



White Paper 2020-03

How To Manage Licensing Requirements in Project Definition and Execution

Depending on the industry, the licensing process and associated requirements can be a critical activity for the success of the project. In highly regulated industry such as aerospace, rail or nuclear, licensing issues can become the critical path and even potentially derail the project. In this White Paper we detail the issues associated with licensing and other regulatory aspects, and what are the best practices to manage them properly in the project definition and delivery process.

Licensing versus regulatory requirements

Regulatory requirements have to be complied with in all cases. Even if no explicit licensing is required, there will still be a need for some requirement compliance management.

Licensing obligations are situations where an explicit approval has to be granted by a licensing body, which is generally a national or local government authority (either directly, or with a delegated authority to an independent organisation). It is generally granted based on an application file, which content is defined by the applicable regulations. A license is granted after careful examination of this file, with or without additional conditions. Sometimes the process includes a public inquiry as well.

Regulatory requirements or licensing obligations may impact the project design, procurement, construction, and sometimes also the final product produced by the facility. For large projects, several regulatory fields may be applicable, and several authorities involved separately. For example, a pharmaceutical facility will be subject both to regulations on the safety of operation and to medical regulations on the quality of the product.

Licensing and regulatory requirements can drive the project schedule

In our ever-increasingly regulated world, licensing requirements can easily become the critical path for large projects. It is often the case at two specific moments:

- End of the definition phase, prior to Final Investment Decision,
- During commissioning, testing and start-up phase up to final acceptance.

This is particularly obvious in many transportation industries, as well as in the nuclear industry. Even on smaller projects where this effect may be less noticeable, the need to go through a licensing process can produce unexpected changes in the project definition and implementation phase.

The issue is compounded by the fact that application file reviews by regulatory agencies are generally not fully predictable in terms of duration and effort, creating a substantial uncertainty as to the project execution schedule.

Conventional best practices regarding licensing

Proven best practices to manage licensing issues include:

- For large projects, do not sign-off the Final Investment Decision prior to receiving the main license and license conditions. This requires the full licensing process to be performed during the project definition phase. This can sometimes lead to actual stand-by moments for the project definition team pending final assessment of the license and integration of its conditions in the design and baseline execution plan,
- For smaller projects, Final Investment Decision can be signed off without the formal main license on the condition that the licensing request has been filed with positive feedback from the authority and the public inquiry has been positive,
- Projects should be executed as much as possible under fixed technical, regulatory and licensing requirements to avoid changes in the course of the project and ensure stability of requirements. This may sometimes require a specific request to the regulator, in particular for long projects,
- In case an operating license needs to be formally delivered after tests and trials and prior to industrial operation, this process needs to be anticipated as much as possible to minimise impact on the project. Construction and commissioning schedules often need to be adapted to start with the priorities of demonstrating compliance with licensing conditions.

Licensing requirements must be taken seriously and are often intrinsically linked to the final performance of the project.

Common challenges related to licensing

The licensing requirements have not been identified in a comprehensive manner

Although it is relatively simple to overcome, this phenomenon happens in countries with very developed regulations: the initial due diligence on licensing requirements has not been comprehensive enough, and the project gets stopped for failing to request a specific license, for example a local construction license for some facilities while the main national license has been granted. This should be resolved through a comprehensive project definition process.

Change in project definition during the licensing process.

Because licensing needs to start early, the definition of the project may evolve in parallel. There needs to be consistency between the licensing request and the concept finally defined. This can be a significant challenge particularly when the licensing process is long-winded and the project is relatively innovative, or if the particular industry evolves rapidly (example of offshore wind farms). The licensing body must allow the licensing file to be updated during the process, within certain reasonable limits; and the licensing case provided must be designed to sufficiently encompass likely evolutions. This situation requires frequent interaction between the Owner and the licensing body.

Under-estimation of licensing requirements impact in brownfield situations

In brownfield projects, the development of a new part of a facility will often lead to the re-evaluation of the licensing case for the entire facility, because of the imbrication between equipment and shared facilities or utilities and because the impact evaluation is performed at site level. Updated regulatory requirements may be imposed on the site requiring a retrofit of parts of the existing facility, which may substantially enlarge the scope of the project, increase cost and schedule, and complicate its execution.

Changes in applicable regulations during the project

For long projects and in certain regulatory situations, applicable regulations may change during the course of the project. This situation is not favourable to successful project execution. Conventionally, the licensing conditions should remain stable at least through the construction process. The final deliverable may be subject to a regulatory re-assessment after start-up that requires modifications and improvements, but that should ideally be disconnected from the project execution itself. However, there are still cases where lessons learned from significant accidents, or regulatory evolutions have to be taken into account immediately, modifying the design during project execution. It is the case when the project duration is longer than the normal licensing case review and re-evaluation frequency. A very strong Management of Change process must be implemented to keep control of the project.

Management of project definition changes created by the licensing conditions

The licensing process itself will create additional requirements applicable to the project. They need to be identified in a timely manner and included in the scope through a proper Management of Change process.

This issue is particularly important and will be developed in the next White Paper [2020-04 'How To Implement Licensing Requirements During Project Execution Phase'](#).

Contractual issues of Owner responsibility with a subcontracted design

All licensing frameworks require the Owner to be fully responsible. However, in most cases the facility will be designed and delivered by a Contractor or a set of Contractors, which may be much more knowledgeable in the process of obtaining licenses. This situation has to be managed carefully by the Owner. The temptation to delegate the production of the safety case and the

relationship with the licensing authority should be resisted because many aspects of the licensing case cannot be delegated e.g. operators' competency and training,

financial capabilities demonstrations, future operational constraints etc. The Owner must be careful to thoroughly understand the underlying assumptions and commitments used to build the licensing case, that will have to be considered as requirements during project execution. Our experience also shows that there are often substantial optimisation margins by rationalising licensing requirements to minimise related ongoing operational expenditures. Therefore, the Owner has to mobilise its own licensing expertise and fully own the licensing case.

Summary

Licensing requirements must be taken seriously and are often intrinsically linked to the final performance of the project. The licensing process can easily become the critical path or jeopardise the effective start-up of the facility. A number of actions must be taken early to include licensing requirements in the project definition process. Still, additional precautions must be considered to avoid the impact of possible change of regulations, licensing conditions and avoid missing some licensing aspects which could be highly detrimental to project realisation and the economics of the future facility.

Changes linked to licensing at various stages of the project can have substantial consequences



**We Empower Organizations to be Reliably Successful in
Executing Large, Complex projects.**

Discover more on
www.ProjectValueDelivery.com