

Weisung KD01202052

Internal Biosafety Audit Procedure

1. Purpose

The purpose of this procedure is to establish a standardized process for conducting internal biosafety audits to verify compliance with applicable biosafety legislation, institutional biosafety requirements, and internal laboratory procedures.

Internal biosafety audits serve to identify potential risks, ensure continuous improvement, and provide documented evidence of compliance during inspections and quality audits.

2. Scope

This procedure applies to all laboratories and facilities operating under the institutional biosafety management system.

3. Regulatory Basis

Internal biosafety audits are conducted in accordance with:

- Swiss Ordinance on Protection against Major Accidents (SAMV), where applicable.
- Swiss Containment Ordinance (ESV; *Einschliessungsverordnung*).
- Institutional Biosafety Guidelines.
- Internal laboratory procedures.

4. Responsibilities

Biosafety Officer (BSO)

- The Biosafety Officer is responsible for:
- coordinating the internal audit programme;
- maintaining the audit checklist;
- reviewing audit results;
- monitoring corrective actions.

Sub-BSOs / Auditors

- The designated auditors are responsible for:
- conducting audits objectively and consistently;
- completing the approved Biosafety Audit Checklist;
- documenting observations and findings;
- reporting non-conformities to the Biosafety Officer.

Laboratory Personnel

- Laboratory personnel shall cooperate during audits and implement agreed corrective actions within the defined timeframe.

5. Audit Frequency

Internal biosafety audits shall be performed approximately **every two months**.

Additional audits may be conducted when required, for example following:

- significant laboratory modifications;
- introduction of new activities;
- incidents or near misses;
- regulatory or institutional requirements.

6. Audit Procedure

Audits shall be performed using the current version of the approved **Internal Biosafety Audit Checklist** (KD01202048).

The checklist covers, where applicable:

- laboratory organisation;
- biosafety practices;
- containment measures;
- waste management;
- documentation;
- training records;
- emergency preparedness;
- equipment;
- housekeeping;
- regulatory compliance.

The completed checklist forms the official audit record.

7. Audit Findings

Audit findings shall be documented and classified as appropriate.

Where deficiencies are identified:

- corrective actions shall be defined;
- responsibilities assigned;
- target completion dates established;
- implementation verified during the next audit or an appropriate follow-up review.

8. Documentation

The following records shall be maintained:

- completed audit checklists (KD01202048);
- records of findings; corrective action records; follow-up documentation, where applicable (Report KD01203628)
- Audit Plan (KD01203629)

9. Record Retention

Audit records shall be retained in accordance with the laboratory's document management and quality management procedures and made available upon request during internal or external inspections.

10. References

- Swiss Containment Ordinance (ESV)
- Swiss Ordinance on Protection against Major Accidents (SAMV), where applicable
- Institutional Biosafety Concept According to ESV and SAMV (KD00908975)
- Internal Biosafety Audit Checklist (KD01202048)