Notification on turnaround times (TATs) NF45

This notification is primarily aimed at laboratories accredited to EN ISO 15189 but may also serve as a useful guide for laboratories accredited to EN ISO/IEC 17025. The following notification includes information on appropriate actions to take when a laboratory is unable to meet published performance criteria – specifically their target or agreed turnaround times (TATs).

Definition from EN ISO 15189:2022:

> ***3.30 turnaround time**: elapsed time between two specified points through pre-examination (3.24), examination (3.8), and post-examination processes (3.23)*

Turnaround Times are mentioned specifically in two clauses of EN ISO 15189:2022

> ***5.5 d)** The laboratory shall establish quality indicators to evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives.*
> *NOTE Types of quality indicators include the number of unacceptable samples relative to the number received, the number of errors at either registration or sample receipt, or both, the number of corrected reports, the rate of achievement of specified turnaround times.*
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> ***7.2.6.1 f)** instructions for samples specifically marked as urgent, which include details of special labelling, transport, any rapid processing method, turnaround times, and special reporting criteria to be followed.*

In addition, TATs are normally part of the information provided to service users, in the form of a Laboratory User Manual or similar (*5.3 Laboratory activities*). They may also form part of Service Agreements (for example as part of national schemes or agreements with referring laboratories) (*6.7 Service agreements*).

Monitoring of TATs fulfils a different function in each situation, but the actions to be taken in the event that a laboratory fails to meet their agreed TATs are similar.

1. **Turnaround time as a Quality Indicator**
   In this situation the TAT is monitored as one of a range of indicators to give feedback on performance of the laboratory and identify any developing problems before they affect quality of the results issued and patient care (for example by identifying areas where there are insufficient staff). The limit for an 'acceptable' TAT should be set such that the laboratory is capable of meeting it when conditions are normal but sensitive enough that it provides an early warning signal of developing problems within the lab, while minimising risk to patient care.

2. **Turnaround times as part of a service agreement**
   A key piece of information required by laboratory service users is the amount of time they can expect to elapse between a patient sample being submitted and a result being issued for their patient. The TATs shall be defined by the laboratory and agreed with service users. These service users may be located within a hospital, a GP practice, another laboratory, or the general public. In some situations, the TATs may also be specified as a condition of participation in a national testing or screening scheme.
   TATs should also be documented in agreements with referral laboratories and monitored to ensure continued conformity as part of review and approval of externally provided products and services.

In either situation the actions to be taken when a laboratory is unable to meet their TATs are similar

- Review and identify the root cause(s) of the failure to meet TATs
- Implement corrective actions to improve TATs
- Review the TATs to confirm that they
    - Minimise the risk of delayed reporting of critical results
    - Minimise the delay in provision of diagnosis and/or treatment
    - Minimise risk to the patient of delayed diagnosis/treatment
    - Are realistic and achievable (i.e. not aspirational)
    - Continue to provide a useful signal as a KPI
    - Meet the agreed requirements of the service users (whether internal/external/national schemes)

- If it is determined that the TATs may be extended without negatively impacting patient care or service users, this may be considered as a corrective action. Extended TATs should be communicated to service users
- If it is determined that TATs cannot be extended, then the laboratory should implement corrective actions and continue to monitor TATs
- If laboratory continues to be unable to meet their TATs, it is a signal that the laboratory may not be meeting the requirements of clause 6.1 and may not "*have available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities*" and/or clause 6.2.1 a) "*The laboratory shall have access to a sufficient number of competent persons to perform its activities.*"

- In this situation the following should be considered;
    - Recruitment of additional staff
    - Reduction of service provided and/or workload
    - Use of referral laboratory
    - Increased automation
    - Suspension of accreditation for these tests (and a notification sent to INAB)

In order to demonstrate conformity to the standard, laboratories should be able to show evidence of:

- Clear communication with laboratory users (for example hospital staff, hospital management, GPs, referral laboratories). This should include appropriate revision of the laboratory handbook (or similar) to show actual rather than aspirational TATs, and evidence that pathology management and hospital management have been informed.
    - This includes communication with agencies responsible for implementing and managing national schemes, and records to demonstrate this.
    - Communication with laboratory users should be clear and specific, and updated regularly if TATs are extended further.

- There should be clear evidence of prioritisation both by specimen type and clinical risk to the patient. There should be evidence of communication with laboratory users to ensure that they are aware of the need to identify patients requiring urgent tests. Triage must be carried out by a competent person with sufficient training and experience to reliably assess which samples should be prioritised. The laboratory must demonstrate that such a policy is in place and is followed in daily practice.

- Laboratories should be engaged in quality improvement activities to improve the service to patients. There should be evidence of systematic review, and actions taken based on identified opportunities for improvement. Evidence of the support of hospital management, together with a clear time frame to implement change is essential. Evidence of such corrective action, together with audit of effectiveness would be required at the next assessment.