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LABS/Q® Actions and measures

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In a laboratory many activities occur which have to be carried out in a defined workflow according to specifications, SOPs, work or process instructions. There may be processes like OOS (out of specification), OOT (out of trend) or the handling of HACCP tests (Hazard Analysis and Critical Control Point). It could also be a DIN ISO 9000 audit with deviations occurring and ensuing actions and measures.

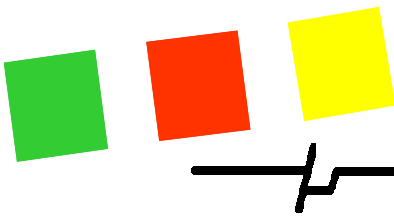
LABS/Q®-version 3.6 has implemented new, optional modules and functions to determine workflow actions and measures as well as carrying them out and evaluating data. Subsequently you will find a fictitious OOS procedure which shows how the newly implanted functions of **LABS/Q®** support laboratory personnel.

Planning a workflow to process an OOS

Company procedures are determined by responsibilities and company structures as well as existing SOPs. A special module is available to represent a specific workflow in **LABS/Q®**. This module determines how an OOS action and its measures are processed.

These are the stipulations:

- **Changes of status**
Chang-over of status to OOS as well as to its measures can be defined individually. You can determine which switch from status to status is possible.
- **Following actions**
After causal research is finished two repetition operations have to be done. Or a complete method repetition is necessary. Or a new sample has to be processed. Maybe a training scheme or a control of instrument or control type is necessary.
- **Information**
A distribution list for the OOS action and its possible measures is determined. It contains information who or which group of people will receive an automatic report following a specific action.
- **Responsibilities**
It can be defined who is responsible for which OOS action or following measures and how these persons can be automatically determined by the system.
- **Date targets**
A maximum period to process an action is determined here. Based on these specifications a deadline monitoring can be effected manually or automatically.
- **Check lists for individual actions**
Check lists and anticipated values can be determined here. Further procedures are initiated according to the results of the check lists.



Example: OOS

Top-Left Window: OOS Action Details

Vorlagen ID: OOS-START | Version: 0 | Aktionstyp: Out of Spec. | Status: in Bearbeitung

Bezeichnung: OOS Vorlage zum Start der OOS

Kurzbezeichnung: OOS Vorlage zum Start der OOS

SOP-Referenz: SOP1001Rev4.doc

Bemerkung: Die OOS soll gemäß der SOP ordnungsgemäß abgewickelt werden.

Text-Klasse zur Kategorie der Aktion festlegen: OOS

Maximale Bearbeitungszeit der Aktion in Tagen festlegen: 2

Gültig ab: 29.11.2005 | Gültig bis:

Top-Right Window: OOS Status Configuration

Welchen Bearbeitungsstatus soll die OOS-Untersuchung bei Erstellung erhalten? in Planung

Beispielingabe für den Wechsel aus Status 2 in 0 und 3: 0,3

Vom Status	erreikbaar		Bearbeitung erlaubt	Recht zum Statuswechsel
Vom Status 0	erreikbaar	1		QS_ERST
Vom Status 1	erreikbaar	0,5		QS_PRUEF
Vom Status 2	erreikbaar			QS_VERMERK
Vom Status 3	erreikbaar		Bearbeitung erlaubt	
Vom Status 4	erreikbaar		Bearbeitung erlaubt	
Vom Status 5	erreikbaar	0,6	Bearbeitung erlaubt	QS_ERST
Vom Status 6	erreikbaar	0,7		QS_PRUEF
Vom Status 7	erreikbaar			QS_VERMERK
Vom Status 8	erreikbaar			

Der Status 9 wird immer zugelassen, wenn der Benutzer das Recht Sperren besitzt.

Bottom Window: OOS Action Context Configuration

Testprüfauftrag: [Dropdown]

Betrieb: [Dropdown] | Statement verwenden | SQL Test zum Betrieb

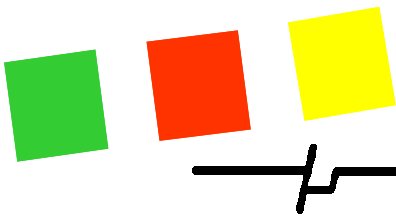
Labor: [Dropdown] | Statement verwenden | SQL Test zum Labor

Verantwortlicher: WINKER | Statement verwenden | SQL Test zum Benutzer

Opening an OOS action

In case of a specification violation the deviation must be dealt with as an OOS. Depending on the particular processing (e.g. sample sequence during chromatography) 1 up to n samples may be affected by this action.

LABS/Q® offers the option to include an OOS action during all results recording functions. All affected properties, even cross-sample ones, can be selected and assigned to the OOS. Depending on the configuration of **LABS/Q®** a submission release is only possible when the complete OOS is processed starting with the opening of an OOS action.



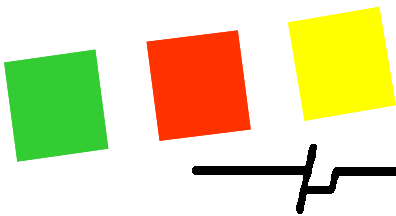
Example: Opening an OOS action within a result entry

Status	Prüfer	Kurzbezeichnung	Ergebnis	Einheit
		Appearance	clearly	
		Methanol	0.123	% (m/m)
		Ethanol	22.2	% (m/m)
		n-Propanol	1.23	% (m/m)
		unbekannter Peak	0.23	% (m/m)
		weiterer unbekannter Peak	< 0.10	% (m/m)
		i-Propanol	n.n.	% (m/m)
		n-Butanol	0.85	% (m/m)
		Summe Alkohole	24.4	% (m/m)

The OOS with a first measure is processed based on the specification “type of action” and “level of work” as well as planning information for the OOS and its actions.

Example of an OOS action

Bearbeitungsstatus	Bearbeitungsstufe	Maßnahme	Bezeichn
0 in Planung	Stufe 0	41	Ursachen



Processing an OOS and its measures

In case an OOS is pending its execution is often regulated via an SOP. Often an internal laboratory causal research is conducted first. This makes use of check lists as tools. Depending on the results authorised persons determine whether a repeated operation or a complete methodical repetition must be done or if even a new sample has to be analysed. After finishing the analysis the OOS is either closed or further actions are taken, e.g. a training session for employees. Maybe the method has to be revised.

In **LABS/Q®** the first measure (e.g. laboratory causal research) can be executed. When the measure is finished consequent measures can be added. You can determine for each measure whether the submission

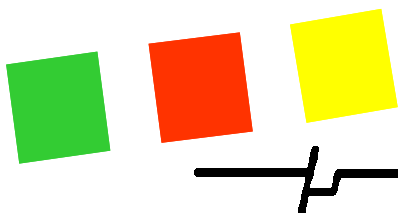
Example: OOS action with 1 action and a check list

The screenshot displays the '1802 - Modul 270' interface. On the left, a 'Checkpunkte bzw. geplante Maßnahme' table lists items like 'Berechnungen ok', 'Gerät kalibriert', and 'Standards in Ordnung'. The main area shows 'Aktions-Informationen' for action ID 30, 'Fehler aufgetreten', and 'Out of Spec.'. Below this is a 'Maßnahmen zur Aktion' table with one entry: '1 in Planung', 'Stufe 0', '41', 'Ursachen'. A 'Maßnahme' dialog box is open, showing details for 'Ursachenforschung im Labor' (ID 41) with a 'Bemerkung' field containing text about laboratory checks.

has to be supplemented by further operations or by additional samples. In case of the latter the submission is automatically supplemented by these specifications and the adequate status.

Example: Inserting further actions to the OOS

This screenshot shows the 'Maßnahme zum OOS einfügen' dialog box. It allows adding a new measure with fields for 'Vorlagen ID' (MASSNAHME), 'Aktionstyp' (Out of Spec.), and 'Bearbeitungsstufe' (Stufe 1). The 'Aktions-Informationen' section on the right shows the current OOS details, including the 'Bemerkung' and 'SOP-Dokument' fields. A table at the bottom shows the history of the OOS, listing creation and modification dates and users.



Evaluation of OOS/OOT actions

In **LABS/Q**® appropriate evaluation functions are at your disposal. These evaluations can be designed individually.

Example: Survey over all OOS's/OOTs during a period of time

HTML-View and Print - [c:\icd\labsq350\labsq350\00158908.htm]

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Auswertung zu OOS-Untersuchungen

Auswertungskriterien

OOS-Grund	Bearbeitungsstatus (OOS)
Stufe (OOS)	Erstelldatum von 01.01.2006 00:00
Erstelldatum bis	Abschlussdatum von
Abschlussdatum bis	OOS-Kategorie
Massnahmekategorie	Prüfplannummer
Batch-ID	Prüfanweisung
Externe Batch-ID	Externe Prüfanweisung
Massnahmen ausblenden	Aufträge ausblenden

Nein Nein

OOS-Nr	Grund	Bearb-Status	Stufe	Labor	Operator	QA-Ansprechpartner	Massnahme	Massnahmebez.	Auftrag	Prüfanweisung	Merkmal	Batch-ID	Material
11	FEHLER	0	0	QV	WINKER		12	Ursachenforschung im Labor	000000632	QV-PM-023	IDT001	200615	37086
13	FEHLER	0	0	QV	WINKER		14	Ursachenforschung im Labor	000000632	QV-PM-023	IDT001	200615	37086
18	FEHLER	0	0	QC	WINKER		19	Ursachenforschung im Labor	000000662	QC-PM-008	IDT016	200628	37848
19	FEHLER	0	0	RA	WINKER		20	Ursachenforschung im Labor	000000670	OES001	CD	2006/222	1008
20	Fehler aufgetreten	8	1	VIF-WVE	WINKER		21	Ursachenforschung im Labor	000000700	LDB-R056-01	VIF013	2/2006	R056

Datum Operator	Datum Supervisor (optional)	Datum Laborleiter / Qualitätsleiter
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1: 401