


Document Information

Title:	
Document #:	Revision:
Status:	Vault:
Author:	Release Date:
Next Review Date:	Archive Date:

Language(s):
Scheme(s):
Impacted Departments/Programs:
Impacted Laboratories:
Document Notes:



Control Information

Owner:	Change Number:
---------------	-----------------------

All dates and times are in



Chemical Inhibitor Approval Scheme (CIAS) Formulation Assessment Audit Procedure

1. Introduction

This audit procedure defines the ongoing requirements for NSF Licence holders of CIAS approved products during their 5 year approval period.

A 'Primary' CIAS chemical inhibitor approved by the Technical Assessment Panel (TAP) will be granted a 'licence' for a period of 5 years. Additional 'factored' brands (secondary approvals), are licensed for the remaining period of the original licence.

2. Scope of audits.

All Primary approved products (chemical inhibitors) shall be subject to **formulation assessment audits** at the place(s) of manufacture and bottling, as appropriate, **twice** within the five year 'licence' period, (see clause 3 below).

3. Formulation Assessment Audit

The NSF CIAS Formulation Assessment Audit will verify the following:

- a) That no change to the formulation has taken place since the original approval was granted (verification of written statement);
- b) That the manufacturer, and or bottler as appropriate, continues to have in place a quality system having ISO 9001 accreditation, the issuing body must be accredited to ISO 17021 by UKAS (or equivalent via the European cooperation for Accreditation (EA) or International Accreditation Forum (IAF).
- c) That the method of manufacture is unchanged from when the original approval was granted;
- d) That the specification of the ingredients used in the formulation are as those confirmed at the time of approval;

Note: NSF will notify the license holder when their place of manufacture and or bottling plant is required to undergo a formulation assessment audit.

To ensure traceability, NSF will require a CIAS Audit Application Form (Form CIAS Audit 1) to be completed and returned to the NSF Scheme Account Manager. NSF will then issue the licence holder with a NSF sample number and instruct the auditor and licence holder of the chemical inhibitors that need to undergo the Formulation Assessment Audit. The auditor will then liaise with the licence holder/manufacturer/bottler to undertake the audit.

The auditor will then undertake the Formulation Assessment Audit using the Assessment Form (Form BC29) and will agree corrective actions at the conclusion of the audit, if required. NSF will confirm the audit findings and if appropriate the corrective actions that must then be undertaken.



Steps for Formulation Assessment Audit

1. NSF shall detail the inhibitor to be audited on the CIAS Audit Application Form and forward the form to the primary licence holder;
2. The licence holder shall fully complete and return the form to NSF;
3. NSF shall issue a sample number;
4. A NSF auditor shall liaise with the licence holder/manufacture/bottler to arrange a formulation assessment audit;
5. Formulation assessment audit undertaken;
6. NSF shall detail, in a letter, the assessment findings and further actions required, if appropriate;

The cost for the Formulation Assessment Audit, including travelling expenses and any subsequent administration, will be invoiced to the licence holder after the audit has been undertaken.

4. Failure of a Formulation Assessment Audit

Failure to comply with the requirements of 3(a), (c) and (d) will require full re-testing of the chemical inhibitor, together with suspension of the licence until such time that the new formulation can be shown to fully comply with the Scheme's requirements. A new application will be required by NSF and subsequently a new licence number will then be issued.

Failure to comply with 3(b) will result in NSF suspending the CIAS the licence until such time that the quality system can be shown to fully comply with the Scheme's requirements.

Administration costs/time incurred by NSF when dealing with audit failures will be invoiced to the licence holder at the Schemes professional rate.

5. Notification of the audit outcome

Pass: The licence holder will be notified formally by NSF that the chemical inhibitor has passed the Formulation Assessment Audit.

6. Audit Cost

Formulation Assessment Audits will be charged at the NSF professional hourly rate plus expenses. The NSF standard hourly rate will be charged for all time associated with the audit process including applications and processing the audit and submission to the TAP if appropriate.

Signature Manifest

Document Number: 29377

Revision: 01

Title: CIAS Audit Procedure CIAS 4

Effective Date: 01 Nov 2021

All dates and times are in US/EASTERN.

CIAS Audit Procedure CIAS 4

3 - Approval (QMS, AM, and Tech Review)

Name/Signature	Title	Date	Meaning/Reason
Simon Warburton (SWARBURTON)		01 Nov 2021, 08:35:04 AM	Approved

4 - Final Approval (Quality)

Name/Signature	Title	Date	Meaning/Reason
Andrea Jones (ANDREAJONES)		01 Nov 2021, 09:08:52 AM	Approved