

Safety Case regulations for Major Hazard Facilities in Cuba

Ilizástigui Pérez, Fidel

Nuclear/Process Safety Specialist, Office for Environment and Nuclear Safety Regulation (ORASEN)

Calle 28 N.504 entre 5ta y 7ma, Miramar, Playa. Cuba

This paper provides an overview of Cuban Safety Case regulations, their historical development and present status and an overall description of how the Safety Case regime has been implemented both in the offshore and onshore major hazard industries in Cuba.

Keywords: Safety Case regulation, Major Hazard Safety regulation, Safety of Major Hazard Facilities

An Overview of the Cuban Safety Case Regulatory Regime

Historical development

The development of the Safety Case regulatory regime for major hazard facilities (MHFs) in Cuba was heavily influenced by the decision taken by the Cuban government to begin deep water exploration drilling activities in the Cuban Economic Exclusive Zone (EEZ). The first attempt to implement a ‘Safety Case’ regime began simultaneously with the plans to drill the first deep water exploration well in the EEZ in 2002. The Cuban Safety Case regulatory approach follows the spirit of the UK Safety Case regime and is focused on major accident prevention. The regime is embedded within a wider prescriptive environmental regulatory framework.

The historical development of the Cuban Safety Case regime can be divided in four periods as indicated below, along with information on the main activities and key deliveries associated with each period:

First period (2002-2003), associated with the planning and construction of the first deep water exploratory well in the Cuban Economic Exclusive Zone (EEZ) in the Gulf of Mexico (GOM).

- ORASEN Regulatory Guidance “Guidelines for the preparation of the Risk Evaluation Reports for offshore drilling facilities (now superseded).
- ORASEN Regulatory Risk Evaluation Assessment Report (containing the results of the Regulatory review of the Risk Evaluation Report).

Second period (2004-2008), associated with the introduction of ‘best practice’ IADC HSE Case guidelines for MODUs.

- ORASEN Regulatory Guidance GRIS 1.1: Guidelines for the preparation of Safety Cases for drilling facilities of oil and gas offshore wells (still in force) [4].
- ORASEN Regulatory Guidance GRIS 1.2: Guidelines for the preparation of Safety Cases for land-based major hazard facilities (still in force) [5].
- ORASEN Regulatory Guidance GRIS 1.21: Safety Assessment for Major Hazard Facilities (still in force) [8].
- The introduction of Safety Cases as an element of permissioning within the Environmental Impact Assessment Process and the Environmental Licence. CITMA Resolution 132 “Rules for Environmental Assessment Impact Process” [3].

Third period (2009-2012), associated with lessons learned from Montara and Macondo accidents.

- ORASEN Resolution No. 73 [9], containing requirements on Safety Case Addendums (SCA)/Well Safety Cases aimed to address well major hazards and jointly prepared by the Well Operator and the Drilling Contractor before the commencement of the well construction activities at the well site.
- The preparation of Safety Case Addendums (SCAs) by Operators with the use of the Bowtie Major Hazard Management Process (BMHM)
- The regulatory review, acceptance and audit of SCAs by ORASEN

Fourth period (2013 - Present); associated with the approval of the Ministerial Resolution 148/2013 which established a Safety Case regulatory regime for all MHFs in Cuba.

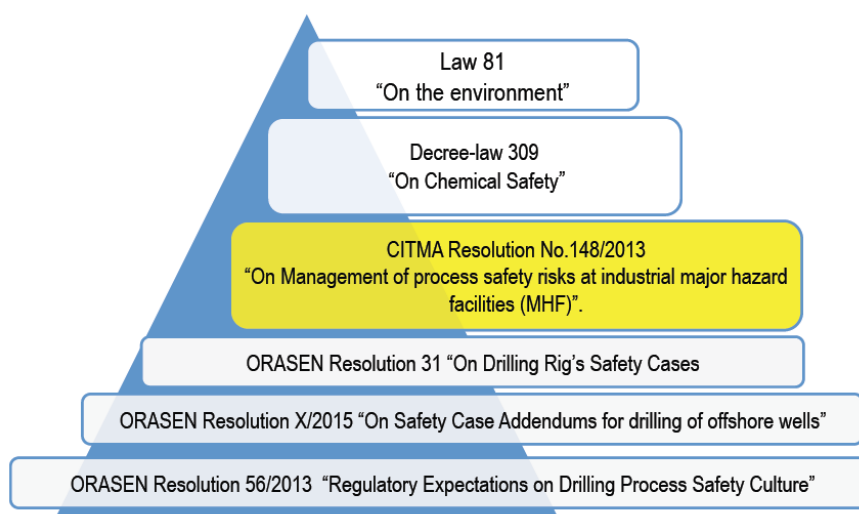
- The issuance of the Decree-Law No.309 “Chemical Safety” and its associated Ministerial Resolution 148/2013 ‘Rules on the management of process safety risks for industrial major hazard facilities’ [1]
- ORASEN Resolution on Regulatory Expectations on Process Safety Culture for Well Operators (Licensees) and Drilling Contractors during deep water drilling activities [10]
- ORASEN Regulatory Guidance GRIS 1.12: Guidelines for the preparation of Safety Case Addendums/Well Safety Cases for deep water exploratory drilling in the EEZ of the GOM (under development) [9]
- Transposition of the Safety Case regime to land-based MHFs

- Preparation and regulatory review of Safety Case Production Plans (SCPP) for land-based MHFs
- Capacity-building Training Courses on planning of Safety Case production process and Human and Organizational Factors (HOFs) in major hazard safety.

The Cuban ‘Regulatory Pyramid’ for Process (Major Hazard) Safety

Fig. 2 depicts the so-called ‘Regulatory Pyramid’ as it exists today for Process (Major Hazard) Safety in Cuba. The Environmental Law which is the overarching regulation for the protection of the environment, constituted the ‘umbrella’ under which the next lower hierarchical level was created by the introduction of the Decree-Law 309 ‘On Chemical Safety’. The Decree-Law 309 specifically addresses aspects concerning the safe management of hazardous chemicals following a ‘from cradle to grave’ approach. It contains specific requirements covering the safety of facilities that produce, process, use and storage hazardous chemicals of the type and in such quantities that can lead to major chemical accidents (termed ‘major hazard facilities’).

Fig.2 Regulatory Pyramid for Drilling Process (Major Hazard) Safety regulation in Cuba



CITMA. Ministry of Science, Technology and Environment

The next lower level corresponds to the CITMA Resolution 148/2013 which further expands the requirements of the Decree-Law 309 by establishing a Safety Case regime for the regulation of major hazard safety at industrial MHFs.

At the lowest level (Fig. 2) there are several ORASEN Resolutions which contain guidelines for the preparation of Safety Cases for drilling facilities of offshore oil and gas wells, land-based major hazard facilities (not shown), Safety Case Addendums/Well Safety Cases, and land drilling facilities (not shown). There is also an ORASEN Resolution that specifically addresses the regulatory expectations regarding process safety culture in deep water exploratory drilling activities (see p. 2.4 ‘Process Safety Culture in deep water exploration drilling’)

CITMA Resolution 148/2013 comprises the following Chapters and Sections summarised in Table 2 below:

Table 2. Contents of the CITMA Resolution 148/2013

Chapter	Sections	Contents
I. General Provisions		Terms and definitions Scope of application
II. Responsibility of Facility Owners in process safety management	First Section	Responsibilities for process safety
	Second Section	Process safety culture and leadership
III. Process Safety Management System	First Section	General requirements
	Second Section	Commitment to process safety
	Third Section	Understanding of process safety hazards and risks
	Fourth Section	Management of process safety risks
	Fifth Section	Learning based on process safety performance
IV. Technical Integrity of Safety Critical Elements.	First Section	Assurance and verification schemes for safety critical elements (SCEs)
	Second Section	Integrity of hydrocarbon wells
	Third Section	Third Parties carrying out independent examination and verification
	First Section	Purpose
	Second Section	Content

V. Facility Safety Case	Third Section	Safety Assessment description
	Fourth Section	Process Safety Management System description
	Fifth Section	Emergency preparedness and response at the facility
	Sixth Section	Limits and conditions for safe operation
	Seventh Section	Use of industry's safety standards and rules within the Safety Case
VI. Safety Case process	First Section	Duties of the Facility Owner
	Second Section	Duties of the Regulatory Authority
	Third Section	Safety Case preparation
	Fourth Section	Safety Case Preparation Plan
	Fifth Section	Participation of consultants in the preparation of the Safety Case
	Sixth Section	Presentation of the Safety Cases to the Regulatory Authority
	Seventh Section	Regulatory review of the Safety Case
	Eighth Section	Acceptance of the Safety Case
	Ninth Section	Duty of the Facility Owner to comply with the Safety Case in force
	Tenth Section	Verification conducted by the Regulatory Authority on compliance with the Safety Case in force
	Eleventh Section	Updating and review of the Safety Case
	Twelfth Section	Review of the Safety Case for operations associated with well of hydrocarbons
	Thirteenth Section	Periodic review of the Safety Case
Special Provisions		

The Safety Case and the Environmental permissioning regime

As was mentioned, the Safety Case regulations operate under the umbrella of the Environmental Law. For MHFs, the Environmental Impact Study (EIA) along with the 'documented' Safety Case constitutes the main documents submitted by the Facility Owners (The Licensees) to the Regulatory Authority in support of the Environmental Licence Application [3].

Unlike the Environmental Impact Assessment (EIA), the Safety Case is not approved but accepted by the Regulator. This establishes a major difference in the way the requirements regarding environmental protection (associated with normal facility operation), and major hazard safety (major accidents) are reflected, respectively, in the Environmental Licence conditions. With regard to major hazard safety, there is a single condition within the Licence requiring the Licensee to comply with the accepted Safety Case (i.e. the Safety Case 'in force' for the facility).

Types of Safety Cases for onshore (land based) and offshore Major Hazard Facilities

Resolution 148/2013 states the following requirements regarding the presentation of Safety Case to the Regulatory Authority:

1. Land-based major hazard facilities:

- The Facility Safety Case must be submitted according to a Safety Case Preparation Plan (SCPP) which is prepared by the Facility Owner and submitted to the Regulatory Authority for acceptance in support of the Environmental Licence application before the commencement of the construction stage of the facility. No construction/installation activities on SCEs are allowed to begin without a SCPP accepted by the Regulator.
- The 'documented' Facility Safety Case (SC), prepared by the Facility Owner according to the SCPP, is submitted to the Regulator Authority for acceptance in support of the Environmental Licence application before the commencement of the operation stage. The Facility Safety Case must be accompanied by the third party review of the Safety Case. The operation of the MHF is not allowed to begin without an accepted SC.

2. Offshore major hazard facilities

- For offshore drilling facilities, the 'documented' Facility Safety Case prepared by the Drilling Contractor must be presented by the Licensee (Well Operator) to the Regulatory Authority for acceptance. Before submission, the Licensee must carry out an independent review of the Rig Safety Case and provide a 'Statement of Adequacy', whereby they express their agreement in relation to the adequacy of the Rig Safety Case for the intended well construction operations. No offshore drilling facility is allowed to enter the drill site without an accepted Safety Case.
- For offshore deep water wells, a Safety Case Addendum (SCA)/Well Safety Case has to be prepared jointly by the Well Operator and the Drilling Contractor, and submitted by the former to the Regulatory Authority for acceptance at least 30 days before the commencement of the well construction activities. The SCA must be accompanied by the results of an independent third party review. No well construction activity at the drill site is allowed to begin without an accepted SCA.

3. Revised Safety Cases – All Major Hazard Facilities

- Revised Safety Cases are submitted by the Licensee to the Regulatory Authority for acceptance along with the corresponding request containing the aspects subjected to review/revision, the reasons why it is needed and timelines for completion. The Regulatory Authority will accept/reject the revised Safety Case within 30 days from the date of submission. Safety Cases subjected to periodic review (5 years) are presented in support of the application for the renewal of the Environmental Licence.

Regulatory review, acceptance and enforcement in relation to the Safety Case

In relation to MHFs, ORASEN is a single Regulatory Authority in Cuba which deals with issues of major hazard safety and environmental protection. Specific timelines are prescribed for the regulatory review of Safety Cases: SC (60 days), SCA (30 days), revised SC (30 days).

The decision to accept the Safety Case requires satisfaction of the Regulatory Authority with the Licensee's approach to controlling major hazards. The Regulator accepts the validity of the described (in the documented Safety Case) approach as being capable, if implemented as described, of achieving the necessary degree of risk control. But the Regulator does not confirm the outcomes of that approach.

The results of the regulatory assessment and review process are reflected in a Technical Assessment Document (TAD) containing information on the revisions made and the final conclusions in relation to the rejection/acceptance of the Safety Case. The decision on acceptance is formalised with the issuance of the Environmental Licence.

Resolution 148/2013 establishes the duty of the Facility Owner to comply with the accepted SC or SCA. In connection with these obligations, the Regulator carries out audits and inspections in order to:

- Check whether the Licensee is fulfilling its prime responsibility for safety by adhering to the commitments made in the accepted Safety Case.
- Assess the effectiveness of the system for the management of risk of major accidents during facility operation in compliance with stated regulatory requirements; and
- Assure itself that the Licensee uses the Safety Case as part of the process of continuous improvement

The Regulator is developing an enforcement model which will allow for a gradual application of enforcement actions, depending on the performance of the Facility Owner. The Regulator has the ultimate power to suspend the validity of the Safety Case in force for the facility.

Process Safety and Disaster Reduction

Resolution 148/2013 and Directive 1 which deals with the reduction of disasters (approved by the President of the National Defence Council), form an integrated and coordinated system for the control of risks of major accidents during the execution of offshore drilling activities. Fig.3 reflects the particularities of each system.

Fig.3 Characteristics of the regulatory systems for major accident prevention and disaster reduction

Goal	Prevent Major Accidents		Mitigate Major Accidents
Regulatory Tools	Rig Safety Case	Safety Case Addendum	Disaster Reduction Plan
Addresses	Rig Process Safety	Well Integrity	Disaster Reduction (Oil Spill/Blowout Response)
Legal Basis	CITMA Resolution 148/2013		Directive 1 President of the NDC
Regulator	ORASEN		EMNDC
Regulatory Action	ACCEPTANCE		APPROVAL
Permissioning Tool	ENVIRONMENTAL LICENCE		CERTIFICATE OF COMPATIBILITY

The use of technical rules and standards within the Safety Case

Resolution 148/2013 places on Facility Owners the responsibility for the specification within the Safety Case, of those safety technical rules, norms and standards (and the corresponding control measures derived from them) that were used as the basis for demonstration that risks have been reduced to a level that is As Low As Reasonably Practicable (ALARP). Additional requirements are specified during this process:

- To show that any safety rule, standard, norm or code is adequate and suitable for the specific major hazard facility considering, among others, its type, magnitude, location and the activities carried out at it or in connection with it.
- To demonstrate consistency among safety rules, norms, codes and standards used, when they form part of different normative systems

The Owner must take compensatory measures if a safety rule, standard, norm or code:

- does not address all kind of incidents that represent the main concern for the facility
- contains gaps which do not allow it to cover all aspects related to the hazards and risks present at the facility
- is outdated with respect to good current safety industry practices, or has been recently updated in such a way that the facility is not in compliance with it
- is in compliance with best current safety practices but it is being applied in the facility or its parts thereof, that have been designed to earlier safety standards and rules

Macondo Lessons Learned: The Safety Case Addendum

The responsibility of the Well Operator

The Safety Case regime established in Cuba before Macondo allowed Drilling Contractors to demonstrate how effectively they managed their process/major hazard safety risks at their facilities through the preparation and implementation of Rig Safety Cases. The Macondo (as well as Montara) accident vividly showed the crucial role the Well Operator played in accident causation and, therefore, the need to reinforce his prime responsibility for ensuring not only the integrity of the well, but the safe conduct of the drilling campaign as a whole.

In an attempt to emulate the best regulatory practice already adopted by Drilling Contractors through the IADC HSE Cases Guidelines, in 2010 ORASEN issued Resolution No. 73 [8], which is now covered in Resolution 148/2013, which extended the Safety Case regime to deep water well construction activities and made Well Operators accountable for both the safety of the whole drilling campaign (The 'Licensee' role) and the management of well integrity risk (The 'Well Operator' role). The emphasis of the SCA is on the management of well barriers and prevention of loss of well control events during well construction operations.

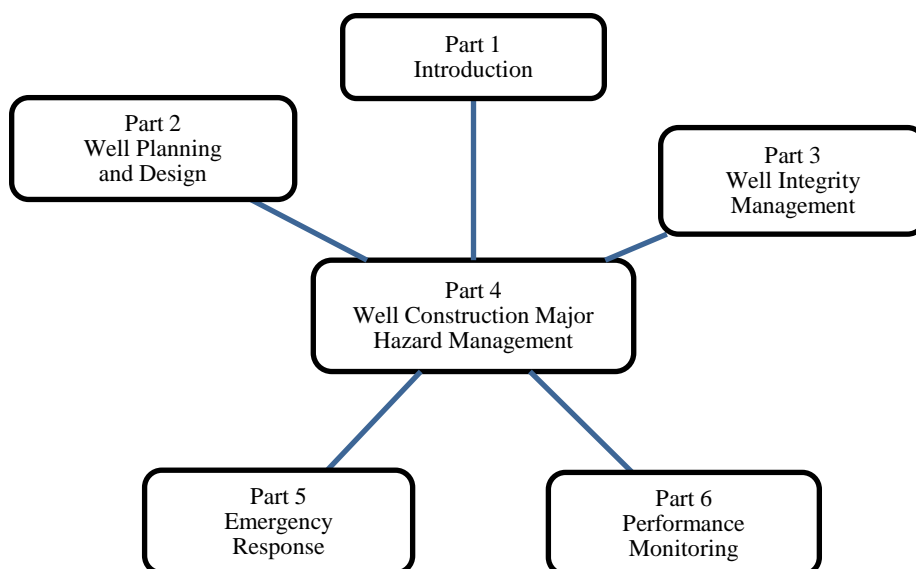
The preparation and submission of the SCA is carried out as explained in p. 1.3.1 above. The SCA thus constitutes the principal means by which Well Operators demonstrate that they have taken all measures necessary to prevent major accidents resulting from loss of well control events and mitigate their consequences. The purposes of the SCA are:

1. Demonstrate internal assurance within Well Operator and Drilling Contractor organizations that deep water well construction activities can be safely managed and that the risk of occurrence of major accidents, in particular loss of well control incidents (i.e. uncontrolled releases of formation fluids) that impact people and the environment during the conduct of these activities are reduced to a level that is ALARP; and
2. Demonstrate to the Regulatory Authority that the following have been achieved:
 - All necessary control measures have been taken to reduce the risk of uncontrolled release of formation fluids throughout the construction of the deep water exploratory well.
 - Management of Change (MoC) and risk assessment processes will apply during well construction activities and competence of the personnel responsible for well control will be assured.
 - Specific responsibilities are assigned to Well Operator's personnel for the integrity of the well and a mechanism is in place for the Drilling Contractor to intervene in case unsafe acts are identified.
 - A sharing of the required well design and construction information, and the Rig Safety Case between the Well Operator and the Drilling Contractor has taken place.
 - An alignment between the Well Operator and the Drilling Contractor Management Systems has been assured in such a way that their respective safety standards are not compromised and that all applicable regulatory requirements are met.

Scope and content of the SCA

The structure of the SCA is reflected in Fig. 3 and the scope and content of each one is summarised in Table 4. below.

Fig. 3 Structure of the SCA



The central part of the SCA is Part 4 “Well Construction Major Hazard Management Process”. It is a process by which the Well Operator demonstrates that all necessary control measures have been taken to reduce the risk of loss of well control and other well integrity incidents, to a level that is ALARP; in particular:

- All Well MAH hazards associated with well construction activities have been identified and their risks evaluated and understood (in particular those related to the loss of well control).
- Sufficiently independent and effective control measures (barriers) are in place to manage those risks to a level that is ALARP; and
- Appropriate management arrangements are in place to support the identified control measures; by ensuring their ongoing integrity and effectiveness.

Table 4. Scope and content of the SCA

1.	Introduction	<ul style="list-style-type: none"> • Objective and scope of the SCA • Ownership of the SCA • SCA production, review and approval processes • Remedial Action Plan (RAP) • Justification for commencing of well construction operations • Management of the Well Construction Project • Well summary information • Rig selection & Safety Case gap analysis information
2.	Description of Well design & Barriers	<ul style="list-style-type: none"> • Well Basis of Design (BOD) • Well Drilling/Test/Abandonment Programs • Well Barrier Policy and Philosophy • Well Control • Statement on compliance with technical rules and standards (i.e. US Drilling Safety Rule, US NTL 06/2010, API Std. 65 Part 2, Montara Action Plan) • Arrangements/schemes of Independent Well Examination
3.	Well Integrity Management during construction	<ul style="list-style-type: none"> • Introduction • Leadership and commitment to well major hazard safety/integrity • Policies and Objectives • Organization, roles and responsibilities + Bridging arrangements (BA) • Major Hazard Risk Management + BA • Drilling Program and Written Work Instructions + BA • Management of Change (MoC) + BA • Human Factors

		<ul style="list-style-type: none"> • Emergency response + BA • Performance Monitoring + BA • HSE Assurance + BA • Management Review + BA
4.	Well Major Hazard Management	<ul style="list-style-type: none"> • Overview of the Well Major Hazard Risk Management Process • Identification of Well Major Accident Hazards (WMHs) • WMAH Risk Assessment • WMAH Bowtie & ALARP Workshops • Compilation of WMAH Risk Register • Identification of Well Safety Critical Elements/Barriers (WSCE) • Development of WSCE Performance Standards (PS) • Development of WSCE independent verification/examination schemes
5.	Contingency planning (linked with the Disaster Reduction Plan, DRP)	<ul style="list-style-type: none"> • Identification of Worst Case release (WCR) scenarios • Blowout Offshore Contingency Plan (BOCP) and Oil Spill Contingency Plan (OSCP) • Emergency Response Organization and Notification • Maintenance of Emergency Response Measures
6.	Performance monitoring	<ul style="list-style-type: none"> • Limits and Conditions for safe (drilling) operations • Well Major Hazard performance indicators • Compliance with ORASEN Resolution 56 On Process Safety Culture expectations during deep water drilling in the Cuban EEZ

The SCA as a risk management tool

The SCA is intended to be an effective tool for managing well process safety risks, actively used throughout the well construction process both by those who carry out the well constructions tasks and take important decisions that can impact on the well integrity (i.e. Well Site Supervisor and Offshore Installation Manager, OIM). Ownership of the SCA by the workforce can be improved by the use of the Bowtie Risk Management methodology as part of the Major Hazard Management Process. Highly interactive Bowtie Major Hazard Workshops (BMHWs) are carried out for each of the WMHs identified in the Well Construction/Drilling HAZID.

The BMHW are led by the Well Operator, facilitated by external consultants and witnessed by the Regulator. All key players involved in the well construction operations participate in the workshops (e.g. Drilling Contractor, Cement/Mud/Casing Subcontractors, Supply Vessel Operator, Emergency Response Organizations, Helicopters Operator and others). The scope of BMHWs is shown in Table 5 below.

Draft Bowties diagrams are prepared and reviewed by all the participants and the following activities carried out:

- Well/Campaign specific Major Accident Hazard Scenarios are agreed as applicable to the operation/location
- Causes and consequences associated with the scenarios are reviewed and confirmed or rejected
- Existing control measures are reviewed and their effectiveness assessed. Improvement actions are agreed in order to eliminate any existing gap in the control measures
- New control measures are identified and implemented in order to reduce the risk of loss of well control/wellbore integrity to ALARP levels.
- Responsibilities are allocated to responsible persons for ensuring integrity of the identified barriers and controls
- Final Bowtie diagrams are agreed and approved by responsible people from Well Operator (Project Manager) and Drilling Contractor (Rig Manager)
- Final Bowties diagrams are communicated to workforce offshore.

Table 5. Scope of Bowtie WMH Workshops for deep water well construction (typical)

	WMH- 1.1 Shallow gas blowout	WMH-1.2 Well kick	WMH-1.3 Blowout	WMH-1.4 Bad cement job/casing failure	WMH-1.5 Plug failure	WMH 1.6 Major Oil Spill – Tier 3	WMH-1.7 Loss of Stability (Rig SC Bowtie)	WMH-1.8 Vessel Collision (Rig SC Bowtie)	WMH-1.9 Helicopter Crash (Rig SC Bowtie)	WMH-1.10 Rig Evacuation	WMH-1.11 Well Testing
Overall Well			●			●	●	●	●	●	
Spudding and drilling of 8 ½” pilot hole (to 20” casing setting depth)	●										
Drilling 42” hole section	●										
Run and cement 36” conductor				●							
Drill 24” hole section	●										
Run and cement 20” surface casing				●							
BOP and Riser running	Rig Safety Case (RSC) “Dropped Objects” Bowtie										
Drill 17½” hole section		●									
Run and cement 13 3/8” casing				●							
Drill 12½” hole section		●	●			●					
Run and cement 9 5/8” casing				●							
Drill 8 ½” hole section		●	●								
Wireline logging and VSP											
Well Testing											●
Abandonment					●						

Process Safety Culture in deep water exploration drilling

In 2013, ORASEN issued Resolution No. 56/2013 [8] which addresses regulatory expectations on process safety culture for deep water exploration drilling activities. According to this Resolution Well Operators and Drilling Contractors must provide in their SCAs information to show that Safety Culture is a concept that is well disseminated, implemented, fostered and continuously developed within their respective organizations. The main aspects covered by this Resolution are:

- Definition of Process Safety Culture
- Basic traits of a Positive Safety Culture
- Requirements on Well Operators and Drilling Contractors regarding self-assessment on Process Safety Culture.
- Requirements regarding the Safety Culture Improvement Plan (SCIP)
- Requirements to submit the results of the self-assessment to ORASEN as part of the ‘documented’ SCA

Implementing a Safety Case regime for land-based (onshore) MHFs

The need for planning the Safety Case production process

The Safety Case regime is widely implemented by oil companies in many regions of the world. IADC HSE Case guidelines are regarded by Drilling Contractors and Oil Companies as a best practice for preparation of Rig Safety Cases and since they operate globally, rigs that entered Cuban waters to carry out deep water drilling operations already had a valid Safety Case in force. The situation in the onshore industry was entirely different as the industry relied on self-regulation and compliance with prescriptive rules and standards. Also, the approach followed to ensure safety of the facilities was one that emphasized accident mitigation at the expense of accident prevention.

The regulator was aware of this situation and decided to adopt an implementation strategy, according to which only a limited number of new MHFs would be incorporated into the regime (at least initially). By reducing the amount of facilities entering the regime, they could manage the ‘burden’ associated with the introduction of stricter requirements and allow for a gradual process of capacity-building and learning, for both Operator and Regulator.

Bearing in mind the lessons learned from Victoria (Australia) and the Nimrod Review, associated with the process of preparation of Safety Cases, the biggest concern of the regulators was the possibility that Facility Operators would regard the Safety Case requirement as the obligation to prepare a document to satisfy the regulator and would not see it as a valuable learning process and an effective risk management tool.

Some requirements were then introduced into Resolution 148/2013 which imposed obligations on the Facility Owners to plan in advance their own Safety Case Production process with the aim of ensuring:

- A proper understanding of both the ‘letter’ and ‘spirit’ of the Resolution 148/2013
- That major hazard/process safety issues are dealt with at the design stage
- That Safety Cases are written ‘right first time’
- Good quality Safety cases, by the avoidance of tight deadlines for their completion
- A process of gradual learning and capacity building for regulators, facility owners and other third parties involved in the Safety Case production (i.e. external consultants)

Following the approval of the Resolution, there were attempts to extend the regime automatically to as many facilities as possible, including some older operating facilities. However, it was then quickly realised that the inclusion of older existing facilities at this stage presented an unacceptable burden on the resources of the Regulatory Authority. As a result, although all major hazard facilities, whether new or already operating, are required to submit their plans for Safety Case production to the Regulator for acceptance but the actual number of MHFs that were allowed to enter the regime is kept minimal (6 in total).

The Safety Case Production Process

As it was mentioned earlier, it is a Facility Owner’s responsibility to define how they intend to produce their own Safety Case. The Facility Owner is required to demonstrate that its Safety Case production process satisfies the requirements set forth in Resolution 148/2013. Facility Owners must show and ensure in their plans that:

- A high level of commitment from the Senior Management towards the Safety Case process exists (i.e. resources, workforce consultation).
- Measures are taken to ensure the quality of the Safety Case process by protecting it from the known ‘common cause failures’, such as resource limitations, tight production schedules, commercial incentives and/or operational pressures.
- An easy-to-use, understandable and accessible (for end key users) document will be delivered on time.
- It will be used as an effective risk management tool in decision-making and management of change processes, supervision and verification of safety critical tasks, training of workforce and identification of corrective actions.
- It will be subjected to review by an independent and competent person and any identified shortcomings addressed and resolved before submission to the Regulator for acceptance.
- The Safety Case will be used as a means to foster and support the development of a strong safety culture

In addition, Facility Owners must implement (as part of their management systems) processes and procedures which address:

- Requirements related to the scope and content of the Safety Cases
- Responsibilities (and competences) for the preparation, implementation, updating and verification of Safety Cases
- Responsibilities for the approval, independent revision of Safety Cases and submission to the Regulator
- Control of Safety Case documentation, including procedures for updating and review of Safety Cases
- Reasons that trigger a review of the Safety case
- Schemes of independent SCE verification and well examination, as appropriate.

The Safety Case Production Plan (SCPP)

The SCPP is a document that contains both the strategy and the plan for the production of the Safety Case. As indicated in p. 1.3.1 above. The SCPP must be submitted to the Regulator for acceptance. The SCPP is aimed at ensuring that Operators:

- Understand the Safety Case regulations and requirements (via a gap analysis against the Resolution 148/2013)
- Plan their Safety Case production work and ensure the resources needed to comply with stated deadlines for completion
- Plan the involvement and consultation of the workforce and other interested parties

The SCPP should include the following:

- Scheduling of tasks and deadlines for Safety Case production
- Methodologies used to carry out the Formal Safety Assessment (FSA)
- Processes of involvement and consultation with the workforce and other interested parties; and
- The manner in which the integrity of the Safety Critical Elements (SCE) will be ensured during construction and installation works (in the case of new facilities)

Presently, Operators are submitting SCPPs that contain information which includes both the Strategy and Plan for the production of their Safety Cases as indicated in Table 6 below:

Table 6. Content of the SCPP (Strategy and Plan)

Strategy	Organization and resources	<ul style="list-style-type: none"> ▪ Senior managers' support ▪ Organizational structure (roles, responsibilities, accountabilities and reporting lines) ▪ Safety Case process leadership (Safety Case lead) ▪ Safety Case Process Manager (SCM) ▪ Safety Case Team (SCT) ▪ Safety Case Authors (SCA) ▪ Intelligent Customer's resources ▪ Independent reviewers (IR) ▪ Safety Case Advisor (if needed)
	Scope and purpose	<ul style="list-style-type: none"> • Clear purposes and scope
	Process	<ul style="list-style-type: none"> ▪ Indicators to monitor the 'health' of the process ▪ Measures against 'common cause failures' (CCFs)
	Lessons learned	<ul style="list-style-type: none"> ▪ Applicable operating experiences (both internal and external)
	Final product	<ul style="list-style-type: none"> ▪ Requirements against to which the end product can be measured (e.g. accessibility and usability)
Plan	Production Plan	<ul style="list-style-type: none"> ▪ Scope of tasks (gap analysis against the requirements of the Resolution)
	Methods, methodologies and resources	<ul style="list-style-type: none"> ▪ Rationale for the selection of methodologies (e.g. for hazard identification, risk assessment and the selection of control measures) ▪ Interactions among the preparation tasks ▪ Workshops to be conducted (i.e. HAZID, Bowtie Workshops) ▪ Number, skills and competence of the resources involved in each of the preparation tasks. ▪ Role of any external resources involved and the extent of involvement
	IT tools and softwares	<ul style="list-style-type: none"> ▪ IT tools (i.e. Electronic Safety Cases). Safety analysis software
	Consultations	<ul style="list-style-type: none"> ▪ Details of the consultation process, types of consultation and use of the outcomes of the consultation process

Shortcoming in the SCPP preparation

The most common shortcomings that regulators have identified in the submitted SCPP are:

- Inadequate specification of the Safety Case production process (resources, workforce consultation, management, measurement of progress, quality assurance)
- The information is limited to the Formal Safety Assessment (FSA) without addressing the management/integrity aspects (process safety/integrity management arrangements)
- No independent verification of the Safety Case is specified
- The Safety Case is perceived as a document rather than a 'documented process'
- Human Factors are largely ignored or not considered at all
- The production of the documented Safety Case has been outsourced to external consultants and the Facility Owner does not plan to act as an 'Intelligent Customer' in relation to the outsourced parts of the Safety Case.

Capacity-building training and workshops

In order to enhance the quality of submissions of the SCPPs, two training courses have been prepared and are expected to be delivered in 2017 to Facility Owners, Consultants and Regulators. A 5-day training course is focused on the Safety Case preparation process and covers the following topics:

- Process safety, Process Safety Management, Human Factors and Process Safety Culture & Leadership
- Safety Case regulations (Resolution 148/2013), Facility Safety Cases, Formal Safety Assessment (FSA) and Assurance of SCE integrity
- Bowtie Risk Management Methodology for the production of Safety Cases
- Planning of the Safety Case Production process. Lessons learned from Nimrod and Victoria
- Practical sessions and exercises

Other 3-day training course focuses specifically on Human and Organizational factors (HOFs) in major hazard safety and covers the following topics:

- Evolution of Human Factor approach to major hazard safety
- Process Safety Culture & Leadership
- Top 10 Human Factors in process safety

- Practical sessions and exercises

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