

From: s22
To: Kerr, Lisa; s22
Cc: s22
Subject: 2432 2425 Assessment Information Document PFE Extension to scope [SEC=No Protective Marking]
Date: Friday, 24 July 2020 2:21:58 PM
Attachments: [02432_02425_TBA_ail.pdf](#)
[02432_02425_TBA_aid.docx](#)

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Hello Lisa, s22 and s22

I trust my email finds you well.

As mentioned in my previous email, please find as attached the Assessment Information Document (AID) for your scope extension.

As well as the AID we will also require the following information to assist with the visit:

1. test methods (where they are not standard methods which is not freely available, a copy of the standard must be provided e.g. overseas standards as, we only have access to all AS methods on line): This will also include any TGA procedure/s where applicable;
2. completed worksheets for the proposed test;
3. completed (not necessarily issued) report for the proposed tests;
4. training, competency and authorisation records for the tests;
5. completed validations and/or verifications/proficiency testing (PT) / quality assurance program (QAP) enrolment details and/or results and/or other quality assurance activities as per the requirements of the relevant Application Document(s);
6. evidence of traceability of results;
7. equipment records as necessary, which may include calibration status, intermediary checks and maintenance.

If possible it would be quite useful to receive the completed AID as soon as practicable. We understand that until you have commissioned the equipment and undertaken training much of the requested information cannot be supplied.

Best regards

s22

National Association of Testing Authorities (NATA)

Web: www.nata.com.au

Level 1, 203 Fullarton Road,
Eastwood SA 5063 Australia

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24 July 2020

Dr Lisa Kerr
Therapeutic Goods Administration
PO Box 100
CANBERRA ACT 2601

lisa.kerr@health.gov.au

Dear Lisa

ACCREDITATION NO: 2432
FACILITY NAME: Therapeutic Goods Administration
SITE NO: 2425
SITE NAME: Laboratories Branch Biomaterials & Engineering
Biomaterials & Engineering

As requested, to assist with the proposed extension to scope I have attached an *Assessment Information Document* (AID) which I would ask you to complete and return as soon as practicable.

Please note as s22 sent you a copy of your current scope of accreditation early this year I have not included another copy.

We will also require the following information to assist with the visit:

1. test methods (where they are not standard methods which is not freely available, a copy of the standard must be provided e.g. overseas standards as, we only have access to all AS methods on line): This will also include any TGA procedure/s where applicable;
2. completed worksheets for the proposed test;
3. completed (not necessarily issued) report for the proposed tests;
4. training, competency and authorisation records for the tests;
5. completed validations and/or verifications/proficiency testing (PT) / quality assurance program (QAP) enrolment details and/or results and/or other quality assurance activities as per the requirements of the relevant Application Document(s);
6. evidence of traceability of results;
7. equipment records as necessary, which may include calibration status, intermediary checks and maintenance.

Your completed documents can be uploaded via our Members portal (attachments limited to 150 MB) or emailed to me at **s22** total email size limited to 24MB). If you are having difficulty uploading your completed documents or any associated records or if you do not receive confirmation of the receipt within a week, please contact me at NATA's Adelaide office.

When returning the completed documents please ensure that any electronic copies of records, procedures or other documents provided are cross referenced to the relevant question or embedded directly into the relevant section of the document. All information supplied will of course be kept confidential.

Please ensure you have the latest copies of all relevant accreditation criteria documents by visiting Accreditation Information on the NATA website. Accreditation Guidance and Information publications are also available from the website and include equipment tables, proficiency testing and measurement uncertainty information. If you have any problems accessing or downloading these documents please let me know.

In accordance with our Work Health and Safety responsibilities, could you please complete in the appropriate section of the AID, any possible health and safety risks the assessment team may be exposed to (including the need for personal protective equipment).

I also request that whilst on-site the assessment team be provided with a brief induction on safety and emergency evacuation procedures.

Please do not hesitate to contact me should you have any queries.

Best regards



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Encl. Assessment Information Document