

# RegStack: Turning Regulatory Logic into Traceable Execution for Product Certification Bodies

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## Abstract

Product certification in Brazil is a regulated, multi-actor operating environment in which mandatory requirements, documented stages, technical review, evidence handling, and formal decision points must coexist within the same process. In practice, certification bodies (OCPs) often run these processes through fragmented coordination based on emails, attachments, spreadsheets, manual follow-up, and individual memory. This paper presents RegStack, a workflow platform that translates ordinance-based regulatory logic into structured, gate-by-gate execution, with evidence bound to workflow context and an assistive AI layer grounded in the applicable ordinance. We report early operational results from deployment at *acertcertificadora*, an Inmetro-accredited OCP (0151), covering two pilot initiatives, approximately 55 process instances, more than 600 centralized evidence items, and an estimated 120 to 180 minutes saved per process. Beyond efficiency, the most visible gain has been operational clarity in workflows that were previously dependent on tacit knowledge and dispersed communication.

**Index Terms**—Conformity assessment, product certification, regulatory technology (RegTech), workflow automation, audit traceability, governance risk and compliance (GRC), assistive AI, Inmetro, ISO/IEC 17065.

## 1. Introduction

In Brazil, product certification is not a simple administrative flow. It is a regulated operating environment shaped by mandatory requirements, documented stages, technical review, evidence handling, testing activity, and formal decision points. This creates a chain involving certification bodies, clients, laboratories, documents, tests, and accountability that all share the same process.

The challenge for product certification bodies (OCPs) is not only understanding the applicable rule. It is making that rule executable in day-to-day operations. In many certification environments the regulatory path may be well known, but execution is still spread across emails, attachments, spreadsheets, manual follow-up, and individual memory. The result is not just inefficiency. It is reduced operational confidence in workflows that should be easier to follow, easier to audit, and easier to defend.

This paper presents RegStack, a workflow platform designed to close that gap. RegStack translates ordinance-based regulatory requirements into structured workflow templates that are executed inside the platform, with evidence bound to the relevant gate, ownership clearly assigned, and an assistive AI layer that operates within the boundaries of the applicable ordinance. The platform has been deployed at *acertcertificadora*, an Inmetro-accredited OCP (registration number 0151), where it has supported real product certification processes under Inmetro Ordinances No. 302/2021 (toys) and No. 148/2024 (household appliances).

The contributions of this paper are threefold. First, we characterize the operational gap between regulatory knowledge and regulatory execution in Brazilian product certification. Second, we describe the design of RegStack, with emphasis on gate-by-gate execution, evidence binding, and ordinance-grounded assistive AI. Third, we report early operational evidence from a real OCP environment, using exact numbers where available and conservative observations where appropriate.

## **2. Background: Product Certification in Brazil**

Product certification in Brazil operates within the Brazilian Conformity Assessment System (SBAC), coordinated by the General Coordination of Accreditation (Cgcre) of the National Institute of Metrology, Quality and Technology (Inmetro). OCPs are private organizations accredited under ISO/IEC 17065 [1] and operating under specific Conformity Assessment Requirements (Requisitos de Avaliação da Conformidade, RAC) issued by Inmetro through ordinances such as No. 302/2021 for toys and No. 148/2024 for household appliances.

Each ordinance defines the certification model (e.g., Model 1b for type approval, Model 2 for type approval with surveillance, Model 5 for type approval combined with quality system audit and continuous surveillance), the documents required at each stage, the testing rules, and the surveillance regime. Witness audits performed by Cgcre on accredited OCPs, governed by norms such as NIT-DICOR-026, evaluate whether the OCP can demonstrate that the path defined in the ordinance was effectively executed and documented.

From an operational standpoint, this regulatory environment imposes a strict need for traceability. Each certification process must show, after the fact, which documents were collected at which stage, who reviewed them, what the technical decision was, and how each piece of evidence relates to the applicable criterion in the ordinance. The cost of failing to demonstrate this is not theoretical: it directly affects the OCP's accreditation status and the validity of certificates issued.

## **3. The Operational Gap**

In practice, the regulatory path described above is often executed through fragmented coordination. Analysts work across email threads, shared folders with inconsistent naming, spreadsheets that track process status manually, and conversations whose content rarely survives in the official process record. Reconstructing the state of a single process can require navigating dozens of files spread across multiple folders, with names such as "F-001 Solicitação Contratual v.04.pdf" or "F-019 Relatório de Avaliação 4-23.pdf", whose semantic relationship to a specific gate in the ordinance is only understood by the analyst who handled the process.

Three operational symptoms recur in this scenario. First, analysts spend significant time reconstructing process status before being able to act. Second, the relationship between an evidence item and the specific ordinance criterion it satisfies is preserved mainly in tacit knowledge, not in the document itself. Third, witness audits and internal reviews require an additional reconstruction effort, because the audit-ready narrative of the process is not the same artifact as the working folder used during execution.

These symptoms point to a specific design opportunity. The regulatory logic is already known and stable. What is missing is an operational layer that makes that logic explicit, executable, and traceable at the moment work happens, not weeks later when an audit is announced.

## 4. Related Work

Several categories of existing systems intersect with the problem space. Document management systems and enterprise content management platforms address storage and retrieval, but treat documents as standalone objects rather than as evidence bound to a regulatory stage. Quality management systems used by certified manufacturers focus on the certified party's internal controls, not on the certification body's evaluation workflow. Governance, risk, and compliance (GRC) platforms address corporate compliance posture and control monitoring [2], but are typically designed for regulated entities rather than for accreditation-bound conformity assessment bodies. Business process management (BPM) suites offer generic workflow modeling, but require substantial configuration to encode the specific logic of an Inmetro ordinance, and rarely provide native support for the document-criterion binding that ISO/IEC 17065 evaluation demands.

Research on regulatory technology (RegTech) has explored automation of compliance checks in financial services and life sciences [3], and recent work in the IEEE community has examined real-time audit readiness in regulated industries [4]. RegStack contributes to this line of work by addressing a domain that has received comparatively little attention in the literature: the execution side of accredited product certification, where the regulator is not a financial supervisor but an accreditation body, and where the unit of evaluation is a multi-stage process rather than a transaction.

## 5. The RegStack Approach

RegStack is designed around five interrelated concepts: ordinance-based workflow templates, gate-by-gate execution, evidence binding, assistive AI grounded in the applicable ordinance, and multi-actor coordination. Figure 1 illustrates how these concepts compose in practice, using an instance based on Inmetro Ordinance No. 302/2021 (toys).

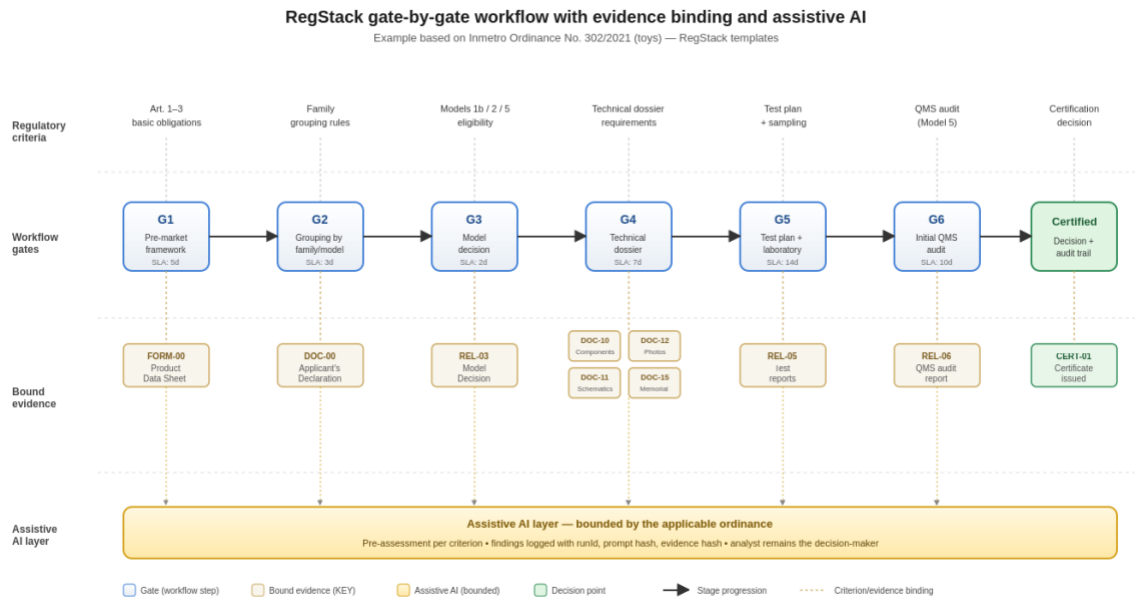


Figure 1. RegStack gate-by-gate workflow with evidence binding and assistive AI, illustrated for Inmetro Ordinance No. 302/2021 (toys). The diagram shows four layers: regulatory criteria from the ordinance, workflow gates (G1–G6) with their service-level agreements, bound evidence identified by regulatory keys (FORM-00, DOC-10, DOC-11,

*DOC-12, DOC-15, REL-03, REL-05, REL-06), and the assistive AI layer that operates within the boundaries of the applicable ordinance.*

### ***5.1 Ordinance-Based Workflow Templates***

For each Inmetro ordinance under the OCP's scope, RegStack maintains a workflow template that decomposes the regulatory path into a sequence of stages (gates) such as G0 (case opening), G1 (pre-market framework and basic obligations), G2 (grouping by family and model rules), G3 (choice of certification model and Model 2 eligibility), G4 (formal request and technical dossier), G5 (test plan, sampling, and laboratory), and G6 (initial QMS audit, when applicable). Each gate carries its competence (expert, evaluator, or decision-maker), its expected service-level agreement (SLA) in days, its technical basis (the section of the ordinance that motivates it), and its regulatory criteria. The current deployment includes templates for Ordinance No. 302 (15 stages) and Ordinance No. 148 (10 stages).

### ***5.2 Gate-by-Gate Execution***

A certification process in RegStack is an instance of a template. At any moment, the analyst sees which gate is current, which gates are completed, which gates are blocked, and which gates are at risk of breaching their SLA. The platform maintains a structured process history that captures stage transitions, decisions, and evidence movements. This replaces the implicit, memory-based view of process status with an explicit view that is the same artifact during execution and during audit.

### ***5.3 Evidence Binding***

In certification workflows, documents are not standalone attachments. They exist in relation to stages, requirements, technical review, and process progression. RegStack assigns each document a regulatory key that identifies which criterion it satisfies (for example, KEY: REL-03 for the Model Decision, KEY: DOC-10 for the List of Components and Suppliers, KEY: DOC-11 for Electrical Schematics, KEY: DOC-12 for Photographic Records and Assembly). The relationship between the document and the criterion is preserved in the platform, not in the analyst's memory. The same document can be reused across processes when reuse is admissible, and the audit trail records when and why reuse occurred.

### ***5.4 Assistive AI Grounded in the Applicable Ordinance***

RegStack incorporates an assistive intelligence layer that operates inside the context of the specific ordinance governing the process. The AI can perform an early pre-assessment of a submitted document against the criteria of the current gate, surface potential gaps or inconsistencies, and produce a structured finding (for example, listing each criterion checked, the evidence considered, and the suggested result). The output is presented as a suggestion to the analyst, who remains the decision-maker. Each AI run is logged with a unique identifier, the prompt template used, and a hash of the input, so that the suggestion itself becomes traceable evidence in the process history. The assistive layer is deliberately bounded: it does not act outside the ordinance loaded into the gate, and it does not replace the analyst's formal decision.

### ***5.5 Multi-Actor Coordination***

Although the primary user is the OCP, the workflow involves additional participants. Clients submit and follow process materials, laboratories contribute tests and technical outputs, and the OCP coordinates

these inputs within the same traceable process. RegStack supports this shared operating logic with role-based visibility: each actor sees what is relevant to their role, while the OCP retains the full coordination view.

## 6. Case Study: Deployment at acertcertificadora

acertcertificadora is an Inmetro-accredited product certification body (registration OCP 0151) operating in Brazil, with scopes that include toys, household appliances, and other regulated product families. RegStack has been deployed in the OCP's real operating environment, with two pilot initiatives completed and ordinance-based templates active for Ordinance No. 302/2021 (toys) and Ordinance No. 148/2024 (household appliances).

During the deployment, the platform has supported approximately 55 process instances, with more than 600 evidence items centralized inside the workflow context and more than 12 distinct workflow gates exercised across the two ordinances. Process instances span the operational reality of a working OCP, including active processes, processes under technical review, and processes flagged at risk against their SLA. Each instance carries its own audit trail, with stage transitions, document submissions, AI assessments, and analyst decisions captured in a structured form.

## 7. Early Results and Observations

We report early indicators rather than mature scale, in line with the early-stage nature of the deployment. Table 1 summarizes the most visible operational results.

| Indicator                           | Observed value                   |
|-------------------------------------|----------------------------------|
| Pilot initiatives completed         | 2                                |
| Real operating environments reached | 1 (acertcertificadora, OCP 0151) |
| Process instances supported         | ~55                              |
| Evidence items centralized          | 600+                             |
| Workflow gates supported            | 12+                              |
| Ordinance templates active          | 2 (No. 302/2021; No. 148/2024)   |
| Estimated time saved per process    | 120 to 180 minutes               |

*Table 1. Early operational indicators from the RegStack deployment at acertcertificadora.*

Beyond these quantitative indicators, the most visible qualitative gain has been operational clarity. Before RegStack, analysts often had to reconstruct the current state of a process from emails, attachments, and side conversations. With RegStack, the process is visible as a structured sequence: the analyst can see the full workflow, understand the current stage, anticipate what is required next, and work with documents and evidence inside the right process context.

A second qualitative gain is the change in the audit-readiness posture. Because evidence is bound to gates, decisions are logged with their context, and AI suggestions are stored with their identifiers, the artifact reviewed during an internal review or a Cgcre witness audit is essentially the same artifact produced during execution. This reduces the additional preparation effort that historically preceded audit events.

We note that the estimated time saving (120 to 180 minutes per process) is a conservative observation based on analyst feedback during the pilots, comparing the effort of reconstructing process status under the previous fragmented coordination with the effort under the structured workflow. We treat it as an indicator, not as a controlled measurement.

## 8. Discussion

Three points are worth highlighting. First, the value of RegStack is not primarily in speed. It is in clarity. The certification workflow becomes easier to navigate, easier to prepare for, and less dependent on tacit knowledge or side coordination. Speed gains are a consequence of clarity, not an end in themselves.

Second, the design treats AI as an assistive, bounded layer rather than as a decision-maker. The platform records the AI suggestion alongside the analyst's formal decision, which is consistent with the accountability model that ISO/IEC 17065 and Inmetro accreditation impose on the OCP. This is a deliberate choice: in accredited product certification, the question is not whether an algorithm can produce a faster verdict, but whether the OCP can demonstrate that the verdict was reached by qualified personnel using a documented procedure.

Third, the operating model is general beyond product certification. The same logic — ordinance-derived workflow templates, gate-by-gate execution, evidence bound to criteria, multi-actor coordination — applies to other evidence-heavy regulatory workflows. Early interest has emerged from adjacent segments such as phytosanitary export workflows for fruits and vegetables, where compliance depends on destination-specific requirements, documentary control, and coordinated execution across multiple participants.

### 8.1 Limitations

The current evidence is from a single OCP and two ordinance templates. The time-saving figure is an analyst-reported observation, not a controlled study. The assistive AI layer is bounded by design, which limits the comparison with broader automation literature. Generalization across other OCPs, scopes, and regulatory domains is part of future work.

## 9. Conclusion and Future Work

RegStack addresses a specific operational gap in Brazilian product certification: the distance between knowing the regulatory rule and executing it in a way that is clear, traceable, and audit-ready in real time. By turning ordinance-based regulatory logic into structured workflow templates, binding evidence to gates, and providing a bounded assistive AI layer, the platform supports OCPs in operating with stronger process visibility and lower dependence on tacit knowledge.

Over the next 12 to 24 months, the priority is to deepen the certification core: strengthen workflow templates, improve evidence organization, expand the audit trail, reinforce role-based visibility, and make execution more reliable in real operating use. From there, the natural expansion is into adjacent compliance

workflows that share the same characteristics — evidence-heavy, multi-step, audit-sensitive processes that depend on structured documentation and accountable progression. The longer-term vision is to evolve from certification workflow support into broader operational infrastructure for compliance.

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