Submitted September 17, 2019, revised December 17, 2019 and February 20, 2020, accepted March 9, 2020.

Digital Object Identifier 10.1109/ACCESS.20XX

On What Goes on with Goal-Oriented Healthcare Equipment Regulations:
An Exploratory Case Study on the Diagnostic Imaging Equipment Industry in Brazil

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ABSTRACT Few economic sectors are more regulated than healthcare. Although excessive healthcare regulation is a bad thing, regulatory compliance may bring with it many benefits, such as market entry, product quality and availability, as well as access to tax rebates and financial incentives. Goal-oriented regulations, in particular, embody in their formulation specific propositions to maximize compliance benefits provided the achievement of public policy goals. In this paper, we develop an in-depth study of goal-oriented healthcare equipment regulations. We use expert knowledge and process-mining techniques to investigate what goes on with regulatory compliance and with the benefits obtained by equipment manufacturers when the healthcare equipment regulation is goal-oriented. We present here a multi-company exploratory case study on the variability of mean times-to-benefit after compliance and on regulatory process improvement, focused on the diagnostic imaging equipment segment and the regulatory context in Brazil. We show that, in some cases, mean times-to-benefit depend on the compliance of different categories of diagnostic imaging equipment with technical requirements found in the applicable norms. Moreover, we present process improvement cases elicited during goal-oriented regulatory process analysis and modeling activities. Our study illustrates the usefulness of applying expert knowledge and process mining techniques together in the healthcare equipment domain. It also suggests that healthcare equipment product-management practices should be concerned not only with analyzing and ensuring regulatory compliance but also with regulation dynamics.

INDEX TERMS Diagnostic Imaging Equipment, Regulatory Requirements, Goal-Oriented Regulation, Healthcare Processes, Public Policy.

I. INTRODUCTION

The quality and strength of the healthcare sector in a country have been used as measures of the development level and capability of the country to face social and economic challenges (cf. UNDP Millennium Development Goals). Few economic sectors, however, are more regulated than healthcare. On the one hand, excessive healthcare regulation is a bad thing, since it may create market access barriers, increase time-to-market and compliance may be costly. It also leads to the risk of crowding out innovative decision making in favor of response mode or risk-averse behavior [1]. On the other hand, regulatory compliance in healthcare may bring with it public welfare and corporate advantages, such as the assurance of market entry, product quality and availability, as well as access to tax rebates and financial incentives. The existence of national standards and the local availability of funding are also important competitiveness factors in the healthcare (equipment) industry [2].

Governments and their policy agencies implement healthcare regulation up to the appropriate extent using economic, social or administrative measures [3]. Economic measures are implemented through standards, market access restrictions and entry conditions. Public health and well-being actions are examples of social measures. In turn, administrative measures are enforced using legal, tax and financial instruments. In particular, it is usual to find in norms and other regulatory documents, such as standards and contracts of compulsory enforcement, references to technical requirements, such as system and software requirements. The respective regulation formulation decisions affect the whole industry operation.

Notably, the regulation of the healthcare sector is frequently formulated in a goal-oriented manner. Goal-orientation means that the regulation embodies specific propositions to maximize compliance benefits provided the achievement of previously established public policy goals. However, differently from traditional regulatory regimes, the formulation of goal-oriented regulations presupposes dialogues between regulators and regulatees in order to reach common understandings among stakeholders and balanced choices between regulation benefits and obligations [4]. Therefore, goal-oriented regulatory processes are an effective instrument to foster innovation and cooperation. Goal-oriented regulations have been adopted with success in many different domains, particularly in the healthcare [4] and financial [5] sectors.

Due to these social and economic reasons, it seems to be worthwhile investigating what goes on with regulatory compliance and with the benefits obtained by equipment manufacturers when the healthcare regulation is goal-oriented. In particular, in the highly competitive healthcare equipment market, the times required from companies to obtain benefits after demonstrating their compliance with regulations, called time-to-benefit measures here, have paramount importance to ensure corporate competitiveness. Therefore, we have wondered if mean times-to-benefit after compliance depend on established public policy goals and adopted regulation formulations. To clarify this, we present here a study focused on the times required from equipment manufacturers to obtain benefits due to their compliance with healthcare, financial incentive and tax benefit regulations. We use our expert knowledge to put together the applicable norms and different data sources in order to develop an empirical study of mean time-to-benefit variability. We examine whether or not mean times-to-benefit depend on the compliance of the different categories of healthcare equipment with technical requirements found in the applicable norms.

Because of this first study, we also felt compelled to question whether or not healthcare equipment goal-oriented regulatory processes could be better understood and improved using process mining techniques [6]. Although empirical and process mining studies could be used for the same purposes, it appeared to us that process analysis and modeling techniques based on mining could offer a higher-level perspective in understanding healthcare regulatory processes. Therefore, we present here a second study providing a high-level mapping of healthcare equipment regulatory processes, identifying their overall organization and eliciting process improvement cases in this domain.

Our research focuses on the diagnostic imaging industry established in Brazil. The reported studies cover ultrasound and magnetic resonance imaging equipment; positron emission tomography equipment; audiological, otoneurological and vestibular imaging equipment; X-rays and computerized tomography equipment; as well as manographs and angiographs. It should be noted that many locally owned companies, in addition to international suppliers, have factories in Brazil. The domestic regulation is similar to those in force abroad and the internal market has a considerable size (in the decade ending in December of 2017, our dataset points out that there were sales of at least 1.725 locally manufactured equipment, worth more than US$ 566 million). These reasons lead us to believe that our findings are of general interest and may be valid regarding other segments and regions.

We consider to be main original contributions of our research:

- The demonstration that, in some cases, mean times-to-benefit depend on the technical requirements included in goal-oriented norms that different categories of diagnostic imaging equipment comply with;
- The evidence that applying expert knowledge and process mining techniques together is useful for process improvement in the healthcare equipment domain;
- The rationale justifying why healthcare equipment product-management practices should be concerned not only with analyzing and ensuring regulatory compliance but also with regulation dynamics.

In fact, this work builds on our previous research presented in [7] by developing the process mapping and analysis study that allowed us to reach the improved regulatory compliance and the process enhancement results reported here.

We organize this paper as follows. Section II contrasts our research to related work. The diagnostic imaging equipment segment in Brazil is described in Section III. Next, Section IV presents the adopted dataset and empirical study methodology. Our data analyses and empirical research findings are detailed in Section V. Subsequently, Section VI presents our process mapping and improvement studies. The validity threats of our work are discussed in Section VII. We conclude the paper with a discussion of our research findings (Section VIII) and with suggestions for future research (Section IX).

II. RELATED WORK

Regulatory compliance and process improvement are recurrent themes in the literature of the healthcare (equipment) sector. When contrasted to related work, we note that the distinctive characteristics of our research are the studied subjects, some adopted investigation methods and the established research goals.

We present a summary of the related work in the following subsections. Table I contains a more systematic comparison of our research to the related healthcare literature.

A. Compliance with Regulatory Requirements

The studies reported in [8] propose an empirically validated quality model to ensure user satisfaction with medical devices. The model underlies an appraisal and measurement methodology that embraces usability and user acceptance

TABLE I - COMPARISON TO THE RELATED HEALTHCARE LITERATURE

Authors (Year)	Ref.	Setting	Type of Study	Methods	Subjects	Research Questions	Main Findings
Dörr et al. (2008)	[8]	Germany	Empirical	Scenario-Based Case Study	Healthcare Equipment	Does the early introduction of usability and user satisfaction aspects in quality models contribute to product improvement?	The usage of such models allows for systematic product enhancement.
Jetley, Iyer and Jones (2006)	[9]	USA	Empirical	Forensic Analysis Case Study	Healthcare Equipment	Is the use of model checking and static analysis techniques effective in medical device reviews?	They are respectively effective in pre and post-market reviews, but their general acceptance may depend on large-scale studies.
Higgins, de Laat, Gieles and Geurts (2003)	[10]	Netherlands	Empirical	Requirement Management Studies	Imaging Equipment	Is the capture and treatment of continuous information flows effective in the requirements engineering of imaging equipment?	Tool-based continuous requirement management processes contribute to better-quality requirements and more predictable times-to-spec.
Erdogan and Tarhan (2018)	[11]	Diverse	Empirical + Process Mining	Systematic Literature Review	Healthcare in General	What is the research space on healthcare process mining reported in the literature, its demographics and trends?	The number of experience report and solution proposition studies is relevant and growing. Validation studies exist, but are still on demand.
Bose, Maggi and van der Aalst (2013)	[12]	Netherlands	Process Mining	Event Correlation Studies	Clinical Processes	Is it possible to exploit data in event logs to discover process maps showing relevant and accurate constraints only?	Discovered process maps can show only the more meaningful event constraints. Data attributes can be used to find discriminatory patterns, outliers and bottlenecks.
Riz, Santos and Loures (2016)	[13]	Brazil	Process Mining	Organizational Process and Social Network Mining Studies	Clinical Processes	Is it possible to obtain knowledge from healthcare organizational flows, organizational structures and social networks?	The use of such process mining techniques is adequate due to the flexibility they provide for a variety of different processes.
Sfyrla, Carmona and Henck (2014)	[16]	France	Process Mining	Petri Net Modelling and Property Verification	Healthcare Equipment	Is it possible to use event logs for safety analysis, testing, conformance checking, performance analysis and optimization of medical devices?	There are many challenges for log-based verification: what information to log, how to distinguish good from bad events, how many scenarios are needed and so forth.

information early in product development. This model relies on evidence-based methods that treat the existing regulations and regulatory compliance as ordinary quality criteria.

The USA Food and Drug Administration (FDA) studies described in [9] address software review methods for medical devices. The authors propose device usage models as a basis for applying formal methods and static analysis techniques in medical device reviews. The paper presents a case study on improving the forensic analysis of software failures of infusion pumps. The proposed methods focus on strengthening the analysis of product registration requests and providing more rigor to regulatory processes.

Enhancing the management of requirement engineering processes of diagnostic imaging equipment is the research goal of the studies in [10]. The authors describe empirically validated improvements in processes that rely on continuous information flows and study the influence of the identified improvements in time-to-specification metrics.

In comparison to the regulatory compliance study reported herein, the related empirical studies focus just on single subjects or processes, consequently not presenting product category breakdowns or extensive analyses of regulatory compliance as a primary research goal.

B. Process Improvement in Healthcare

A systematic mapping of process mining studies in the healthcare domain appears in [11]. The study defines process mining as a management technique for process discovery, conformance checking and enhancement of business processes based on event data on information systems.

In [12], the treatment of patients diagnosed with cancer in a Dutch hospital is analyzed using process mining techniques. The paper identifies that event correlations can be provided by domain experts or automatically learned from event logs in order to prune constraints and disambiguate associations. This data are used to find discriminatory patterns, identify outliers and analyze treatment bottlenecks. The case study presented in [13] covers patients receiving chemotherapy treatment in a Brazilian hospital. The authors use organizational model mining and social network analysis to elicit a comparison matrix addressing the involved stakeholder interactions, which is similar to the factorial designs derived from correlation matrixes adopted in statistical analyses. These techniques are used in informed decision-making and problem-solving.

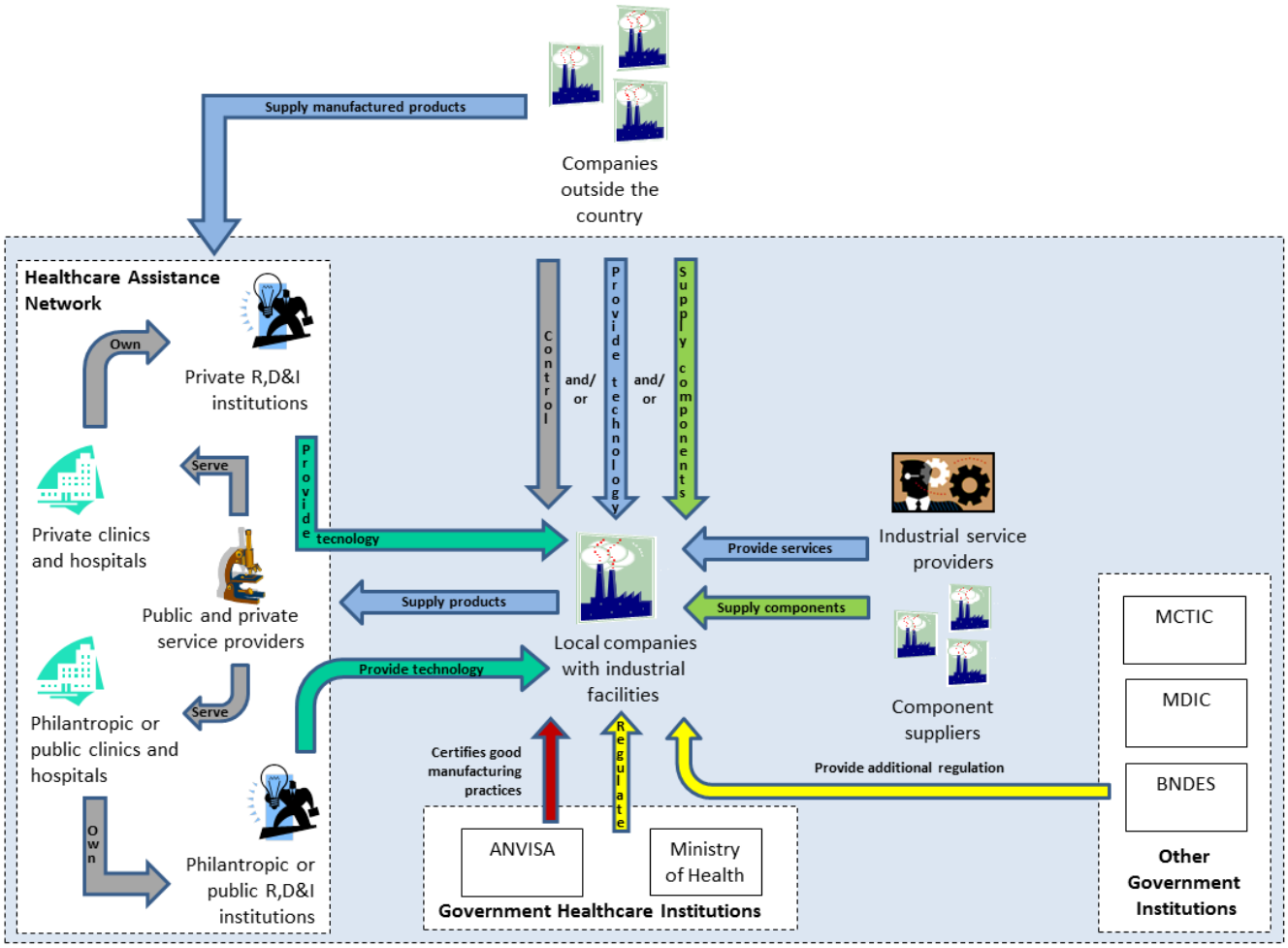

FIGURE 1. **The healthcare ecosystem in Brazil.**

Although not constrained to the healthcare domain, the authors of [14] propose a generic approach for computing alignments with process models using partially ordered event traces. They illustrate this idea by using a patient treatment process derived from a simulation model. The authors also propose a quantitative quality metric to compare alignments with respect to their ideal counterparts. The research reported in [15] extends the idea of using partially ordered event log graphs to address the problem of online process discovery.

Finally, concerning medical devices, [16] recognizes that process mining techniques have seldom been adopted. The paper suggests the application of process mining in a real use case concerning infusion pumps. The focus of such a study would be on analyzing and ensuring device safety properties based on the logs generated by the behavior of the device. In this way, it would be possible to perform analyses without transforming existing models into formal descriptions, such as those required by model checkers.

There are many commonalities of the related process mining research with the process mapping and improvement studies presented here, particularly concerning the adoption of the aforementioned techniques and methods. Despite these, the related process-oriented research focuses just on clinical or corporate goals, but takes no notice of goal-oriented public policy concerns.

III. THE BRAZILIAN HEALTHCARE ECOSYSTEM

The Brazilian healthcare sector operates in the form of a unified healthcare system aiming to provide universal and decentralized health assistance to the whole population. The system comprises a myriad of public, private and philanthropic institutions. Fig. 1 presents its overall structure.

A. The Production & Operational Context

Healthcare equipment companies with businesses in the Brazilian market manufacture products locally, relying on endogenous component suppliers and service providers, or import entire products either directly or through distributors. Companies that design or manufacture products locally frequently rely on the services provided by a network of research, development and innovation (R,D&I) institutions, which are connected to hospitals and clinics in many cases. All these institutions form the local healthcare ecosystem.

The Ministry of Health is responsible for coordinating and orchestrating the activities and procedures performed in the local healthcare ecosystem. In its turn, the Brazilian

Health Regulatory Agency (ANVISA) is the autonomous agency in charge of the regulation and compliance assurance of production, marketing, sales and use of healthcare products and services.

B. The Regulatory Context

The public policies regarding the healthcare sector in Brazil have been anchored in healthcare regulation measures enforced by ANVISA (c.f. Section III.B.1), as well as in financial incentives and tax benefits provided by other government organizations (c.f. Sections III.B.2 and III.B.3). Many types of regulatory documents implement such public policies: laws, decrees and interim measures; govern agency ordinances, resolutions and adjustments; public agreements and contacts.

In our studies of the healthcare regulatory context in Brazil, we attribute a unique acronym to each normative document and make reference to their parts using the specific indexing patterns specified in the Brazilian Republic Decree 4.176/2002. Moreover, we define norm part identifiers by prefixing norm acronyms to part indexes. For example, here (DUS 1.I) stands for item I of Article 1 of MCTI/MDIC Ordinance 256/2013, whereas (SSP 25.§1) denotes Paragraph 1 of Article 25 of Law 6.360/1976.

1) THE HEALTHCARE REGULATION

The healthcare equipment regulation in force in Brazil is analogous to that implemented by the USA FDA and that enforced by the European Community through the CE marking. It also leads to automatic compliance with some international standards, such as the ISO 13.485 Standard for Medical Devices [17].

The central norm regulating the Brazilian healthcare sector is Law 6.360/1976 (SSP), which establishes health protection and surveillance measures covering medicines and correlated products (including medical devices). For example, item X of SSP Article 3 defines product registries:

> **(SSP 3.X)** Registry: Registration, in the proper book, after the concessionary order of the head of the responsible Ministry of Health organizational unit, under the order number, of the products referred to in (SSP), with their names, manufacturers, provenances, purposes and other characteristic elements;

Product registries are valid for five years and may be revalidated (SSP 12.§1). In addition, registries and their revalidations only take effect from the date of their publication in the Official Press onwards (SSP 12.§4).

SSP poses many requirements on registry processes and the production, marketing, sales and usage of healthcare products. For example, no healthcare product, including imported ones, may be industrialized, exposed for sale or used by consumers in Brazil before effectively registered (SSP 12). Moreover, apparatus, instruments and accessories used in medicine, dentistry and related activities can only be imported or manufactured after the Ministry of Health rules on whether or not registration is mandatory (SSP 25).

SSP also poses requirements on each company that deals with healthcare products. The operation of such companies depends on the authorization of the Ministry of Health, given the indication of the respective industrial activities, the nature and species of the products, as well as insurance of technical, scientific and operational capacity (SSP 50). Moreover, such companies are obliged to keep sufficiently qualified technicians in order to provide adequate coverage of the various production species and devices in each establishment (SSP 53).

This norm initially recognized the Ministry of Health as the sole government institution in charge of the entire regulatory process. However, the Decree 8.077/2013 (SPR) issued later on specified that, in order to exercise activities related to healthcare products, companies also depend on the authorization of ANVISA and the licensing of establishments by competent health agencies of the States, Federal District or Municipalities (SRP 2).

ANVISA Resolution 185/2001 (REG) established the procedures for creation, change, revalidation and cancelation of registries. This Resolution classifies healthcare equipment according to their inherent operational and environmental risk. Invasive equipment or those that may impact the environment belong to the highest risk class. Diagnostic imaging equipment have an intermediate risk classification. While the lowest risk healthcare equipment only have their data stored in ANVISA databases, the other products must be effectively registered and comply with traceability requirements:

> **(REG 4)** The manufacturer or importer shall, in a visible place on the equipment surface, present the following labeling information indelibly: a) manufacturer identification (name or brand); b) equipment identification (name and model); c) serial production number; d) ANVISA registration number;

2) THE FINANCIAL INCENTIVE REGULATION

Many financial institutions provide long-term credit in the Brazilian market aiming to foster the local development. The healthcare service and equipment industry segments are often among their targets.

The case of the Brazilian Development Bank (BNDES) is paradigmatic. This is a state-owned company constituted under private law, which has the Brazilian Workers Assistance Fund (FAT) as its primary source of funding. In order to meet FAT investment goals, BNDES is allowed to apply the supplied resources only in financing projects and products with high degrees of local content or which comply with local value-addition basic production processes (PPBs).

BNDES staff members perform accreditation activities to ensure credit eligibility: the process of officially

recognizing a company as having the manufacturer status and a product as being eligible for financing. Accreditation comprehends: (i) verifying if a company and its products fulfill the applicable requirements; (ii) classifying products as machines, equipment, systems or components; (iii) provided company and product eligibility, granting access to specific BNDES credit lines.

It is important to mention that accreditation processes are rather selective concerning the analyzed companies and products, consequently resulting in frequent denials of access to BNDES credit lines. Typical cases of failure for companies result from the lack of evidence, in the scope of accreditation requests, of manufacturing capability within the country. For products, these denials typically result from the lack of compliance with any of the definitions of machines, equipment, systems or components, such as surgical implants, which instead are regarded as single medical apparatus in Brazil (cf. SPP 25).

Resolution 2.819/2015 (CFI) passed by the Board of Directors of BNDES formally regulated the accreditation process until December of 2018. Since January 2019, however, a new regulation has been in force, as discussed in Section VI.B. Typical duties of accredited companies included: the obligation to inform BNDES about any change in manufacturing processes affecting product local content indexes and value addition processes (CFI 23.XII); the assurance of no intellectual property rights violation arising from accreditation requests or accredited products (CFI 23.V); and the acceptance of exclusive manufacturer responsibility for problems related to product quality, warranty, price, technical assistance, delivery times and customer assistance (CFI 23.IV).

There were also specific requirements on the products subject to accreditation and their sales. For example, they were required to be completely functional (CFI 5.§1) and new (CFI 5.§2). In each sales invoice, manufacturers were required to make reference to the serial numbers (CFI 23.VI) and the accreditation codes (CFI 23.VII) of the products sold with BNDES financial support, which should be identical to those indelibly labeling or contained in plates affixed to the products. Moreover, companies were required to sell with BNDES credit only products that complied with the descriptions provided during the respective accreditation processes (CFI 23.XVI).

In each product accreditation request, a manufacturer could choose between two distinct criteria to be used during accreditation analyses: the attainment of local content indexes or the performance of local value addition steps in basic production processes. In attempts of accreditation due to indexes attainment, the obligations involved:

(CFI 17) For the accreditation of a product based on its local content, the product must attain simultaneously minimal value and weight indexes;

(CFI 10) The local content value index is calculated according to the formula $I_v = (1 – X/Y) *100$, where X is the foreign content cost and Y is the sales price;

(CFI 11) The local content weight index is calculated according to the formula $I_p = (1 – X_p/Y_p)*100$, where X_p is the imported content weight and Y_p is the total product weight;

In turn, only companies in the scope of Law 8.248/1993 (ITL) qualified for accreditation due to PPB fulfillment (CFI 18). The manufacturer obligations included:

(CFI 18.I) Provide evidence of fulfillment of some PPB, which will be evaluated based on habilitation documents jointly issued by the Ministry of Science, Technology and Innovation (MCTI) and the Ministry of Development, Industry and Commerce (MDIC), in addition to other documents requested by BNDES;

(CFI 23.XIII) Keep up to date its documents and data (and those of contract manufacturers) regarding PPB fulfillment and habilitations;

The paradigmatic example of a financing instrument that requires beforehand product accreditation is BNDES Finame (long-term credit for product acquisition, taking the product itself as a guarantee). We focus on this instrument in this paper and provide details on PPBs in the sequel.

3) THE TAX BENEFIT REGULATION

In the Brazilian economy, the use of tax benefits is considered complementary to financial incentive instruments in the formulation of public policies. The healthcare equipment sector is no exception since it is not only benefited by credit lines but also covered by tax incentives granted to the Information and Communication Technology (ICT) sector through ITL. This law ensures rebates of manufacturing taxes over ICT goods in exchange for the application of a percentile of corporate revenues in R,D&I activities performed in cooperation with local universities or research centers, provided that the executed production steps comply with some chosen PPBs.

In order to put ITL effectively in force, it was necessary to provide some additional regulation and promote an extensive regulation revision in this norm, through Law 10.176/2001 (ICC). ICC changed the required percentiles of investment in cooperative R,D&I activities so that they became decreasing with time and regionally dependent. It also modified the percentage of permitted tax rebates, which became decreasing over time. Moreover, this law defined in a precise way the categories of products dealt with by the ICT sector.

Later on, Decree 5.906/2006 (ICR) provided supplementary regulation to ITL and ICC. This decree set ICT products, components, software and services as the items fostered by the regulation. In addition, the decree specified an extensive list of equipment, parts, components and accessories with embedded electronics as the goods

eligible to obtain tax benefits. It also stipulated what it means for the responsible government institutions to establish PPBs and how each ICT company can request tax rebate habilitations.

According to ICR, joint ministerial ordinances published in the Brazilian Official Press establish PPBs for eligible families of ICT goods. Each ordinance specifies production steps and obligations that companies must fulfill in order to enjoy tax rebates. PPB establishment ordinances are goal-oriented norms [4], since they are issued based on public consultations to inquiring manufacturers about the feasibility of performing, even if gradually, production steps and R,D&I investments locally. To obtain a tax rebate habilitation due to the compliance with an established PPB, each company must submit a specific claim to the responsible ministries on how to carry out local production in fulfillment of an established PPB. In case of approval, this leads to the publication in the Official Press of a PPB habilitation ordinance. From the publication date onwards, the manufacturer can enjoy tax rebate benefits. Technical staff members of BNDES consider both types of PPB ordinances while performing product accreditation.

The Joint MCTI/MDIC Ministries Ordinance 101/1993 established a generic PPB (GPP), which applies to the production of any eligible family of ICT goods. We list below the items of GPP that are relevant to our studies:

(GPP 1) For the purposes of (ITL), ICT goods manufactured in the country have local added value if they meet the following production process steps:

(GPP 1.I) Assembly and welding of all electronic components on printed circuit boards (PCBs);

(GPP 1.II) Assembly of electrical and mechanical parts totally disaggregated at the basic level of components;

(GPP 1.III) Integration of printed circuit boards, electrical and mechanical parts to form the final product, assembled following (GPP 1.I-II);

(GPP 1.IV) Management of the quality and productivity of the production process and final product, involving the inspection of raw materials, intermediates, secondary materials and packaging, the process control, as well as the respective tests and measurements;

Instead of obtaining a tax rebate habilitation due to compliance with the generic steps and obligations established in GPP, it is possible to comply with specific PPBs established in particular ordinances, which are restricted to a product model or generic by addressing an entire product family. Table II details the established PPBs applicable to diagnostic imaging equipment.

The requirements posed by the specific PPB ordinances in Table II vary substantially. While the ultrasound equipment ordinance requires the local production of transducers (DUS 1.I) and assembly of PCBs which implement signal detection, processing and output (DUS 1.II), the MRI PPB requires only the local final assembly of the magnet (MRI 1.I) and fueling of coolant (MRI 1.III). Both PPBs also require software installation and configuration locally. In turn, the production steps specified in PPBs establishment ordinances of X-Ray based equipment require locally mounting connections with emission tubes and assembling detectors, as well as aligning them with each other.

TABLE II. DETAILS OF SOME PPB ESTABLISHMENT ORDINANCES

Name	Equipment Model/Category Name	#	Publication
GPP	Any Digital ICT Equipment	101	07/04/1993
CT	Computerized Tomography Equipment	24	09/02/2010
MRI	Magnetic Resonance Imaging Equipment	26	09/02/2010
DUS	Doppler Ultrasound Equipment	256	21/08/2013
FXR	Fixed Digital X-Ray Equipment	19	28/01/2014
MXR	Mobile Digital X-Ray Equipment	24	05/02/2014
PET-CT	Positron Emission Tomography Equipment	26	05/02/2014
NA	Other Not Covered by the PPB Legislation	–	–

There are also many commonalities in the requirements posed by these ordinances. For example, the acquisition of computers, printers and power generation, management and distribution systems manufactured according to the respective PPBs is compulsory in sales of diagnostic imaging equipment with these components. As an alternative to the integration of such locally produced computing and power supply components into healthcare equipment, higher than usual investments in cooperative R,D&I activities are allowed.

As it can be seen, such specific PPBs trade in a way locally assembling and welding PCBs, which may be challenging to perform locally depending on the complexity of the respective manufacturing process, for the local production of critical sub-systems or additional investments in R,D&I activities. The commonalities and differences of requirements in the respective ordinances are what we analyze in the sequel, considering healthcare, accreditation and habilitation compliance, as well as sales, data.

IV. EMPIRICAL METHODS AND PROCEDURES

A. Norm Data Collection & Treatment

The starting point of our empirical study was the set of norms that capture public policies regarding the diagnostic imaging equipment segment in Brazil. Initially, we had to identify which were those norms (outlined in Section III.B), then obtain their textual contents online and later on transform the representation of these documents into a tabular format.

Afterward, we carried out another kind of transformation while preserving the hierarchical structure and semantics of each norm. This transformation was applied in order to eliminate irrelevant norm parts for the purposes of our analyses, such as norm title, headings, type, number and date, keeping just the norm body. The structural elements used to ensure just the effective

presentation of each norm were also eliminated, such as redundancies and unnecessary punctuation.

We respectively captured the external and internal structure of the studied regulation through the unique identification of norms and their parts using the pattern mentioned at the beginning of Section III.B. As a final step in treating regulatory documents, we traversed each norm to substitute cross-references by the respective identifiers.

B. Compliance and Sales Data Collection & Treatment

The main subjects of our study were the producers of diagnostic imaging equipment established in Brazil. According to ANVISA, there existed just 52 companies with some (imported or not) registered healthcare equipment at the end of 2017 [18]. We gathered a dataset containing only the 13 local manufacturers, those that could decide to comply or not with the whole set of studied regulations. However, just nine of them had their sales observed in our data collection process and only six had habilitations to enjoy tax rebates at the end of 2017, according to MCTI [19]. Table III presents the demographics of the studied companies and products.

TABLE III. DEMOGRAPHICS OF STUDIED COMPANIES & PRODUCTS

Company	Origin of Capital	Products in Dataset	Product Types	PPBs
A	South America	8	DUS	Yes
B	South America	3	Other	No
C	South America	1	Other	No
D	North America	11	CT,DUS,MRI MXR	Yes
E	South America	1	FXR	No
F	Europe	16	CT,DUS,FXR,MRI,Other	Yes
G	Europe	12	CT,DUS,FXR,MRI	Yes
H	Asia	8	CT,DUS,MRI	Yes
I	South America	3	Other	No

We organized our dataset in terms of the Brazilian Corporate Tax Payer Registry (CNPJ) unique identification number of each company. The dataset also contains the company name, primary origin of share capital, product portfolio, compliance and sales data: dates in which registry, tax benefit habilitation and credit accreditation, as well as sales, first happened for each studied product.

We gathered compliance and sales data from primary sources only. To begin with, we run queries using business intelligence solutions of BNDES to obtain financed sales data. The studied companies, when questioned, reported the existence of some other sales. Next, we queried online public databases to obtain registration [18], habilitation [19] and accreditation [20] data. Finally, we sent particular questions to companies to clear apparent inconsistencies in the collected data, which were then answered and treated.

It is important to mention that our data collection procedure followed a sequential and exhaustive procedure rather than random sampling. The primary rationale for adopting this decision was the high coverage of BNDES financed sales data in relation to all the sales in the analyzed period. According to the studied companies, typically more than 80% of their sales were financed by BNDES in this period. We are aware that this decision poses vital threats to the validity of the reported research, which are analyzed in Section VII.

We formulated the following definitions to refer to the dates of PPB establishment, compliance and first sales:

d_e: Establishment of a PPB applied to an equipment production;
d_h: Tax rebate habilitation to foster an equipment production;
d_r: ANVISA registration of an equipment;
d_a: BNDES accreditation of an equipment;
d_{fs}: First BNDES Finame financed sale of the equipment;
d_{os}: Other reported or observed sales of the equipment;
$d_s = min\ (d_{fs}, d_{os})$: Date of the first sale;

Fig. 2 provides a diagrammatic representation of these dates and the corresponding measures:

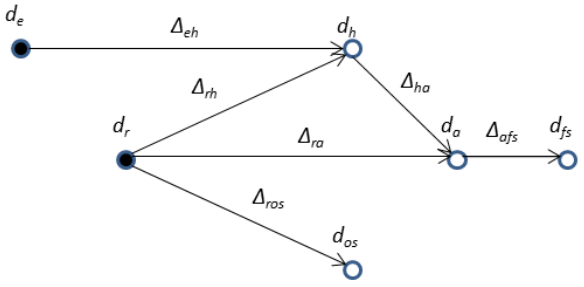

FIGURE 2. Partial temporal order of dates and respective measures.

All the equipment models explicitly mentioned in Table II appear in our dataset, except PET-CT devices, which have not been produced in Brazil. The dataset also contains observations regarding other products, such as audiological, otoneurological and vestibular imaging equipment, as well as manographs and angiographs, whose production processes either comply with the generic PPB or do not comply with PPBs at all (therefore accredited by BNDES due to the attainment of local content indexes). Table IV presents the statistical outline of our dataset.

C. Data Adjustment, Filtering & Computation

We had to perform many adjustments to recognize under some companies the habilitations issued to subsidiaries, a common practice among foreign capital manufacturers established in Brazil. We also recognized under some manufacturers the registries, habilitations and accreditations initially granted to other companies, due to merger and acquisition processes, in addition to economic group reorganizations, happening over time in the country.

TABLE IV. STATISTICAL OUTLINE OF OUR DATASET

		Products							
	Companies	**NA**	**GPP**	**CT**	**MRI**	**DUS**	**FXR**	**MXR**	**PET-CT**	**TOTAL**
Registries	52	123	NA	52	44	134	40	34	12	439
In Dataset	13	32	7	21	18	15	2	1	0	96
Coverage	25%	26%	NA	40%	41%	11%	5%	3%	0%	22%
Habilitations	6	NA	13	41	27	20	7	2	0	110
In Dataset	6	NA	7	21	18	15	2	1	0	64
Coverage	100%	NA	54%	51%	67%	75%	29%	50%	NA	58%
In Dataset	13	32	7	21	18	15	2	1	0	96
Selected	9	9	6	17	14	14	2	1	0	63
Coverage	69%	28%	86%	81%	78%	93%	100%	100%	NA	66%

We organized the collected data in distinct time series of registries, habilitations, accreditations and sales. Some of these series begun in January of 1998 and end in December of 2017, but we noticed high variability in the beginning of this period due to regulatory transitions. Indeed, the practices adopted in Brazil until 2017 appeared only after the Brazilian Government passed REG in 2001 and ICR in 2006, as well as BNDES changed CFI to adopt PPBs as an alternative accreditation criterion in 2007. Consequently, we decided to apply a temporal filter ignoring any observation corresponding to sales before 2008 (that is, we analyzed only the ten years from 2008 to 2017). The last three lines of Table IV reflect this filter.

Taking into account the partial temporal ordering of registration, habilitation, accreditation and sale events, we finally used the definitions above to compute derived data, according to the measure specifications below:

$\Delta_{eh} = d_h - d_e > 0$: Time to comply with an established PPB;
$\Delta_{rh} = d_h - d_r$: Time from registry to habilitation;
$\Delta_{ra} = d_a - d_r$: Time to comply with the accreditation norm;
$\Delta_{ha} = d_a - d_h$: Time from habilitation to accreditation;
$\Delta_{ros} = d_{os} - d_r > 0$: Time from registry to first non-financed sale;
$\Delta_{afs} = d_{fs} - d_a > 0$: Time from accreditation to first financed sale;
$\Delta_{rfs} = d_{fs} - d_r > 0$: Time from registry to the first financed sale;
$\Delta_{rs} = min\ (\Delta_{rfs}, \Delta_{ros})$: Time from registry to the first sale.

V. DATA ANALYSES AND RESEARCH FINDINGS

Now we show that some elicited time-to-benefit measures depend on the technical requirements found in the studied norms. We demonstrate here significant differences in some observed measures depending on the distinct regulations that the studied categories of diagnostic imaging equipment comply with. This is, in fact, an extended version of the research first reported in [7].

Our time-to-benefit measures have two baselines: the issue date of a PPB establishment ordinance for an equipment category (d_e) and the healthcare product registry date with ANVISA (d_r). The terminal dates in our measurements are those in which benefits are ensured to companies: the dates from which tax rebates can be enjoyed (d_h) and credit for sales can be obtained (d_a), as well as the effective market entry date (d_s, the lesser of d_{fs} and d_{os}).

The partial temporal order emerging from such events highlights possible statistical relationships and causal connections between the respective occurrence dates. Thus, we arranged our measures according to a factorial design by computing a correlation matrix between pairs of observed measures. Since our definitions already explain some correlations, we focused on the correlations that do not exist just by definition and derived conclusions from the alternative paths allowed by the implied order.

Despite the existence of any such correlation, observations of our measures are statistically independent of one another, in the sense that each observation does not affect the probability of occurrence of another one of the same kind. This fact allowed us to perform statistical analyses in order to determine dependencies and causal connections between measure groups, as well as to study their relationships with normative technical requirements.

We wondered whether distinctions in measure observations happened just by chance. The standard technique to investigate such situations is hypothesis testing, which was adopted here. Variance analysis and *post hoc* multiple comparison methods also helped us in identifying distinctive groups of observations and spotting where variance lied. Since our data were not normally distributed and were arranged in groups of different sizes, we chose to adopt non-parametric statistical tests that treat these circumstances.

We applied Kruskal-Wallis tests to determine differences between group means [21]. The test ranks all observations, combines them in groups and compares average group ranks. The null hypothesis corresponds to a situation in which all groups have the same mean (that is, the same average rank), consequently not presenting statistical distinction among themselves. The main hypothesis is that some groups have distinctive means. Since the test only works appropriately for groups with five or more observations, we put together all the data from groups with up to four elements, forming a single distinct group.

We also performed *post hoc* analyses to identify which groups were different from each other. These analyses demanded the computation of z indexes based on the differences between the average ranks of each pair of groups. The computed indexes were then checked against the z statistics for significance. We adopted a significance level of *0.05* in our whole study.

A. Tax Rebate Time-To-Benefit

Recall that Δ_{eh} measures, since the establishment of a specific PPB, the time spent by a manufacturer to provide the responsible ministries with convincing evidence of compliance with the production steps and R,D&I obligations posed by the chosen PPB establishment ordinance. This effort is driven by the interest of the manufacturer to obtain attractive tax conditions for launching a new product in the market, since this company can enjoy, once habilitation is granted, rebates in production taxes charged in the event of each sale. Even before any sale, customers can perceive this benefit when the tax rebate is treated as a deduction in pricing models. Since the PPB establishment ordinances applicable to diagnostic imaging equipment are diverse, this led us to formulate the following research question:

(RQ 1) Does tax rebate time-to-benefit depend on the normative technical requirements of diagnostic imaging equipment?

We tried to answer (RQ1) arranging the Δ_{eh} data in groups organized according to the PPB ordinances that could be adopted in the production of each ICT good (listed in Table II). We ended up with *54* observations distributed in five groups of different sizes. In order to apply the Kruskal-Wallis test, we computed, from group sizes and their average ranks, a statistics $H = 30.5974$ with four degrees of freedom, yielding a *p*-value of *0,000004*, which is smaller than our significance level. This allowed us to reject the null hypothesis and confirm that there was some group with a distinctive Δ_{eh} mean. Since we arranged Δ_{eh} groups according to PPB establishment ordinances and each ordinance poses distinct normative technical requirements on (the manufacturing processes of) diagnostic imaging equipment, this allowed us to answer (RQ1) positively.

We also performed a *post hoc* analysis to identify pairwise differences in Δ_{eh} means between groups. The analysis showed statistically significant differences in Δ_{eh} means of diagnostic imaging equipment complying with GPP in relation to the groups determined by CT, MRI, DUS and FXR+MRX, as well as for DUS equipment when compared to those complying with CT or MRI. The box-plot in Fig. 3 illustrates this situation.

The box-plot in the figure shows distinctions in Δ_{eh} means (the square box inside each fat bar) and variability (presented through the height of each bar) between groups. In particular, it elucidates the distortion caused by the fact that GPP was established long ago, nevertheless putting complying equipment in a distinct group. Besides, the box-plot presents without distinction the CT and MRI groups, which in turn are displayed apart from the DUS group. Finally, the graph also depicts our reason for joining the FXR and MXR groups: their small number of observations.

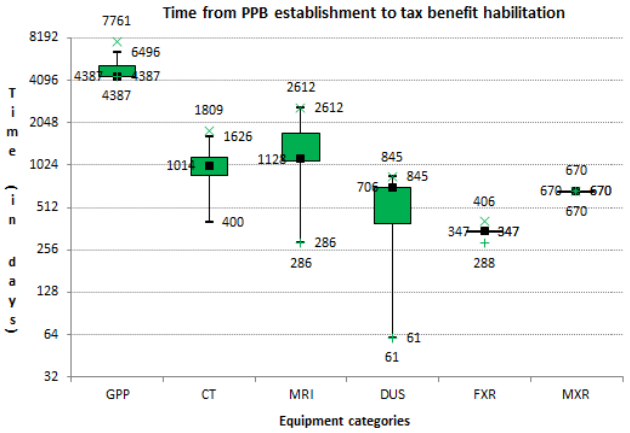

FIGURE 3. Box-plot of tax rebate time-to-benefit measures.

When we treated the GPP group distortion, by adopting the 2008 version of this PPB establishment ordinance instead of its 1993 version, we reached the same conclusions. We also noticed that, in each product category, there were no significant differences in measure observations from one company to another. Thus, we concluded that the significant distinctions in tax rebate time-to-benefit measures between the groups GPP, CT+MRI and DUS were due to the different technical requirements in the ordinances giving rise to these groups. As an aside, we also noted that the lack of distinction between the CT and MRI groups arose from the similar requirements established in the respective PPB ordinances, since diagnostic imaging equipment in these categories are structurally similar, much as their assembly processes. Moreover, because of the existing distinctions between and within groups, there was considerable variability: Δ_{eh} average was 743 days and standard deviation 793 days after treating the GPP ordinance distortion.

B. Credit Time-To-Benefit

Recall that Δ_{ra} measures, since the registration of a healthcare product with ANVISA, the time spent by a manufacturer to provide BNDES with acceptable evidence of compliance with the requirements posed by a chosen PPB establishment ordinance or the attainment of local content indexes. This effort is driven by the interest of the manufacturer to obtain attractive financing conditions for launching a new product in the market, since this company can enjoy, once accreditation is granted, credit for product sales. Even before any sale, customers can notice this benefit when commercial proposals make explicit reference to the available financing conditions. Considering that the PPB establishment ordinances applicable to diagnostic imaging equipment are diverse and a manufacturer may even decide not to comply with any of them, this led to the following research question:

(RQ 2) Does credit time-to-benefit depend on the normative technical requirements of diagnostic imaging equipment?

We tried to answer (RQ2) arranging Δ_{ra} data in groups corresponding to the PPB ordinances listed in Table II and the attainment of local content indexes (denoted by NA). We ended up with *55* observations in six groups. To apply the Kruskal-Wallis test, we computed a statistics $H = 6.2915$ with five degrees of freedom, yielding a *p*-value of *0.2788*, higher than our significance level. This prevented us from rejecting the null hypothesis and from answering (RQ2) affirmatively. We present the respective box-plot in Fig. 4.

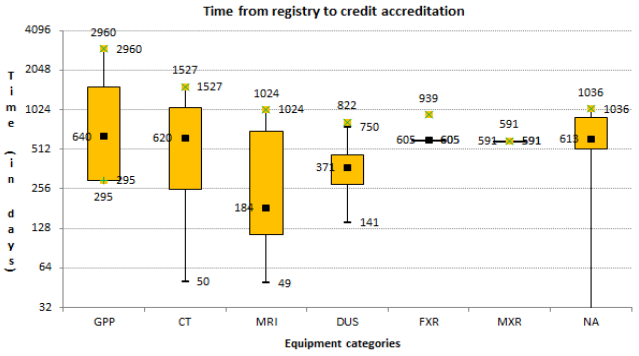

FIGURE 4. Box-plot of credit time-to-benefit measures.

Although this conclusion may appear to be a surprise, sufficient justification arises from the fact that BNDES accreditation is not tightly connected to product registries or tax rebate habilitations, which are not mandatory for accreditation. Indeed, our box-plot shows that mean credit time-to-benefit is not sensibly different among groups, but variability is high: Δ_{ra} average was 565 days and standard deviation was 484 days.

C. Market-Entry Time-To-Benefit

Recall that Δ_{rs} measures, since the registration of a product with ANVISA, the time spent by a company to perform the first product sale. This effort is driven by the interest of the company in introducing the new product into the market. Considering that PPB establishment ordinances applicable to diagnostic imaging equipment are diverse, but a company may decide not comply with any of them to introduce a product in the market, this led us to formulate the following research question:

(RQ 3) Does market entry time-to-benefit depend on the normative technical requirements of diagnostic imaging equipment?

We tried to respond (RQ3) arranging the computed Δ_{rs} data in groups formed by the adopted PPB ordinances or the attainment of local content indexes. We ended up with 62 observations in six groups. We applied the Kruskal-Wallis test and computed a statistics $H = 9.1642$ with five degrees of freedom, yielding a *p*-value of *0.1027*, which is higher than our significance level. This did not allow us to reject the null hypothesis, preventing an affirmative answer to (RQ3). Fig. 5 depicts this situation.

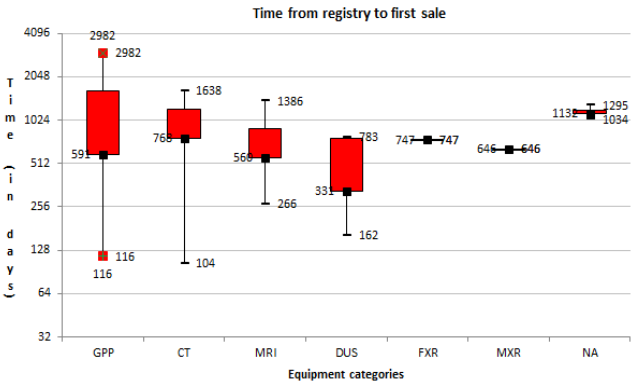

FIGURE 5. Box-plot of marker entry time-to-benefit measures.

Again, this conclusion is not surprising, given that, although performing similar functions, diagnostic imaging equipment are not required to comply with PPB establishment ordinances when introduced into the market. Also, notice that, in this case, Δ_{rs} average was 734 days and standard deviation was 536 days.

VI. FROM COMPLIANCE TO PROCESS IMPROVEMENT

Even though the empirical study described so far was effective to identify distinctions in time-to-benefit measures, its low level of abstraction was evident, since the underlying regulatory processes were hidden underneath statistical models and analyses. Consequently, higher-level process mining studies were considered necessary.

In the healthcare sector, process models have been used to describe business and regulatory processes, to guide automated executions, to communicate with stakeholders, to evaluate and improve designs [14]. With these goals in mind, we decided to adopt process-mining techniques for model elicitation and process improvement. We present in this section the outcomes of these activities.

A. Healthcare Regulatory Process Mapping

In order to approach healthcare equipment and their regulations from a process mining perspective, we adopted the same dataset described in Section IV. Consequently, we defined, as in [12,14], that a case is a process instance, that is, an execution of a process; an activity is a well-defined task in a process model; an event is an occurrence of a process activity, and a trace is an ordered sequence of process events.

Here, each case corresponds to the lifecycle of specific diagnostic imaging equipment, which is uniquely identified in our dataset by the respective BNDES accreditation code. The studied activities correspond to the relevant events that may happen during the equipment lifecycle (ANVISA Registration, Tax Rebate Habilitation, BNDES Accreditation, Finame Sale and Other Sale). The respective events carry the activity name and completion date, as well

as the product name, the CNPJ number and the equipment manufacturer name.

Our event log is an orthogonal aggregation of data in our original dataset (described in Section IV), which contains 62 cases and 251 events related to the five activities mentioned above. In accordance to the process mining methodology, the name and date of issue of the PPB establishment ordinance adopted in manufacturing each kind of equipment (if any) were considered process resources, in the sense that they were available beforehand and could be chosen in defining process cases. Moreover, due to the initial treatment of our original dataset, we could notice that all the performed cases were complete [6], meaning that their traces contained at least an ANVISA Registration and some sale (either Finame or Other Sale events).

We adopted the ProM[1] toolkit to deal with event logs. Our dataset was imported into ProM using the Smart CSV Importer Tool. Internally, this tool treats imported data using the IEEE 1849-2016 Standard format for eXtensible Event Streams (XES). While the standard allows for associations of formats to data, the tool also permits the specification of their semantic roles in generating process models.

In our study, the ProM Causal Activity Discovery Tool [22] received the derived log as an input. This tool implements a process discovery algorithm that allowed us to elicit the respective causal graph and transition matrix. The corporate perspective area of Fig. 6 presents the model derived from these data structures as a state-based process map. In order to comprehend the elicited data in this state-based manner, we decided to connect the respective activities to initial and final states, as in [14]. In addition, we added a governmental perspective to the model to represent the lifecycle of the resources used in the corporate perspective.

The precise and simple process model presented in Fig. 6 allowed us to develop a refined understanding of the overall structure of the healthcare equipment regulatory process in Brazil. From the government perspective, the process begins with the preliminary studies and public consultations needed for the issuance of a PPB establishment ordinance. Once each ordinance of this kind is effectively issued, companies may initiate the cases specified in the corporate perspective on this basis. From the corporate point of view, each case begins with an ANVISA Registration, a Tax Rebate Habilitation or a BNDES Accreditation. Each of these cases is concluded with the introduction of a product in the market, corresponding to the first product sale event (financed or not). Our model also presents, as additional information next to each state transition, the computed causal connection measures between activities in the event log (where one would correspond to perfect causality) [22].

The elicited model explicitly captures the perspectives and activities of the studied processes and makes it possible to identify relationships between perspectives. Specifically, it

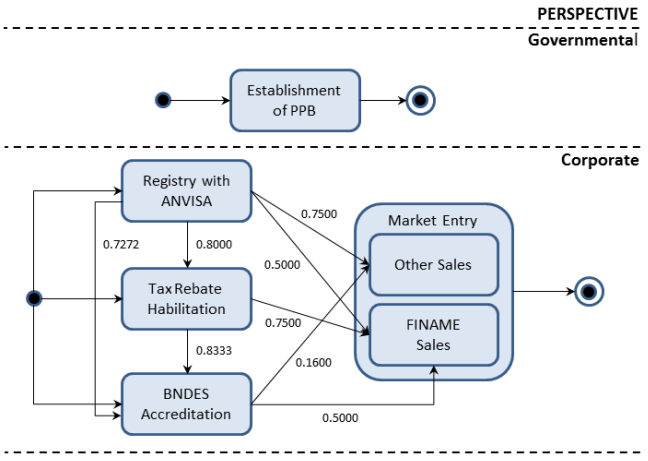

FIGURE 6. Elicited regulatory process model of healthcare equipment.

allowed us to identify that the government perspective generates resources to be used in the corporate perspective. In this respect, we noticed that there are hidden resources in the respective process, namely the BNDES and ANVISA regulations, which rarely change and had not changed in the initially studied period. For this reason, they were considered as immutable regulations, which are not represented in the derived state-based model. The model also helped us in clarifying two important precedence relations [12]: if a PPB habilitation occurs, then the respective PPB establishment happened before, and, if sales occur, then the respective registry happened before.

B. Subsequent Process Improvement Activities

From 2015 to 2017, the technical staff members of BNDES conducted a series of studies (including that reported in Sections III-V) aiming to reduce the duration of benefit granting processes and increase their efficacy in what regards the achievement of public policy goals. Indeed, at that time, the duration of these processes was high, as well as their temporal variance. Although this is not explicit in the box-plots presented in Section V, due to the logarithm scales adopted therein, the average and deviation data presented at the end of its subsections depict the situation at that time clearly. Consequently, the evaluation of the policy measures then in force was that benefit-granting processes had not always been effective in fostering local R,D&I and production.

As a first process improvement attempt, the studies that led to the elicitation of the process map in Fig. 6 were performed in order to ground subsequent activities. Next, a new accreditation regulation was proposed and approved by the Board of Directors of BNDES at the end of 2017. This new regulation became in force in December of 2018.

The main change in the accreditation process was in local content indexes. Instead of using value and weight indexes, which are not always effective and may be subject to manipulation, a product structure index was adopted. This new index is computed in terms of the local direct cost of

[1] http://www.processmining.org

production in proportion to the total direct production cost of each product. Moreover, it became possible to attribute bonuses to index computations, depending on the satisfaction of elective quantifiers. The admissible quantifiers have been the percentage of local and total components embedded in the product that are supplied by technology-intensive industries, as well as the added-value increment, the innovation effort, the amount of exports and the technical workforce maintained by each company. It should be noted that the adoption of accreditation quantifiers turned this into a more dynamic goal-oriented regulation.

Meanwhile, there was a complete digitization of the submission and analysis of accreditation requests, through the design, implementation and deployment of two new information systems. The model presented in Fig. 6, as well as the respective precedence relations and other additional sources, served as inputs for the respective requirements elicitation activities. In total, 164functional requirements and quality attributes were specified in the textual form as a result of these activities. Specifically, event log data pointed out informational requirements (typically user interface and database fields). In contrast, process activities and their precedence relationships were used to derive information processing requirements (typically data transformations and ordering constraints). Furthermore, the elimination of paperwork and the adoption of automated workflows were considered key non-functional requirements in systems design, implementation and deployment activities. The respective software development processes adopted agile methods so that delivery times were acceptable.

All these accreditation process changes promoted a sensible reduction in accreditation times and enhancements in the quality of collected information on accredited companies and products. In particular, it became possible to measure in days, instead of months, the duration of accreditation request analyses, procedures of document recovery and generation of audit traces. Regarding the specific treatment of healthcare equipment, the feasibility for each company of satisfying all elective accreditation quantifiers was considered beneficial to this segment by the respective healthcare equipment manufacturer associations.

In the same period, since July of 2015, there has been a vital dispute mediated by the World Trade Organization (WTO) regarding the compliance of the Brazilian PPB legislation with international trade agreements and standard international commerce practices. The Japanese government raised this dispute with the support of other countries. In January of 2019, the Appellate Body of the WTO settled the discussion by considering that most of the PPB legislation is admissible, provided the elimination of exemptions or reductions of internal taxes affecting the condition of competition between similar products. Besides, the WTO considered that specific formulation aspects, namely the recursive definition of PPB establishment ordinances in terms of other ordinances (such as those mentioned at the end of Section III.B.3), should be removed from this regulation. As a result of the commitment with this decision, the Japanese and Brazilian governments reached an agreement.

Because of the established agreement, the competent Brazilian authorities have implemented a revision process in the tax rebate regulation. Apart from changing adopted taxation bases from production taxes to general tax credits, this revision has introduced into the regulation a scoring procedure similar to that adopted in the new BNDES accreditation process. In other words, the improved process introduced the possibility of issuing tax rebate habilitations depending upon the scoring of quantified and cumulative execution of basic production processes.

The staff of MCTI/MDIC have carried out the necessary changes in a stepwise manner, based on an exhaustive map containing all the PPB establishment ordinances currently in force, as well as their dependencies. This is a general PPB legislation map, in which Table II is included. This revision process has gradually eliminated recursive definitions in PPB establishment ordinances while implementing therein the execution scoring criteria. Regarding the treatment of healthcare equipment in general, public consultations have been issued and their results analyzed. In particular, the public hearings addressing fixed and mobile X-Ray equipment were issued on 28 May 2019 and, as a result, on 27 August 2019, two new versions of FXR and MXR were published in the Brazilian Official Press. In turn, PPB habilitation ordinances do not require any modification, since they are issued on behalf of specific companies to enforce public policies, rather than to specify the policies applicable to specific categories of ICT goods.

In these regulation improvements, teams of MCTI/MDIC and BNDES staff members benefited from cooperation. For example, in order to answer queries from healthcare equipment manufacturers, it has been clarified that the usage of remanufactured components, particularly MRI magnets, would not qualify manufacturers to obtain tax benefits and financial incentives. This was formalized as a supplementary MRI PPB ordinance by MCTI/MDIC and as an internal BNDES technical note, in compliment to regulation that already addresses entire manufactured products (cf. CFI 5.§2). Such regulation enhancement processes are still underway and, in the end, the applicable regulation will become more straightforward, transparent and easily enforceable, thus ensuring legal certainty.

In terms of the measures discussed in Section V, the described regulation changes have produced only preliminary results so far, due to their limited time in force. Indeed, only incomplete cases have been observed: there were only five diagnostic imaging equipment accreditation analyses underway within BNDES in August 2019, from three different companies, without observed sales at that time. Nevertheless, the respective process improvement activities have substantially changed the applicable regulation, making it more data-oriented and goal-driven. In particular, regulated

process duration and variance have already decreased, as well as data quality on products and companies increased. Thus, the effectiveness of corresponding public policy measures is about to increase, particularly with the foreseeable reduction in mean times-to-benefit. These enhancements would not be possible without an improved regulated process understanding such as ensured by the performed empirical study and the elicited process map.

VII. THREATS TO VALIDITY

The main threats to the validity of our empirical study findings are related to the constructs and variables we have adopted, respectively formulated in the planning phase of our study and used in our data collection, adjustment and derived data computation procedures. Apart from these, there may exist concerns regarding the correct derivation of our conclusions from statistical analyses (conclusion validity) and the complete explanation of these conclusions in terms of studied dependent variables (internal validity). External validity, on the other hand, was not among our concerns, since the studied companies, products and regulations are relevant within the Brazilian economy only.

Concerning the collected data and their initial treatment, even though we adopted multiple and sometimes divergent sources, we perceive data quality to be high in our studies because government institutions originally compiled these data for official purposes. In fact, the capability of integrating different public data sources around company CNPJ and product name was a critical enabling factor for conducting data collection procedures. Subsequently, we also cleared all apparent data inconsistencies by directly querying the studied companies.

Raw data was adjusted and filtered, as well as derived data computed, in many different situations. Frequently, adjustments were required due to the changing structure of the studied economic groups over time. Despite the observed changes, in the studied context, they involved legal aspects only, but not operational ones, consequently not disturbing production or value addition processes, neither our analyses. Likewise, transient instabilities in the studied legislation led us to apply temporal filters in order to eliminate their effects from our analyses. Finally, to make relationships between events explicit, we performed derived data computations. We believe that these adjustments, filters and computations mitigate potential construct validity threats that could have arisen otherwise.

We collected a dataset covering 25% of the companies and 22% of the products registered with ANVISA (which correspond to 100% of the companies and 92% of the products with local production respectively). We decided to adopt this high coverage of the studied domain to avoid internal validity threats such as incomplete capture. However, data collection followed a sequential and exhaustive procedure, but not random sampling. The lack of randomness may harm the possibility of generalizing our findings obtained from statistical hypothesis testing, since the general validity of their results depends on the randomness assumption.

Nevertheless, we provided statistically significant evidence that tax rebate time-to-benefit measures depend on the technical requirements found in norms applicable to the diagnostic imaging equipment segment in Brazil. We found no evidence that something similar holds regarding credit and market entry time-to-benefit measures. We reached these conclusions from samples covering 57%, 44% and 22% of the respective populations. Higher coverages could hardly be obtained in these cases, due to the unavailability of additional public data sources. In other to validate these findings further, another BNDES technical staff member reviewed our data collection and analysis procedures, apart from taking part in the discussion of the research findings. We carried out this second opinion-gathering procedure to reduce any existing expert opinion biases. We also developed alternative analyzes and performed cross-validation using descriptive statistics and charts, as well as complementary process mining studies, which confirmed our conclusions. The adoption of these alternative validation methods also mitigates the risk of existing confounding factors not considered in our analyses.

Due to the lack of randomness in our data sampling procedures, it is a subject for further research to determine whether or not our conclusions hold regarding other healthcare equipment types and regions, as suggested in Section IX.

VIII. DISCUSSION

Healthcare processes are highly dynamic and complex, increasingly multidisciplinary and often performed in *ad hoc* ways [14]. Typical problems in this domain are failures in the formulation of process models, low compliance between applicable rules and the actual processes executed, and interoperability barriers due to the required intense interdisciplinary cooperation [13]. Thus, a high level of governance in these processes is required.

The research we have developed contributes to improving the governance of the diagnostic imaging equipment segment. As we could notice, the applicable regulation comprises diverse (kinds of) documents, is frequently goal-oriented and sometimes subject to substantial changes. Moreover, this regulation typically covers many disciplines, such as clinical, biomedical, financial, production and electrical engineering. Regulated processes are not always well known and compliance is often subject to the relatively hermetic assessment of specialists. Public policy goals are often retargeted and technical requirements recalibrated. These challenges point out the need for monitoring healthcare equipment regulatory processes continually with a view of mitigating compliance violation risks [13], as well as exploiting opportunities for process improvement.

From the governmental perspective, our work is relevant because it suggests improvements in regulatory processes and norms. Our studies are suggestive of the formulation of a new PPB establishment ordinance containing the commonalities in the treatment of all types of diagnostic imaging equipment. Such a new ordinance can, in relation to the already established PPBs, balance in a distinct way required production steps and R,D&I obligations in comparison to the benefits granted to manufacturers, thereby yielding alternative time-to-benefit choices. This would ensure more freedom to and require more responsibility from corporate managers of healthcare equipment companies, since they could adopt a more rational approach in their decision-making processes, going beyond the mere adherence to regulatory requirements [1]. This path has been pursued in Brazil regarding the telecommunications and industrial automation equipment segments, but not regarding the diagnostic imaging equipment segment, something already suggested to the competent authorities.

From the societal perspective, the collection and analysis of empirical data in the way proposed here, integrated to the development of process-oriented studies, seems to be convenient, since this may contribute to affordability, cost-effectiveness and broader patient accessibility goals in healthcare. Indeed, there is widespread recognition that healthcare costs are escalating in unprecedented and sometimes unpredictable ways [13,23], in many cases due to the high costs of the technology-intensive equipment offered by suppliers. Besides, the lack of compliance with clinical procedures and healthcare process models is an identified cause of outliers and bottlenecks [12], which restrict patient diagnosis and treatment capabilities. Thus, not only the empirical collection and analysis of healthcare equipment data, but also the planned action based on respectively elicited process maps, seem to define a safe path to ensure improved productivity and sustainability in the healthcare sector.

Furthermore, from the corporate perspective, it is crucial to study times-to-benefit and their variability for financial reasons. This is so because private companies usually seek to stay ahead of the competition by ensuring high levels of customer satisfaction and strict compliance with regulations, bearing in mind their revenues and costs, respectively. As we have shown, some of the respective measures depend upon the compliance of healthcare equipment manufacturing processes with technical requirements present in norms. Although [10] develops a particular analysis on how enhanced requirement engineering processes influence time-to-specification measures, here we have extended this kind of analysis to various time-to-benefit metrics, covering regulatory requirements and manufacturing processes. Taking into account this kind of analysis, diagnostic imaging equipment manufacturers should be compelled to consider times-to-benefit in their management decisions covering process or product variability [24], in order to achieve their corporate goals. Moreover, such companies should be concerned with analyzing and ensuring compliance, as well as with regulation dynamics, since these contribute to tuning processes and improving products considering current regulatory and market needs.

IX. CONCLUSION

In this paper, we presented an exploratory case study showing that mean tax rebate times-to-benefit depend on the compliance of diagnostic imaging equipment with technical requirements found in the applicable Brazilian goal-oriented regulations. We have also provided evidence that the expert knowledge underlying this study, when used in conjunction with process-mining techniques, contributes to process improvement in this context. These findings provide sufficient justification and motivation for healthcare equipment product-management practices to be concerned not only with analyzing and ensuring regulatory compliance but also with regulation dynamics, due to their impact in corporate finance.

Although the context of our studies is local and just a specific market segment is covered, we believe that our research findings are of general interest and may be valid regarding other healthcare equipment segments and regions. We describe in [25] another example related to the transformation of the healthcare sector in Brazil. In fact, the joint adoption of expert knowledge, empirical methods and process improvement techniques has been a pivotal instrument to promote digital transformation in healthcare and society. We hope that examples like these serve as inspiration for government agencies, private companies and society to pursue the transformational path.

The research reported here is part of a broader agenda, which seeks to demonstrate and assess the contributions to ICT businesses of normatively treating technical requirements. The additional illustration of these contributions in practice, for example with the transportation of this study to other healthcare equipment segments and other regions, is a definite candidate for future work.

X. ACKNOWLEDGMENTS

The author is an employee of the Brazilian Development Bank (BNDES). BNDES finances most of the companies analyzed in the reported research. The author had full access to the data used in his research and takes complete responsibility for data integrity, the accuracy of data analyses and the interpretation of research outcomes. The assumptions, views and opinions in this paper are solely those of the author and do not necessarily reflect the official policy, strategy or position of any Brazilian government entity.

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