



Forensic Science Regulator

Regulator's Notification: No. 01-2024

Issue

Publication of the FSR's Lessons Learnt Review: Quality Failure in s5A Drugs Driving Analysis.

Background and Description of Notification

In January 2023, the National Police Chiefs Council (NPCC) issued a press release setting out that they had concluded their review into Synlab's analysis of drug driving samples, specifically Section 5A Road Traffic Act 1988 (Drug Driving) toxicology testing for controlled drugs (s5A analysis). The NPCC reported that 1,778 samples had drug levels reported by Synlab Laboratory Services as above the prescribed limit, and these results had been rescinded.

The Regulator has undertaken a wider Lessons Learnt Review that considers the events, decisions and organisational responses in this quality failure and outlines lessons learnt where actions should be taken to reduce the risk of a similar failure in the future. The Regulator will follow up on the learning points identified in this report through making amendments to the Code of Practice, engagement with stakeholders and reporting on progress and outcomes through the FSR Annual Report. There are four areas covered by the Lessons Learnt Review;

Underlying Science, this was subject to review by an Independent Adviser who established the root cause of the quality failure was the lack of the correct application of a robust scientific method and ineffective quality control processes such that the results reported to the CJS could not reliably determine that the level of drug or drugs found in a person's blood exceed the specified limit.

Wider organisational risk management, this focuses on the recognition of risks to the CJS by those involved in procurement of drugs driving analysis. The Regulator highlights the need for a more in depth consideration of risks in procurement and commercial processes used by police organisations.

Accreditation and Regulatory processes, accreditation and subsequent review work did not sufficiently expose the risks and it took a defence examination and the work of the Independent Adviser to reveal the root cause which ultimately led

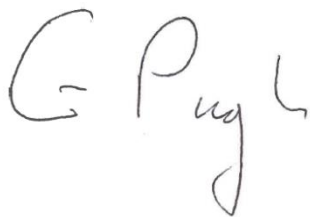
to the rescinded prosecutions. The Regulator highlights the need for more effective escalation of risks. At the time of this quality failure the Regulator had no statutory powers but now there is a statutory basis for regulation and the Regulator has powers to investigate and issue a Compliance Notice.

Effectiveness of the non-statutory Codes and regulatory requirements. The analysis of blood specimens to establish whether a person has a level of drug above the specified limit is an extremely complex scientific analysis not least in the levels of quality control and statistical analysis required to be confident that the level reported exceeds the specified limit. When the drugs driving legislation that set specified limits was introduced the then non-statutory Regulator set out the requirements that provided the basis for reporting consistent and reliable results through an Appendix to Codes. While there are a relatively small number of providers of drugs driving analysis to construct a regulatory approach that would allow this complex scientific analysis to be undertaken consistently was a major challenge and the approach adopted allowed for organisations to develop their own methods and policies for this analysis. The Regulator would not normally prescribe the method of analysis but drugs driving analysis is the exception that proves the rule and it is the Regulator's intention to adopt a more prescriptive approach to reduce the risk to the CJS of quality failure. A working group has been established to produce revised regulatory requirements that will be incorporated into the statutory Code.

The Regulator thanks those who contributed their views and accounts to inform this review and to the Independent Adviser for their detailed review into the scientific basis of the quality failure.

Any enquires about this lessons learnt review should be made to:

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14 May 2024