

# 以 ISO/IEC 17025 國際規範建立實驗室認證及風險管理-

## 以屏東水生動物實驗室為例之常見問題探討

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### 摘要

ISO/IEC 17025 國際規範衷旨為維持實驗室的能力、公正性及一致運作，以達國家甚或是國際公信力。實驗室常利用風險管理措施，持續鑑別風險的種類，並找出風險所在，以及時採取適當措施確保實驗室之穩定運作。實驗室之風險必然存在，包括外部風險如：客戶抱怨、國家政策轉變及國際情勢動盪等及內部風險如：人員訓練、儀器設備及文件檔案等；「風險管理」即是在有風險的環境下，利用適當管理'法，把風險帶來的威脅降至最低。有別於以往實驗室只針對個別不符合工作加以作「矯正」措施，風險管理更加入較全面性「預防」的思維，成為 ISO/IEC 17025：2015 年版規範修正後認證實驗室的新課題。不良的風險管理會妨礙實驗室活動，甚至是產生新的危機，但良善的風險管理，可發掘潛在風險及提升實驗室公信力，本次以屏東水生動物實驗室為例，探討 2015 年迄今之不符合工作事項已發生情形，結果發現以品質管理居多。實驗室藉由 PDCA 管理循環模式(Plan→Do→Check→Action, PDCA)進行原因分析及風險評估，並經確實執行矯正措施後，成功使風險降低至實驗室可接受之低風險等級，並

持續保持監控，目前實驗室仍藉由持續定期蒐集相關案件實例加以分析討論，以優化實驗室的風險管理技術。

# **Establishing international laboratory certification and risk management procedure according to the ISO/IEC 17025 the Pingtung Aquatic animal Laboratory as a case study**

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## **Abstract**

The ISO/IEC 17025 International Standard specifies the general requirements for the competence, impartiality and consistent operation of laboratories and enables them to thereby promote confidence in their work both nationally and around the world. Risk management processes are often undertaken to enable laboratories to consistently inspect and identify possible risk factors hidden in the operation process of the laboratory and to deal with them with appropriate measures in time.

Risk factors are inevitably involved in laboratory operations and can be simply classified as external and internal risks. For instance, client complaints, policy changes, and the international turbulence are common external risks; on the other hand, common internal risk factors include employee training, the maintenance of experimental instruments, and the loss or damage of critical documents. In order to deal with these troublesome situations, the process of risk management is introduced into many operations.

The essence of risk management processes is to minimize the threat brought by risk factors through appropriate measures under risk-involved environments. Unlike the “Correction” process normally taken previously by laboratories which only fixes individual nonconformities, the risk management process introduces a much more comprehensive “Prevention” concept. After the amendment of ISO/IEC 17025: 2015 version, how to realize the essence of the risk management process has become a new task for accredited laboratories to carry out. Poor risk management not only sabotages laboratory operations, but also give rise to new crises; whereas excellent risk management prevents potential risks as well as promotes laboratory credibility.

As an example, at the Pingtung Aquatic Animal Laboratory, it was determined that quality management problems were the root cause of non-compliance for certain products from the 2015 to present. The laboratory employed the PDCA management cycle mode (Plan→Do→Check→Action) for cause analysis and risk assessment, and after the implementation of corrective measures, we were able to successfully lower

the risk factors to an acceptable low-risk level and maintain consistent surveillance on laboratory operations. Currently, the laboratory continues to collect relevant case studies for analysis and discussion, in order to optimize the risk management capabilities of the laboratory.