



Deviation Control (DevCon)

Brief Description: Process-driven application for the management of deviations or

variations (controlled waivers to operate outside the integrity envelope

provided risk mitigation is in place)

Front End Software: Web-Based (Internet Explorer 6.0 or newer)

Database Platform Supported: MS Access, Oracle, MS SQL Server (any version)

Functionality Details:

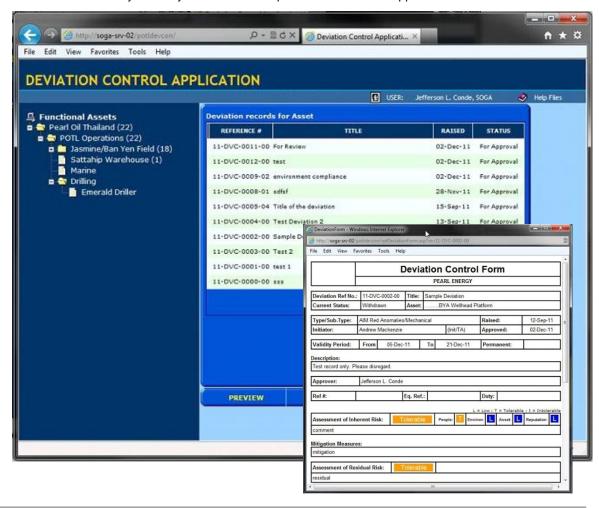
DevCon leads the user through the process involved in raising, approving and managing deviations.

Automatic reminder emails are sent out to staff whenever an action is required from them.

DevCon features configurable, role-based user control. Users can only update data when it is appropriate to their role.

Deviation or variation control procedures vary from client to client, however at a high level, a role-based process of raise-review-risk assessment-approve-closeout is generic across clients. DevCon is designed around this generic process, and can be easily configured to specific client procedures.

DevCon can be used stand-alone or integrated with the ISR application. When used with ISR, Deviations can be initiated directly from any Red Condition reported within the ISR application.



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DevCon includes the following specific functionality features:

- Web-based front end
- User registration, role assignment, user rights assignment
- On-screen display and function permissions according to user role
- Event driven automatic email notification to configurable recipients
- Automatic update of deviation status according to configurable rules
- Paperless, process driven logic configurable to follow client's procedure
- Suite of reports

