HALOPV 3.1 Release Notes
Final
Version 1.0
Department: Product Development

Document Approvals

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1. Overview

Insife "HALOPV" 3.1 contains new features described in the "**New Features and Enhancements**" section. Section "**Issues Addressed**" mentions all the issues addressed in this release.

1.1. Upgradability

HALOPV 3.1 can be upgraded from any previous HALOPV release. It can also be deployed as a standalone full installation.

1.2. Features affected in this release

The following features are affected in this release. For a detailed description of changes, please refer to section 3 below:

PSMF Module

- PSMF review form
- Workflow revision logic

Submissions module

- Submission overview

Requirements Intelligence module
- Form / field updates for Requirements Intelligence module

General features

- Attachment copying
- OneDrive integration (token expiry)
- User warning on load from OneDrive to HALO
- Notification placeholders (parent link)

Data loading
- Excel loader (formatting of loaded Excel files)

2. Compatibility

HALOPV 3.1 is compatible with the following systems:

- Argus 8.2.1.1 and Argus 8.2.3 (Please contact us for compatibility with earlier / later versions)
- ARISg 7.2 (Please contact us for compatibility with earlier/ later versions)
- Browser Compatibility
  HALOPV requires a JavaScript enabled browser and supports the current and prior major release of **Google Chrome**, **Mozilla Firefox**, and **Microsoft Edge**. HALOPV leverages Oracle APEX framework and is compatible with browsers supported by it.

  OBS: Support of **Microsoft Internet Explorer** will not be enabled from HALOPV 3.1 onwards.

The following Oracle Support documents should be considered for compatibility:

Oracle Software Web Browser Support Policy

https://docs.oracle.com/en/database/oracle/application-express/20.2/htmig/apex-installation-requirements.html#GUID-02BE4A34-B631-412C-8A82-EB92DABBACE0

At the time of release, Chrome was on version 85 and Edge on version 94.

3. Changes since last release

The following features have been updated in this release:

Area/Process/Group	Title	Description	Impact	Requirement traceability
PSMF module	PSMF review form (multiple reviewers)	The PSMF review form is updated to allow modification of the comments until completion of the workflow (non-current revisions cannot be modified).	**Minor** This change only impacts the PSMF module, and only workflows where the PSMF comment page (for caption of multiple reviewer comments) is used.	SS-39-PAGE-156 JIRA HAL-79
PSMF module	Workflow revision logic	The workflow revision logic is updated to avoid that the content of the PSMF Details form is included when a new revision of an Annex is initiated – instead the PSMF Detail form will be cleared. The previous entry can still be seen by opening previous revisions.	**Minor** This change only impacts the PSMF module. All workflows where the PSMF Details form is used will be impacted by the updated logic.	SS-04-30 JIRA HAL-89
Submissions module	Submission overview	The Submissions overview page has been updated to filter out any non-current and/or nullified data – this applies to both tabulations and line listings in the overview and works independent of the user-defined filters which can be set on the page	**Minor** This change impacts the overview of submissions (minor update to the filtering logic). There is no update to the actual Submission data stored in the system.	SS-39-PAGE-1000 JIRA HAL-70
General features	Attachment upload	The Attachment page (general record attachments) is updated to warn the user	**Minor**	SS-39-PAGE-113

		when loading files from the Working file area into the standard attachment area (warning the user to ensure that working files are closed in OneDrive before loading into to HALO).	This change only impacts customers using the OneDrive integration in HALO (Working files). There is no change to the actual logic, but the user receives a warning when loading OneDrive files into HALO	JIRA HAL-76
General features	Re-activation of records after soft-delete / nullification	The Nullification (soft-delete) functionality is updated to prevent users from re-activating records by clicking Initiate workflow – instead a dedicated button is now available (Re-activate record) which will un-delete the record. After re-activating a record, the user can then initiate the workflow using existing functionality.	**Minor** This update impacts all record types and workflows (the new functionality is general). The update is however minor, and the core functionality of case nullifications remains unchanged.	SS-04-30, SS-04-17, SS-39-PAGE-119 JIRA HAL-77
General features	Email notification links	Email notification functionality is updated with a new standard placeholder tag {LINK_PARENT_RECORD} (standard placeholders are hard-coded in contrast to the user-defined placeholders). The new placeholder tag dynamically inserts a link to the parent record of the record triggering the notification. This can be used i.e., to add a link to the ICSR, when a notification triggers on a submission record.	**Minor** This update has no direct impact on customers but allows the use of a new placeholder type in notifications. If taken into use, the impact is limited to the notifications where the new placeholder is applied.	SS-06-20 Notifications JIRA HAL-78
Data loading	Excel document formatting	The Excel Data loader is updated to remove Excel formatting before loading data into HALO. This ensures that data can be loaded independently of any formatting applied to the cells in the Excel source documents.	**Medium** This change impacts customers using the Data loader module to import external Excel-data into HALO.	SS-39-PAGE-122 JIRA HAL-90

			This change impact all data loader tasks by applying an extra step of processing while loading the Excel external data. From an end-user perspective, the update ensures that users should not need to worry about formatting of their uploaded source documents. There are minor changes to the loading process (making the progress tracking easier). This has no impact on the actual data loading mapping or logic.	
General features	Copying attachments	A new task action has been added to allow the user to copy attachments from the latest, previous record revision into the current revision – this might be desirable when the user wants to continue the work on the attachments in the new revision without having to download and re-upload the attachment (per default the user can access previous revision attachments, but they cannot be edited).	**Minor** This update does not add any new, core capabilities, but simplifies the task of moving existing tasks into the latest revision. Users can still perform the same process manually if desired.	SS-39-PAGE-132 JIRA HAL-84
Form updates	Minor field updates to existing forms	The following new fields are added: *ICSR Requirement details form > Include Placebo Cases?* (only available on Clinical case types)	**Minor** These are all minor configuration updates of existing forms. The updates only impact customers using the Requirements Intelligence module and the SDEA organizational entity forms.	URS 01.15 (no update) JIRA HAL-156

		Signal Requirements form > 2 Is signal notification required for marketed products? > Signals being refuted? *Signal Requirements form > 2 Is signal notification required for marketed products? > Timeline* *Signal Requirements form > 2 Is signal notification required for marketed products? > Signals leading to label update?* *Signal Requirements form > 2 Is signal notification required for marketed products? > Timeline* *Organizational entity form (SDEAs) > Partner product in scope for SDEA* (free-text)		

4. Bugs resolved in HALOPV 3.1

Area/Process/Group	Title	Description	Impact	Requirement traceability
General features		The OneDrive integration (used for Working files) is updated to improve the stability of the OneDrive connectivity. The HALO Azure login function is updated to check the lifetime of the existing token. Only if expired (+ 20 minutes) a new token is created (before, a new token was created for each call)	**Minor** This change only impacts customers using the OneDrive integration. From an end user perspective, functionality remains the same but provides a more stable integration with OneDrive.	SS-39-PAGE-113 JIRA HAL-72, JIRA HAL-35
General features		Minor bug fixes to the notification framework: - Backend notifications are updated to avoid sending notifications to users with read-only access to the record where the notification triggers - Email content is updated to send valid links also for closed records (not in active workflow)	**Minor** This update impacts customers using email notifications. The update are minor improvements / fixes to existing functionality and do not include any core new features	SS-06-20 Notifications JIRA HAL-64

5. Features removed from HALOPV 3.1

Support of Internet Explorer browser

6. Known issues & workarounds

There were no known issues from HALOPV 3.1.

7. Contact

Contact Insife service desk (support@insife.com) for any query related to installation or changes in this release.

8. Change Log

Revision	Date	Author	Description
1.0	29-OCT-2021	Praveen Gupta	New document