REGULATORY FUNCTION: **PUBLIC HEALTH** | **PH2F**

OBJECTIVE PH2

Regulatory compliance with water and sanitation safety plans is monitored through collected information on water quality

ACTION CARD PH2F

DEVELOP PROTOCOLS FOR INSPECTING LABORATORIES UNDERTAKING REGULATORY COMPLIANCE ANALYSES, IN CONJUNCTION WITH RESPECTIVE ACCREDITATION BODIES

COST: Medium **FREQUENCY:** One time

TARGET GROUPS: Regulators, laboratories, service operators, ministries of health

DESCRIPTION

Regulators support systematic audits or inspections of accredited laboratories on behalf of national health authorities. If delegated to regulators, this action is performed in accordance to transparent inspection protocols, predefined and accessible to accredited laboratories. These protocols must present how inspections are conducted, approved, and reported. Regulators must also transparently outline laboratories' obligations and rights during inspection procedures, along with the time sequence of audits.

EXPECTED OUTCOMES

- Accredited laboratories are regularly inspected.
- Dangerous impacts on public health are prevented.
- Water and sanitation safety plans are complied with by the implementation of corrective measures.

EXAMPLE: IRELAND

The European Council adopted Directive 2004/10/EC and Directive 2004/9/EC relating to the application of the good laboratory practice (GLP) principles. These Directives lay down the obligation of Member States to designate the authorities responsible for GLP inspections in their territory.

In **Ireland,** the National Standards Authority (NSAI) provides requirements for reporting and for the internal market (i.e., mutual acceptance of data), and procedures for inspection and verification of good laboratory practice (GLP). The standard which details criteria in relation to GLP and quality assurance is ISO 17025. Although accreditation to an NSAI standard is not a license requirement, all laboratories conducting analysis should have in place a robust quality system to demonstrate compliance with license conditions. In determining the performance characteristic of a method, and determining its suitability for test matrix data, the following must be obtained through evaluation and testing.

- Limit of quantification: the lowest concentration that can be determined with acceptable laboratory reproducibility and trueness.
- Accuracy: how close the measurement is to the true value expressed as the mean.
- Precision: how close the measurement is to the mean value expressed as the standard deviation.
- Uncertainty of measurement: uncertainty in the measured value.

To determine the suitability of a method and investigate for known interferences, 'spiking' should be conducted. This is the adding of a predetermined sample to a concentration in the range of interest or at least a minimum of 50% of this value. Recovery of the

added spike should not be significantly less than 90 percent or greater than 110 percent. When testing organic methods, recovery of the added spike should not be significantly less than 80 percent or greater than 120 percent.

LINKS

Irish Environmental Protection Agency:
http://www.epa.ie/enforcement/ensuringhighqualityaqueousemissionsmonitoringdata/goodlaboratorypracticesandqualityassurance

NSAI: https://www.nsai.ie

OECD Guidance on principles of GLP:
http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

INTERNAL CAPACITIES NEEDED AND THE ROLE OF PARTNERS

Developing protocols for inspecting laboratories undertaking regulatory compliance analyses, in conjunction with respective accreditation bodies, requires prior capacity in terms of an understanding of laboratory testing capacities and limitations, so as to set realistic inspection targets. Protocols will also need to factor in the capacity of inspecting institutions. Development partners can support ministries of health in providing targeted technical assistance for developing protocols, and in capacity training to conduct inspection activities.