

SAHPRA Head Office
Building A
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Arcadia
0083

## **09 February 2024**

Enquiries: X-Ray Licensing Deputy Manager

Mr Mqondisi Maphophe

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**ATTENTION: INSPECTION BODIES** 

Dear Inspection Body(s)

Kindly take note of the following regarding Seal/Unseal:

- 1. No sealed machine should be tested/serviced without a Tech unseal letter.
- 2. Tech unseal should be requested from the SAHPRA inspector who sealed the unit (details are on the sealing stickers Licence holder can share that information).
- 3. Tech unseal should be requested in writing via email, and allow 3 days turnaround time for SAHPRA to process the request.
- 4. Inspection Body inspector must reseal the machine post the test/service, and tests must be uploaded in the Electronic Submission template.
- 5. Note that sealing of a machine is an enforcement action, and performing QC Tests/service does not mean the Licence holder should resume using the unit.
- 6. Permission to Unseal and permission to use the machine is granted to licence holder once QC tests are reflecting on the SAHPRA database, and the sealing inspector confirms no other outstanding non-conformances.

- 7. Inspection body must encourage the licence holders to do the follow ups to speed up their queries.
- 8. Note, as per POPI Act and Hazardous Substances Act licence holders' information will not be disseminated to the third party.

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