

## Safety Case process in Cuba: Transition from theory to practice

Fidel Ilizástiguí Pérez, Principal Consultant, Todus Advisors, Cuba

Hani Salem Morales, Consultant, Risquest Safety Consultants, Cuba

Cuban Major Hazard Safety regulations require that Facility Operators produce Operational Safety Cases with the aim of demonstrating that they can manage their risks from major accidents during facility operation to a level that is As Low as Reasonably Practicable (ALARP).

The production of a good quality Safety Case is a complex issue and must be cautiously approached by Facility Operators. Lessons from the Victoria Safety Case implementation and the Nimrod Review highlighted the need to ensure that a robust Safety Case process is in place before starting the work. The latter is of paramount importance in producing a Safety Case that is SHAPED (Succinct, Home-Grown, Accessible, Proportionate, Easy-to-understand and Document-lite).

This paper provides insights into the manner in which the Cuban Regulator requires Facility Operators to produce their Operational Safety Cases in accordance with a Safety Case Preparation Plan, which must be previously accepted by the Regulator. The Plan must be written in a way that defines the Safety Case process, emphasizes ownership and leadership of the process by the Facility Operator, maximizes workforce involvement in the production of the Safety Case deliverables and demonstrates and facilitates accessibility and usability of the final product – the documented Safety Case.

The paper also provides information on the ‘Pilot’ Safe Case strategy which is a step-by-step, case-by-case process, currently implemented by the Regulator, to lessen the ‘burden’ of compliance with Safety Case requirements stated in the Regulations. According to this strategy the entry of Major Hazard Facilities into the new regime will take place gradually and will not be linked to any specific licensing process.

Keywords: Safety Case regulations, Safety Case process, Major hazard safety

### Introduction

In 2013, Cuba issued Resolution 148 of the Ministry of Science, Technology and Environment (CITMA) which implemented the Safety Case approach to major hazard safety regulation for both offshore and onshore (land-based) Major Hazard Facilities (MHF), hereinafter, ‘the Regulations’.

Experience gained from the application of the Safety Case approach to regulation of major hazard sectors in developed countries (United Kingdom, Australia) has pointed to a need for the safety case process to be carefully planned and executed in order to secure the multiple advantages that the approach provides for the management of major hazard risks.

Given the importance of having a robust safety case process in place, the Cuban Regulator is presently focusing on incorporating information that demonstrates robustness and effectiveness of the process in the Safety Case Preparation Plan (SCPP) that Facility Operators (Facility Operator) must prepare and submit to the Regulator for acceptance before commencing Safety Case production.

In order to lessen the ‘burden’ of compliance with Safety Case requirements stated in the Regulations, the Cuban Regulatory Authority is implementing a ‘case-by-case’ and ‘step-by-step’ strategy, according to which the entry of MHFs into the new regime will take place gradually and will not be linked to any specific licensing process. The idea of producing ‘Pilot’ Safety Cases has its origins in the study of the ‘Exemplar’ Safety Cases in Victoria, Australia (PACIA, 2003).

### Lessons learned from preparation and implementation of Safety Cases: Victoria and Nimrod

The Cuban regulator carried out an in-depth study of the experiences gained from the wide scale implementation of the safety cases in developed countries with mature regulatory frameworks. This revealed that any attempt to implement the Safety Case approach in an aggressive timeframe, and without creating a set of minimal conditions, can lead to considerable expense in terms of time, resources, money and most importantly, the expected results in terms of safety not being fully attained. An important lesson that was learned – the preparation and subsequent implementation of safety cases is a huge, time-consuming, costly and challenging task both for the industry and the Regulator.

#### Victoria, Australia

Lessons learned from the preparation and implementation of Safety Cases for land-based MHFs in Victoria, Australia, pointed out that the Safety Case process must be planned thoroughly and minimal conditions created to ensure the delivery of a good quality Safety Case. The Cuban Regulator incorporated lessons learned from Victoria Safety Cases by introducing specific requirements into Regulations which require Facility Operators to produce Safety Cases in accordance with a Safety Case Preparation Plan (SCPP) that should be accepted by the Regulator. In this way, previous recommendations contained in the Regulatory Guide GRIS-1.2 “Preparation of Safety Cases for land-based Major hazard facilities” in 2009 were further consolidated and expanded, taking into consideration further recommendations issued in Australian WorkSafe’s Guidance Note: Safety Case Outline (Worksafe, 2011). They included:

- a) The obligation of Facility Operators to prepare a SCPP and submit it to the Regulator for acceptance before commencing the Safety Case production work.
- b) The purpose, scope and content of the SCPP.

- c) Change proposals to the SCPP.
- d) The manner in which the SCPP should be reviewed by the Regulator.
- e) The use of consultants and third parties in the production of the Safety Case.
- f) The regulatory review and acceptance of SCPP by the Regulator.

### **The Nimrod Review**

Another important source of learning in relation to the Safety Case production work was obtained from the study of the Nimrod Review. Lessons learned from the Nimrod Review covered many areas involving the safety case process and its formal roles: Safety Case Owner, Safety Case Authors and Independent Reviewers, as well as organizational and cultural aspects of the process, all of which it is not feasible to summarise here. In addition, Safety Assessment Principles (SAPs) and 'Right First Time Safety Case (RFTSC)' concept developed by UK Office of Nuclear Regulation (ONR) were also considered by the Cuban Regulator in an attempt to address the underlying reasons for poor quality safety cases by focusing on causes (safety case process) and not symptoms (final product).

It is the Facility Operator's responsibility to define how they intend to produce their own Safety Case. As regards the Safety Case process and the documented Safety Case, Regulations required that:

- A high level of commitment on the part of Senior Management exists towards the Safety Case process (in terms of resources, workforce consultation, etc.).
- 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 Safety Case (for key end users) is delivered on time.
- The Safety Case is 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.
- The Safety Case is 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 is used as a means to foster and support the development of a strong safety culture

Despite these additional requirements introduced in the Regulations regarding some of the key potential weaknesses of the Safety Case production, it was felt that the extent of coverage of Safety Case aspects in the Regulations was insufficient to address the totality of key potential weaknesses associated with both the process and the final product (the documented Safety Case).

More recently, the Cuban Regulator has conducted additional studies of available published guides from the UK Office of Nuclear Regulation (ONR) on the safety case process as well as recommendations from the UK Nuclear Safety Case Forum Guide "Right First Time Safety Cases": How to Write a Usable Safety Case (UK SCF, 2014). The Cuban regulator strongly believes that all these recommendations are of significant value to ensure the robustness of the safety case process in other major hazard industry sectors apart from the nuclear sector. They represent an invaluable guidance on how to produce Safety Cases that are SHAPED (Succinct, Home-Grown, Accessible, Proportionate, Easy-to-understand and Document-lite), as it was suggested by Haddon Cave QC in his 'Best Practices for Safety Cases' contained in the Nimrod Review (Haddon Cave QC, 2009).

### **How MHF Operators are presently developing their SCPP**

#### **The 'daunting' reality**

With the approval of the Regulations came the next challenge, which was to ensure compliance with the above requirements, both regarding the safety case process and the safety case as the final product. Civil defence regulations which existed before the Regulations required the Facility Operator to conduct Hazard, Vulnerability and Risk Studies (HRVS) for land-based MHFs with disaster potential. HRVS were carried out for the purposes of preparation of Disaster Reduction Plans (DRP) and thus, the focus was essentially on accident mitigation. These studies were carried out entirely by external consultants with limited involvement of the Operator's personnel, not actively reviewed by Operators and prepared solely to satisfy the Regulator under a 'compliance' mentality. In addition, resulting Actions Plans (APs), which contained improvement actions, were not consistently followed up. In summary, drafting of the DRP was seen as the final goal and HRVS sat on the shelf.

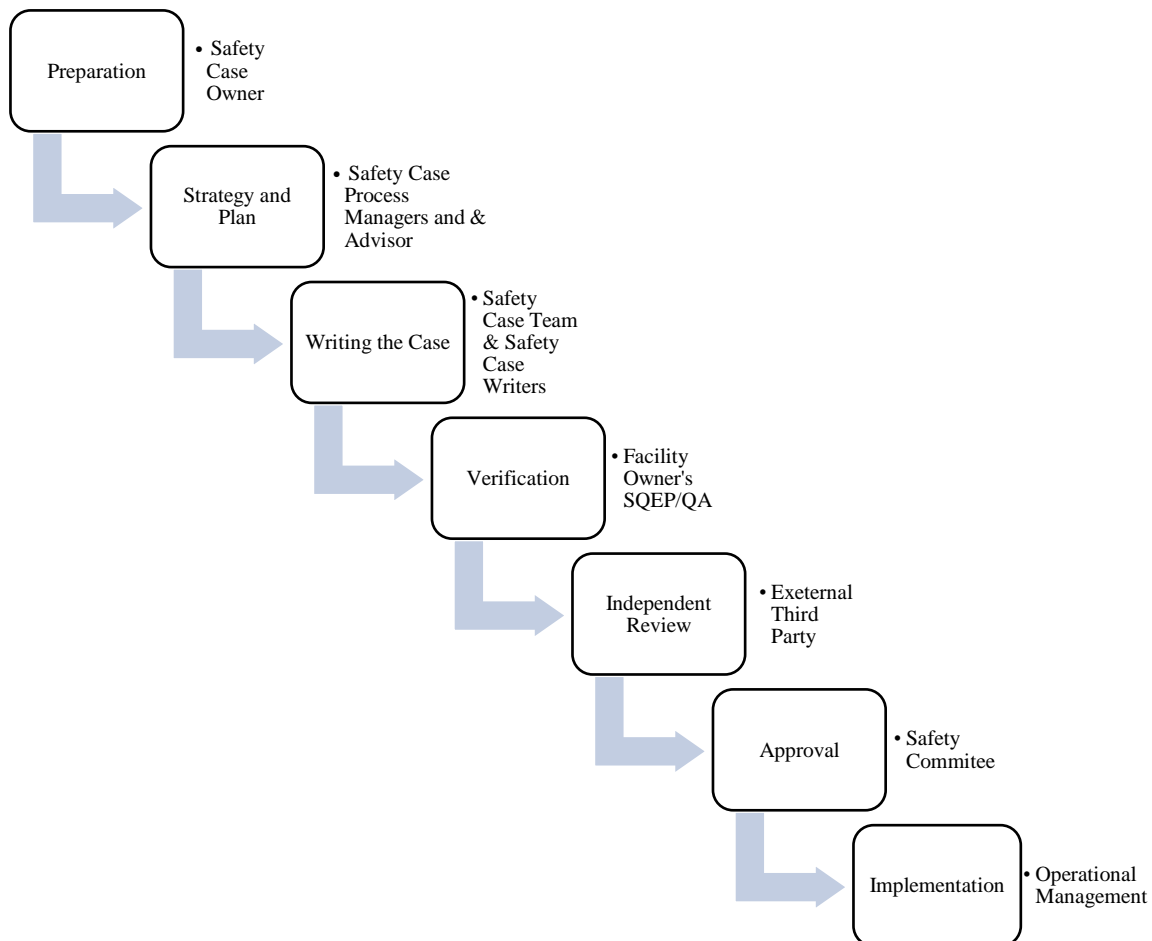
With the advent of the Regulations, they continued seeing the Safety Case requirements as another document that needed to be produced to satisfy the Regulator and not as a 'true' learning process that needs to be planned, owned, conducted, monitored and challenged by the Facility Operator itself. The 'compliance' mentality was therefore entrenched and it is proving to be a very important obstacle to overcome to create a new mindset.

## The Safety Case process and its essential features

As we are all aware now, the process of producing the Safety Case is as important as the final product. In this regard, a good quality, SHAPED Safety Case can only be the result of having a robust Safety Case process in place.

All this challenged the old, 'compliance' mentality. Facility Operators should now hold prime responsibility not only for the adequacy of their Safety Case, but also for the robustness and effectiveness of the whole safety case process. The Cuban Regulator is now requiring Facility Operators to think thoroughly how they are going to produce their safety cases by ensuring that the whole process for delivering the safety cases is well defined, demonstrably robust and reliable. In addition, they have to ensure that the process is continually monitored to ensure it remains robust.

The Cuban Safety Case process model that is being currently followed by Facility Operators, replicates the one recommended by UK ONR with typical elements in the whole safety case process as shown in fig. 3 (UK ONR, 2016)



**Fig. 1: The Safety Case process (with process stages)**

In order to address all aspects regarding the Safety Case production are addressed in one document, the Cuban Regulator allows Facility Operators to include aspects of the whole safety case process in their SCPP. It must explain the process, reflects the safety case production strategy and contains details on how the respective safe case deliveries will be produced according to a specific timescale. The Cuban regulator also allows Facility Operators to involve experienced safety case consultants in the preparation of their SCPP. This is meant to ensure the incorporation of existing best Safety Case practices whilst providing support to Facility Operators to enhance understanding and knowledge in relation to regulatory expectations in this regard.

Presently, the Facility Operators must show within their SCPP a demonstration that the Safety Case process:

- Is well defined, robust and reliable
- Is designed and operated commensurate with the hazard, using concepts that apply to high reliability systems
- Is protected from known common cause failures that can affect the entire safety case process (i.e. resource limitations, programme pressures, commercial interests and incentives)
- Exhibits some kind of diversity within the process, such as an independent review, by suitably qualified and competent persons, that are independent from those involved in the preparation.
- Takes into consideration the needs of those that will use it to ensure safe operation

- Will be permanently monitored to ensure its continued robustness
- Takes into consideration the manner in which different levels of documentation are integrated to cover the entire scope and content of the document.
- Is managed as any other project, by applying best practice principles of project management

In addition, in order to ensure that each of the stages in the safety case process is effective the following is also required:

- A clear specification of the purpose, standards and expectations of each stage of the Safety Case process
- Identification of potential weaknesses and failure modes and the appropriate defences or barriers designed to prevent the failure of the safety case process due to: resource limitations, time pressure due to schedule delays, economic and incentive motivations, commercial and operational pressures.
- Monitoring and testing of the process, carried out to ensure that each stage continues to function according to required standards and specifications.
- Feedback mechanisms to ensure significant aspects of safety case quality are reviewed and underlying defects and weaknesses of the process are eliminated.
- The definition of necessary training and qualifications for formal roles within the process to ensure that those who adopt formal roles are suitably qualified and experienced.

### Management arrangement with formal roles

The SCPP should clearly state how the Facility Operator ensures management of the Safety Case process through definition of an organizational structure with formal roles. Fig. 2 shows the typical management arrangement that is being adopted by Facility Operators for the Safety Case process and the formal roles within the process.

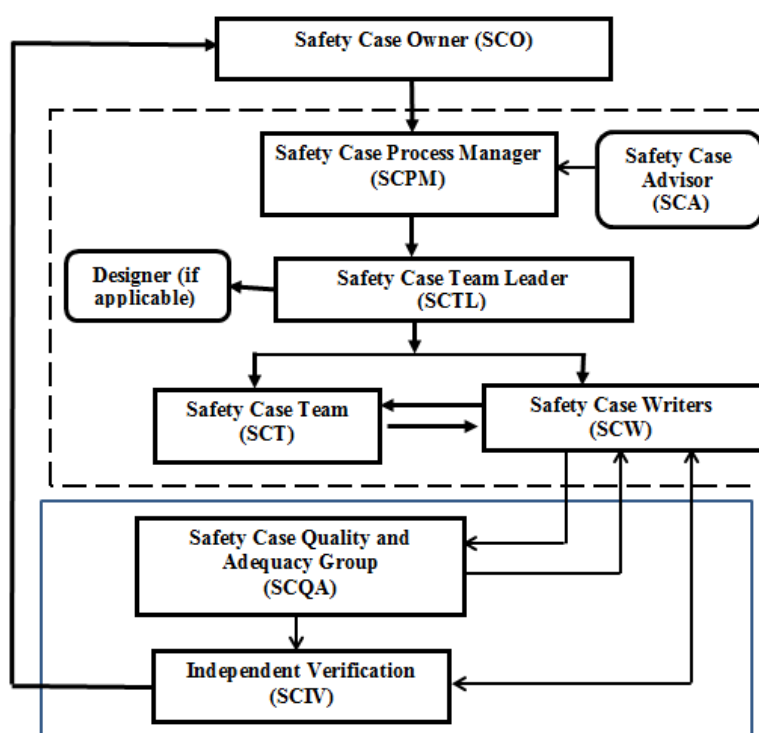


Fig. 2: Management arrangement and formal roles

The brief overview of responsibilities for each of the formal roles is shown in Table 1 below:

Table 1. Formal roles and responsibilities within the safety case process

Role	Responsibility	Position
Safety Case Owner (SCO)	Safety Case process leadership	Facility Operator
Safety Case Process Manager (SCPM)	Safety Case delivery and implementation/Safety Case process health check	Operations Superintendent
External Safety Case advisor (SCA)	Competent Safety Case Advice	External Consultant

Safety Case Team Leader (SCTL)	Ensures safety and technical interdependencies/intelligent customer capability/external interactions (i.e. designer, authors)	Process Engineer
Safety Case Team (SCT)	Provide competent, accurate and experienced input	Operations/Maintenance/Plant Managers/Supervisors/Engineering/HSE/QA/IT
Safety Case Writers (SCW)	Write the Safety Case	External Consultants
Safety Case Quality and Adequacy Team (SCQA)	Check technical accuracy, consistency. Test accessibility and usability	QA/Selected workforce personnel
Independent Review Team (IRT)	Independent review of the Safety Case	External Third Party

ONR states the following (UK ONR, 2016):

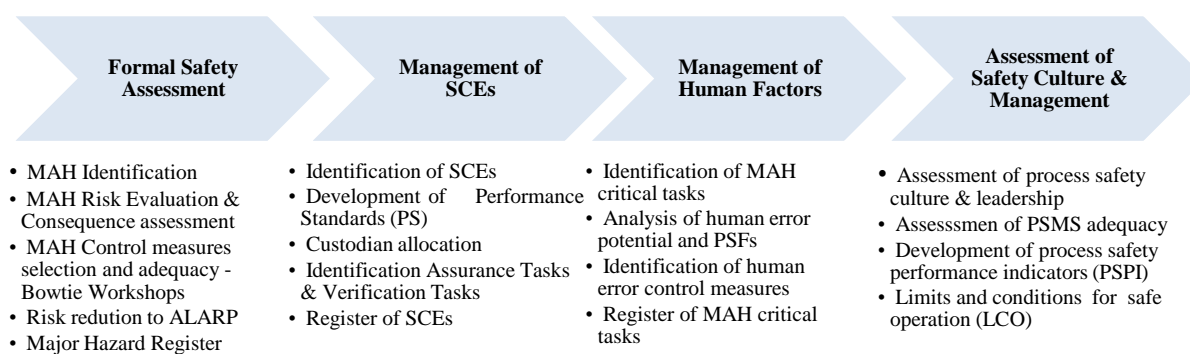
*'A robust Safety Case process is dependent upon a good safety culture. It is essential that the different steps in the process are seen to be important defences that help ensure safety and not as obstacles that need to be overcome (especially when the pressure is on). Culturally, undermining or short-cutting steps in the Safety Case process is akin to defeating plant interlocks because they 'get in the way of progress'. Experience shows that significant problems with Safety Cases can occur when the process is put under severe pressure'.*

Particular attention is paid today by the Cuban Regulator to the latter statement during the review and acceptance of a Facility Operator's SCPP.

### Safety Case production strategy, plan and delivery

The following overall safety case strategy is presently being followed to ensure a thorough consideration of technical, human and managerial aspects of safety. The stages and deliverables (evidence/demonstrations) that are being produced are shown in fig. 3 and briefly explained below. The principal deliverables are grouped in four stages:

1. Formal Safety Assessment (FSA)
2. Management of Safety Critical Elements (SCEs)
3. Management of Human Factors
4. Assessment of Process Safety Culture, Management and Leadership



**Fig. 3: Safety Case development strategy (with key deliverables)**

A plan for production of each deliverable is prepared with specification of the party/person responsible for its production (internal/external resources), timelines for completion, method/methodologies to be used for production of each deliverable, verification activities and how each deliverable will contribute to the documented Safety Case (see p. 4 'Writing the Safety Case').

One of the principal methods which is actively encouraged by the Cuban Regulator for producing SHAPED Safety Cases is the BowTie methodology (Iizastigui, 2017). This barrier-based risk management method is a perfect tool for implementing the Safety Case process that represents a 'true' aid to thinking and delivery of 'usable' Safety Cases. BowTie workshops, the cornerstone of the Bowtie method, are carried out involving both Suitably Qualified and Experienced People (SQEP) both from Facility Operators and plant workforce, as well as final users to analyse each Major Accident Hazard Scenario (MAE). As a result, a very comprehensible diagram is obtained that shows strong links between hazards, threats, consequences and barriers. In addition, with the Bowtie methodology it is possible to link each technical barrier (SCE) or human barrier (Operator's action) to the management system through MAH safety critical tasks which ensure that these barriers will be effective at all times.

## Writing the Safety Case

In 2009, before the Regulations came into force, the Cuban Regulator issued guidelines in relation to the scope and content of safety cases for land-based MHFs. These guidelines were in fact an adaptation of the IADC HSE Case Guidelines for Drilling Contractors, which are considered to be best practice guidance on HSE Cases in the offshore oil and gas drilling industry. It was also thought that following the structure of IADC HSE Case guidelines would also assist Facility Operator in the production of fit-for-purpose Safety Cases for land-based MHFs, irrespective of their type.

The GRIS-1.2 “Preparation of Safety Cases for Major Hazard Facilities” (2009) guidelines recommend the following scope and content of the Safety Case (fig. 4).

1. Introduction
2. Process Safety Management
3. Facility Description
4. MAH Risk Management
5. Emergency Response
6. Performance Monitoring

In this way, each deliverable analysed in p. 3.4 contributes to a specific part of the Safety Case. Facility Operators may use external consultants to help them write their Safety Cases. However, writing of the Safety Case must be carried out on the basis of deliverables produced earlier with the involvement of the Facility Operator’s Safety Case Production Team and plant workforce. It prevents the Safety Case development from becoming a ‘paper exercise’. Should there exist deliverables completely produced by external consultants, these need to be independently reviewed by the Facility Operator using ‘intelligent customer’ capabilities. The Facility Operator must always keep in mind that the Safety Case doesn’t belong to the authors of the documentation, but to the entire Facility Operator’s organization.

When the Safety Case is written, it is submitted to validation by internal sources and independent verification (presently by third parties). The Facility Operator must ensure that the independent reviewer is a SQEP. Once these steps are completed, the Safety Case is internally approved by the Facility Operator and submitted to the Regulator for acceptance, along with the results of the independent review.

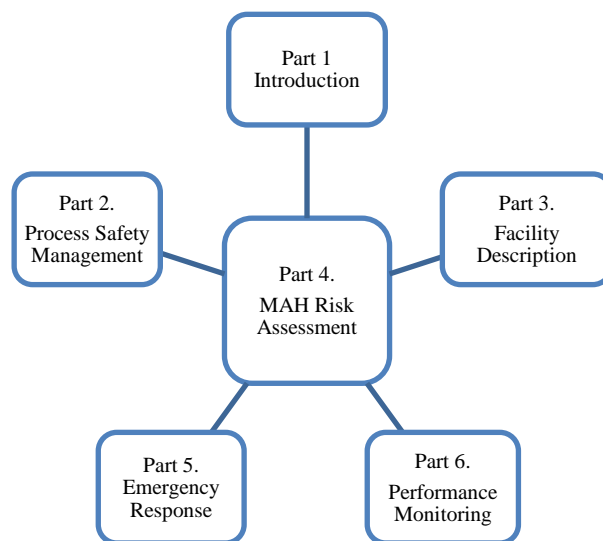


Fig. 4: Safety Case content

## Regulatory review and audit of the SCPP

Regulations specify the role of the Regulator in relation to the SCPP. The regulatory role starts with the SCPP review and acceptance. Regulators accept or reject the SCPP submitted by Facility Operators, and therefore have the opportunity to question and challenge aspects relating to the robustness and reliability of the whole Safety Case process. As stated in the Regulations, during the review of the SCPP, the Regulator seeks evidence of the following:

- The owner's safety philosophy is clearly reflected in the SCPP;
- Tasks required for the Safety Case production have been identified in a systematic and sequential manner showing the Facility Operator’s understanding of the interactions and links between them;

- Tasks have completion deadlines and outcomes; and a series of measurable deliverables have been established within the preparation phases of the Safety Case to allow the follow-up of the progress achieved in relation to the plan.
- Adequate and appropriate human and time resources have been allocated for each task;
- Balance between human resources, internal vs. external, is adequate to ensure the Facility Operator's ownership of the Safety Case process;
- Methodologies for safety assessment and other tasks are adequate for the specific facility and are compatible with the Facility Operator's safety philosophy;
- Basis to demonstrate suitability, including risk criteria, is appropriate for the specific facility and is compatible with the Facility Operator's safety philosophy;
- Identification of the requirements and processes for consultation and involvement of:
  - Workers;
  - Population;
  - Emergency response services;
  - Defence councils; and
  - Other MHFs, as necessary.
- Manner in which the results of consultation will be used in the Safety Case;
- A mechanism is in place to ensure the integrity of Safety Critical Elements during construction and assembly work (for new facilities).

According to Regulations, the regulatory acceptance of the SCPP is a binding condition for granting of the environmental licence. However, according to the 'Pilot' Safety Case strategy, the first Safety Cases are being produced without linking them to any kind of licensing process (see p. 7). Once the SCPP is accepted the Regulator carries out audits to ensure the process is being conducted according to the accepted SCPP. During audits, the Regulator looks for compliance against the SCPP. This is achieved by spotting any weaknesses in the management of the Safety Case process and interviewing people who hold formal roles in the process. The latter is of importance to ensure the effectiveness of the audit.

### **Main shortcomings identified during Safety Case production**

The Cuban Regulator has identified a number of weaknesses during the Safety Case process. These point to the need to devote more attention to aspects of ensuring a higher level of preparation and understanding on the part of the Facility Operator before starting the work, even when there is a SCPP accepted by the Regulator, especially in relation to cultural aspects of the process, some of which are indicated below:

- Owners view the Safety Case as a document, not as a documented process.
- There are still significant gaps in process safety/major hazard knowledge
- Safety case process and its stages are not thoroughly understood.
- Formal roles receive insufficient training on how to carry out their responsibilities
- The process is frequently affected by 'fire fighting' or competing priorities. Barriers that were claimed to be in place to address this issue are often absent or not used at all.
- Lack of competent resources (i.e. verification, intelligent customer capability, independent review), even though they were planned beforehand.
- Consultants have limited expertise which does not cover important areas of process safety management and human factors
- Internal quality verification of the Safety Case deliverables is not being carried out
- Independent review is relied on to ensure the quality of the work
- The progress of the Safety Case process is not measured against the allocated time.

### **'Pilot' Safety Case strategy**

To reduce the burden associated with the introduction of regulations and allow a better organization of available resources, a step-by-step, case-by-case strategy of implementation of safety cases for onshore/land-based MHFs has been devised by the Regulator. Initially, only a limited number of MHF Owners from a variety of industry sectors will be entering the regime. Those entering the regime will start producing the so-called 'Pilot' Safety Cases (PSC) based on previously accepted SCPPs by the Regulator. The development of PSCs is meant to be an active 'learning by doing' process. Once the MHF Owner

knows how-to produce a good quality Safety Case, they will be able to use the experience gained and expand the concept to the rest of their MHFs.

Specific education and training on the Safety Case process, good quality Safety Cases and their implementation is provided by competent consultants to MHF Owners who are required to produce PSCs. The scope and content of the PSCs, as well as the specific deadlines for delivery are agreed with the Regulator and specified in the SCPP. The process is not linked to any specific licensing process. The aim of a PSC is, therefore, to create a minimum standard of capabilities within the Facility Operator to ensure the production of good quality, fit-for-purpose Safety Cases.

Production of PSCs should not be seen only as a learning process for the Facility Operator, it is also a learning process for Regulators and Consultants. Since all parties are involved in the production process, it is also of paramount importance to ensure a close interaction between them during this stage. It is also important to clarify and understand regulatory expectations in relation both to the process and the final product.

To ensure quality of the production work the following need to be assured:

1. Establish a mechanism for permanent coordination (Working Group or other) between Industry, Consultant and the Regulator, under the direction of the former, for the planning of PSCs.
2. Ensure that the industry carries out a rigorous internal planning of the PSC production process, by preparing comprehensive SCPPs.
3. Ensure a steady pace of progress in the preparation of PSCs, avoiding stagnation of the process or sacrificing production quality in order to accelerate the process. This is best achieved by establishing realistic and challenging time frames from the outset.
4. Ensure that competent advice and support is available throughout the Safety Case process as well as subsequent implementation of the PSC.
5. Ensure that the experiences derived from the PSC process are extended to other MHFs, as well as taking into account the regulatory guidance on the Safety Case process in particular and Safety Case in general during the preparation.
6. Ensure that detailed guidance is prepared to serve as a basis for the preparation of PSCs and that it is available to the industry prior to the start of the PSC process.

### **Education and Training**

One of the first steps which is currently taken to support the Pilot Safety Case strategy is to reinforce education and training in the Safety Case process for Facility Operators. A basic training course is delivered by external consultants to senior management and plant management which provides both theoretical knowledge and practical training in aspects related to planning of the Safety Case process in accordance with the requirements of the Regulations. It comprises the following modules:

- Module 1. Purpose of Safety Case Regulations. Cuban Resolution 148/2013
- Module 2. Shortcomings in Safety Cases: Lessons learned from Victoria and Nimrod and Safety Case models
- Module 3. General recommendations on the Safety Case process. Robustness, Management and formal roles
- Module 4. Recommendations for the preparation of SCPP. Safety Case strategy
- Module 5. Regulatory acceptance and audit of the SCPP
- Practical session 1. Planning the Safety Case process – Teamwork session
- Practical session 2. Cross-checking of SCPPs.– Teamwork session

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