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Chemical Inhibitor Approval Scheme (CIAS) Audit Procedure

1. Introduction

This audit procedure defines the ongoing requirements for BuildCert 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). Sample selection for performance audit testing should also be undertaken at the time of one of the audits.

All Primary products (chemical inhibitors) shall be subject to a **performance audit test** at least **once** within the five year 'licence' period, (see clause 5 below).

3. Formulation Assessment Audit

The BuildCert 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 operating in accordance with ISO 9001, 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). If this is not available a quality audit will be conducted by BuildCert.

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 those confirmed at the time of approval;

Note : BuildCert will notify the license holder when their place of manufacture and or bottling plant is required to undergo a formulation assessment audit. The audit must be undertaken within 6 months of this notification.

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To ensure traceability, BuildCert will require a CIAS Audit Application Form (Form CIAS Audit 1) to be completed and returned to the BuildCert Scheme Administrator (sarah.johnson@buildcert.com). BuildCert will then issue the licence holder with a BuildCert 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. BuildCert will confirm the audit findings and if appropriate the corrective actions that must then be undertaken.

Steps for Formulation Assessment Audit

1. BuildCert 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 compete and return the form to BuildCert;
3. BuildCert shall issue a sample number;
4. A BuildCert auditor shall liaise with the licence holder/manufacture/bottler to arrange a formulation assessment audit;
5. Formulation assessment audit undertaken;
6. BuildCert 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 BuildCert and subsequently a new licence number will then be issued.

Failure to comply with 3(b) will result in BuildCert undertaking an ISO 9001 quality audit, together with suspension of 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 BuildCert when dealing with audit failures will be invoiced to the licence holder at the Schemes professional rate.

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5. Performance Audit Testing

The BuildCert CIAS Performance Audit Test will verify the following:

a) That the chemical inhibitor continues to satisfy the performance requirements of the CIAS scheme.

BuildCert will notify the license holder when their chemical inhibitor is required to undergo a Performance Audit Test. The audit must be undertaken within 6 months of this notification.

To ensure traceability BuildCert will require a CIAS Audit Application Form (CIAS Audit 1) to be completed and returned, BuildCert will then issue the licence holder with a BuildCert sample number and instruct the licence holder of the Performance Audit Test that will need to be undertaken in accordance with the : *BuildCert CIAS Standard Specification for the Performance of Chemical Inhibitors for Use in Domestic Hot Water Central Heating Systems*

(NOTE: If the performance standard method has altered since that undertaken at the time of the approval then the original method at the time of approval shall be applied).

The cost for the Performance Audit Testing shall be agreed between the licence holder and the chosen CIAS BuildCert approved test laboratory.

The results of the Performance Audit Test must be forwarded to BuildCert by the testing laboratory, and to the licence holder. The results will then be submitted to the BuildCert TAP Committee for review, as required.

BuildCert will confirm the performance audit test result and, if appropriate, any further action to be undertaken.

The Scheme will retain the audit sample for future reference.

Steps for Performance Audit Testing

1. BuildCert shall detail the inhibitor to be audited and the performance test to be undertaken on the CIAS Audit Application Form and forward the form to the primary licence holder;
2. The licence holder shall compete and return the audit application form to BuildCert;
3. BuildCert shall issue a sample number;
4. The licence holder shall liaise with the independent test house upon testing to be undertaken;
5. Samples shall be selected by the BuildCert auditor and sent to BuildCert;
6. A sample shall be sent to the independent test laboratory.
7. The single Performance Audit Test, as detailed by BuildCert, shall be undertaken;
8. Test report sent to BuildCert and the licence holder
9. BuildCert shall detail, in a letter, the performance test findings and further actions required if appropriate.

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6. Selection of products for Performance Audit Testing

Three samples from a minimum sample batch size of 30 units on sale from the manufacturer's or bottlers in-house 'off the shelf stock', will be selected for Performance Audit Testing at the time of the Formulation Assessment Audit. These shall be selected and bonded by the BuildCert auditor. The audited company is responsible for forwarding these bonded samples to BuildCert. BuildCert will forward **one** sample to an independent test laboratory for performance audit testing.

7. Failure of a Performance Audit Test

If an inhibitor fails the Performance Audit Test, the laboratory will inform the licence holder and BuildCert immediately, and the remaining two samples may then be tested (see notes below).

Notes:

1) The licence holder may decide, after consideration, that the failure was an isolated incident in which case they can instruct the laboratory to undertake further Performance Audit Test using the two remaining samples (BuildCert to supply). Additional testing is at the license holder's expense. If both samples subsequently pass the test, then the chemical will be deemed to comply with the CIAS requirements and the results will be submitted to the BuildCert TAP Committee for review, as required.

2) Alternatively, the licence holder can provide a written assessment to the BuildCert TAP Committee, which includes a description of the anomaly found, the remedial action necessary, the estimated timescale needed to resolve the issue and how they intend to address any products affected that are currently available in the market place.

3) If the BuildCert TAP Committee disagree with the proposals, the licence holder will be notified and given the opportunity to provide an alternative proposal.

4) If the BuildCert TAP Committee further rejects the proposal then the licence holder will be informed and the Performance Audit Test shall continue using the remaining two samples held by the laboratory.

5) If the BuildCert TAP Committee accepts the proposal (original or final) from the manufacturer, then the manufacturer will be informed and required to provide further random samples (3) selected from new stock by a BuildCert representative, and subjected to a further Performance Audit Test.

If **two** Performance Audit Test results (in total) identify a failure, then BuildCert must receive a full explanation for the audit failures. BuildCert will then require full re-testing to be undertaken against the BuildCert performance standard and a full Formulation Assessment Audit must also be undertaken.

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If **three** Performance Audit Test results (in total) identify a failure, then BuildCert will suspend the 'primary approval licence' and any 'secondary approvals' associated with the chemical inhibitor, until a positive result from full retesting and Formulation Assessment Audit is received by BuildCert, agreed by the TAP, together with a full explanation for the performance audit failures. The licence holder and the secondary license holder(s) must also detail actions to address the issue of defective stock in the market place.

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

8. Notification of the audit outcome

a) **Pass:** The licence holder will be notified formally by BuildCert that the chemical inhibitor has passed the Formulation Assessment Audit or the Performance Audit, as appropriate.

b) **1 Test Failure**: The licence holder will be notified formally in writing by BuildCert that the chemical inhibitor has failed the Performance Audit Test requirements, and asked how they wish to proceed.

c) **2 Test Failures**: The licence holder will be notified formally in writing by BuildCert that the chemical inhibitor has failed two Performance Audit Tests, and asked how they wish to proceed.

The licence holder will be requested to acknowledge, in writing their intention:

i. To submit for full testing, or
ii. Not to resubmit, in which case, the 'licence' will be withdrawn immediately.
iii. Give an explanation as to why production samples of the inhibitor are now failing the performance audit test.
iv. The licence holder and the secondary license holder(s) must also detail actions to address the issue of defective stock in the market place.

d) **3 Test Failures**: The licence holder and any secondary license holders will be notified formally in writing that the chemical inhibitor has failed three Performance Audit Tests and that the 'licence(s)' have been suspended.

The licence holder will be requested to acknowledge, in writing, their intention, either to:

i. Submit for full testing, or
ii. Not to resubmit, in which case, the 'licence' will be withdrawn immediately.

9. Audit Cost

Formulation Assessment Audits and Performance Audits will be charged at the BuildCert professional hourly rate plus expenses. The BuildCert 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.