Data Integrity Policy and Procedures for Portland Water Bureau Laboratory and Water Quality Data Activities

Effective Date: July 2024

Note: This policy and procedure replaces the previous policy dated April 2023.

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A. Purpose and Application of the Data Integrity Policy and Procedures

1. **Mandate:** This policy and procedure is mandated under the current National Environmental Laboratory Accreditation Program (NELAP) = TNI Standards; 2016 The NELAC Institute (TNI); Environmental Laboratory Sector: Volume 1, Management and Technical requirements for Laboratories Performing Environmental Analysis Module 2: Quality Systems General Requirements (EL-V1M2-ISO-2009 - 4.2.8.1). These Standards are implemented in Oregon by the Oregon Health Authority under the authority of the Oregon Environmental Laboratory Accreditation Program (ORELAP), the accrediting authority for the Portland Water Bureau Laboratory.

2. **Requirements for Portland Water Bureau Lab Accreditation:** As a laboratory accredited to perform drinking water and environmental water analyses in Oregon, all staff members of the Portland Water Bureau Laboratory are required to comply with the Data Integrity Policy and Procedures, and training documentation must be available for ORELAP On-Site Assessors.

3. **Water Bureau Policy Mandates:** As a policy in the Water Bureau, all Water Bureau employees who engage in laboratory activities, collection of samples, and/or use of water quality data and data reporting as defined in this document are also required to comply with the Data Integrity Policy and Procedures. Compliance and training documentation for non-lab employees are not required for ORELAP On-Site Assessments, or Portland Water Bureau Laboratory ORELAP accreditation.

B. Data Integrity and Ethics Mission and Policy Statement

1. **Data Integrity Mission:** *The mission of all Water Bureau employees who engage in laboratory and/or water quality data related activities is to operate under the following goals:*
    a. *Consistently producing valid and representative water quality samples,*
    b. *Consistently producing valid and reliable data resulting from the collection and analysis of those samples,*
    c. *Consistently producing valid data reports and appropriate use of water quality data, and*
    d. *Conducting all activities covered by this Policy with honesty and full disclosure*

2. **Definition and Application of Data Integrity and Ethics:** In the context of this policy and procedure, data integrity and ethics:
    a. Are the positive principles of conduct as related to the activities covered by this policy.
    b. Provide assurances that a highly ethical approach governs the appropriate conduct of the activities covered by this policy. In addition, these principles are a key component of all planning, training and implementation of procedures and practices related to activities covered by this policy, and
    c. Recognize the critical need for honesty and full disclosure during all aspects of the activities covered by this policy.

3. **Water Bureau Management Support of the Policy:**
    a. This policy and procedure are supported and upheld by all senior management levels at the Portland Water Bureau whose work groups are involved in the activities described in this policy. This includes the Laboratory Manager of the Portland Water Bureau Laboratory, the Operations Group Director (the Lab is a member of the Operations Group), and the supervisors of all other work groups who undertake activities covered by this policy.
    b. The Administrator of the Portland Water Bureau also supports and upholds this policy and procedure.

    These entities acknowledge the support of the data integrity procedures by upholding the spirit and intent of the procedures, by effectively and consistently implementing all specific requirements of these procedures in their work areas, and by participating in training on this policy as per the Water Bureau mandate defined in Section A.

C. Intentions of the Data Integrity Policy and Procedure

1. Convey and support the expectations of appropriate conduct associated with all laboratory and water quality activities undertaken by Water Bureau personnel and as defined in this policy.

2. Convey expectations regarding investigations of potential data integrity and ethics violations, and penalties that will result from improper, unethical or illegal actions in the conduct of laboratory and water quality activities, including the potential for termination of employment, and civil or criminal prosecution in courts of law.

3. Provide training and education on the ethical and legal responsibilities, including possible penalties for improper, unethical or illegal actions, for all Water Bureau employees who engage in the laboratory and water quality activities.

D. Activities and Locations Covered by this Policy

1. **Activities Covered by this Policy:** *The following activities are covered by this Policy:*

a. Preparation of sample bottles, sample coolers, and sample kits
b. Preparation of Chain of Custody forms (as required)
c. Collection of water quality samples
d. Measuring and recording water quality data and sample data
e. Handling of samples and field data after collection
f. Transport of samples and field data to the Lab or to other site for analysis
g. Receipt, acceptance and log-in of samples at Lab or other site for analysis
h. Handling of samples by Analyst after receipt from Sample Custodian
i. Analysis of water quality samples or other samples
j. Entry of data and associated documentation into the LIMS system
k. Review of completed sample data by the Analyst or sample collector
l. QA review of data by the QA Coordinator or designee
m. Final review and approval of sample results by the Lab Manager or designee
n. Reporting of water quality data
o. Use of water quality data by the bureau end user
p. Any other activity related to water quality samples or data that is undertaken by Portland Water Bureau personnel

2. Locations Covered by this Policy: The activities described above can be undertaken by Portland Water Bureau personnel at any of the following locations, and are thus covered by this Policy:

a. Any sample or water quality data collection site in the Bull Run watershed
b. Any sample or water quality data collection site within the distribution system of the Portland Water Bureau
c. The Portland Water Bureau Laboratory at 2010 N. Interstate Avenue
d. The Headworks Treatment facility
e. The filtration and corrosion pilot treatment buildings
f. The Lusted Hill facility
g. The Groundwater facility
h. Any other bureau or field location where the activities covered by this Policy are undertaken by Portland Water Bureau personnel

E. Expectations of Appropriate Conduct Related to Water Quality Sample and Data Activities

1. **Day-To-Day Expectations:** ***All Water Bureau personnel who engage in the activities as defined in this Policy are expected to:***
    a. Consistently comply with all aspects of all applicable Standard Operating Procedures (SOPs) and established protocols while doing your work.
    b. Follow the SOP even if you are not sure why the given steps are required or important, or if you expect that the final sample results would not be affected if the SOP was not followed.
    c. Consistently operate under the goals of:

1) Producing valid and representative water quality samples and field data,
2) Producing valid and reliable data resulting from the analysis of those samples, and
3) Producing valid data reports and appropriate use of water quality data

d. Conducting all activities covered by the Policy with honesty and full disclosure

2. **Oregon Direct Lab Reporting Rule Expectations:** When sample results exceed any MCL that has been established by state and federal drinking water regulations, then Water Bureau Laboratory personnel are required to immediately comply with the appropriate steps and actions for the Oregon Direct Lab Reporting Rule. The data must be reviewed and validated, and the required report must be faxed to State of Oregon Drinking Water Program personnel within 24 hours for all chemistries (except nitrate) and 48 hours for positive coliform bacteria and nitrate after notification by the analyst of results that exceed an MCL. This includes but is not limited to positive Total Coliform Rule compliance samples and any resamples. The Water Bureau's LIMS system is configured to display colored cells in the Results Entry spreadsheet to cue the Analyst and further facilitate compliance with these requirements. Compliance with the requirements of the Direct Lab Reporting Rule by Laboratory staff is a requirement of current Oregon Statutes and is managed by one of the following persons the LIMS Application Administrator, Laboratory Manager, or Lab Coordinators.

****NOTE: Total coliforms are reported within 24 hours of validation.**

3. Automated Daily Exception Report Expectations: High and low limits in LIMS have been established for all analytes and sample locations. These reports are automatically emailed early in the morning on a daily basis and summarize all field and lab results where a LIMS limit was exceeded in the past 24 hours. Applicable bureau staff then respond as needed to these notifications. The LIMS Application Administrator or designee is responsible for ensuring that LIMS limits are established for all analytes and locations, and for maintaining the automated reporting function and making changes as needed.

It should be noted that while positive Total Coliform Rule compliance samples appear in the next day's automated reports, Lab staff provide immediate same-day notification to water quality staff. It should also be noted that even when LIMS limits are not exceeded, conditions may exist requiring an analyst to provide notification (section 4).

4. Suspect, Questionable or Incomplete Data Expectations: There can be instances when Water Bureau personnel who are undertaking activities described in this Policy find that the resulting data comply with all quality assurance requirements but are suspect or questionable for a variety of reasons. These reasons might include, but are not limited to:

a. Unusually high or unusually low analytical result(s)
b. Sample(s) that contains foreign material
c. Sample(s) with unusually high turbidity or color
d. Questionable sample result(s) or questionable sample conditions of any kind

In these instances, LIMS limits are usually not exceeded. If the data are suspect or unusual for any reason, Water Bureau personnel are expected to send an email to WB Lab and WB WQComp with the details. These emails are then forwarded by the Lab Manager and/or Water Quality Compliance staff to others in the bureau as needed for follow-up.

In addition, where appropriate the Analyst must also provide written narration in LIMS in cases where the analytical data may be useful but are in some sense or another partially deficient.

5. Troubleshooting Expectations: There can be instances when Water Bureau personnel who are undertaking activities described in this policy find that an analytical method or piece of equipment requires troubleshooting before the method performs correctly and produces acceptable QA/QC results and sample results.

a. As troubleshooting is being undertaken, the Analyst is required to write notes on the raw data sheets/lab notebook/raw data printouts that provide a narrative to document all the following in the chronological order in which each occurred:
   1) The problem(s) encountered,
   2) Each of the remedy or remedies attempted,
   3) Decisions made during data review,
   4) Resolution of the troubleshooting activities, and
   5) Anything else that describes what transpired or could contribute to resolving the troubleshooting.

b. All such documentation must be completed during the troubleshooting activities, and not at a later time or date. When troubleshooting is completed, or when the Lab Coordinators or Laboratory Manager so instructs, the Analyst is also required to add a "Sample Comment"(s) or "Analysis Comment"(s) in LIMS that completely and accurately describes all of the troubleshooting activities.

It should be noted that compliance with the above requirements for troubleshooting by Portland Water Bureau Laboratory staff is required to maintain lab accreditation under ORELAP.

c. If troubleshooting is required in the field or during sample collection, then the Water Bureau personnel performing those activities are required to document the troubleshooting activities as above on their field data sheet. If a sample is transported to the Lab, then the Sample Custodian will confer with the sample collection personnel and make the necessary entries in LIMS to document the troubleshooting activities.

In addition, it is expected that such troubleshooting would include the direct notification of the Laboratory Coordinators or Field Supervisor for assistance or advice.

6. Consistent and Effective Work Performance Expectations: All employees engaging in water quality sample and data activities are always expected to consistently perform their work completely and accurately.

a. This policy is NOT intended to apply to routine, unintentional errors than can and do occur from time to time. However, when errors or omissions occur, employees are expected to report and document their actions, and are expected to fully and faithfully participate in corrective action activities as assigned.
b. Documentation of such errors or omissions needs to be detailed and complete to allow for a third party (e.g. ORELAP On-Site Assessor) to recreate the entire process, including decisions made during data review. If this is not done, what actually happened or didn't happen is open to anyone's interpretation after the fact.
c. Investigations and determinations of gross negligence or clear dereliction of duty may be conducted under this policy and the applicable City of Portland Human Resources Administrative Rules and applicable Union contracts.

d. Substantiated findings of gross negligence or clear dereliction of duty are violations of this policy and can result in discipline up to and including termination.

F. Examples of Fraud, Improper or Illegal Actions, and Breaches of Ethical Behavior

The following examples of improper or illegal actions and breaches of ethical behavior are provided to illustrate the kinds of purposeful activities that would be considered in violation of this policy and will result in a detailed investigation that could lead to very serious consequences up to and including termination, and civil or criminal prosecution.

Such improper activities include, but are not limited to:

1. Purposeful omission of required steps in any Standard Operating Procedure, protocol or established practice for activities covered under this Policy
2. Omission of required steps in any Standard Operating Procedure, protocol or established practice for activities covered under this Policy because it is expected that final sample results would not be affected by the omission
3. Not reporting an error made during the performance of activities covered under this Policy
4. Purposefully not preparing reagents or media as per instructions in the analytical Standard Operating Procedure
5. Purposeful recording of times in a manner that does not reflect the actual time that a given step in the Standard Operating Procedure, protocol or established practice was performed
6. Falsely altering Quality Control results
7. Purposefully not completing required QA/QC tasks as assigned
8. Falsely altering sample results
9. Inventing or fabricating data
10. Deleting data, samples, or scheduled tests in a manner not in accordance with established protocols
11. Misrepresenting the location at which a sample was collected
12. Purposeful contamination of a sample
13. Purposeful omission of required sample preservatives
14. Purposeful contamination of sample bottles
15. Purposefully not transporting samples on ice and in an insulated cooler after being instructed to do so
16. Purposefully changing analysis date records to falsely show samples were analyzed within prescribed holding times
17. Manual integration or false manipulation of raw Chromatograph data to falsely alter sample or Quality Control results
18. Improper data manipulation(s) of any kind
19. Adjustment of time clocks on instruments or computers
20. Falsely or inappropriately changing the concentrations of reference or calibration standards
21. Not treating batch QC samples in the same way as the rest of the batch of samples
22. Reserving special glassware or lab ware for blanks, Quality Control or Proficiency Testing samples
23. Selective removal of calibration values to avoid re-running calibration standards

24. Removal or addition of data to give the appearance of non-detect results, or to give the results that are "expected"
25. Selective removal of data during MDL (Method Detection Limit) determinations
26. Producing raw data that doesn't contain all the data generated (i.e. omission of data that failed QC limits)
27. Using calibration procedures that are not allowed by the required or established methods
28. Changing a computer-generated report to represent sample results that were not actually generated
29. Using the results from one sample and applying to other samples as an accurately determined result for each sample
30. Manually entering random values for results that were not determined by analysis
31. Entering raw data or sample results from memory instead of actually recording the data at the time it was generated

G. Implementation and Monitoring of Data Integrity

Three Levels of Data Review and Validation: On a routine basis, there are three levels of review and validation of data collected at the Portland Water Bureau:

- First a Quality review of each analysis batch by the employee that generated the field or lab data (the Laboratory Analyst, the sample collector, the Treatment Operator, etc)
- Next a Quality review of each analysis batch by the Laboratory Coordinators or the sample collector's Supervisor
- Review by the project manager

Elements of review include:

- Review of QA/QC data and requirements
- Review of exceedances of any LIMS limits,
- Identification of any questionable sample results, and
- Identification of any potentially suspect incidents of Data Integrity or ethics violations, or fraud

Expectations for Monitoring Data Integrity and Implementing the Policy: Analysis and review as described above may result in identification of data that are suspicious in nature, or suspected actions that may be fraudulent and may be in violation of the Data Integrity Policy and Procedures. Any bureau personnel that suspect incidents of data integrity or ethics violations or fraud shall report those incidents as noted in the next section.

Personnel in the Water Quality Compliance work group prepare reports for submission to regulators, and for internal and external use, publication, etc. Managers of bureau projects also prepare reports for internal use, external use, publication, etc. These staff members also perform a variety of statistical and trend analyses on the water quality data and review the data in detail. Such analysis and review may result in identification of data that are suspicious in nature, or suspected actions on the part of individuals or groups that are fraudulent and may be in violation of the Data Integrity Policy and Procedures. Any Water Quality Compliance personnel or project managers that suspect incidents of data integrity or ethics violations or fraud shall report those incidents as noted in the next section.

Through other means that cannot be predicted or anticipated, information may come to light that identifies water quality data that are suspicious in nature, or suspected actions on the

part of individuals or groups that may be in violation of the Data Integrity Policy and Procedures. Any bureau employees that suspect incidents of data integrity or ethics violations or fraud shall report those incidents as noted in the next section.

H. How and When to Report Data Integrity and/or Ethics Violations

Expectation to Report:

All Water Bureau employees are expected to report all suspected or potential violations of data integrity and/or ethics as soon as possible after the suspected or potential infraction occurs or is discovered.

To Whom to Report: Employees can report suspected violations to any of the following persons:

- Laboratory Manager of the Portland Water Bureau Laboratory
- Operations Group Director
- The employee's Group Director
- The employee's Supervisor
- Water Bureau Administrator
- Human Resource Coordinator assigned to the Water Bureau

How to Report:

- Suspected or potential violations can be reported orally, or in writing (including email).
- Those persons providing oral reports will generally be asked to provide some form of written report as a follow-up so that the details of the incident can be made as clear as possible.
- All reports should include as many specific details as possible, such as dates, times, specific actions observed, etc.
- Those reporting suspected, or potential violations may do so confidentially. However, during the course of an investigation, all employees involved are expected to respond to questions fully and truthfully, and to provide full disclosure.
- All suspected or potential violations are referred to the Laboratory Manager of the Portland Water Bureau Laboratory for investigation.
- If the Laboratory Manager is suspected to have violated this Policy, then the suspected or potential violation is referred to his/her supervisor.

I. Procedures for Investigation of Possible Data Integrity and Ethics Violations

Personnel Conducting the Investigation: The Laboratory Manager of the Portland Water Bureau Laboratory will investigate alleged violations of this Policy with the assistance of Water Bureau and City Human Resources personnel.

If the Laboratory Manager is alleged to have violated this Policy, then his/her supervisor will conduct the investigation.

Protocols for Conducting the Investigation:

- Fair and thorough investigations will be conducted to acquire and document the facts that can be substantiated related to any given incident.
- All investigations will be conducted in accordance with current City of Portland Human Resources Administrative Rules and established policies and practices.
- The results of all investigations and related personnel or disciplinary material are confidential and can only be accessed as per City of Portland Human Resource Administrative Rules.
- All investigations will be deemed high priority work, and the investigations will be initiated without delay, and completed as soon as possible.
- During the course of any investigation, all employees involved are expected to respond to all questions fully and truthfully, and to provide full disclosure.
- All investigative interviews will be recorded on audio tape.
- All audio tapes will be transcribed to provide accurate written documentation of all the specifics related to the investigation, and to provide a competent resource for the Lab Manager (or his/her supervisor) to prepare the confidential summary report of the Data Integrity investigation.

Potential Outcomes of an Investigation: Any potential infraction of the Data Integrity procedures will result in a detailed investigation. If violations of the Data Integrity Policy are substantiated, that could lead to very serious consequences:

- **Discipline, up to and including immediate termination, and/or**
- **Civil or criminal prosecution, including fines and/or jail time.**

Follow-Up Report and Documentation of All Investigations:

- After the investigation is completed, the Lab Manager will prepare a confidential summary report of the findings and any other material related to the investigation. This report will be written and archived for all investigations, regardless of whether the investigation resulted in the substantiation of Data Integrity and Ethics violations or not.
- If the Lab Manager is the focus of the investigation, then his or her supervisor will prepare the follow-up report.
- The report will summarize all the necessary and relevant information from confidential personnel files for the purposes of documenting compliance with this Policy and for the purposes of maintaining the Portland Water Bureau Lab's ORELAP accreditation. Specific memos, recorded interviews, and contents of personnel files that relate to the possible data integrity and ethics policy violations will be accurately summarized in the report, but will not actually be included in the report.
- The intent of the summary report will be to provide a detailed summary of the investigation and follow-up related to the investigation of possible Data Integrity and ethics policy violations for the incidents referenced above. The report will not focus on material related to any additional, non-Data Integrity related performance issues for the employee that was the target of the investigation. The report must be made available to ORELAP Assessors during On-Site Assessments, or at other times as requested by ORELAP staff.

J. Procedures and Consequences When Data Integrity and Ethics Violations are Substantiated

Consequences of the Start of an Official Data Integrity/Ethics Investigation: If an investigative interview for the purposes of this Policy results in sufficient supporting evidence to justify the start of an official Data Integrity/Ethics investigation, then the employee involved will be temporarily assigned to different work that is not related to any of the activities covered under this Policy, or will be granted Administrative Leave until the investigation is completed.

All temporary assignments or leave granted will be in accordance with Union contracts and City of Portland Human Resource Administrative Rule requirements.

Potential Disciplinary Actions and Penalties: When investigations find a Water Bureau employee to be in violation of this Policy, the employee will be subject to disciplinary action for cause as per the current Human Resources Administrative Rules. Such discipline may include, but is not limited to, an oral reprimand, written reprimand, demotion, loss of pay, or suspension. Very serious infractions could also result in discharge or termination, or civil or criminal prosecution.

In all cases, the level and degree of penalty shall be in keeping with the seriousness of the offense, taking into account the circumstances relevant to the incident.

Sample Results and Substantiated Violations of the Policy: When substantiated data integrity or ethics violations are documented as per this policy, all related sample analyses and results involved in the fraud will be invalidated as per Portland Water Bureau Laboratory protocols. All invalidated results will be accompanied by appropriate audit trails and narrative comments in LIMS. Any sample results involved in the fraud will not be reported.

Reporting of Substantiated Violations of the Policy: When substantiated data integrity or ethics violations are documented as per this policy, appropriate State of Oregon officials will be notified. In all cases, substantiated fraud will be reported to the Oregon Environmental Laboratory Program (ORELAP) Administrator at OHA. In the case of sample results that are reportable to the Oregon Health Authority (OHA), fraud will also be reported to officials at the Oregon Drinking Water Program.

K. Management Review of the Data Integrity Policy and Procedures

Schedule and Protocols for Management Review:

- The Laboratory Manager of the Portland Water Bureau Laboratory will conduct an official review of the Data Integrity Policy and Procedures annually.
- Reviews will be conducted at other times if it is deemed necessary (e.g. receipt of review feedback from the City of Portland Bureau of Human Resources).
- Content of each annual review will be summarized in a written report.
- Any needed revisions or updates to the Data Integrity Policy and Procedures are made upon completion of the review.
- Conduct and content of the review are documented in Portland Water Bureau Laboratory files.

- If the Lab Manager has been the focus of an investigation, then his or her supervisor will conduct the management review.

Content of Management Review: The annual review includes:

- Review and evaluation of the current version of the written Data Integrity Policy and Procedures, and retention of the file with changes tracked
- Review of any changes in NELAC standards for Data Integrity, and incorporation of those changes into the Data Integrity Policy and Procedures
- Review and evaluation of the past year's implementation of the Data Integrity Policy and Procedures, and conduct of any necessary corrective action or improvements
- Review and evaluation of the past year's training records, and development of training plan for the upcoming year
- Identification of any additional external training resources, and incorporation of those resources into the Data Integrity Policy and Procedures

L. Internal Training Schedule

The Laboratory Manager of the Portland Water Bureau Laboratory (or his/her trained designee) schedules and conducts a training session(s) for the following work groups annually:

- Laboratory staff and LIMS Application Administrator (required for Portland Water Bureau Laboratory ORELAP accreditation)
- Portland Water Bureau Operation Engineers and Treatment Operators (not required for Portland Water Bureau Laboratory ORELAP accreditation)
- Water Quality Compliance (group members who report data to the Oregon Department of Human Services; not required for Portland Water Bureau Laboratory ORELAP accreditation)

Individual, one-on-one training is scheduled for any group members above who are unable to attend a scheduled training session.

All other work groups in the Water Bureau who fall under the purpose and intent of the Data Integrity Policy and Procedure as data end users are provided training on an annual basis whenever possible.

M. External Training Requirements and Resources

City of Portland Human Resources Administrative Rules: All Water Bureau employees are required to complete training on the current version of the City of Portland's Human Resources Administrative Rules. With respect to ethics, the following Human Resource Administrative Rules (HRAR) apply:

- HRAR 11.01, Statement of Ethical Conduct (adopted in 2005 and revised in 2013) https://www.portland.gov/sites/default/files/2020-06/11-01-statement-of-ethical-conduct.pdf
- HRAR 11.02, Prohibited Conduct (adopted in 2020) https://www.portland.gov/sites/default/files/2020-06/11.02-prohibited-conduct_0.pdf
- HRAR 11.03, Duty to Report Unlawful or Improper Actions (adopted in 2002 and revised in 2018) https://www.portland.gov/sites/default/files/2020-06/11-03-duty-to-report.pdf

City of Portland Code of Ethics: City Code and Charter, Chapter 1.03, Code of Ethics; http://www.portlandonline.com/auditor/index.cfm?c=28153 applies to all Water Bureau employees as well in the conduct of their assigned duties. This material is covered in the training on Human Resource Administrative Rules that is required of all Water Bureau employees.

The Chemist's Code of Conduct: American Chemical Society web site
The Chemical Professional's Code of Conduct - American Chemical Society (acs.org)

N. Internal Training Procedures

Trainer: The Laboratory Manager of the Portland Water Bureau Laboratory (or his/her trained designee) schedules and conducts all training sessions for the Data Integrity Policy and Procedure.

Training Content and Methods: All training sessions include links to the following:

- A copy of the current PowerPoint presentation on the Data Integrity Policy and Procedures
- A copy of the current Data Integrity Policy and Procedures document for future reading and reference

Training sessions are conducted using the PowerPoint presentation, and thorough discussion of each topic below:

- Purpose and application of the Data Integrity Policy and Procedures
- The mission of all Water Bureau employees who engage in laboratory and/or water quality data related activities
- The intentions of the Data Integrity Policy and Procedures
- Explanation of appropriate lab-related activities, which particular attention to:
  - What to do when field or lab results are unusual or questionable, and
  - What to do when a field or laboratory analytical method or piece of equipment that requires troubleshooting before the method performs correctly.
- Explanation of activities that are not covered by this policy and procedure
- Examples of improper or illegal actions, and breaches of ethical behavior
- Description of how Data Integrity procedures are implemented and monitored
- Explanation of how and when to report data integrity and/or ethics issues
- Description of how possible data integrity and ethics violations are investigated, with particular emphasis on:
  - The fact that any infraction of the Data Integrity procedures will result in a detailed investigation that could lead to very serious consequences up to and including termination, or civil or criminal prosecution.
  - Providing examples of infractions that would lead to termination, or civil or criminal prosecution.
- Procedures and consequences when data integrity and ethics violations are substantiated
- Explanation of how the Data Integrity Policy and Procedures undergo annual review
- Explanation of training schedule for bureau employees
- Description of additional, external training requirements and resources on ethics.

In addition:

- The trainer asks the trainees for additional examples of work that may (or may not) apply under the policy and procedures.
- The trainer answers the trainees' questions. If any questions cannot be answered at the time of the training session, the trainer makes note of the question, seeks an answer to the question after the session, and provides that information to participants.
- The trainer also records notes on any ways that the policy and procedures need to be revised or can be improved. These notes are retained for use during the annual management review. If changes needed are significant, then those changes are made and documented immediately, independent of the annual review.

O. Internal Training Records and Documentation

Signature Attendance Sheets: The trainer obtains a signature attendance sheet at the beginning of each training session. Completed attendance sheets are stored in the Portland Water Bureau Laboratory files to document the training records for the Data Integrity Policy and Procedures.

Ethics Agreements: At the end of each training session, the trainer provides a copy of the written Ethics Agreement to each participant and ensures that signed and dated agreements are obtained from all attendees. The trainer explains that the purposes of the agreement are to document completion of the training, and to obtain the employee's written agreement to comply with the requirements of the Data Integrity Policy and Procedures. The Agreements are also signed and dated by the trainer. Completed agreements are stored in the Portland Water Bureau Laboratory files.

Training Records: In addition to the written training records above, the Laboratory Manager maintains a summary table of all training conducted. Training records are stored in Portland Water Bureau Laboratory files.

Data Integrity Policy and Procedures

Training for:
- Treatment Operators
- July 22, 2024

Trainer: Marsha Farooqui
Portland Water Bureau Laboratory

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To Whom Do the Policy and Procedures Apply?

- Portland Water Bureau Laboratory staff:
  Required under The NELAC Institute (TNI) standard; 2016 Section 5.2.7 and Oregon Environmental Laboratory Accreditation Program (ORELAP)
- All Portland Water Bureau staff who generate and/or use water quality data:
  Portland Water Bureau policy
- *This means*
  1) Laboratory staff (data generators)
  2) Water Quality Compliance staff(data reporters)
  3) Other Operations staff (sample collectors and data generators)

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Updates

- Interim Director - Ed Campbell
- Operations Group Director – Kim Gupta
- Bull Run Supply & Treatment Manager - Lyda Hakes
- Treatment Supervisor - Sam Ewing

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What is Data Integrity?

- For the Water Bureau, Data Integrity is the *positive principles of conduct* as they relate to *laboratory activities and water quality data*
- Data Integrity provides assurance that a highly ethical approach is a key component of all activities

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Data Integrity Mission and Policy Statement

- Mission is to consistently produce:
  1) Valid/representative samples
  2) Valid/reliable data from samples
  3) Valid reports and use of data
- Honesty, full disclosure at all levels
- Policy must be upheld by those who use it on a daily basis, and by all management levels of the Water Bureau, including the Administrator

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Intentions of the Policy and Training

1. Characterize appropriate conduct for the entire "sample train":
   - Preparation of sample bottles/kits
   - Collection of samples
   - Handling and transporting samples
   - Analysis of samples
   - Generation of data in the field, lab, at Headworks, Lusted Hill, Groundwater
   - Entry of data into LIMS
   - Validation of data
   - Approval of sample results
   - Reporting and using water quality data

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Intentions of the Policy and Training, continued

2. Convey expectations regarding:
   - Investigation of potential ethics violations
     Penalties that will result from improper, unethical, illegal actions
3. Provide training and education that is consistent for all employees
4. Define Ethics
5. Define Data Integrity

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Ethics Defined

- A system of moral principles governing the appropriate conduct for a person or group
- Doing the right thing
- Being honest and straightforward not lying or cheating
- A code of conduct
  - ACS web page "The Chemist's Code of Conduct" www.acs.org/careers search Code of Conduct
  - ACIL web page Code of Conduct for Laboratorieswww.acil.org look under About Us

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Why Act Ethically

- Your personal reputation and the reputation of your organization or business depends upon it
- Decisions we make as scientists and environmental professionals affect the environment and the lives of others
- Acting ethically can enrich your work life as well as your home life
- The penalties for misconduct for you and your organization can be substantial

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Data Integrity

- The condition that exists when data are sound, correct, and complete and accurately reflects activities and requirements."
- It is achieved by preventing accidental or deliberate but unauthorized insertion, modification or destruction of data.

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Threats to Data Integrity

- Improper practice
  - A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable.
- Fraud
  - The deliberate falsification of analytical or quality assurance results, where failed method requirements are made to appear acceptable during reporting.
  - The intentional recording or reporting of incorrect information
  - An intentional gross deviation from method specified analytical practices, combined with the intent to conceal the deviation.

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What is Laboratory, Sample or Data Fraud?

- The deliberate falsification of results
- The intentional recording or reporting of incorrect information
- An intentional deviation from an established method or practice
- Any of the above with the intent to conceal the deviation

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Sometimes the difference between fraud, improper practice and honest mistake is simply lack of proper documentation.

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Example: # 1

- You're in a hurry because you got a late start and two extra sites had been added to your route. You are almost done with your route when the pH meter appears to be giving the wrong value. Your check standard read an acceptable value just five minutes before. You should resample and check the value again but you are running late. You call in but no one answers. This sample station has always read 7.95 why is it at 7.5 today?
- What do you do? It's just this one time. You write down 7.95 on the field sheet.

Is this Fraud or Improper Practice?

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Example # 2

- Max is scheduled to read some Colilert results in the afternoon, he gets very busy with an emergency with another analysis which makes him late for his son's big game and he totally forgets about the micro samples.
- The next morning Max looks at the samples and they are all clear. The clear color indicates a negative result.
- Sure the 24 hour window has past but they are still negative why not write down yesterday's date and move on.

Is this Fraud or Improper Practice?

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Example # 3

You saw Max taking readings in the morning and know they should have been done yesterday.

What should you do and why?

Is this Fraud or Improper Practice?

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Example #4

- Julie is being pressured by her supervisor to complete the report. She was only able to get the results yesterday and she hasn't had time to review the numbers. The lab always checks their data. She decides that she can just pull the data and add it to the report in half the time to solve her dilemma.

Is this Fraud or Improper Practice?

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Preventing Improper Practices

- Policies and procedures
  - QA program
    - QA Manual
    - SOPs
    - CARs
    - Internal audits
  - Policy statements
  - Training (Demonstration of Competency)
  - Instrument maintenance
  - Housekeeping and supplies

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How Do I Know a Practice is Improper ??

- Does it violate policy or procedure?
  SOPs / Quality Manual
- Would an auditor approve
- Gut check – Do I really feel this is right

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Why do Improper Practices Occur?

- Bench Reasons:
  - To make QC PASS
  - To avoid re-running sample
  - To avoid instrument maintenance
  - To avoid missing sample hold times
  - To avoid getting in trouble with the boss
  - To complete work within a specific time frame
- Management Reasons:
  - To avoid looking bad to upper management
  - To please clients
  - To avoid hiring more personnel
  - To save money on supplies or materials
  - To avoid purchasing new instrumentation

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Preventing Fraud

CULTURE OF INTEGRITY

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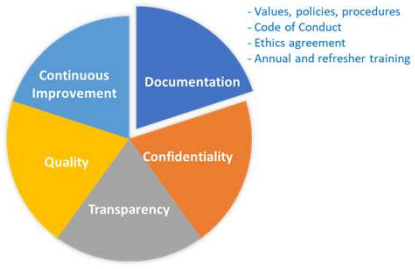
Preventing Fraud

CULTURE OF INTEGRITY



- Values, policies, procedures
- Code of Conduct
- Ethics agreement
- Annual and refresher training

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Preventing Fraud

CULTURE OF INTEGRITY

- Values, policies, procedures
- Code of Conduct
- Ethics agreement
- Annual and refresher training

- Whistle blower/anti-retaliation policy
- Investigations

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How and When to Report Suspected Data Integrity and/or Ethics Violations

- When – AS SOON AS POSSIBLE
- Report to ANY of the following:
  - Lab Manager (Marsha Farooqui)
  - Operations Group Director (Kim Gupta)
  - The employee's Supervisor
  - Water Bureau Administrator – Ed Campbell
  - Human Resource Coordinator assigned to the Water Bureau – Shane Davis

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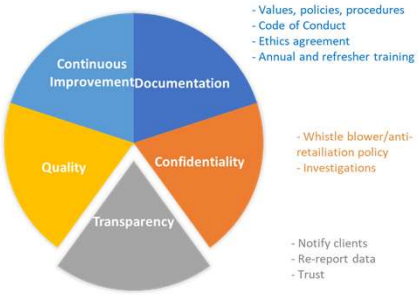
Preventing Fraud

CULTURE OF INTEGRITY



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Procedures and Consequences When Data Integrity/Ethics Violations are Substantiated

- For the Lab, in all cases, substantiated fraud is reported to the ORELAP[1] Administrator
- In the case of sample results that are for compliance with drinking water regulations, OHA-DWP[2] officials are notified

1 Oregon Environmental Laboratory Accreditation Program
2 Oregon Health Authority Drinking Water Program

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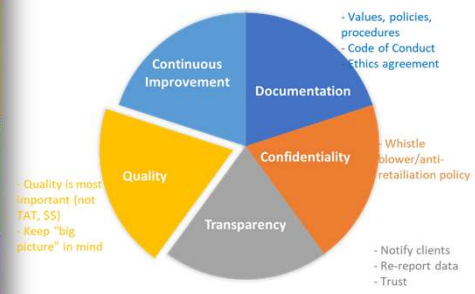
Preventing Fraud

CULTURE OF INTEGRITY



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Routine Data Review:

- Three levels of data review and validation are used routinely:
  - Quality review by the employee that generated the data (Analyst, sample collector, Treatment Operator, etc)
  - Quality review of each analysis batch (by Lab Coordinators, Lab Manager or employee's Supervisor)
  - Quality review of data by Project Manager

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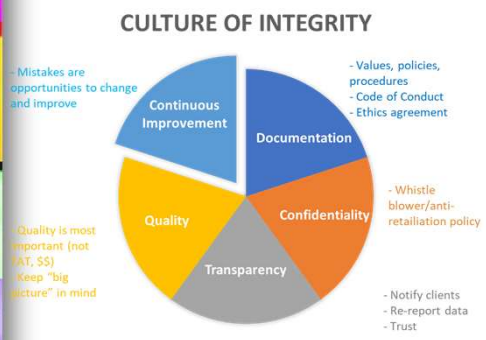
Preventing Fraud



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What are the Criminal Penalties for Conviction of Fraud?

- The following have penalties of up to 5 years in prison and/or a $500,000 fine:
  - **False claims**
  - **False statements**
  - **Mail fraud**
  - **Wire fraud**
  - **Conspiracy**
  - **Obstruction of Justice**
- The following has a penalty of up to 3 years in prison and/or a $500,000 fine:
  - **Concealment of a felony**

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Preventing Fraud

- Follow policies and procedures
- Ask for help
- Help others
- Report violations
- Self survey:

I am an ethical person.
I will do the right thing even if no one knows
I will do the right thing even if under pressure
I want other people to think I'm honest and ethical.
I will do the right thing even if no one else is doing it.

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Good people can do bad things……

but are less likely to do so when:

- ***There is a culture of honesty, quality and integrity.***
- ***There are clear policies and procedures in place.***
- ***They understand the "big picture" and the value of the work that they do.***

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An Ounce of PREVENTION:

- If you miss a holding time or make a mistake, be honest about it. Covering it up can take it from honest mistake to fraud.
- Don't be clever be smart, in the long run it takes less effort to just follow policy than to find clever ways to circumvent it.
- QC is used to determine sample, equipment, or method issues, not how good you are at your job.
- Talk with your Supervisor or QA Coordinator if you have questions.

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Misconceptions

Its OK if…

- If its in the SOP
- If lab is audited and problem is not found
- Data manipulation had very little if any effect on data results
- Never find analyte in samples, so QC not important
- Monitoring sample with nothing before so why analyze (rationalization for fraud)

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Flint Water Crisis:

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Flint Water Crisis: How did it happen?

- 2011: State of Michigan takes over Flint's finances (emergency manager runs the city – there was 4)
- April 2014: Flint switches water supply
- June 2014: Flint residents begin complaining about the water
- Aug-Sept 2014: boil water advisories
- Oct 2014: GM plant stops using Flint river water
- Jan 2015: public notified of disinfectant byproducts; Flint declines to reconnect to Lake Huron
- Feb 2015: EPA detects high lead levels (10-1000x higher than limit!)
- The state revises a city report and invalidates 2 water samples high in lead (LCR limit thus meet the federal standard for lead

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Flint Water Crisis: How did it happen?

- Sept 2015: 2 studies released
  - 40% of homes have high lead
  - 2-3x as many children have high lead levels in their blood
- Oct 2015: Schools test high for lead; Flint switches back to Lake Huron ($12 million)
- Nov 2015: Class action lawsuit
- Dec 2015: Flint declares state of emergency
- Jan 16, 2016: President Obama signs emergency declaration and orders federal aid for Flint
- Jan 2016: **Legionnaires' Disease Compounds Flint's Lead Poisoning Water Crisis**
  - There have been 87 cases in Genesee County from June 2014 to November 2015 — and 10 of those cases resulted in death, said Dr. Eden Wells, chief medical executive with the Michigan Department of Health and Human Services, or MDHHS.
  - That number is a jump from previous few years, when the county saw between 6 and 13 cases.

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By not adding anticorrosives in order to save $100/day, there is now a crisis estimated to cost more than $1 billion.

Toxic Waters

Contaminants associated with Flint's drinking water crisis:

CONTAMINANT	EFFECTS
Lead	Neurotoxin that can have long-term cognitive effects, especially in children who are exposed.
E. Coli	Bacteria that can cause diarrhea or respiratory illness, among other illnesses.
Trihalomethanes	Chemicals that can cause kidney, liver or central nervous system damage.
Legionnella	Causes Legionnaires' disease, a form of pneumonia. *Possibly in water — it hasn't been confirmed that Flint's Legionnaires' outbreak was linked to the water, though it occured over the same time period as the water switch.*

Sources: CDC, news reports
Photo: Virginia Tech University

The Huffington Post

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Pay Attention to Unexpected Consequences

- Supplying safe drinking water needs a critical balancing act.
- A water system's underlying job is simply not to just meet compliance. But to distribute truly safe drinking water and thereby protect public health.

The legacy of the Flint water crisis - Bing video

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What are the Day-to-Day Expectations?

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What are the Day-to-Day Expectations?

- Consistently conduct your activities with the goal of producing:

1) Valid/representative samples

2) Valid/reliable data from samples

3) Valid reports and use of data

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Laboratory Responsibility

- Continuously monitor data on a periodic but random basis – data audits
- Provide clear guidance and policies for ethical behaviour - code of conduct statement signed yearly
- Provide ongoing training to employees
- Perform confidential investigations if a problem is detected.
- Notify clients and reissue reports if data is negatively impacted.
- Eliminate undue pressure on analysts – quality ahead of TAT
- Provide mechanism for confidential reporting of abuse without recrimination – whistle blower policy

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Employee Responsibilities

- Uphold the ethics policy and practices as demonstrated in their daily conduct.
- Seek help when the proper course of action is unclear or unknown to them.
- Remain alert and sensitive to situations that could result in actions by any employee that are improper, illegal, unethical, or otherwise
- Consistently comply with all SOPs and established protocols while doing your work
- Follow the SOP even if you're not sure why the steps are required or important, or if you expect that the final sample results would not be affected if the SOP was not followed
- Review your SOPs on a routine basis
- Mistakes happen – we need to do appropriate follow-up when mistakes happen

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Expectations – Suspect or Questionable Data

- There can be instances where water quality results are suspect or questionable, but all QA/QC requirements are met
- LIMS limits usually won't be exceeded
- We rely on YOUR expertise!
- Lab staff – Send an email to Lab Manager and coordinators with the details
- Field staff – Write comments on field sheet and they will be recorded in LIMS

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Expectations – Troubleshooting Activities

- MUST Document in writing all of the following as troubleshooting is being undertaken:
  - Problem(s) encountered
  - Each of the remedy or remedies attempted
  - Decisions made during data review
  - Final resolution of troubleshooting
  - Anything else that could contribute to resolving the troubleshooting
- Write notes directly on field sheet, lab notebook, or data printout

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Expectations – Consistent and Effective Work Performance

- Policy does NOT apply to routine, unintentional errors
- BUT if there is an error or omission, all employees are expected to:
  - Accurately and completely report and document what happened
  - Fully and faithfully participate in corrective action activities as assigned

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Expectations – Consistent and Effective Work Performance, continued

- Documentation of errors or omissions must be detailed and complete, so as to allow for a third party (e.g. ORELAP On-Site Assessor) to recreate the entire process, including decisions made during data review
- If this is not done, what actually happened or didn't happen is open to anyone's interpretation after the fact
- ORELAP Assessors will say – "if it isn't documented, it didn't happen"

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Examples of Lab or Water Quality-Related Improper or Illegal Actions, and Breaches of Ethical Behavior, page 1

- Purposeful omission of required steps in any protocol or established practice for lab or water quality-related activities
- Not reporting an error made during the performance of lab or water quality-related activities
- Falsely altering sample results
- Inventing or fabricating data
- Deleting data or samples in a manner not in accordance with established protocols

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Examples of Lab or Water Quality-Related Improper or Illegal Actions, and Breaches of Ethical Behavior, page 2

- Misrepresenting the location at which a sample was collected
- Purposeful contamination of a sample
- Purposeful omission of required sample preservatives
- Purposeful contamination of sample bottles
- Purposefully not transporting samples on ice and in an insulated cooler

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Examples of Lab or Water Quality-Related Improper or Illegal Actions, and Breaches of Ethical Behavior, page 3

- Purposefully changing analysis date records to falsely show samples were analyzed within prescribed holding times
- Improper data manipulation(s) of any kind
- Adjustment of time clocks on instruments or computers
- Any other lab or water quality-related activities that are unethical or threaten data integrity

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Remember the following:

- It is OK to make a mistake. It is NOT OK to hide that information.
- It is OK to have QC out of limits. It is NOT OK to hide QC that is out of limits or make it appear to be within limits when it is not.
- Whatever the problem, it is not worth losing your job or going to jail!
- If you have questions, talk with your supervisor, the Coordinators, or the Lab Manager.

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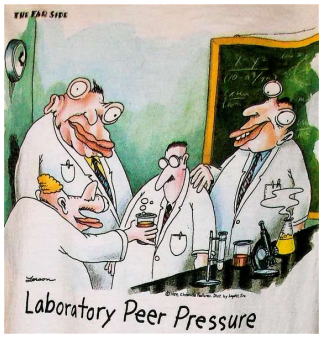
Thanks for attending this required training!



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Instructor Background And Information Form

Thank you for filling out this form.

Presentation Title: Data Integrity Policy and Procedures

Presenter: Marsha Farooqui Title: Laboratory Manager

Employer: Portland Water Bureau Address: 2010 North Interstate Ave.

City: Portland State: OR Zip: 97227 Phone: 503-823-1839

Summary of Lesson content: For the Water Bereau, data integrity is the positive priciples of conduct as they relate to laboratory, field activities, and water quality data. Data integrity provides assurance that a highly ethical approch is a key component of all activities. The power point also covers the City Ethics Policy as it relates to employees.

Professional Background: (Note a brief - 2 page maximum - resume may be submitted in lieu of the following data. Please be sure the resume includes all requested information. Qualifications should be related to your presentation.) Use the reverse side of this form if more room is needed to fully answer the following questions.

Primary Knowledge/Skills/Abilities related to presentation: Knowledge of scientific disciplines, and City HR and ethics training. Knowledge of rules and regulations governing all aspects of a drinking water laboratory for a large water utility.

Education (High School, Upgrades, Colleges and Degrees): B.S. in Chemistry

Professional Registration/Certification: Member of Oregon Technical Advisory Committee (OTAC) to Oregon Environmental Lab Accreditation Program (ORELAP), US EPA Drinking Water Microbiology Lab Certification Officer.

Related papers/instruction you have presented:

Title: _____ Date: _____ Event: _____

Title _____ Date: _____ Event: _____

Professional Organizations/Activities:

_____ Date: _____

_____ Date: _____

Course sponsor: _____

Signature of Instructor: Marsha Farooqui Digitally signed by Marsha Farooqui Date: 2024.09.12 09:01:13 -07'00' Date: 09/12/2024

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Date Evaluated: _____ By: _____ Approved: Yes_____ No _____

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