The Lead Inspector completes the inspection close out section of the inspection record and saves it back into TRIM...'	2(f)1. The section 4 Inspection close-out & report did not fully complete as LI did not indicate the final compliance rating	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
2g	TEMP 5.3.j	Inspection report	2(g)i. SOP 5.4 under step 11 requires '...The Inspection Report, Post Closeout is saved into	2(g)i. The Inspection report (D22-5699269) was not declared final in TRIM.	The SOP will be reviewed and revised to streamline the steps where possible.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			the relevant TRIM container, declared final and e-singed in TRIM…' 2(g)ii. TEMP 5.3. j should be used for drafting the post closeout inspection report 2(g)iii. Step 12 requires '…The Lead Inspector issues the Inspection Report, Post closeout to the manufacturer via an email….' & '…The email to the manufacturer should also be saved in	2(g)ii. The TEMP 5.3.j format was not completely adhered when preparing the Inspection report. The finalised inspection report did not seem to contain information including summary and conclusion about assessment of manufacture's responses, Final evaluation and recommendations, Brief report of inspection activities undertaken, etc. 2(g)iii.	A refresher training course will be performed for the Inspection section on SOP 5.4. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			relevant TRIM container.	Email inspection report to the manufacturer was not saved in TRIM	
3a	Inspection Preparation and Planning s22 [redacted] s22 [redacted] SOP 5.2 ver 3.1	Announcement letter	3(a)i. SOP 5.2 under step 11 requires '...The Lead Inspector declares the document 'Final' in TRIM only after the review of the WHS responses by the DI and including whether it will be a remote, onsite or hybrid and signed by DI and LI....' 3(a)ii. Step 12 requires '...Email the announcement letter....Files the email in TRIM...'	3(a)i. Announcement letter was saved and esigned by the LI, however the letter did did not include signature from the DI and was not made Final. 2(a)ii. No email of announcement letter was saved in TRIM.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.2. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
3b		Inspection plan	SOP 5.2 under step 20 requires '...The Lead Inspector or delegate prepares an Inspection Plan...The Lead Inspector or delegate saves the Inspection Plan in TRIM and prepares an agenda and prints hard copies of the agenda...'	No inspection plan saved in TRIM	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.2. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
3c		Inspection Attendance Sheet	3(c)i. SOP 5.2 under step 23 requires '...Lead Inspector or delegate prepares an Inspection Attendance Sheet and an Inspection Closing	3(c)i. No Inspection Attendance Sheet nor closing meeting summary template saved in TRIM.	The SOP will be reviewed and revised to streamline the steps where possible.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			Meeting Summary, save both in TRIM…' Step 24 requires '…All information is be held in the 'Pre-Inspection (Inspectors)' TRIM folder…' 3(c)ii. SOP 5.3 ver 3.2 under step 9 requires '…The manufacturer representatives are asked to complete the Inspection attendance sheet…'. TEMP 5.2b as template used for attendance sheet	3(c)ii. A copy of attendance sheet with entries made by the manufacturer was saved in TRIM. However, the format of attendance sheet was not following the current TEMP 5.2 as information such as Manufacturer detail, inspector name, standards, attendee initial to opening meeting or close meeting, opening meeting time, closing meeting time etc, was not included in the document.	A refresher training course will be performed for the Inspection section on SOP 5.2. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
3d	WI 5.1.9 ver 1.0	MIS 'Assign & Schedule Audit' Task	The SOP 13 requires 'complete the MI 'Assign & Schedule Audit Task' following the WI 5.1.9...' The WI 5.1.9 under step 6 of complete the Assign & Schedule Task section requires '...complete the "Assigned To" field by clicking on the twisty, then type in 'Audit Completion – Medicines' or 'Audit Completion – BT&CT'...'	The MIS Task – Assign & Schedule Audit assigned to was not updated according to the WI. The entry to the Assigned to was entered 'Inspectors'	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on WI 5.1.9. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
3e	Conducting an Inspection s22 [redacted]	Post Inspection letter (PIL)	3(e)i. The SOP 5.3 under step 25 requires '...A PDF version of the PIL, created after the Word version was finalised	3(e)i. The word version of PIL (D22-5717324) was not e-signed for peer review (the peer review was noted according to the inspection	The SOP will be reviewed and revised to streamline the steps where possible.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
	s22 [redacted] SOP 5.3 ver 3.2		and e-signed in TRIM…The email to the manufacturer is also saved in the relevant TRIM container…' 3(e)ii. '….The email to the manufacturer is also saved into the relevant TRIM container…'	record), and was not made final. 3(e)ii. No email of PIL was saved in TRIM	A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
3f	Inspection Review, Close Out and Completion s22 [redacted] s22 [redacted] SOP 5.4 ver 3.3	Close out record	SOP 5.4 under step 5 requires '…Lead Inspector saves e-copies of the responses provided by the manufacturer in the relevant TRM container…' Step 8 requires '… The Lead Inspector 'finalises' and e-signs	No email correspondence saved in TRIM indicating the close out record saved in TRIM was an actual response provided by the manufacturer. The response was e-signed, however was not made final.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.4. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			the reviewed response document in TRIM…'		processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
3g		Inspection report	The SOP 5.4 under step 12 requires '…The lead inspector issues the Inspection Report, Post Closeout to the manufacturer via an email…The email to the manufacturer should also be saved into relevant TRIM container…'	The email of Inspection Report to the manufacturer was not saved in TRIM.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.4. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
4a	Inspection Preparation and Planning s22 [redacted] s22 [redacted] SOP 5.2 ver 3.1 SOP 5.10 ver 2.0 FORM 5.10.a ver 1.0	Oversea Remote Pre-inspection Checklist	The SOP 5.2 under step 2 requires '...In conjunction with this SOP, the relevant WI(s) are followed: Remote inspection (Overseas) SOP 5.1.0....' The SOP 5.10 under step 10 requires '....Advise the manufacturing site that the TGA want to conduct a remote inspection and send the "Overseas Remote Pre-inspection Checklist"...'	No 'Overseas Remote Pre-inspection Checklist' saved in TRIM, not email saved in TRIM confirming the checklist was sent to the manufacturer.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.2. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
4b		Announcement letter	The SOP 5.2 under step 12 requires '...Emails the announcement	No emails of announcement letter was filed in TRIM.	The SOP will be reviewed and revised to streamline the steps where possible.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			letter... files the email in TRIM...' The SOP 5.10 under step 11 requires '...send the announcement letter to confirm the agreed dates and any instructions regarding supply of documents/methods of contact & communications. Saves the document in the "Pre-Inspection preparation" TRIM inspection container and e-signs it in TRIM...'		A refresher training course will be performed for the Inspection section on SOP 5.2. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
4c		RFI 1&2, inspection time sheet	4(c)i. SOP 5.10 under step 18 requires '... the Lead Inspector makes a primary request for documents be provided	4(c)i. No email request filed in TRIM, nor documents provided by the Manufacturer or any reference to the system	The SOP will be reviewed and revised to streamline the steps where possible.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			by preferred method….The manufacturer should be instructed to upload these documents into the agreed system at least 12 weeks prior to the inspection date, or email the documents by an agreed time…' 4(c)ii. Step 20 requires '….All inspection team members should keep records of all hours worked during review of the Primary Request for Information. These details should be collated and records in the Inspection time sheet..'	where manufacturer uploaded their documents were found in TRIM. 4(c)ii. No inspection time sheet saved in TRIM. Additionally, it was noted the documents were requested throughout the 3 day inspection period according to the inspection plan/agenda (D22-5757311, D22-5757318, D22-5757324), however time was not recorded for direct discussions. It was unclear weather there has been any review of documentation prior to the inspection. If the review was done prior to the	A refresher training course will be performed for the Inspection section on SOP 5.10. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			Step 28 requires '...All inspection team member should keep records of all hours working during the direct discussion(s). These detail should be collated and recorded in the Inspection time sheet...' Step 29 requires '...The time spent at the closing meeting should be recorded in the Inspection Time sheet...'	inspection, then the hours spent during the review of primary or secondary request for information was not being recorded.	
4d	WI 5.1.9 ver 1.0	MIS 'Assign & Schedule Audit ' Task	The SOP 5.2 under step 13 requires 'complete the MI 'Assign & Schedule Audit Task'	The MIS Task – Assign & Schedule Audit assigned to was not updated according to the WI. The entry to the	The SOP will be reviewed and revised to streamline the steps where possible.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			following the WI 5.1.9…' The WI 5.1.9 under step 6 of complete the Assign & Schedule Task section requires '…complete the "Assigned To" field by clicking on the twisty, then type in 'Audit Completion – Medicines' or 'Audit Completion – BT&CT'…'	Assigned to was entered 'Inspectors'	A refresher training course will be performed for the Inspection section on WI 5.1.9. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
4e	Conducting an Inspection s22 [redacted] s22 [redacted] SOP 5.3 ver 3.2 SOP 5.10 ver 2.0	Post Inspection Letter (PIL)	The SOP 5.3 under step 25 requires '…A PDF version of the PIL, created after the Word version was finalised and e-signed in TRIM…The email to the manufacturer is also saved in the relevant TRIM container…'	The work version of PIL (D22-5580487) was e-signed for peer review, however was not made final. There were still tracked changes in it. No email of PIL to the manufacturer was saved in TRIM.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
4f	Inspection Review, Close Out and Completion s22 [redacted] s22 [redacted] SOP 5.4 ver 3.2 SOP 5.10 ver 2.0	Inspection Report	The SOP 5.4 under step 12 requires '...The lead inspector issues the Inspection Report, Post Closeout to the manufacturer via an email...The email to the manufacturer should also be saved into relevant TRIM container...'	The email of Inspection Report to the manufacturer was not saved in TRIM.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.4. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
5a	Inspection Preparation and Planning	Announcement letter	5(a)i. SOP 5.2 under step 12 requires '...There is no need to save PDF attachment back into	5(a)i. Announcement letter was saved in PDF instead of WORD format.	The SOP will be reviewed and revised to streamline the steps where possible.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
	s22 [redacted] s22 [redacted] SOP 5.2 ver 3.1 TEMP 5.2a ver1.7		TRIM, as they are considered 'electronic prints' of the related Word document....' 5(a)ii. TEMP 5.2a is used for drafting the announcement letter.	5(a)ii. The TEMP 5.2a format was not completely adhered when preparing the announcement letter where the attachment 1 – Pre-inspection questionnaire was not included in the letter sent out to the manufacturer.	A refresher training course will be performed for the Inspection section on SOP 5.2. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
5b		Inspection Attendance Sheet	SOP 5.2 under step 23 requires '...Lead Inspector or delegate prepares an Inspection Attendance Sheet and an Inspection Closing Meeting Summary, save both in TRIM...'	No Inspection Attendance Sheet nor closing meeting summary template saved in TRIM.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.2. This is planned for week 5 June 2023

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			Step 24 requires '...All information is be held in the 'Pre-Inspection (Inspectors)' TRIM folder...'		In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
5c	WI 5.1.9 ver 1.0	MIS 'Assign & Schedule Audit' Task	The SOP 13 requires 'complete the MI 'Assign & Schedule Audit Task' following the WI 5.1.9...' The WI 5.1.9 under step 6 of complete the Assign & Schedule Task section requires '...complete the "Assigned To" field by clicking on the twisty, then type in 'Audit Completion – Medicines' or 'Audit Completion – BT&CT'...'	The MIS Task – Assign & Schedule Audit assigned to was not updated according to the WI. The entry to the Assigned to was entered s47F	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on WI 5.1.9. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
					checks performed at audit completion to ensure these are done.
5d	Conducting an Inspection [redacted] [redacted] SOP 5.3 ver 3.2	Inspection Attendance Sheet	The SOP 5.3 under step 9 requires '...The manufacturer representatives are asked to complete to Inspection attendance sheet...'	Again, there was no inspection attendance sheet filed in the TRIM, therefore unable to verify the entries made by the manufacturer.	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
5e		Post Inspection Letter (PIL)	The SOP 5.3 under step 25 requires '...A PDF	The work version of PIL (D22-5485832) was e-	The SOP will be reviewed and revised to streamline the steps where possible.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			version of the PIL, created after the Word version was finalised and e-signed in TRIM…'	signed for peer review, however was not made final. There were still tracked changes in it.	A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023 In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
5f	Inspection Review, Close Out and Completion s22 [redacted]	Inspection Report	The SOP 5.3 under step 11 requires '…The Inspection Report, Post Closeout is saved into the relevant TRIM container, declared final and e-singed in TRIM…'	The original Word version of the inspection report post closeout was not saved in TRIM, only a PDF copy was saved (D22-5505098).	The SOP will be reviewed and revised to streamline the steps where possible. A refresher training course will be performed for the Inspection section on SOP 5.3. This is planned for week 5 June 2023

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
	s22 [redacted] SOP 5.4 ver 3.2				In the meantime, a reminder will be sent to the section to ensure all documents are in TRIM and e signatures performed to current QMS processes. Also a reminder for the EL2 QA checks performed at audit completion to ensure these are done.
6a	Inspector Training Program SOP2.1 ver2.0	Inspector training records are maintained and current	Training records SOP 2.1 requires '...Training and progressions is recorded on FORM 2.1.1.c. Competency in the preparation, onsite performance is recorded in section 3 of Form 2.1.1.c....' '..The observation of training at on-site inspection is recorded by the trainer on FORM 2.1.1.h or FORM 2.1.1.i	No form 2.1.1.c or equivalent records were available and supplied for s47F [redacted], at the time of the internal audit. No form 2.1.1.h or i or equivalent records were available and supplied for s47F [redacted], at the time of the internal audit.	s47F [redacted] to different inspection training procedure to what is in the current QMS.

#	Process or QMS Document (Reference)	Requirement	Evidence/notes	Findings (summary)	Response to internal audit
			providing feedback in relation to the trainee's performance...'	Recommendation: noting the records were captured in high level, it will be good to link each inspection to the corresponding TRIM document.	

Name			
Signature		Date	

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing Quality Branch

MQB – Form

FORM 1.6.b	Internal Audit Record		
Comes Under	1.6 – Internal Audits		
Process Owner	Assistant Secretary, MQB	Authorised by	Quality Manager
Date Issued	28 July 2015	Version #	1.3

This form, when completed, will be classified as **'For official use only'**.

Internal Audit

Inspections Section 2023 – 2024 FY

30 April 2024 – 9:00am – 5:00pm

TRIM Container: E23-340375

Background

This internal audit is part of the overall Branch internal audit program and will focus on data entry into the IBM Notes (MIS) records management system within the Inspections Section.

Scope:

The intention of this audit is to review the data entry of performed inspections (status of 'scheduled', 'carried-out', 'conducted' and 'completed) for the 2023 – 24 FY within the IBM Note (MIS) records management system, specifically within the Audit Support Tool (AST) as of 20 April 2024.

- Assess that 'conducted' inspections have the 'actual inspection information' added within three days of returning to the office (only for the status of 'scheduled').
- Ensure that inspector information contained with the AST is correct:
  - Only inspectors who have inspected (or observed an inspection) are included in the AST.
  - That 'cost recovered' and 'non-cost recovered' specialities have been correctly applied.
  - The duration of any specialists has been correctly applied.
  - Where multiple inspectors go to a site, that information in the AST is correct.

Internal Auditors:

- s47F [redacted] - GMP Operations and Strategy.

Method:

A list of inspections performed in the 23-24 FY was extracted from MIS on 30 April 2024, which identified 238 inspections which met the selection criteria (status of 'scheduled', 'carried-out', 'conducted' and 'completed) -.

Each inspection was reviewed in IBM Notes (in the AST)

- Assess that 'conducted' inspections have the 'actual inspection information' added within three days of returning to the office (only for the status of 'scheduled').
- Ensure that inspector information contained with the AST is correct:
  - Only inspectors who have inspected (or observed an inspection) are included in the AST.
  - That 'cost recovered' and 'non-cost recovered' specialities have been correctly applied.
  - The duration of any specialists has been correctly applied.
  - Where multiple inspectors go to a site, that information in the AST is correct.

Key Documents:

D24-1715304	Qlik Inspection Extract
R12/640998	SOP 5.3 - Conducting an Inspection - Version 3.2 – Issued
D20-834302	WI 5.9.4 - Recording Inspector Training in MIS - Version 3.0 - Issued

Findings/Proposed Actions:

Inspections Reviewed	Inspections Requiring Potential Amendment
238	40

A list of all identified inspections (and the 40 which require potential amendment / details of the potential issues with the inspections) can be found located in TRIM - **D24-1715304**.

Green highlighted cells in excel indicated no findings against the inspection.

Orange highlighted cells in excel indicate a finding against the inspection – specific details will be provided in the comments column (column AD).

The response / resolution to the findings / issues should be provided in the excel spreadsheet in the response column (column AE).

Implications for MQB QMS

Any corrective actions which are implemented from the identified non-conformities will be managed via the MQB Quality Management System.

Name	s47F [redacted]		
Signature	eSigned in TRIM	Date	27/5/24

(note: eSigned document in TRIM on 27 May 2024 but internal audit conducted on 30 April 2024)

Version history

Version	Description of change	Author/s	Effective date
V1.0	New Document, supersedes FB1.05a	s47F [redacted]	18 July 2014
V1.1	Minor title changes to reflect new structure	s47F [redacted]	5 September 2014
V1.2	Alignment with Department of Health business structure Remove Section 3: Internal audit response as NC/CAPA Procedure introduced Update Section 2: Internal audit report to include Process/QMS Document and classifications of NC/O/R/OFI	s47F [redacted]	2 February 2015
V1.3	Inclusion of link to Document Change Proposal Form Included briefing information and reference to the findings of a deep dive and/or the need to undertake a DD review (to align with changes to the IA SOP)	s47F [redacted]	28 July 2015

Name			
Signature		Date	

Audit ID	Tracking Number	Inspection Type	Client ID	Manufacturer	Site ID	Site Address	Inspector Qualifications	Zone	Location	Audit Status	Due Date	Est. Duration	No. of Inspectors	Total Duration	Act. Duration	Act. Hours	Act. Start Date	Act. End Date	All Inspectors in MIS	Lead Inspector in MIS	Other Inspector in MIS	Specialist	Spec. Days	Speciality	Audit Notes	Inspectors Correct?	Dates / Hours Correct?	Comments	Inspection Section Resolution / Response
MIP-2020-03372-1	s22	Re-inspection	s22	s22			s47F	s22		Carried-out	s22								s47F		s47F	s47F	s22	Accompanying Inspector (cost recovered)	s22	No	No	s47F as been given 5 cost recovered days and s47F in lieu of the 5 cost recovered days, even though s47F only did 2.5 hours cost recovery and s47F of none.	
MIP-2021-06553-1		Compliance								Carried-out														Accompanying Inspector (cost recovered)		No	Yes	(A) Audit records as 1 Inspector x 1.5 days, rather than 2 Inspectors x 1.5 Days.	
MIP-2021-06838-1		Re-inspection								Carried-out														Accompanying Inspector (cost recovered)		No	Yes	The audit was only invoiced for one inspector, so I'm guessing the s47F as a trainee (and consistency will need to be updated to non-cost recovered)?.	
MIP-2021-08352-1		Re-inspection								Carried-out														Microbiology - Laboratory		No	Yes	Wrong speciality used for s47F Should be trainee inspector / accompanying inspector cost recovered).	
MIP-2021-08868-1		Re-inspection								Carried-out														Microbiology - Laboratory		No	Yes	Wrong speciality used for s47F Should be trainee inspector / accompanying inspector cost recovered).	
MIP-2022-00275-1		Re-inspection								Carried-out														Accompanying Inspector (cost recovered)		No	Yes	The audit was only invoiced for one inspector, so I'm guessing the s47F as a trainee (and consistency will need to be updated to non-cost recovered)?	
MIP-2022-01210-1		Re-inspection								Carried-out														Accompanying Inspector (cost recovered)		No	Yes	The audit was only invoiced for one inspector, so I'm guessing that s47F as a trainee (and consistency will need to be updated to non-cost recovered)? YES CORRECTED TO NON	
MIP-2023-05395-1		Re-inspection								Carried-out												-				No	Yes	s47F [redacted] missing from the audit as the second inspector for the site and will need to be added.	
MIP-2022-04508-1		Re-inspection								Carried-out												s47F		Training Assessor (cost recovered)		No	No	Invoiced for 2 days of hour s47F s lead for 1 days, s47F specialist for 1 day. Invoiced hours do not align to assigned inspectors.	
MIP-2023-07446-1		Initial								Carried-out											s47F			Accompanying Inspector (cost recovered)		No	No	Assigned inspectors, audit comments and invoiced hours do not align.	
MIP-2023-06548-1		Initial								Carried-out														Trainee Inspector (non-cost recovered)		No	No	Assigned inspectors, audit comments and invoiced hours do not align.	
MIP-2023-07515-1		Initial								Carried-out														Cellular		No	No	Assigned inspectors, audit comments and invoiced hours do not align. Incorrect speciality selected.	
MIP-2020-02247-1		Re-inspection								Closed-out														Trainee Inspector (non-cost recovered)		No	No	Assigned inspectors, audit comments and invoiced hours do not align.	
MIP-2021-05062-1		Re-inspection								Closed-out												s47F		Trainee Inspector (non-cost recovered)		No	No	Assigned inspectors, audit comments and invoiced hours do not align.	
MIP-2021-08914-1		Re-inspection								Completed											s47F	-		-		-	Yes	No	27.5 hours for pre inspection work have been included in the hours (and therefore a being represented in QBL).	
MIP-2022-01683-1		Re-inspection								Completed												s47F		Accompanying Inspector (cost recovered)		?	No	Check invoiced hours.	
MIP-2022-05845-1		Initial								Completed																No	Yes	s47F [redacted] resolve from the audit as the other auditor.	
MIP-2023-02668-1		Initial								Completed												s47F		Accompanying Inspector (cost recovered)		?	?	ed for one Inspector, s47F was a trainee? If so, need to update audit to make him non-cost recovered.	
MIP-2019-03424-1		Initial								Completed												s47F		Accompanying Inspector (cost recovered)		?	?	Only Invoiced for one Inspector, s47F as a trainee? If so, need to update audit to make him non-cost recovered.	
MIP-2022-10047-1		Special								Completed														Trainee Inspector (non-cost recovered)		No	Yes	Incorrect speciality used for s47F	
MIP-2022-06841-1		Initial								Completed														Trainee Inspector (non-cost recovered)		No	Yes	Incorrect speciality duration for s47F	
MIP-2021-03950-1		Re-inspection								Conducted														Accompanying Inspector (cost recovered)		No	No	Assigned inspectors, audit comments and invoiced hours do not align.	
MIP-2021-05405-1		Re-inspection								Conducted														Accompanying Inspector (cost recovered)		No	No	Assigned inspectors, audit comments and invoiced hours do not align.	
MIP-2022-02102-1		Re-inspection								Conducted														Accompanying Inspector (cost recovered)		No	No	Assigned inspectors, audit comments and invoiced hours do not align.	
MIP-2022-04223-1		Re-inspection								Conducted														Accompanying Inspector (cost recovered)		No	No	Assigned inspectors, audit comments and invoiced hours do not align.	
MIP-2022-05195-1		Re-inspection								Conducted														Accompanying Inspector (cost recovered)		No	No	Assigned inspectors, audit comments and invoiced hours do not align.	
MIP-2022-06144-1		Re-inspection								Conducted														Trainee Inspector (non-cost recovered)		Yes	No	Need to reduc s47F activities hours down to 1.5 days	
MIP-2022-06538-1		Re-inspection								Conducted											s47F	-		-		-	Yes	No	37.5 hours for pre inspection work have been included in the hours (and therefore a being represented in QBL).	
MIP-2023-11678-1		Special								Conducted												s47F		Accompanying Inspector (cost recovered)		No	Yes	s47F should not be in MIS - will need to be updated.	
MIP-2019-06583-1		Re-inspection								Scheduled												s47F		Accompanying Inspector (cost recovered)		No	No	(A) Audit records as 1 Inspector x 3 days, rather than 2 Inspectors x 3 Days. (B) Scheduled dates in March, conducted dates not entered.	
MIP-2019-07643-1		Re-inspection								Scheduled												s47F				No	Yes	(A) Audit records as 1 Inspector x 5 days rather than 2 Inspectors x 5 days.	
MIP-2021-04008-1		Re-inspection								Scheduled											s47F	-		-		-	Yes	Yes	(B) Conducted dates not entered into MIS. Corrected	
MIP-2021-06647-1		Re-inspection								Scheduled												-		-		-	Yes	Yes	(B) Conducted dates not entered into MIS. CORRECTED	
MIP-2021-07830-1		Re-inspection								Scheduled											s47F	s47F		Trainee Inspector (non-cost recovered)		No	Yes	(A) Need to fix up trainee vs cost recovered. Currently duplicating days fo s47F	
MIP-2022-04047-1		Initial								Scheduled												-		-		?	No	(B) Scheduled dates in August 2023, conducted dates not entered into MIS.	
MIP-2022-05099-1		Re-inspection								Scheduled												s47F		Accompanying Inspector (cost recovered)		Yes	Yes	This appears to only be a 2.5 day inspection, so s47F should be added as non-cost recovered. CORRECTED	
MIP-2022-08430-1		Re-inspection								Scheduled											s47F	-		-		?	?	Only one inspector was invoiced for, so guessing the s47F as not cost recovered and audit will need to be updated accordingly.	
MIP-2022-06253-1		Re-inspection								Scheduled												-		-		?	?	Only one inspector was invoiced for, so guessing the s47F as not cost recovered and audit will need to be updated accordingly.	
MIP-2024-01207-1		Special								Scheduled												s47F		Microbiology - Laboratory		?	No	(A) Check specialist & (B) scheduled dates back in March, not yet conducted	
MIP-2023-10507-1		Initial								Scheduled											s47F	-		-		?	No	Scheduled in April, but not yet conducted.	
MIP-2020-05726-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2020-05750-1		Re-inspection								Carried-out											s47F	-		-		Yes	Yes	N/A	
MIP-2021-07318-1		Compliance								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-03647-1		Re-inspection								Carried-out												s47F		Accompanying Inspector (cost recovered)		Yes	Yes	N/A	
MIP-2021-05835-1		Re-inspection								Carried-out														Accompanying Inspector (cost recovered)		Yes	Yes	N/A	
MIP-2023-10359-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2021-05428-1		Re-inspection								Carried-out												s47F		Trainee Inspector (non-cost recovered)		Yes	Yes	N/A	
MIP-2021-06483-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2021-07212-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-04625-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-04648-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2021-07915-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-08235-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2023-07238-1		Re-inspection								Carried-out											s47F	-		-		Yes	Yes	N/A	
MIP-2022-00364-1		Re-inspection								Carried-out												s47F		Accompanying Inspector (cost recovered)		Yes	Yes	N/A	
MIP-2022-01213-1		Re-inspection								Carried-out														Accompanying Inspector (cost recovered)		Yes	Yes	N/A	
MIP-2022-05134-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-11184-1		Initial								Carried-out											s47F	-		-		Yes	Yes	N/A	
MIP-2022-03134-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2024-00312-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-09730-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-04686-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-04753-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2023-08830-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-00218-1		Special								Carried-out											s47F	-		-		Yes	Yes	N/A	
MIP-2022-04710-1		Re-inspection								Carried-out											s47F	-		-		Yes	Yes	N/A	
MIP-2022-06895-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-07077-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-07930-1		Compliance								Carried-out											s47F	-		-		Yes	Yes	N/A	
MIP-2024-00582-1		Re-inspection								Carried-out											s47F	-		-		Yes	Yes	N/A	
MIP-2022-08407-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-08304-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2023-07458-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-11005-1		Re-inspection								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-02782-1		Special								Carried-out												-		-		Yes	Yes	N/A	
MIP-2023-08795-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2023-08413-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-01810-1		Special								Carried-out												-		-		Yes	Yes	N/A	
MIP-2022-01434-1		Re-inspection								Carried-out												s47F		Accompanying Inspector (cost recovered)		Yes	Yes	N/A	
MIP-2023-10507-1		Initial								Carried-out												-		-		Yes	Yes	N/A	
MIP-2023-06047-1		Initial								Carried-out											s47F	-		-		Yes	Yes	N/A	
MIP-2024-01583-1		Special								Carried-out												-		-		Yes	Yes	N/A	
MIP-2024-01538-1		Special								Carried-out												-		-		Yes	Yes	N/A	
MIP-2023-09404-1		Initial								Carried-out											s47F	-		-		Yes	Yes	N/A	
MIP-2023-07930-1		Re-inspection								Carried-out												s47F		Trainee Inspector (non-cost recovered)		Yes	Yes	N/A	
MIP-2021-02655-1		Re-inspection								Closed-out												s47F		Trainee Inspector (non-cost recovered)		Yes	Yes	N/A	
MIP-2021-02870-1		Re-inspection								Closed-out												-		-		Yes	Yes	N/A	
MIP-2021-05508-1		Re-inspection								Closed-out												-		-		Yes	Yes	N/A	
MIP-2021-05680-1		Re-inspection								Closed-out											s47F	-		-		Yes	Yes	N/A	
MIP-2021-06515-1		Re-inspection								Closed-out												s47F		Accompanying Inspector (cost recovered)		Yes	Yes	N/A	
MIP-2022-01544-1		Re-inspection								Closed-out											s47F	-		-		Yes	Yes	N/A	
MIP-2022-03911-1		Re-inspection								Closed-out												-		-		Yes	Yes	N/A	
MIP-2023-08022-1		Re-inspection								Closed-out												s47F		Accompanying Inspector (cost recovered)		Yes	Yes	N/A	

MIP-2022-07442-1	s22 [redacted]	Re-inspection	s22 s22 s47F s22 [redacted]	Closed-out	s22 [redacted]	s47F [redacted]		s47F [redacted]	s22 [redacted]	Trainee Inspector (non-cost recovered)	s22 [redacted]	Yes	Yes	N/A
MIP-2022-10767-1	[redacted]	Re-inspection	[redacted]	Closed-out	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-10769-1	[redacted]	Re-inspection	[redacted]	Closed-out	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-10773-1	[redacted]	Re-inspection	[redacted]	Closed-out	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-06271-1	[redacted]	Initial	[redacted]	Closed-out	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-09265-1	[redacted]	Compliance	[redacted]	Closed-out	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-10525-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2019-06722-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2020-01001-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2020-01008-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2020-01535-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		s47F [redacted]	[redacted]	Accompanying Inspector (cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2022-10513-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		[redacted]	[redacted]	Trainee Inspector (non-cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2022-01144-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-04540-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		s47F [redacted]	[redacted]	Trainee Inspector (non-cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2021-04669-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-05975-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-03672-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-07625-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-08243-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		s47F [redacted]	[redacted]	Accompanying Inspector (cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2021-08203-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-01006-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-01209-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-01319-1	[redacted]	Compliance	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-05066-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-05866-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-07763-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-02101-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-00146-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-02055-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-02617-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-10799-1	[redacted]	Special	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-08146-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-08230-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-06352-1	[redacted]	Special	[redacted]	Completed	[redacted]	[redacted]		s47F [redacted]	[redacted]	Trainee Inspector (non-cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2023-00138-1	[redacted]	Special	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-03985-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-04160-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-10318-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		s47F [redacted]	[redacted]	Accompanying Inspector (cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2022-04654-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-02798-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-00229-1	[redacted]	Compliance	[redacted]	Completed	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-01538-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-04874-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-04670-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-05597-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		s47F [redacted]	[redacted]	Accompanying Inspector (cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2022-06335-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-06334-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-01125-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-01638-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-04051-1	[redacted]	Special	[redacted]	Completed	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-01548-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-01674-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		s47F [redacted]	[redacted]	Accompanying Inspector (cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2023-05869-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-05870-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-08459-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-02923-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-05249-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-09490-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-04179-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-09806-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-04397-1	[redacted]	Special	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-05599-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		s47F [redacted]	[redacted]	Accompanying Inspector (cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2023-07280-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-11287-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-08370-1	[redacted]	Special	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-07727-1	[redacted]	Re-inspection	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-09178-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-08299-1	[redacted]	Special	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-09141-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-08929-1	[redacted]	Special	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-08934-1	[redacted]	Special	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-07371-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-09073-1	[redacted]	Special	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-06611-1	[redacted]	Initial	[redacted]	Completed	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2019-08062-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2020-03002-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2020-09025-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-08349-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-04390-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		s47F [redacted]	[redacted]	Accompanying Inspector (cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2021-05581-1	[redacted]	Compliance	[redacted]	Conducted	[redacted]	[redacted]		[redacted]	[redacted]	Accompanying Inspector (cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2021-06287-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2021-06345-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		s47F [redacted]	[redacted]	Trainee Inspector (non-cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2021-08351-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-03229-1	[redacted]	Initial	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2020-08889-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		s47F [redacted]	[redacted]	Accompanying Inspector (cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2021-09387-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-00339-1	[redacted]	Compliance	[redacted]	Conducted	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-02955-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-00329-1	[redacted]	Initial	[redacted]	Conducted	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-03635-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-04710-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-04752-1	[redacted]	Re-inspection	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-05433-1	[redacted]	Compliance	[redacted]	Conducted	[redacted]	[redacted]	s47F [redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-11061-1	[redacted]	Initial	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A

Document 6

MIP-2023-05169-1	[redacted]	Special	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-06382-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-10642-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-08443-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-08451-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-05360-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]	[redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-00352-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]	[redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-09473-1	[redacted]	Special	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-09497-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-11782-1	[redacted]	Special	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-08492-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-06028-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2024-00507-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-03743-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-10561-1	[redacted]	Special	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2024-00161-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-06406-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Conducted	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-00234-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-00863-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-00965-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]	[redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-05905-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-05907-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-01113-1	[redacted]	Special	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-05852-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		[redacted]	[redacted]	Accompanying Inspector (cost recovered)	[redacted]	Yes	Yes	N/A
MIP-2022-04590-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-04848-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-05598-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-05785-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-04716-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-00423-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-08137-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-06689-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-02268-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]	[redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-06248-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-07071-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2022-10177-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-04851-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-09448-1	[redacted]	Special	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-01400-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-08520-1	[redacted]	Special	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-01563-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-10191-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]	[redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-09420-1	[redacted]	Re-inspection	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-08926-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-11880-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2023-10909-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2024-00136-1	[redacted]	Special	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2024-00044-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]	[redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2024-00729-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]	[redacted]	-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2024-00733-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A
MIP-2024-00519-1	[redacted]	Initial	[redacted]	[redacted]	[redacted]	[redacted]	Scheduled	[redacted]	[redacted]		-	[redacted]	-	[redacted]	Yes	Yes	N/A

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing
Quality
Branch

MQB – Template (TEMP)

TEMP 1.7.a	Quality Management Review Form		
Process Owner	Director, Inspections	Authorised by	Quality Manager
Date Issued	17 January 2019	Version #	2.0

General

Quality Management Review	
QMS Review Financial Year Period:	1 July 2022 to 30 June 2023
Date Primary Objectives Report Generated:	28/11/2023
Date Secondary Objectives Report Generated:	18/12/2023
Date QMR Meeting Held:	07/02/2024
Routine Periodic QMR or Ad Hoc?	Routine Periodic QMR
Attendees:	s47F [redacted] and s47F [redacted]
Apologies:	N/A
Minutes Approved:	eSigned by Jenny Burnett - Assistant Secretary, MQB

Introduction

The following Quality Management Review Report (QMR) covers the financial year between 1 July 2022 and 30 June 2023*.

The report is based on SOP 1.7 – Quality Management Review (D18-11036187) and is split into two sections; the primary objectives (covered by step 2 of the procedure) And the secondary objectives as an addendum to the primary objectives (covered by step 3 of the procedure).

The reporting timelines for the primary objectives is 1-2 months post financial year, and the secondary objectives is within 4-6 months post financial year.

All actionable items are logged in the 'MQB Issue, Planned Deviation and CAPA Log' (R15/100842) and the actionable item report numbers are included in the summary review, along with the conclusions and recommendations section of this report.

*This report is based on available data at the time of writing this report and is based on the previous financial year (2022 – 2023).

Primary Objectives Report

Review Inputs	Summary Review, Conclusions & Recommendations
a) 85% Close-out of Inspections on Time MQB KPI data is no longer published in the Portfolio Budget Statements.	This KPI is part of the existing Quality Management Review template as it was previously published in the Department of Health Portfolio Budget Statements. However, as MQB inspection close-out data is no longer published in the Portfolio Budget Statement (*the MQB information was last published in 17-18 Portfolio Budget Statement*), it is no longer being tracked by the MQB Inspectorate and will not be reported upon in the 2022-23 FY Quality Management Review.
b) Inspections Conducted Within Target Timeframes: i. 85% of initial domestic inspections conducted within 3 months. ii. 80% of domestic re-inspections conducted within 6 months. iii. 85% of overseas initial inspections conducted within 6 months. iv. 80% of overseas re-inspections conducted within 6 months. The internal KPI percentages for each inspection type are available in the 2022-23 MQB Branch Business Plan Tracker. This data (excluding our internal KPIs) is published in 2022-23 TGA Regulator Performance Report, which is available at: Performance reports.	**These KPI targets were not met in the 2022-23 FY.** A backlog of inspections built up during 2020-2023 primarily resulting from interruptions to inspections during the COVID-19 pandemic. Through this period, priority was given to very urgent initial or variations inspections. ***Table 1: Inspections of Australian Manufacturers*** See table below. [a] Six domestic initial inspections did not achieve the three-month processing timeframe in 2021-22 due to manufacturers not being ready for inspection. [b] The 2022-23 data does not include inspections that were delayed at the request of the manufacturer. [c] Twenty-six of the delayed re-inspections were blood and biological manufacturers. ***Table 2: Inspections of Overseas Manufacturers*** See table below.

	2021-22	2022-23
Processing Time		
Initial inspections conducted within 3 months of application	9 of 15 (60%) [a]	10 of 15 (67%) [b]
Re-inspections conducted within 6 months of due date	34 of 95 (36%) [c]	16 of 90 (18%)

	2021-22	2022-23
Processing Time		
Initial certification inspections conducted within 6 months of application	8 of 37 (22%) [a]	9 of 33 (27%) [b]
Certification re-inspections conducted within 6 months of due date	2 of 66 (3%)	4 of 66 (6%)

Review Inputs	Summary Review, Conclusions & Recommendations
	[a] Twenty-nine overseas initial inspections did not achieve the six-month processing timeframe due to manufacturers not being ready for inspection. b The 2022-23 data does not include inspections that were delayed at the request of the manufacturer. **Activities to Improve Performance Against this KPI:** • A business case submitted by MQB to substantially increase the number of inspectors was approved by TGA Executive. • Project planning commenced on a new 'Surveillance' inspection process to enable shorter duration inspections of manufacturers with a good compliance history. • Additional Qlik tools have been created to provide greater visibility of inspector workloads and assist with inspection allocation decisions.

Review Inputs	Summary Review, Conclusions & Recommendations
c) 90% of GMP Clearance Applications Processed Within Target Timeframes: v. 30 workdays for MRA. vi. 60 workdays for CV Non-Sterile API. vii. 75 workdays for CV Sterile API. viii. 90 workdays for CV Non-Sterile FP. ix. 120 workdays for CV Sterile FP.	**These KPI targets were not met in the 2022-23 FY.** The number of GMP clearance applications has risen significantly in recent years. Further, the complexity of assessments has increased due to the lack of primary evidence available during the COVID-19 pandemic. This has required the assessments performed by MQB to be more in-depth and resource intensive than was previously the case. Priority has been given to assessing MRA pathway applications. ***Table 3: GMP Clearance Applications*** 2021-22 / 2022-23 Per cent processed within target timeframes MRA: 98% / 84% CV Non-Sterile API: 99% / 71% CV Sterile API: 100% / 48% CV Non-Sterile FP: 98% / 68% CV Sterile FP: 100% / 59% **Activities to Improve Performance Against this KPI:** • A business case submitted by MQB to substantially increase the number of clearance assessors was approved by TGA Executive. • Measures introduced in 2020 in response to the COVID-19 pandemic for processing GMP Clearance MRA applications were extended and amended in October 2022. • We have communicated the delays of the GMP Clearance processing times with the regulated industry at the industry stakeholder forum (TIWGG).

Review Inputs	Summary Review, Conclusions & Recommendations
d) Timeliness of Recall Actions i. 85% of all recall actions agreed within 7 days. ii. 90% of all new notifications assessed.	**KPI targets i and ii were not met in the 2022-23 FY.** ***Table 4: Recall Actions*** **Activities to Improve Performance Against this KPI:** • Recalls personnel has increased and several existing vacant positions have been filled. It is expected this should see the section return to aim in the meeting its KPIs in the next FY. Work is progressing on the Recall Reforms Program that will make improvements to Australia's recall processes and deliver efficiency gains for the TGA and its key stakeholders.

	2021-22	2022-23
Per cent processed within target timeframes		
Recall actions agreed within 7 days	85%	77%
New notifications assessed within 2 days	83%	83%

Review Inputs	Summary Review, Conclusions & Recommendations
e) International Harmonisation: 1. Contribute to the evolving international environment to help support the quality and safety of medicines in Australia. 2. Increase engagement with overseas regulators in comparable health systems, and with regional and international organisations to improve public health and safety. 3. Strengthen inter-agency partnerships to enable greater monitoring and use intelligence to target non-compliance.	MQB continued to improve the global framework for regulating manufacturing standards for medicines. We led or participated in many international working groups focussing on a wide range of regulatory issues. These committees are listed at **D23-3381609**. We also worked closely with comparable regulators to share knowledge and information. **Pharmaceutical Inspection Cooperation Scheme (PIC/S)** • The TGA is the Chair of the PIC/S Sub-committee on Strategic Development (SCSD), attending twice yearly in-person meetings of the PIC/S Executive Bureau (PIC/S EB) and regular teleconferences of both the EB and the SCSD. • Chaired and/or contributed to strategic committees and working groups within PIC/S aimed at fostering greater Inspection Reliance between members, consistency of data collection, development of training materials and alignment of processes. • Participated in the revision and training in updates to the PIC/S Guide to Good Manufacturing Practice (GMP) for medicinal products (manufacturing standard) for sterile medicines, quality risk management and biological medicines. • Continued to work with our regulatory partners in Pharmaceutical Inspection Cooperation Scheme (PIC/S) on a best practice remote inspection process to enhance the remote inspection tool with agreed approaches. **Mutual Recognition Agreements** • Operationalised additional countries under the EU-Australia Mutual Recognition Agreement for GMP and established reoccurring forums with MRA partners. • Engaged with MRA partners on sites of common interest related to GMP inspections for COVID-19 vaccines to avoid duplication of effort. **Other** • Contributed to the International Coalition of Medicine Regulatory Authorities (ICMRA) projects on Pharmaceutical Quality Knowledge Management System (PQKMS). • Worked closely with Access Consortium members on the joint statement on GMP Inspection Reliance and Recognition. • Contributed to various Regulatory Strengthening Program (RSP) Regulatory Practice Workshops, including on reliance and different areas of technical or product expertise.

Review Inputs	Summary Review, Conclusions & Recommendations
	Recalls • Shared information and participated in international meetings on post-market review investigations, recall actions and safety signals with comparable overseas regulators that we have agreements with, to help the TGA take faster action to safeguard consumers and patients.

Secondary Objectives Report (Addendum):

Review Inputs	Summary Review, Conclusions & Recommendations
a) Results of External Audits:	No external audits were performed in the 2022-23 FY.

b) Results of Internal Audits:	Internal audits of the following areas were performed in the 2022-23 FY:
	• Inspections (E23-533983),
	• Licencing and certification processes in the GMP Operations and Strategy Section (GOSS) (E23-533994),
	• Recalls (E23-188215).
	These audits covered the following aspects of the PIC/S related functions in each area:
	• Compliance with relevant SOP's and Work Instructions,
	• Record Keeping / Documentation,
	• Review of IT database and recording of information,
	• Training records.
	Key Findings
	1. While a considerable number of observations were made and recorded in the internal audits, few non-conformities were identified.
	2. SOP's and WIs were being used despite still being in draft format and/or not being released in the QMS, including:
	  • WI 5.3.1 - Inspecting a BT&CT manufacturer,
	  • Numerous Recalls SOP's and WI's.
	3. There were many examples of documents not being filed in TRIM as required by WI's.
	4. There were many examples of steps in MIS not being completed as required by WI's.
	5. Formal responses were received from the Inspections Section, Recalls Section and GOSS. These included actions to address all issues raised and these actions will be reviewed during the 2023 – 2024 FY internal audit schedule.

c) Feedback from Clients and Interested Parties: e.g. Review of stakeholder surveys, feedback, meetings with stakeholders (e.g.	N/A – see Assistant Secretary Comments (on page 13).

Review Inputs	Summary Review, Conclusions & Recommendations
TIWGG, TWG), compliments etc.	
d) Safeguarding Impartiality:	Procedures are in place to ensure that all personnel perform their duties in a fair and unbiased way and that the performance of those duties is not influenced by personal interests, private affiliations, or the likelihood of personal gain or loss. The following SOPs are currently being reviewed to ensure that these processes remain fit-for-purpose: • SOP 2.7 - Potential conflicts of interest, • The components of SOP 5.4 - Inspection Review, Close Out and Completion that relate to inspectors declaring in the Inspection record for each inspection any improper influences by a person or organisation external to TGA (specifically a manufacturer or sponsor).
e) Status of Corrective Actions	Thirty-one planned deviations or CAPA's were raised in 2022-23. Note: As of 18 December 23, 15 remain open and 16 are closed. These issues were classified by the initiators as: • 5 non-conformances, • 7 corrective actions, • 19 planned deviations. A backlog of CAPA's from 2022-23 and earlier years that which were not recorded as being closed will be addressed by the Quality Manager in conjunction with Directors and section quality coordinators in the next FY (2023-24). **Key Issues** • Many of the 2022-23 planned deviations relate to inspection reports not being written or not being completed before a licence or certificate was issued. • There were several instances for correct actions / non-conformances where the scope of a conducted inspection led to errors and complications with the issuing of licences, certificates and clearances. • Inconsistent filing of key documents caused problems with responding to FOI requests and represent a risk to MQB being able to fully justify regulatory decisions. • Issues with the currency and accuracy of training records indicate risks to the processes for allocating inspectors to inspections and associated risks relating to invoicing.

Review Inputs	Summary Review, Conclusions & Recommendations
	The corrections outlined in the CAPA's that relate to the above issues were either deemed to be adequate in each case or negotiation is still ongoing for preventative actions. However, overall, our approach to these issues could be the subject of further audit and remediation. **Impacted Processes for Planned Deviations:** - 8 Clearances - 7 Inspections - 2 Certification - 1 Licence - 1 Travel **Impacted Processes for Non-conformance / Corrective Actions:** - 6 Inspections - 2 Licence - 2 Certification - 1 Management Review - 1 Training
f) Status of Actions to Address Risk: Review against E18-282813 for specific financial year reporting under 'what may prevent us'- specific to Inspectorate only	The branch risk management plan for 2022-23 was developed as part of the business planning process in accordance with HPRG requirements. The MQB Business and Risk Plan 2022-23 is at: **D22-5893847**. These risk mitigation activities were undertaken as planned and additional measures were enacted as outlined in the Primary objectives report and at Attachment A (**D23-4362852**). In addition, the following QMS specific actions were undertaken in 2022-23: • A new dedicated resource was allocated to the Quality Manager position to commence July 2023 (for the 23-24 FY), • An update to the quality manual was commenced (which was delivered in the 23-24 FY).
g) Follow-up Actions from Previous Management Reviews: Review previous QMR report to identify any potential recurring challenges and	Nil

Review Inputs	Summary Review, Conclusions & Recommendations
verify recommendations have been completed.	

Review Inputs	Summary Review, Conclusions & Recommendations
h) The Fulfilment of Quality Objectives: Refer to Primary Objectives report	Primary objectives were not fulfilled in 2022-23 mainly because of higher and more complex workloads and resource constraints.
i) Changes that Could Affect the Management System:	Nil
j) Appeals and Complaints:	Two complaints were made against the MQB Inspectorate in 2022-23. In these two cases the manufacturers felt they had been treated in an unfair or inconsistent manner. All complaints were managed to the satisfaction of the external stakeholder.

QMR Summary:

QMR Outputs	Final Conclusions and Recommendations:
Improvements Needed to Maintain the Effectiveness of the QMS and its Processes	• Simplification of select QMS procedures to make them easier to follow, such as those relating to: - Documentation system and document change management, - PD and CAPA management, - Change management. • Review of existing SOPs and WIs to improve alignment with updated quality manual and removal of documents which are not required, • Review of the existing SOPs and WIs to ensure that process owners are identified, and that periodic review and update of documents is occurring, • Further training of quality coordinators, • Ongoing management of the PD and CAPA processes to ensure completion, • Broader awareness and understanding of QMS across MQB.
Resource Needs	Additional resources that will be allocated in 2023-24 FY (new quality manager and new section quality coordinators) which will enable improvements to be made to the QMS itself and will assist MQB to make better use of the QMS.
Revisions of MQBs Policy and Objectives	Nil.

Assistant Secretary Comments:

The information provided as part of the QMR for "(Secondary Objectives – C) Feedback from Clients and Interested Parties" has been removed following the QMR meeting held on 7 February 2024. The information which was originally provided from the TGA stakeholder survey 2022 did not relate to the Manufacturing Quality Branch specifically and therefore should not have been included.

As agreed at the QMR meeting, the Quality Manager, in consultation with the Directors and Assistant Secretary, will update the QMR template (TEMP 1.7.a) ahead of the 2023 – 2024 QMR to ensure that the information contained in the next report is fit for MQB's purposes and continues to align with the requirements of the PI-002 – 3 quality standards (Recommendations of Quality System Requirements for Pharmaceutical Inspectorates).

Version History

Version	TRIM Reference	Description of change	Author/s	Effective Date
V1.0	R13/943193	New document	s47F [redacted]	17 September 2014
V1.1	R13/943193	Alignment with Department of Health business structure	s47F [redacted]	2 February 2015
V1.2	R13/943193	Revised template, Additional inputs included as per ISO 9001 Outputs included as per ISO 9001 Additional inputs included as per ISO 17021 Inclusion of the requirement to report on threats to impartiality. Inclusion of requirement to report on MDSAP activities where relevant.	s47F [redacted]	09 November 2015
V2.0	R13/943193 SOP 1.7 - Quality management review -	Updated QMR template to current format and to better align with MQB's Inspectorate operational QMS including: 1. Portfolio budget statement KPIs, 2. International regulation harmonisation 3. PIC/S Participating Authority Quality system requirements for pharmaceutical inspectorates (PI 002-3) ISO 17021:1:2015 (secondary guidance document)	s47F [redacted]	17 January 2019

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing
Quality
Branch

MQB – Template (TEMP)			
TEMP 1.7.a	Quality Management Review Report Template		
Process Owner	Assistant Secretary, MQB	Authorised by	Quality Manager
Date Issued	17 January 2019	Version #	2.0

General

Header	
QMS review financial year Period:	1 July 2023 to 30 June 2024
Date Primary Objectives Report generated:	3 October 2024
Date Secondary Objectives Report generated:	9 December 2024
Date QMR meeting held:	Initial briefing with AS – 20 December 2024 QMR Meeting – 3 February 2025
Routine Periodic QMR or Ad hoc?	Routine QMR
Attendees:	3 February 2025: Hongxia Jin – Assistant Secretary, MQB s47F [redacted] Inspections Section s47F [redacted] GMP Operations and Strategy Section s47F [redacted] Recalls Section s47F [redacted] GMP Clearance Section s47F [redacted] MQB
Apologies:	s47F [redacted] Recalls Section
Minutes approved:	*To be eSigned by Assistant Secretary (AS) in TRIM*

Introduction

The following Quality Management Review (QMR) Report covers the financial year between 1 July 2023 and 30 June 2024*.

The report is based on SOP 1.7 – Quality Management Review (D18-11036187) and is split into two sections: the primary objectives and the secondary objectives as an addendum to the primary objectives.

All actionable items are logged in the 'MQB Issue, Planned Deviation and CAPA Log' (R15/100842) and the actionable item report numbers are included in the summary review, along with the conclusions and recommendations section of this report.

*This report is based on available data at the time of writing this report and is based on the previous financial year (2023 – 2024).

Primary Objectives Report:

<table>
<tr><th>Review Inputs:</th><th>Summary review, conclusions & recommendations (Include issue Report Number- where applicable)</th></tr>
<tr><td>a) 85% close out of inspections on time:

Information obtained from Qlik and in alignment with PBS

Review KPI data from previous financial year http://www.health.gov.au/internet/budget/publishing.nsf/Content/2017-2018_Health_PBS search for current financial year data, under regulation, safety and protection, performance criteria</td><td>This KPI is part of the existing Quality Management Review template as it was previously published in the Department of Health Portfolio Budget Statements.

The information is available and tracked within MQB, however, is not within the scope of the quality management review and will not be reported upon within the 2023-24 FY report or for any future QMR report.

The impact of the delays incurred during the COVID-19 pandemic is still reflected in the measures of the primary objectives report. The Manufacturing Quality Branch is aware of the impact and is continually working towards achieving the measures and returning to normal levels.</td></tr>
<tr><td>b) Inspections Conducted Within Target Timeframes:

i. 85% of initial domestic inspections conducted within 3 months.

ii. 80% of domestic re-inspections conducted within 6 months.

iii. 85% of overseas initial inspections conducted within 6 months.

iv. 80% of overseas re-inspections conducted within 6 months.</td><td>The information for this KPI is available and tracked within MQB and has been included as part of the 2023-24 FY quality management review. However, this information is not within the scope of the quality management review and will not be included within any future QMR report.

The following KPI information is also available within the 2023-24 TGA performance report.

The impact of the delays incurred during the COVID-19 pandemic is still reflected in the measures of the primary objectives report. The Manufacturing Quality Branch is aware of the impact and is continually working towards achieving the measures and returning to normal levels.

Domestic Inspections:

<table>
<tr><th>Processing Time</th><th>2022-23</th><th>2023-24</th></tr>
<tr><td>Initial inspections conducted within 3 months of application</td><td>10 of 15 (67%)[a]</td><td>17 of 34 (50%)[b]</td></tr>
<tr><td>Re-inspections conducted within 6 months of due date</td><td>16 of 90 (18%)</td><td>17 of 112 (15%)</td></tr>
</table>
a. The 2022-23 data does not include inspections that were delayed at the request of the manufacturer.
b. The 2023-24 data does not include inspections that were delayed at the request of the manufacturer

Overseas Inspections:

<table>
<tr><th>Processing Time</th><th>2022-23</th><th>2023-24</th></tr>
<tr><td>Initial certification inspections conducted within 6 months of application</td><td>9 of 33 (27%)[a]</td><td>22 of 41 (54%) [b]</td></tr>
<tr><td>Certification re-inspections conducted within 6 months of due date</td><td>4 of 66 (6%)</td><td>5 of 47 (11%)</td></tr>
</table>
</td></tr>
</table>

Review Inputs:	Summary review, conclusions & recommendations (Include issue Report Number- where applicable)
	a. The 2022-23 data does not include inspections that were delayed at the request of the manufacturer. b. The 2023-24 data does not include inspections that were delayed at the request of the manufacturer
c) 90% of GMP Clearance Applications Processed Within Target Timeframes: v. 30 workdays for MRA. vi. 60 workdays for CV Non-Sterile API. vii. 75 workdays for CV Sterile API. viii. 90 workdays for CV Non-Sterile FP. ix. 120 workdays for CV Sterile FP.	This KPI is part of the 2023–24 FY Quality Management Review template as it was previously reported in the 2022–23 FY QMR report. The information is available and tracked within MQB, however, is not within the scope of the quality management review and will not be reported upon within the 2023-24 FY report or for any future QMR report. The impact of the delays incurred during the COVID-19 pandemic is still reflected in the measures of the primary objectives report. The Manufacturing Quality Branch is aware of the impact and is continually working towards achieving the measures and returning to normal levels.
d) Timeliness of Recall Actions i. 85% of all recall actions agreed within 7 days. ii. 90% of all new notifications assessed.	This KPI is part of the 2023–24 FY Quality Management Review template as it was previously reported in the 2022–23 FY QMR report. The information is available and tracked within MQB, however, is not within the scope of the quality management review and will not be reported upon within the 2023-24 FY report or for any future QMR report. The impact of the delays incurred during the COVID-19 pandemic is still reflected in the measures of the primary objectives report. The Manufacturing Quality Branch is aware of the impact and is continually working towards achieving the measures and returning to normal levels. While not reported as part of the QMR, the KPIs for the timeliness of recalls were met.

Secondary Objectives Report (Addendum):

Review Inputs:	Summary review, conclusions & recommendations
a) Results of External Audits: List all external audits completed in the reporting period, including TRIM links & CAPA reference numbers	**Audit:** European Union (EU) Active Pharmaceutical Ingredients (API) Audit – Conducted 27 February – 1 March 2024. **TRIM Container:** E24-73255 **Findings:** 1 • To ensure that active pharmaceutical ingredient manufacturers comply with the requirements laid down in the current version of the applicable good manufacturing practice standards, in line with Article 2(a) of Implementing Decision 2013/51/EU. **Status:** Open – response to information / documentation request of 25 October 2024 required to be provided to the EU. **Timeline:** **27 Feb – 1 Mar 24:** audit conducted **18 Mar 24:** draft report provided to TGA **24 Apr 24:** comments on draft report provided to EC **7 May 24:** final report / findings issued to TGA **4 Jun 24:** response to final report / findings provided to EC **5 Jul 24:** further info request / discussion at IWG on response issued to TGA **16 Jul 24:** TGA request to attend closed session of IWG to explain adoption process **25 Jul 24:** attendance at closed session of IWG accepted **18 Sep 24:** TGA attends closed session of IWG **25 Oct 24:** further information request for documentation prior to making final assessment issued to TGA. **Internal CAPAs Raised:** **2403001 -** A random selection of conflict of interest were assessed and a number of deviations from the procedures were observed - D24-890661. **2403002 -** TGA has not yet adopted version 16 of the PIC/S Guide to Good Manufacturing Practice - D24-1010537.

Review Inputs:	Summary review, conclusions & recommendations
b) Results of Internal Audits:	**2023–24 FY Internal Audit Schedule:** D23-3860347 **Note:** CAPAs were raised for all non-conformities (NC) identified in the internal audits. **January 2024: GMP Clearance** **TRIM Container:** E23-340371 **Scope:** Compliance verification (CV) application process **Status:** Closed **Findings:** 4 non-conformities, 6 observations and two recommendations. **Comments:** NC related to incomplete or missing training records, observations related to general administrative low impact deviations from QMS and recommendations related to updates to QMS documents. **March 2024: GOSS** **TRIM Container:** E23-340374 **Scope:** Section training records **Status:** Closed **Findings:** 11 observations and two recommendations. **Comments:** observations relate to general administrative low impact deviations from the QMS and findings from previous internal audits and recommendations related to updates to QMS documents. **April 2024: Inspections** **TRIM Container:** E23-340375 **Scope:** Inspection data entry into MIS **Status:** Open **Findings:** findings not yet classified **Comments:** internal audit provided 27 May 2024 - no response has been provided by the Inspections Section yet. Findings not yet actioned. **May 2024: Recalls** **TRIM Container:** E23-340379 **Scope:** Recalls processes from 2024 (post QMS document update) **Status:** Closed **Findings:** one non-conformity, four observations and two recommendations. **Comments:** the NC related to incorrect QMS templates being used in RAMP, the observations related to general administrative low impact deviations from the QMS and findings from previous internal audits and recommendations related to updates to QMS documents. **June 2024: QMS** **TRIM Container:** E23-340382 **Scope:** SOP 1.3 and associated processes **Status:** Closed **Findings:** 5 observations and two recommendations. **Comments:** the observations related to general administrative low impact deviations from the QMS and recommendations related to updates to QMS documents.

Review Inputs:	Summary review, conclusions & recommendations
c) Feedback from clients and interested parties: e.g. Review of stakeholder surveys, feedback, meetings with stakeholders (e.g. TIWGG, TWG), compliments etc.	N/A – no relevant feedback within the reported period.
d) Safeguarding impartiality: Review of all annual Inspectorate conflict of interest records have been completed (PH18/103650, E17-27552, E17-28361)	The Department of Health and Aged Care updated their Conflict of Interest Policy (to Version 2.2) on 20 June 2024. This update provided additional information regarding the identification and management of COI. An update to the MQB Conflict of Interest procedures (SOP 2.7, FORM 2.7.a, FORM 2.7.b and FORM 2.1.1.o) commenced in the 2023-24 FY (and was issued into the QMS in September 2024). The updates to the MQB procedures / forms: - Removed the requirement to use the Departmental form for negative COI declarations and negative annual COI declarations (*i.e. no conflict to declare*). - Requirement to read the most up-to-date Department policy when signing a conflict of interest, particularly in relation to what constitutes an actual or perceived conflict of interest (e.g. previous employment). - Updated FORM 2.7.a to record negative COI declarations and created a new streamlined form (FORM 2.7.b) to record annual COI declarations. - Linked the Department form and policy as a URL throughout our documents, rather than having it embedded in the QMS forms (*which allows us to use the most up-to-date version*). - Allowed for the eSigning of COI documents. - Administrative corrections / update of flowcharts in SOP. **2023–24 FY Inspectorate Annual Conflict of Interest:** All annual conflicts of interest for the Inspectorate were performed in the 23 – 24 FY, as confirmed by Director, Inspections.

e) Status of corrective actions Review TRIM CAPA log status for number of CAPA and current status (TRIM 2015/001594)	Corrective and Preventative Actions (CAPA) and Planned Deviations (PD) in the 2023-24 FY: **Total PD and CAPA Raised:** 46 - **Inspections:** 27 - **Clearances:** 3 - **Recalls:** 0 - **GOSS:** 16 The 46 raised PD and CAPA is an increase from the 2022-23 FY, where only 32 were raised (44% increase from the previous FY). **Trends of CAPA and PD:** 1. Incorrect information on licence or certificate requiring a re-issue. 2. Requests to issue a licence or certificate earlier in the process (i.e. before inspection report written). 3. Missing inspection report / inspection report not written. 4. Extended expiries for GMP Certificates due to protracted inspection close-out / inspection scheduling. **Total PD and CAPA Completed:** 40 - **Inspections:** 13 - **Clearances:** 5 - **Recalls:** 0 - **GOSS:** 22 The 40 completed PD and CAPA is an increase from the 2022–23 FY, where only 13 were completed (208% increase from the previous FY). **Currently Ongoing / Open PD and CAPA:** 56 *(as of 3 February 2025)* - **Inspections:** 40 - **Clearances:** 1 - **Recalls:** 0 - **GOSS:** 14 - **QMS:** 1 **Note:** for future QMR reports, the combined numbers above will be separated into planned deviations and CAPAs. **QMS Investigations Performed:** **Identified Trend:** Incorrect information on licence or certificate requiring a re-issue. **Outcome/s:** - Discussions held with impacted areas (Delegates, AFT, Directors of GOSS and Inspectorate). - Procedural changes and training sessions held. - Following the commencement of this investigation into the licence / certificate re-issue requests, we have noted that number of CAPAs have significantly dropped from 8 in 2023 to 5 in 2024 (with only 1 being requested since the investigation has commenced). **TRIM:** E24-406008

Review Inputs:	Summary review, conclusions & recommendations
f) Document Change / Change Control	**Document Change:** **Document Change Requests:** 35 **Document Changes:** 217 The 217 document changes (across 35 requests) is a significant increase from the 2022–23 FY, where there were only 67 (224% increase from the previous FY) document changes across 12 requests (192% increase from the previous FY). **Change Control:** **Change Control Requests:** 2 - Quality Manual update - Surveillance inspection project The two change control requests is an increase from the 2022–23 FY, where no change control requests were submitted.
g) Status of actions to address risk: Review against E18-282813 for specific financial year reporting under 'what may prevent us'- specific to Inspectorate only	The branch risk management plan for the 2023-24 FY was developed as part of the business planning process in accordance with HPRG requirements. The MQB Business and Risk Plan for the 2023–24 FY is available in TRIM at D23-2663993.

h) Follow-up actions from previous management reviews: Review previous QMR report to identify any potential recurring challenges and verify recommendations have been completed.	**1) Simplification of select QMS procedures to make them easier to follow, such as those relating to:** - **Documentation system and document change management,** - **PD and CAPA management,** - **Change management.** **Update:** drafts have been circulated among Section Quality Coordinators as part of a project to refresh and simplify the QMS. Expected to be completed by June 2025. **2) Review of existing SOPs and WIs to improve alignment with updated quality manual and removal of documents which are not required,** **Update:** 70 documents removed from the QMS during the 2023-24 FY. 10 documents removed from Part 1 of the QMS which were outdated and not required underneath the new quality manual and the remaining 60 outdated documents removed from Recalls, Inspections and GOSS. **3) Review of the existing SOPs and WIs to ensure that process owners are identified, and that periodic review and update of documents is occurring,** **Update:** process owner review conducted in February 2024. 148 documents were updated to have a new process owner. As a result, all documents in the QMS now have an identified process owner (which is either the AS or a relevant Director). **4) Further training of quality coordinators,** **Update:** a new quality coordinator training form was developed (FORM 2.1.1.p) and all quality coordinators have a training form saved in TRIM - E24-16396. Monthly quality meetings are held to discuss ongoing issues and to seek feedback on the QMS. **5) Ongoing management of the PD and CAPA processes to ensure completion,** **Update:** QM following up with SQCs and relevant Directors to ensure that PD and CAPA processes are closed out. PD and CAPA close-out rate up 200% compared to the 2022-23 FY. **6) Broader awareness and understanding of QMS across MQB.** **Update:** a Branch QMS Qlik app has been developed to give Branch visibility – https://qlik.central.health/sense/app/e0a52404-d502-403f-a3e7-1862ef537583 A review and streamlining of the QMS TRIM structure was performed - PH12/343. A review and streamlining of the master index was performed - R14/937422 - and the naming convention of all QMS documents was updated to ensure they are easily identifiable and the correct version number was referenced. All QMS changes are communicated to the Branch via the SharePoint message. Additionally, section quality coordinators are responsible for communicating the updates within their own sections. Ad hoc updates are provided to the Branch via the Branch meeting.

Review Inputs:	Summary Review, Conclusions & Recommendations
i) The fulfilment of Quality Objectives:	The quality objectives for the 2023-24 FY have been fulfilled. The QMS is working as intended and is continuing to identify areas for further improvement. The reporting of planned deviation (PD) and CAPA has increased 44% from the previous FY. The closure of PD and CAPA has increased 208% from the previous FY. Document change requests have increased 224% from the previous FY. Change control requests are being used for significant QMS changes, where they were not previously utilised. The internal audit schedule for the 2023-24 FY was met with all internal audits performed. The use of Section Quality Coordinators, training records and regular meetings has been re-established. Overall, the increase in the quality objectives indicates a significant increase in the engagement with the MQB QMS. Note: the number of applications and recalls that the Branch receives and the number of inspections performed is not within control of the QMS and the performance KPIs have been identified for review for appropriateness of monitoring the QMS effectiveness.
j) Changes that could affect the management system: Review TRIM 2013/003127, 2013/002439, 2012/023588 and change control log R12/1139256 for status and completion	CC2311001 – MQB Quality Manual update.
k) Appeals and complaints: Review any appeals against any Inspection related decisions made under the Therapeutic Goods Act and Therapeutic Goods Regulations. Review complaints against MBQ Inspectorate (This can only be with the Branch Head (AS) due to the sensitive nature and will not be documented other than basic reporting numbers).	Three complaints were made against the MQB Inspectorate in the 2023-24 FY. In these three cases the manufacturers felt they had been treated in an unfair or inconsistent manner. Note: these complaints were discussed with the Branch Head.

QMR Summary:

QMR Outputs:	Final Conclusions and Recommendations:
Improvements needed to maintain the effectiveness of the QMS and its processes	• Assess the requirements to include the 'Primary Objectives Report' for future quality management reviews. If required, TEMP 1.7.a – 'Quality Management Review Report Template' to be updated to remove the section. • Request for planned deviations and CAPAs to be separated into their own categories under "e) status of corrective actions" for future QMR. • A recommendation for QMS process owners to delegate the approval process to another.
Resource needs	The current resources within the Branch seem appropriate for the management of the quality management system. There is currently 9 staff members (1 quality manager and 8 section quality coordinators) responsible for the quality management system.
Revisions of MQBs policy and objectives	N/A

AS (Branch Head) Comments:

N/A

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	R13/943193	New document	s47F [redacted]	17 September 2014
V1.1	R13/943193	Alignment with Department of Health business structure	s47F [redacted]	2 February 2015
V1.2	R13/943193	Revised template, Additional inputs included as per ISO 9001 Outputs included as per ISO 9001 Additional inputs included as per ISO 17021 Inclusion of the requirement to report on threats to impartiality. Inclusion of requirement to report on MDSAP activities where relevant.	s47F [redacted]	09/11/2015
V2.0	R13/943193 SOP 1.7 - Quality management review -	Updated QMR template to current format and to better align with MQB's Inspectorate operational QMS including: 1. Portfolio budget statement KPIs, 2. International regulation harmonisation 3. PIC/S Participating Authority Quality system requirements for pharmaceutical inspectorates (PI 002-3) ISO 17021:1:2015 (secondary guidance document)	s47F [redacted]	17 January 2019

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing Quality Branch

MQB - Standard Operating Procedure (SOP)

SOP 5.2	Inspection Preparation and Planning		
Process Owner	Director, Inspections	Authorised by	Quality Manager
Date Issued	7 June 2024	Version #	3.2

Purpose

To specify the process of preparation for an inspection once the inspection has been assigned to an Inspector in MIS.

This procedure does not cover aspects related to organising travel. Refer to WI 2.8.2 for these aspects.

Inspector related inspection risk management and WH&S risk management for domestic travel are included in WI 5.2.3

Responsibility

Director Inspections (DI)	To maintain oversight of the inspections being done by all inspectors in the inspection group. To provide technical assistance to inspectors, where appropriate.
Lead Inspector (LI)	For team inspections: To manage the inspectors or specialists assigned to the scheduled inspection. Ensures all team members understand their role in the inspection and are adequately briefed on reporting requirements. Ensures that any specific requirements for inspections of BTC&GT, APVMA or conduct of clinical trials are applied throughout the inspection preparation process. Provide travel requests to travel section according to timeframes outlined.
Inspectors (and Specialists where relevant)	To be familiar with the specifics of the inspection, particularly the inspection scope, and assist in preparation for the inspection as instructed by the LI.

Process

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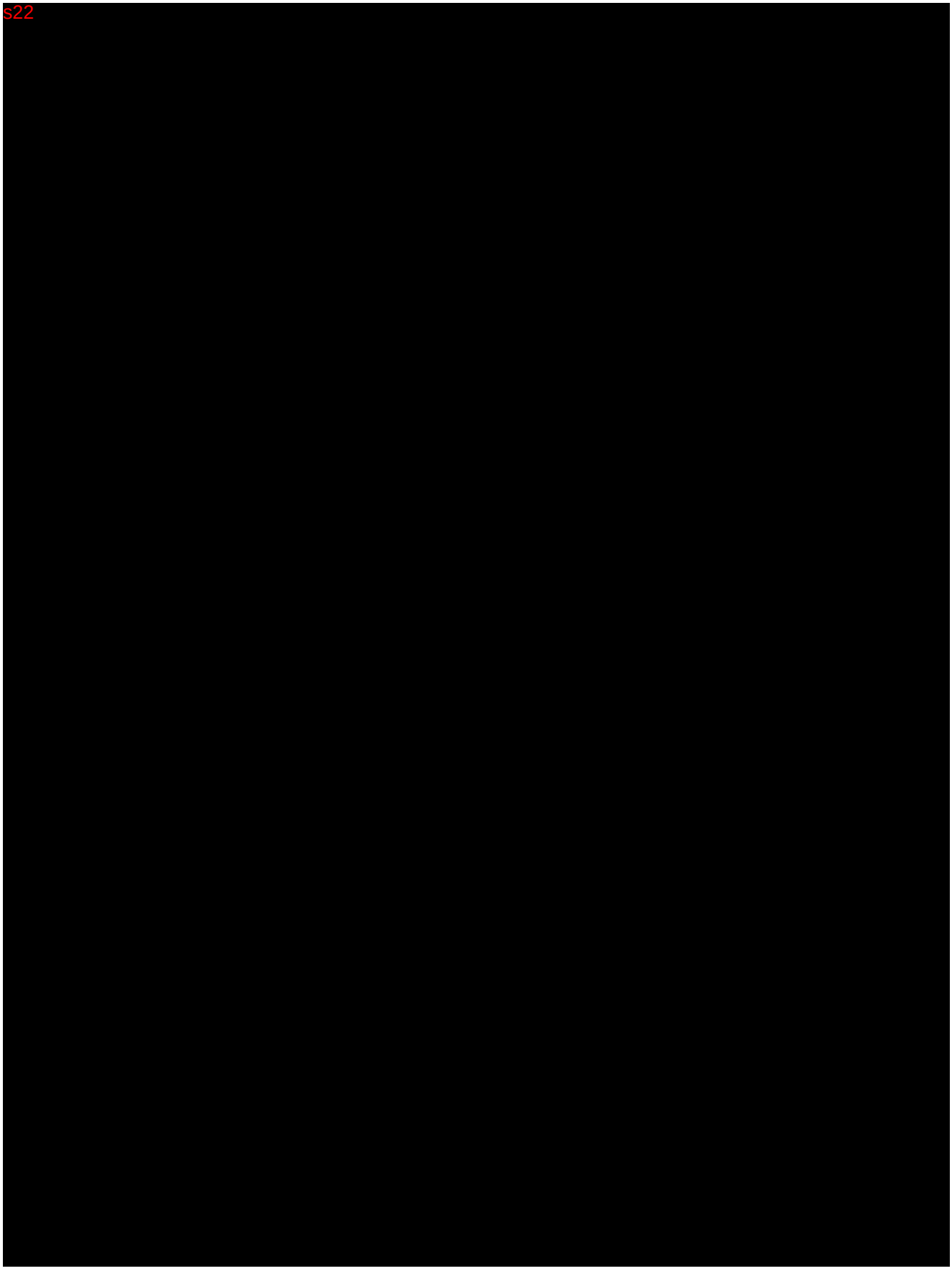

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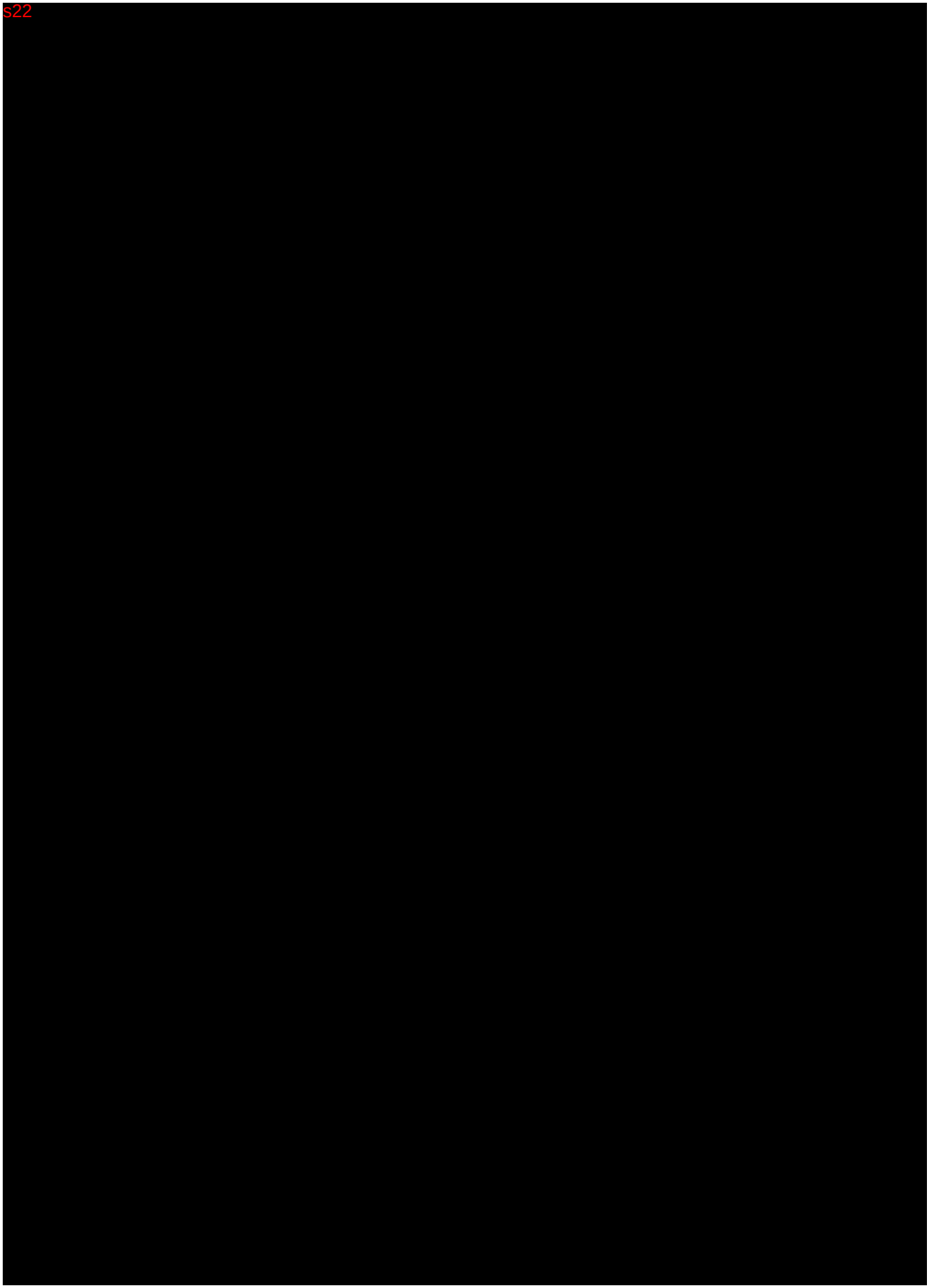

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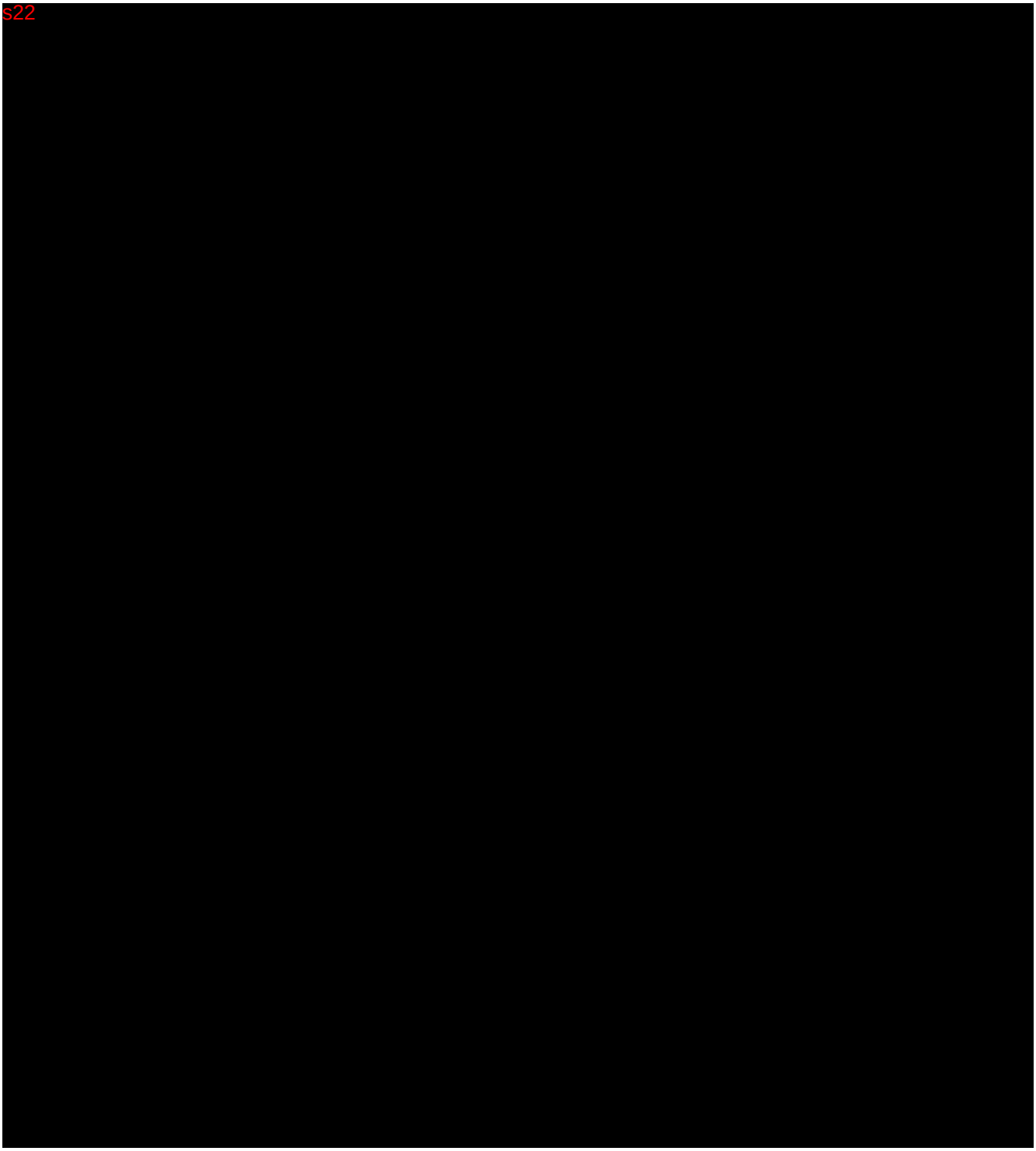

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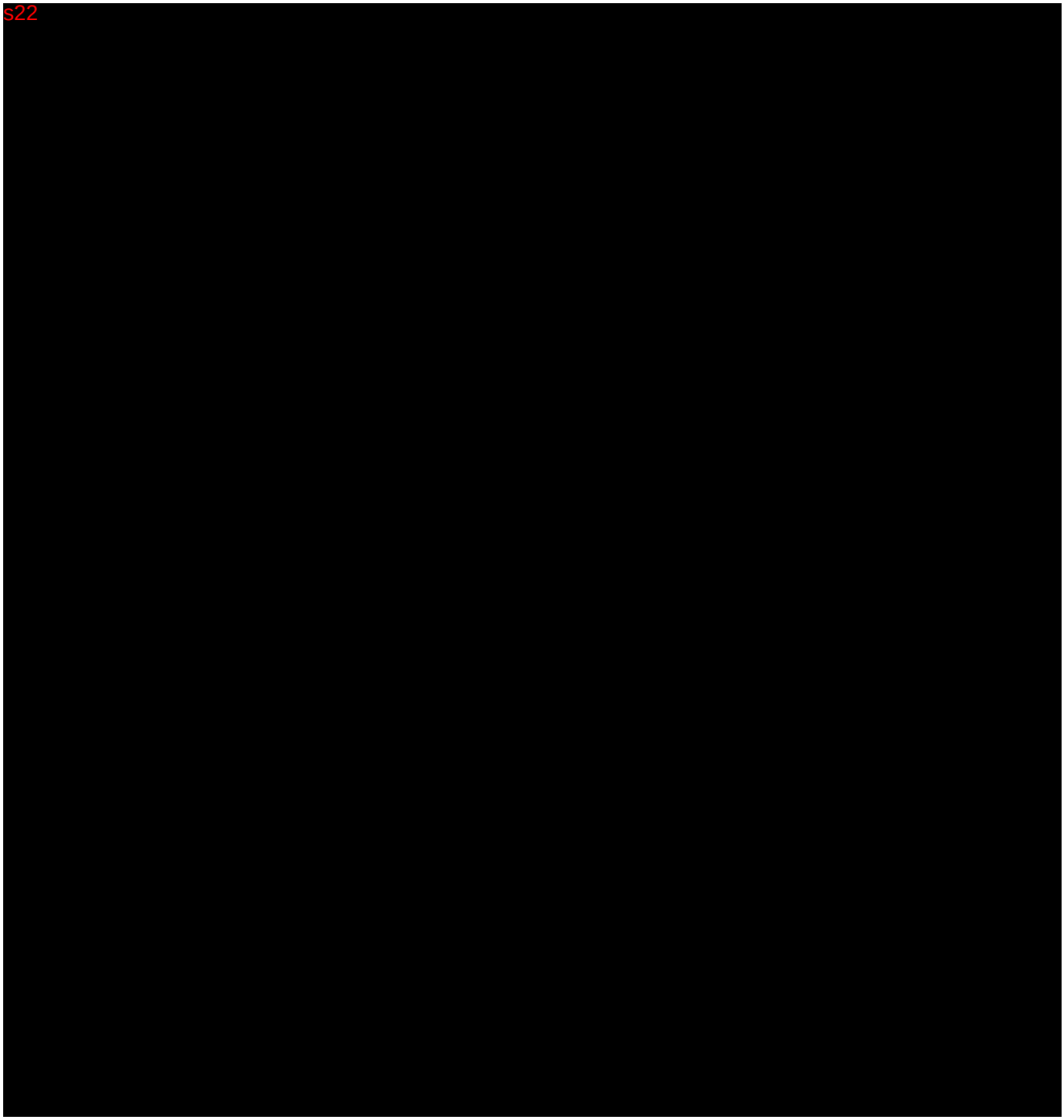

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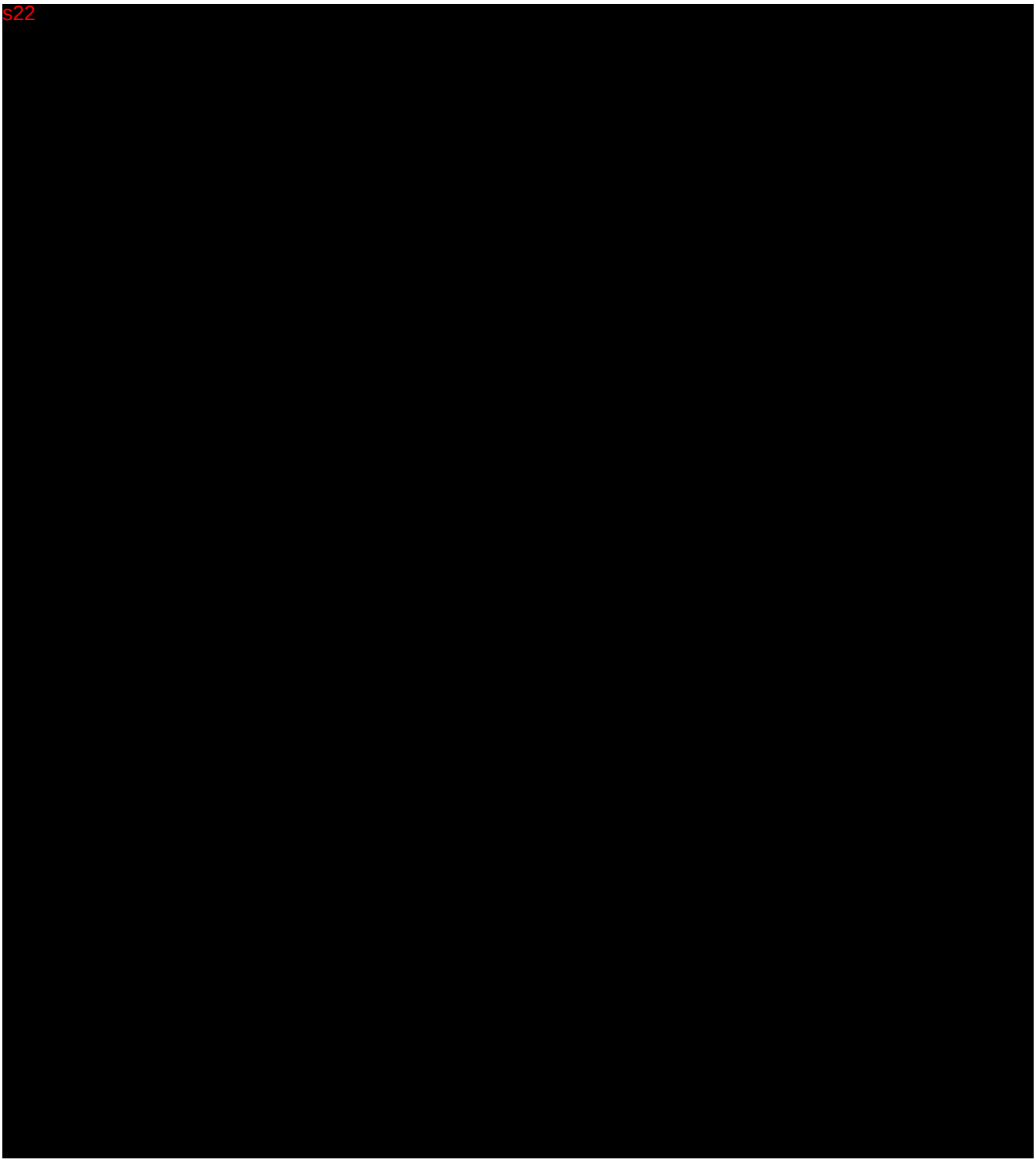

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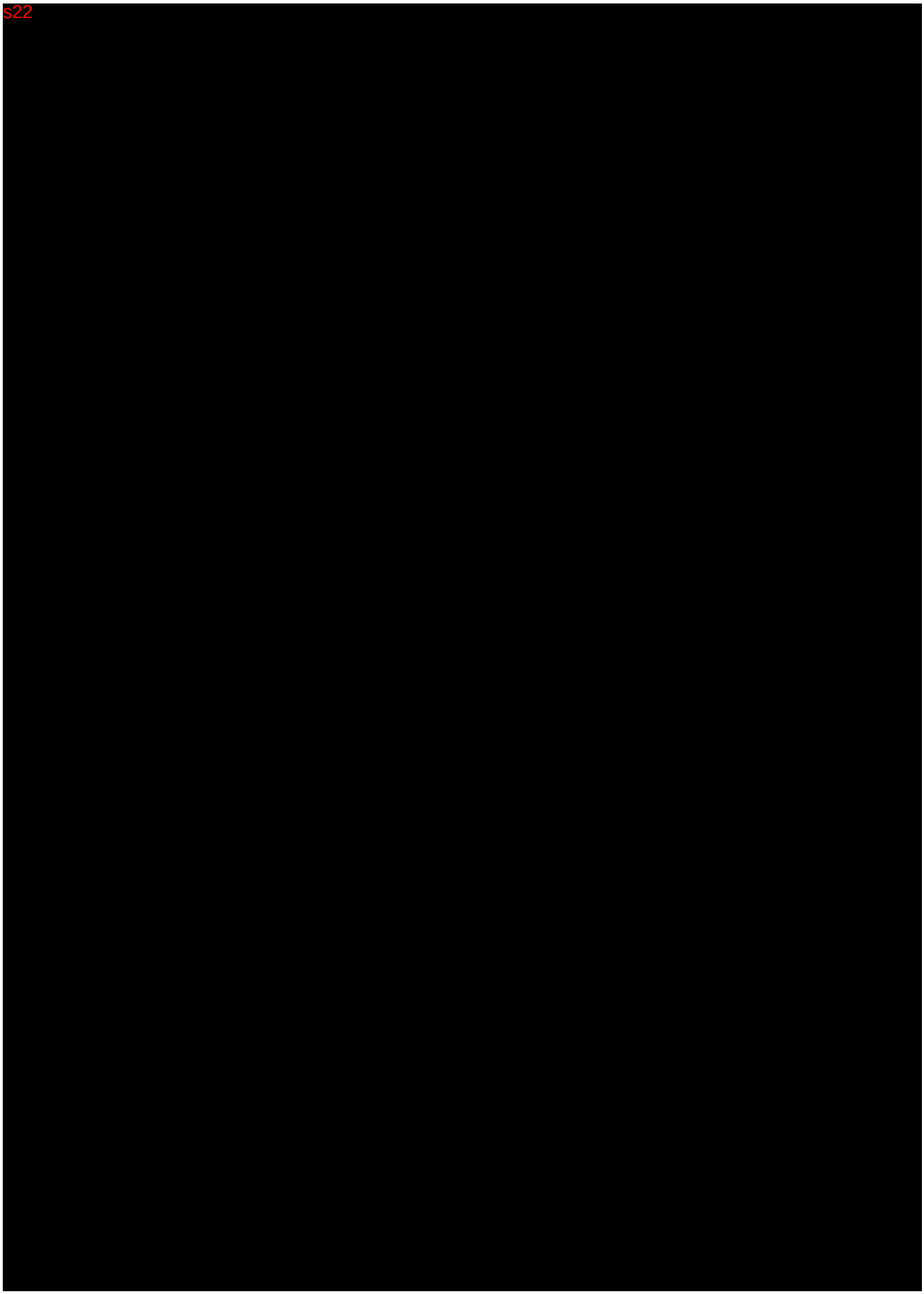

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#	Inspection Announcement	Reference
16	The Lead Inspector prepares an overview of a selection of products manufactured at the facility to be inspected: • For medicines & API, from entries in the ARTG relating to the manufacturer ,as well as any API, IMP or unapproved medicines manufactured by the site for the Australian Market • For BTC&GT inspections: from entries in the ARTG and in addition the overview of products manufactured is included on the licence and the Lead Inspector takes a copy for this purpose. For Overseas inspections, the Lead Inspector should review the Travel Costing Calculator (TCC) to confirm which Sponsors have agreed to contribute to the inspection costs and focus on the related products. Products relating to Sponsors that have declined to contribute to inspection costs should not be included in the scope of the inspection. Refer to Appendix 2 for instructions. The Lead Inspector selects products that will be reviewed and verified during the inspection. For medicines inspection, this includes a verification of compliance with the marketing authorisation and is facilitated by obtaining copies of the relevant pharmacopeial monographs for the dosage forms and key ingredients used in the products selected, and by reviewing the MA dossier held within docuBridge (AUSTR goods only). For API inspections, the LI must obtain a copy of the current Drug Master File, (DMF, but sometimes referred to as an Active Substance Master File (ASMF)), and verify compliance with the DMF registered with the TGA. The DMF may be requested from the manufacturer, found in TRIM or by reviewing the MA dossier held within docuBridge (AUSTR prescription goods only) For BTC&GT inspections, this includes contacting the biological science section (BSS) and informing them of the inspection and ask if there are any issues that require follow-up and a verification of compliance with the marketing authorisation for Biologicals and Technical Master File for blood, blood components and Haematopoietic progenitor cells. The Lead Inspector saves this overview in the relevant TRIM inspection container and takes a copy to the inspection.	

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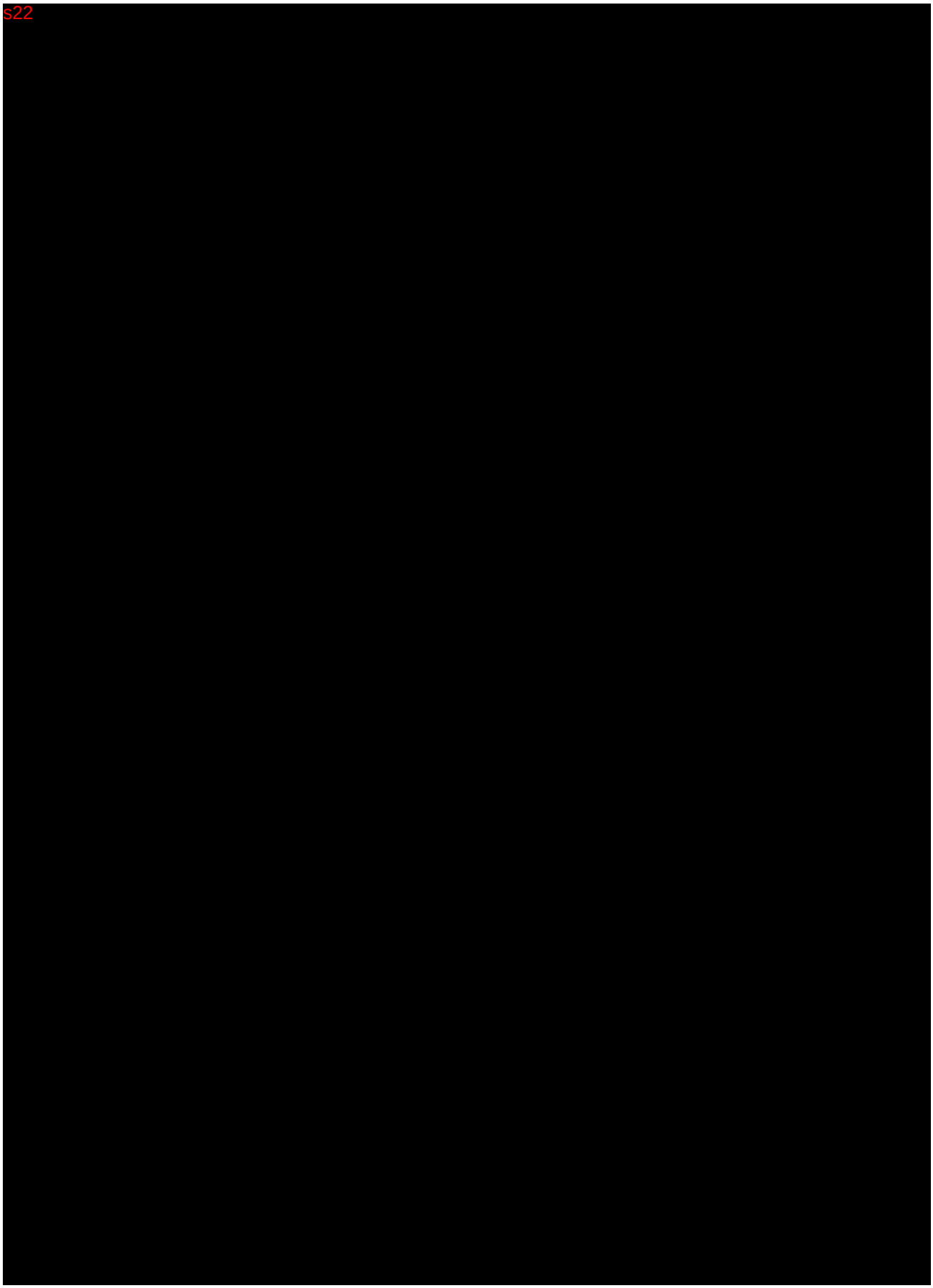

Version history

Version	Description of Change	Author/s	Effective Date
V1.0	New procedure, collating and updating several parts of previous procedures from the B4 series, specifically B4.02.	s47F	17/10/2012
V1.1	Update of Departmental crest to Department of Health.	s47F	29/10/2013
V1.2	Minor amendments to reflect new structure.	s47F	05/09/2014
V1.3	Alignment with Department of Health business structure.	s47F	02/02/2015
V2.0	Removal of reference to the review of blood and tissue recalls in step 14. Removal of devices. Significant rewrite to include aspects associated with updated RBI framework, including reduced scope inspections, on-site follow-up of CAPA. Scheduling aspects moved to SOP 5.1. Expansion of flowchart to include all inputs and outputs into process. Separation of text into general, inspection announcement, inspection preparation and inspection planning.	s47F	21/08/ 2017
V2.1	Added detail regarding on-site hours for inspections. Include reference to review Qlik App as part of inspection preparation Added timeframes for submitting travel requests to travel team	s47F	10/ 09/2021
V3.1	Added timeframes for notification to MQB Travel for overseas inspections (step 13) Links to remote inspection processes and risk management procedures added.	s47F	27 May 2022
V3.2	Amendments to permit saving of documents other than Word in TRIM. Removal of COVID-19 risk assessments. Addition of Surveillance Inspections instructions and WI. Minor clarifications.	s47F	7 June 2024

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Document 9

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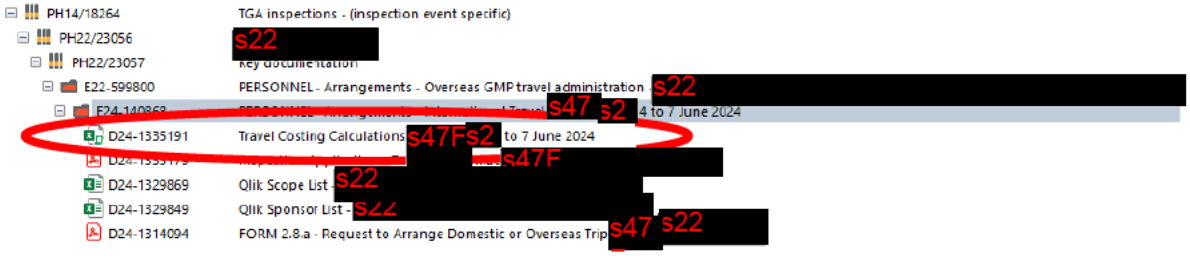
Appendix 2: Confirming contributing Sponsors using the Travel Costing Calculator (TCC)

When performing overseas inspections, it is important to confirm which sponsors have agreed to contribute to the cost of inspections, in order to accurately determine the scope of the inspection.

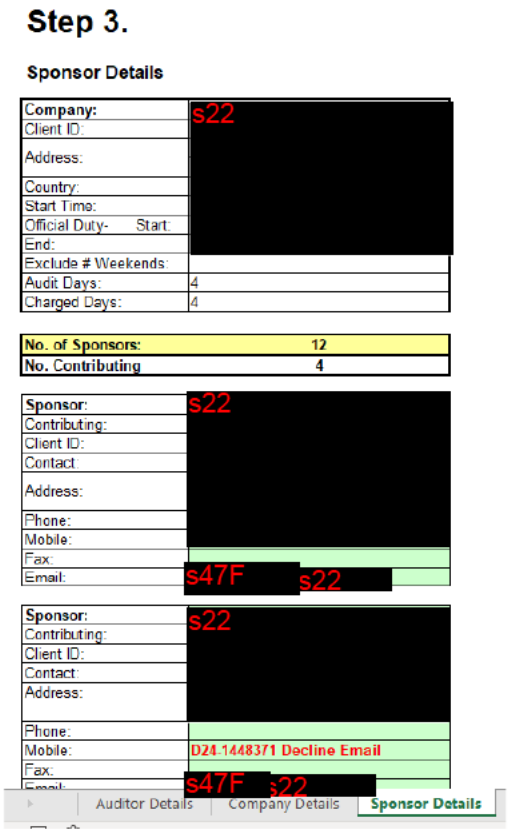
For each overseas trip, a Travel Costing Calculator (TCC) is created which identifies and tracks Sponsor participation for each manufacturing site inspected.

The TCC for a specific manufacturer can be found as an Excel file in the "PERSONNEL-Arrangements – Overseas GMP Travel Administration" folder under the "Key Documentation" placeholder for the inspection, as shown below.



Open the file as View Only, and select the "Sponsor Details" tab as shown below. This view will then indicate the total number of Sponsors identified for each manufacturing site in the trip, their details and also whether they have agreed to contribute. The products relating to sponsors that have agreed to contribute [Contributing: YES] should be targeted in the inspection scope. Products relating to sponsors that have not agreed to contribute, [Contributing: NO] should be not be targeted during the subsequent inspection; however, the LI is not prohibited from reviewing product related data should it be relevant to goods supplied.

If the [Contributing] cell is blank, it may indicate that a response is pending. Contact GOSS should you require any clarity.



Australian Government
Department of Health
Therapeutic Goods Administration

Manufacturing Quality Branch Technical Knowledge Module

Module 1 – Core

Introduction to TGA and Inspection Module

INTERNAL USE ONLY

TGA Health Safety Regulation

Version history

Version	TRIM Ref.	Description of change	Author	Effective date
V1.0	D19-6521997	New document	s47F	10 December 2019

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Compliance to marking authorisation

- During inspection preparation: collect ARTG description of the contents of selected products.
- During inspection: compare these with manufacturing formulae and with the bill of materials / weighing record in completed batch records.
- Be mindful of any ingredients in ARTG that are not weighed as such, e.g. components of coating liquids, components of empty capsules etc. It is an ARTG requirement to have then stated per unit.
- If a discrepancy is identified:
    - Give the manufacturer an opportunity to explain.
    - Consider where it is a grandfathered product.
    - Check who is responsible: manufacturer or sponsor.
    - Ask whether /when a variation was submitted.
    - Identify the date since discrepancy introduced.
    - Consider the therapeutic relevance to determine seriousness of the discrepancy.
    - Consider whether sampling / Laboratories testing is justified.
    - After inspection: involve regulator where relevant.

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