PW 54-2021 Appendix 3

INTERNAL AUDIT REPORT

General Elements

Niagara Region All Wastewater Systems Internal Audit

October 12 - October 27, 2021



1.0 INTRODUCTION

1.1 Purpose

The 2021 internal audit was undertaken:

- To verify that the Wastewater QMS conforms to the requirements of the DWQMS¹ and the requirements of the Wastewater QMS Operational Plan; and
- To verify the effective implementation and maintenance of the Wastewater QMS for all Niagara Region's wastewater systems.

Audits were completed between October 12th and October 27th, 2021. Wastewater internal audits are not a legislative requirement, but are performed annually out of due diligence and best practice. Internal audit interviews were conducted with wastewater Operating Authority personnel and other members of the division, as required.

1.2 Scope

The scope of the 2021 Wastewater QMS internal audit was modified in consideration of the ongoing COVID-19 pandemic and associated impacts to W-WW work processes. The Lead Auditor placed a focus on elements/processes of the QMS that could be audited remotely in effort to minimize additional workload for front-line management and staff.

The 2021wastewater internal audit was conducted as an element-based audit.

In an **element-based audit**, auditors examined specific elements to ensure that requirements of the WWQMS and the associated procedures are met. Element-based audits do not typically examine adjacent processes.

¹ As modified by Niagara Region to suit our wastewater services.



The following elements were examined during the 2021 internal audit:

- Element 2 Quality Management System Policy
- Element 4 Quality Management System Representative
- Element 5 Document and Records Control
- Element 6 Wastewater Systems
- Element 11 Personnel Coverage
- Element 12 Communications
- Element 13 Essential Supplies & Services
- Element 21 Continual Improvement

Elements that were not audited during the 2021 internal audit will be included in future internal audits such that frequency requirements specified in *Internal Auditing* (QMS-WW-ALL-P-190, rev1, effective 30Sep2019 are satisfied.

1.3 Selection of Internal Audit Team

Michelle Max acted as Lead Auditor for this internal audit.

Auditors were assigned as follows:

- Element 2 Quality Management System Policy: Molly MacDonald
- Element 4 Quality Management System Representative: Molly MacDonald
- Element 5 Document and Records Control: Molly MacDonald
- Element 6 Wastewater Systems:
 - Area 1: Jason Oatley, Michelle Max
 - Area 2: Dawn MacArthur
 - Area 3: Dana Knegt
- Element 11 Personnel Coverage: Janet Rose
- Element 12 Communications: Rachel Whyte
- Element 13 Essential Supplies & Services: Molly MacDonald, Michelle Max
- Element 21 Continual Improvement: Rachel Whyte

All internal auditors have completed Internal Auditor Training as required by the *Internal Auditing* (QMS-WW-ALL-P-190, rev1, effective 30Sep2019).



1.4 Criteria and Methodology

Audit criteria included the following:

- Internal Auditing (QMS-WW-ALL-P-190, Rev1, effective 30Sep2019);
- Niagara Region Wastewater Operational Plan (QMS-WW-ALL-MAN-010, Rev4, effective 4Feb2020) and supporting procedures; and
- Internal audit training materials (various auditor training courses).

Audits were conducted by assigned auditors as noted in Section 1.3 of this report. Operating Authority personnel were also interviewed by assigned auditors. Auditor checklists were completed and reviewed with the Lead Auditor; the checklists are not attached, but are filed as per the **Document & Records Control Procedure** (QMS-WW-ALL-P-050, rev2, effective 16Sep2021).

Remote work arrangements remain in place due to the ongoing COVID-19 pandemic; as such, formal opening and closing meetings were not held with auditors or auditees. The Lead Auditor assembled the audit team and assigned auditors to audits via email. Initiation of the audit was communicated to Top Management and Divisional staff via email.

Audits were conducted by assigned auditors as noted in Section 1.3 of this report. Where required, auditors completed interviews with various members of Divisional staff to support audit findings. These checklists were submitted to the Lead Auditor and used as input to this report.

The audit findings will be communicated via e-mail circulation of this Internal Audit Report and assignment of associated corrective actions, preventive actions, and best management practices.

Internal audit checklists, along with copies of communication emails, are retained as per **Document & Records Control** (QMS-WW-ALL-P-050, Rev2, effective 16Sep2021). These can be found in the "Records Control" module of EtQ.



2.0 INTERNAL AUDIT RESULTS

2.1 Review of Previous Internal Audit Findings

Previous internal audit findings were not reviewed during this internal audit, as much work was done in advance of the internal audits to address and close open corrective actions from the previous internal audit in 2019. These efforts were summarized in a memo to Public Works Committee (PWC-C 8-2020, 10March2020).

2.2 Review of Previous External Audit Findings

Not applicable. The Wastewater QMS is not subject to external auditing at this time.

2.3 Summary of New Internal Audit Findings

Findings are categorized as follows and are summarized in Table 1 below.

- **Conformance:** Audit interviews and sampled records indicate that QMS requirements are met and applicable procedures are implemented as written.
- Non-conformance: Audit interviews and sampled records indicate that a requirement of the QMS Standard was not met or a documented procedure was not implemented as written. These findings require corrective action.
- **Potential non-conformance:** A non-conformance has not yet occurred, but a trend or pattern indicates that occurrence of a non-conformance is likely. These findings require **preventive action**.
- Best practice for evaluation: A best practice behaviour or opportunity for improvement is identified. Program, process, procedure or improvement which, if implemented, may assist in the collection and treatment of wastewater, provide efficiencies in operational processes or provide information to assist in future planning. These findings are brought forward to the appropriate level of management for review and consideration, and those requiring Top Management direction or input are reviewed at the annual Management Review.



Table 1: Summary of Internal Audit Findings - Number and Type

Element	NC	PNC	ВР	Total
Element 1 – Quality Management System	-	-	1	1
Element 3 – Quality Management System Policy	-	-	ı	-
Element 4 – Quality Management System Representative	1	•	1	1
Element 5 – Document and Records Control	2	•	1	3
Element 6 – Wastewater Systems	1	-	1	2
Element 11 – Personnel Coverage	4	1	3	7
Element 12 – Communications	1	-	1	2
Element 13 – Essential Supplies & Services	3	-	4	7
Element 21 – Continual Improvement		-	3	4
Total	13	0	14	27

Table 2 provides a summary of findings from the QMS Internal Audit. In reviewing Table 2, the following acronyms should be noted:

Acronym	Definition
С	Conformance
NC	Non-Conformance
PNC	Potential Non-Conformance
ВР	Best Practice for Evaluation



Table 2 is provided below.

Table 2: Summary of Findings – 2021 Internal Audit

Finding	WWQMS Standard Element
Element 1:	Operational Plan
BP	The following procedure improvements are recommended under the <i>Wastewater Operational Plan (QMS-WW-ALL-MAN-010, Rev4, 4Feb2020)</i> section 6.1.1, Table 1: Niagara Region's Wastewater Systems:
	 The Niagara Falls WTP contributes water residuals to Garner Road Biosolids, however this is not included under the municipal collection system for Garner Road. Consider including.
	There is an opportunity to include the following facilities under the corresponding wastewater systems:
	 Grimsby Works Yard combined sewage detention facility, Niagara Road 12 Landfill leachate pumping station, Park Road, Sann Road and Thirty Road odour control facilities under the Baker Road wastewater system.
	 Lock Street Sewage Detention Facility under the Port Dalhousie wastewater system.
	 Peel Street Sanitary Storage Facility under the Port Weller wastewater system.
	The format of Table 1 for Seaway could be updated. It appears that it used to extend to the next page and includes wording "Continued" on the pdf format. The two separate cells for Seaway could be combined and the "continued" be removed.
	The Operational Plan and the Wastewater System documentation do not explicitly state that the local area municipalities are the Owner and Operating Authority of their systems. Consider clarifying.



Finding	WWQMS Standard Element
Element 3:	Quality Management System Policy
С	The Wastewater QMS conforms to the requirements of this element.
Element 4:	Quality Management System Representative
NC	Element 4 of the <i>Wastewater Operational Plan (QMS-WW-ALL-MAN-010, Rev4, 4Feb2020)</i> states "Top Management has appointed the Water-Wastewater Quality Management Specialist (reporting to the Manager, Quality & Compliance – Wastewater) as the QMS Representative for Niagara Region's drinking water systems." Update to reflect wastewater systems instead of drinking water systems.
Element 5:	Document and Records Control
NC	Section 5.4.2 of the <i>Document and Records Control</i> (<i>QMS-WW-ALL-050</i>), <i>Rev2</i> , <i>16Sep2021</i>) states, "Records required to support the QMS are identified in Table 2." Table 2 lists that certificates of analysis are to be kept by the Operations Managers and maintained at respective WWTPs. When asked to provide a certificate of analysis for a delivery of sodium bisulphite on 2-Sept-2021, the auditee was unable to present it and confirmed that the Certificate of Analysis was not provided.
NC	Section 5.4.2 of the <i>Document and Records Control</i> (<i>QMS-WW-ALL-050</i>), <i>Rev2</i> , <i>16Sep2021</i>) states "The majority of QMS documents are typically reviewed every three (3) years unless otherwise indicated in the document header." The auditor discovered eight (8) QMS documents that were not reviewed within the specified timeframe.



Finding	WWQMS Standard Element	
Element 5:	Document and Records Control	
BP	Section 5.4.3 of the <i>Document and Records Control</i> (<i>QMS-WW-ALL-050</i>), <i>Rev2</i> , <i>16Sep2021</i>) states that "the emergency response plan (ERP) documents are typically reviewed annually. Reviews can be performed through any one of the following means: document review in EtQ, monthly e-learning assignments and table top workshops." It may be beneficial to include a note in EtQ for each ERP document indicating when training was last issued and the method delivered (i.e. e-learning exercise, table top workshop) to ensure the annual review is captured.	
Element 6:	Wastewater System	
NC	Element 6 of the standard indicates that the Operating Authority shall ensure that the description of the system is kept current. Non-conformances have been noted in several wastewater system documents for this element: • Anger Avenue WWTP System Description (QMS-WW-FE-P-060, Rev1, 11Apr2019): - The system schematic shows the effluent from Anger Avenue wastewater treatment plant going to Lake Erie, however the effluent is directed to the Niagara River. • Niagara Falls WWTP System Description (QMS-WW-NF-P-060, Rev1, 27May2019): - The auditor identified that the RBC effluent polymer system has been in service since 2018. As this will stay in place into the capital project, it should be described as a temporary system under section 5.5.2.	



Finding	WWQMS Standard Element
Element 6:	Wastewater System
continued	 Queenston WWTP System Description (QMS-WW-QT-P-060, Rev1, 3Feb2020): Section 5.4.2 specifies that the screened wastewater is sent to the plant's treatment processing via five (5) submersible pumps installed in the wet well. The auditee identified that only two (2) submersible pumps are installed in the wet well. Seaway WWTP System Schematic (QMS-WW-SW-V-061, Rev8, 28Sep2021): Marina 3 SPS is listed in the operational plan and the Seaway wastewater system description but it is not included in the Seaway WWTP system schematic. Review station status and consider removing or adding from documentation as necessary. Consider adding the storm chlorine contact tank and chlorination/dechlorination details for plant overflows from the CSO storage tank to section 5.4.5 and 5.4.6. Alternatively, consider including a separate section for wet weather flow treatment/ mitigation. Seaway WWTP System Schematic (QMS-WW-SW-V-061, Rev8, 28Sep2021): Section 5.4.8, methane gas produced by the digesters is not currently utilized in the boilers. Gas is sent to the flare stack. The document should be
	updated to reflect this.



Finding	WWQMS Standard Element
Element 6:	Wastewater System
continued	Port Weller Wastewater System Description (QMS- WW-PW-P-060, Rev2, 20Apr2021):
	- Section 5.4.1 specifies "Influent flows for treatment are passed through a screening process consisting of three (3) parallel mechanical bar screens that are 1,800mm wide with 10 mm bar openings." Updates to the influent screening were performed in 2020, which consisted of two (2) 6 mm mechanical screens, each rated at 136,200 m3/d and one (1) 16 mm bar screen.
	- Section 5.4.6, indicates that the east bank clarifiers (5&6) have a total combined surface area of 7,868m2. The auditor identified that the east bank clarifiers (5&6) should have a combined surface area around 1,700m2.
BP	Best practices for evaluation are recommended in several wastewater system documents:
	Anger Avenue WWTP System Description (QMS- WW-FE-P-060, Rev1, 11Apr2019):
	 Section 1, update spelling of Catharine Street to Catherine Street.
	 Section 5.3.2 - Downstream Processes states "The Niagara Falls WTP draws raw water from the Niagara River via the Welland River (Chippawa Creek) downstream of the Anger Avenue WWTP." The auditor has suggested that the text be updated to "The Niagara Falls WTP draws its water from the Welland River."



Finding	WWQMS Standard Element
Element 6:	Wastewater System
continued	Stevensville-Douglastown Lagoon System Description (QMS-WW-SD-P-060, Rev1, 22Sep2020):
	 Section 1 states "the Stevensville-Douglastown (works #120003110) and associated sewage pumping stations are owned and operated by the Niagara Region." The auditor noted that the Black Creek sewage pumping station is not owned, but rather monitored by the Region. Consider clarifying.
	Stevensville-Douglastown Lagoon System Schemotic (OMS M/M SD V 064, Box 7, 2Mov 2024).
	 Schematic (QMS-WW-SD-V-061, Rev7, 3May2021): The auditor noted that the Stevensville sewage pumping station is capable of an overflow under certain conditions. It would be beneficial to depict the overflow in the system schematic. Niagara Falls WWTP System Description (QMS-WW-
	NF-P-060, Rev1, 27May2019):
	 Section 5.5.11 states "the WWTP is equipped with two (2) primary anaerobic digesters." Due to operational issues, digester #2 has been out of service for several years. The description should be revised to state that digester #2 is "out of service".
	Queenston WWTP System Description (QMS-WW-QT-P-060, Rev1, 3Feb2020):
	 Section 5.4 lists chlorine pump failure as one of the common event-driven fluctuations. The auditor identified that a second stand-by chlorine pump can be put into service in the event that the lead pump fails. It may be beneficial to include details that a stand-by pump can be placed into service if needed, as an action/control measure.



Finding	WWQMS Standard Element
Element 6:	Wastewater System
	currently in use. Return and waste activated sludge are on a common header pipe. Return activated sludge valve #1 and #2 are used to restrict return flow and divert waste activated sludge to the gravity belt thickener. Valving is in place to go to waste holding tanks, but common practice is to waste directly to the gravity belt thickener. - Scum handling is not included in the description. Consider including. - Section 5.4.8, consider including dosage point for dechlorination for consistency with disinfection section.



Finding	WWQMS Standard Element
Element 6:	Wastewater System
	 Public Notification (OP-WW-SW-P-002) procedure. Section 5.4.2 refers to the aerated grit tanks, however Seaway has vortex grit removal tanks. Recommend updating section title to reflect the proper description. Consider adding phosphorus removal as a separate section for ease of reference.



Finding	WWQMS Standard Element		
Element 6:	Wastewater System		
continued	Seaway Wastewater System Description (QMS-WW-SW-P-060, Rev1, 13Jan2020):		
	 Section 5.4.3, consider adding details that specify that primary tanks can be used (as storage) to mitigate storm flow if available and where capacity allows. 		
	 Section 5.4.6, consider adding dosage point for dechlorination to be consistent with disinfection section. 		
	 Section 5.4.8, the sentence "sludge from the primary and secondary clarifiers is sent to primary digester" is vague. Consider updating to state "raw sludge and co-thickened waste activated sludge from the primary clarifiers is sent to the primary digester." 		
	Seaway WWTP Process Schematic (QMS-WW-SW-V- 060, Rev4, 6Feb2020):		
	 Update wording from "Natural Gas Boiler/Waste Boiler" to "Natural Gas Boiler/Waste Burner." 		
	Welland Wastewater System Description (QMS-WW- WE-V-060, Rev2, 9Mar2021):		
	 The descriptions for the raw sewage pumps under section 5.1.3 does not accurately describe the equipment currently on-site. The section describes the pumps that are to be installed as part of the plant upgrade, which has been delayed. Consider updating to reflect equipment currently in use. Section 5.4.5 states that for the primary storm clarifiers "gates are operated by RPU program set parameters." Gates are currently being operated in manual mode, pending completion of phase 1 capital upgrades. Consider adding operating mode to the description. 		



Finding	WWQMS Standard Element
Element 6:	Wastewater System
continued	 Welland Wastewater System Description (QMS-WW-WE-V-060, Rev2, 9Mar2021): The disinfection and dechlorination processes are
	described under the disinfection heading for section 5.4.7. Consider separating into two separate sections to keep consistent with the other area system descriptions.
	 Section 5.4.8 - anaerobic digestion process, consider updating sentence to state "the remaining solids are hauled off-site for dewatering and/or application."
	 Consider adding phosphorus removal as a separate section for ease of reference. Currently, included in the secondary clarifiers section.
	The Welland WWTP environmental compliance approval (ECA) link in section 7 points to the Port Weller ECA. For consistency, consider incorporating a general link that points to the wastewater
	operations page on the Vine and listing all stations with ECA's under the references/other attachments section.
	Port Dalhousie Wastewater System Description (QMS-WW-PD-P-060, Rev1, 29May2019):
	The influent and effluent wastewater characteristics outlined in Table 1 and 2 depict data from 2012-2017. Consider updating to reflect current plant performance data.
	It was identified that metering and sample locations have been included in the Seaway WWTP Process Schematic (QMS-WW-SW-V-060, Rev4, 6-Feb-2020) consider adopting this approach in other.
	2020) consider adopting this approach in other WWTP process schematics as best practice.



Finding	WWQMS Standard Element
Element 6:	Wastewater System
continued	It may be beneficial to include details on the active discharge agreements under the critical upstream and downstream processes section for all the WWTP Process Descriptions.
	It was identified in several of the wastewater treatment plant system descriptions that in Table 2: WWTP Effluent Wastewater Characteristics the "typical values" for wastewater effluent are listed, but are not reflective of the monthly averages for each effluent parameter. Consider removing this column from the tables.
Element 11:	Personnel Coverage
NC	Section 5.4.2 of the <i>Document and Records Control</i> (QMS-WW-ALL-P-050, Rev2, 16Sep2021) states "The majority of QMS documents are typically reviewed every three years unless otherwise indicated in the document header." The auditor identified that the <i>On-call Scheduling</i> (ADM-ALL-ALL-P-005, Rev3, 2Aug2017) procedure referenced in section 5.1.3 and 5.2.1 of the <i>Personnel Coverage</i> (QMS-WW-ALL-P-110, Rev4, 6Oct2021) was out of date with a review date of 2-Aug-2020.
NC	Section 5.3.2 of the <i>On-call Scheduling (ADM-ALL-ALL-P-005, Rev3, 2Aug2017)</i> procedure states "The Program Assistants check for change requests on a daily basis and updates the On-Call Managers Schedule when changes are received." The auditor identified an incident where the on-call calendar had not been updated correctly after a change request had been made. It may be beneficial to have managers check the calendar when changes are made to confirm they have been recorded correctly.



Finding	WWQMS Standard Element
Element 11:	Personnel Coverage
NC	Section 5.1.1 of the <i>Wastewater Treatment Plant</i> Logbook Entries (OP-WW-ALL-P-024, Rev3, 8Sep2021) procedure notes that the overall responsible operator is to be identified as per the Personnel Coverage procedure. It also required that an overall responsible operator and any operator making a log entry for the day be included in the shift details. The auditor identified an incident where changes to the on-call schedule were made, however the corresponding logbooks were not updated to reflect the change in personnel. It may be beneficial to consider how changes in on-call manager duties are communicated to staff to ensure logbooks accurately reflect any changes.
NC	Section 5.1.1 of the <i>Wastewater Treatment Plant Logbook Entries (OP-WW-ALL-P-024, Rev3, 8Sep2021)</i> notes "staff on duty during the shift holding an Operator-in-Training wastewater treatment licence are to be designated as OIT" and "staff on duty during the shift holding a Class I, II, III, or IV wastewater treatment licence are to be designated as operator in charge." The auditor identified that on 20-Oct-2021, a System Operator holding Class I treatment licence was noted as OIT in the logbook when they should have been recorded as an OIC.
ВР	The <i>Personnel Coverage (QMS-WW-ALL-P-110, Rev4, 6Oct2021)</i> procedure states "The Manager On-Call Schedule is established collaboratively by the Associate Director Wastewater Operations and Maintenance and the Area Operations Managers". In practice, the schedule is based on an on-going rotation, which continues to roll-over each year. As this seems to be the common practice, it may be beneficial to state in the procedure that collaboration is possible where/when needed.



Finding	WWQMS Standard Element
Element 11:	Personnel Coverage
BP	It is recommended that a formal program be implemented during the on-boarding of new maintenance staff to prepare, track and document the readiness of staff for on-call duties. Currently, it is up to the discretion of the managers as to when a new staff member be placed on-call.
BP	It may be beneficial to consider developing a process or formal document for the Associate Director and new Manager to complete that acknowledges that the Manager is ready to be on-call.
Element 12:	Communications
NC	Communications (QMS-WW-ALL-P-120, Rev3, 12Aug2021) specifies that Top Management communicates with Operating Authority staff through division-specific orientation training for new employees. This in-person training was paused at the start of the COVID-19 pandemic in Q1 2020, and no evidence was observed to indicate that employees hired after March 2020 have received this orientation training.
ВР	The PWC report and presentation include a discussion of Wastewater QMS risk assessment results, however, risk assessment is not included in the list of Annual Report inputs in <i>Communications (QMS-WW-ALL-P-120, Rev3, 12Aug2021)</i> . Consider adding "risk assessment results" to the procedure.
Element 13:	Essential, Supplies & Services
NC	Bulk Chemical Deliveries (OP-ALL-ALL-P-001, Rev8, 7Feb2020) Table 1 specifies that aluminum sulphate and hydrogen peroxide % concentration was based on w/v. In reviewing the tender documents for the chemicals (contract #1147, #943), the auditor identified that both chemicals unit of concentration specified % w/w.



Finding	WWQMS Standard Element
Element 13:	Essential, Supplies & Services
NC	Section 5.1.6 of the <i>Bulk Chemical Deliveries (OP-ALL-ALL-P-001, Rev8, 7Feb2020)</i> states "The system operator unlocks the cap on the appropriate fill pipe. Some fill caps may not be locked if they are located behind a locked door." The auditor observed that all of the fill ports were not securely locked at the Niagara Falls, Welland and Baker Road WWTP.
NC	Section 5.2.3 of the <i>Essential Supplies & Services (QMS-WW-ALL-P-130, Rev 8, 7Feb2020)</i> states "Chemical delivery/offloading is not initiated until the Manifest, Bill of Lading, and Certificate of Analysis have been checked to confirm that the requirements are met". Several chemical deliveries for each of the wastewater facilities were reviewed. The auditor identified that only the manifest was provided for a sodium bisulphite delivery at the Welland WWTP on 2-Sep-2021. Since the Bill of Lading and Certificate of Analysis for the sodium bisulphite delivery was not provided at the time of chemical delivery/offloading, this would also be in non-conformance to section 5.1.2 of the <i>Bulk Chemical Deliveries (OP-ALL-ALL-P-001, Rev8, 7Feb2020)</i> which describes that the System Operator obtains the Bill of Lading and Certificate of Analysis from the driver and verifies the product name, quantity, seal number, and product UN number. Verification of documents was not confirmed upon arrival therefore, the Operator did not confirm that the chemical quality and quantity requirements were met.
ВР	It was identified that a Seasonal Grounds Complaint link is provided on each of the area's e-boards to record any issues with seasonal grounds maintenance activities. In reviewing the <i>Essential Supplies & Services (QMS-WW-ALL-P-130, Rev 8, 7Feb2020)</i> the auditor noted that there is no program in place for evaluating suppliers and/or service providers. It is strongly recommended that a program be adopted for evaluating contractors.



Finding	WWQMS Standard Element
Element 13:	Essential, Supplies & Services
ВР	Essential Supplies & Services (QMS-WW-ALL-P-130, Rev 8, 7Feb2020) specifies "any staff procuring supplies or services are responsible to ensure that the supplier or service provider has up-to-date WSIB insurance." There is an opportunity to improve/clarify the process for verifying insurance coverage requirements of a supplier or service provider.
BP	The auditor had identified that an Emergency Spill Response Information document exists for several of the wastewater facilities. Consider including reference to these documents in the <i>Bulk Chemical Deliveries (OP-ALL-ALL-P-001, Rev8, 7Feb2020)</i> procedure.
BP	Section 5.1.12 of the <i>Bulk Chemical Deliveries (OP-ALL-ALL-P-001, Rev8, 7Feb2020)</i> states "the System Operator confirms delivery quantity on SCADA and records delivery details in the plant logbook." Observed log entries were made but little detail was provided in terms of quantity and quality. The operator accepting the delivery should note the certificate of analysis has been checked to conform to the procedure and total volume received to ensure accuracy.
Element 21:	Continual Improvement
NC	Corrective Action, Preventive Action, and Best Practices (QMS-WW-ALL-P-210, Rev1, 1Apr2020) specifies that a root cause analysis is completed to identify why a non-conforming condition was allowed to occur. The procedure also states that the QMS Representative monitors the effectiveness of the corrective action by assigning a date for follow-up and verifying the effectiveness of the corrective action on or immediately before that date. Root causes were not identified for two of the non-conformance records that were reviewed (WWCAR-20-001 and 20-004), despite the records having been pushed beyond the "root cause" stage of the workflow. Additionally, WWCAR-19-007 was closed without verifying the effectiveness of the corrective action.



Finding	WWQMS Standard Element
Finding	WWQMS Standard Element
Element 21:	Continual Improvement
BP	Corrective Action, Preventive Action, and Best Practices (QMS-WW-ALL-P-210, Rev1, 1Apr2020) describes the process for identification and management of QMS non-conformances, as well as QMS potential non-conformances and QMS best practices. A potential non-conformance can be loosely defined as "a corrective action that hasn't happened yet, but will likely occur given adequate time". The implication is that there is a root cause that needs to be addressed, and that doing so shouldn't be considered as an optional exercise. It may therefore be beneficial for PNCs to follow the "corrective action" route rather than the "best practice" route.
BP	The Operating Authority may wish to consider identifying criteria to indicate what level of verification of effectiveness is required and/or identifying examples of activities that could be undertaken to verify effectiveness. Some corrective actions may require a simple review of a standard operating procedure, while others may require more intense monitoring and study. There may even be corrective actions that don't require any monitoring of effectiveness at all.
ВР	There may be an opportunity to review open BPEs that are currently in the draft phase and assign them to process owners, particularly those that precede the most recent audit.

Prepared by: Michelle Max

Date: October 29, 2021 (rev0)