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AN INVESTIGATION INTO AN APPROACH FOR AUTOMATED SUPPLY CHAIN ONBOARDING

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ABSTRACT
The COVID-19 pandemic has brought the cold chain for biopharmaceutical products to the spotlight. To preserve their structure and function, biopharmaceuticals such as cells, proteins and enzymes, RNA molecules, and RNA-based drugs (e.g., mRNA-based COVID-19 vaccines) require low temperatures for proper handling, storage, and transport. Due to the sensitivity of these products transported through cold chains and the lack of traceability, risks associated with the stability, efficacy, safety, tardiness, quality, and waste are significant. For this reason, the ability to quickly find, connect, and do business with a new supply chain partner, such as in cold chain partnering is essential. Many researchers suggested various approaches to improve the effectiveness of cold chains. However, standardization and interoperability remain open challenges. Motivated by the biopharma risks and the need for interoperability, this paper presents a preliminary investigation into a novel approach for automating the onboarding of new supply chain partners. Based on the analysis of previous efforts in the cold chain domain, the notion of external context is recognized. In addition, the paper introduces the notion of business context which is proposed as a basis for a novel approach to achieve agile supply chain via automatic supply chain partner onboarding. Cold chain networking is used as a specific case study. The investigation results show that, with identified improvements, the approach has a potential to increase the automation in supply chain integration.
Keywords: Cold Chain; Context-awareness; Integration; Standardization; Supply Chain, Biopharmaceutical.

1. INTRODUCTION
The COVID-19 pandemic has brought cold chain for biopharmaceutical products to the spotlight. Biopharmaceuticals such as cells, proteins, enzymes, and RNA-based drug products (mRNA COVID-19 vaccines), are extremely temperature sensitive and require very low temperature (e.g., -70 °C) during transport and storage. A reliable cold chain has become an important issue in the biopharmaceutical supply chain. Due to the sensitivities of raw materials and products transported through the cold chains and the lack of traceability concerns about quality and waste are significant. Cold chain is defined as a "temperature-controlled supply chain" [1]. As the cold chain operates in a temperature-controlled environment, it is imperative that they do not face any interruptions along both the forward logistics for raw materials and the distribution of finished products.

Many researchers suggested various supply information integration approaches to improve the effectiveness of cold chains; however, Pal et al. indicated that standardization and interoperability remained open challenges [2]. Specifically, the problem we are interested in is that the traditional, long-running approach for supply chain partner onboarding is ineffectively addressing situational supply chain issues. Supply chain partner onboarding is the process of identifying a trading partner and establishing electronic communication between trading partners. The traditional onboarding approach requires trading partners to have continuous business relations and their business systems can be communicated ahead of any business needs. However, such requirement renders supply chain integration less agile and inadequate to address unplanned disruptions that require immediate resolution such as in the case of the cold chain. It is important to note that unless trading partners have continuous trading relations, electronic communications established *a priori* may also not work at the moment needed because business systems may have evolved [1]. Recently, a novel approach based on a business context for improved standards-based systems integration was proposed [3] that could automate part of the supplier onboarding process pertaining to determining and establishing the compatibility of business semantics between trading partners in electronic communication. The results of that study will be employed as a foundation for onboarding automation in this paper.

The contribution of the paper is a preliminary evaluation of the novel solution for automated supply chain onboarding using a simplified cold chain scenario. The purpose of such evaluation is to identify gaps that establish a foundation for more detailed studies. The use case uses message standards from the Express Pack (see Section 2.4 for a discussion of EPs) for Real-Time Release of Raw Materials (RTRRM), which was recently released by Open Application Group Inc. (OAGi). RTRRM has predefined supply chain messages profiled for application integration in the biopharmaceutical industry [4]. Specifically, we use the Shipment message from the package for our evaluation. RTRRM was created by using the Score platform, which was developed in cooperation between the National Institute of Standards and Technology (NIST) [5] and OAGi [6] to support standards' development and usage processes [7,8].

Central to the evaluation is the concept of context-awareness. We identified two context notions. The first notion is *external context*, which allows for more effective adjustments of the underlying business processes. This type of context was analyzed by many researchers [9–11] to enhance the traceability of cold chains, and as a basis for decision-support systems in the cold chain domain [10,12,13]. The second notion is *internal context*, also known as *business context*, which was recently investigated for its potential to improve the standardization of integration messages [14]. In this paper, we investigate the potential of the same *business context* notion to automate the supply chain partner onboarding whose one of the essential tasks is to establish the electronic communication between dynamically determined business systems.

The remaining parts of the paper are structured as follows. Section 2 introduces the needed background. Section 3 describes the envisioned approach. Section 4 offers a preliminary evaluation of the approach using a biopharmaceutical domain use case. Section 5 discusses the results and future work. Section 6 closes the paper with concluding thoughts.

2. BACKGROUND

According to Bamakan, et al., cold chains can be classified into four categories: (1) perishable products; (2) flowers and ornamental plants; (3) fresh agricultural products; and (4) pharmaceutical products [11]. In the recent COVID-19 pandemic when billions of doses of environmentally sensitive biologic products such as mRNA vaccines and monoclonal antibodies (mAbs) need to be available for the mass, cold chains for biologic products and their raw materials were brought to the spotlight [1,15,16]. They are sensitive to temperature, shock, and vibration during transportation [17]. In this paper, we consider the temperature aspect of the sensitivity. This section reviews challenges that prevent effective operation of cold chain networks as well as the important of context-awareness to improve the cold chain effectiveness. Also, it provides more detail about the business context notion for driving the supply chain onboarding automation. Lastly, we introduce and discuss the notion of Express Pack as a collection of profiled messages from a message standard specification.

2.1 Cold chain challenges

Since cold chains operate in a temperature-controlled environment it is extremely important that they do not face any interruptions along the distribution [18]. Different biologics have varied cold chain requirements. For example, the transportation of the COVID-19 vaccines should be completed within a few days [15]. Cell therapy products, while can be shipped at room temperature or frozen, require "just-in-time delivery" to maintain the quality and ensure timely patient treatment [19]. Due to the sensitivity of cold chain, risks associated with the stability, efficacy, safety, tardiness, and waste problems are significant [20]. To reduce these risks, traceability and supply chain agility must be improved. Many approaches have been suggested to enable cold chain traceability and agility. Tsang, et al. suggested an IoT-based monitoring system [9]. Li et al. developed a framework that enables cold chain logistics traceability using the Quick Response (QR) code [10]. Most recently, Bamakan et al. developed a system that employs blockchain technology for product traceability and waste management [11].

Despite well-equipped transportation, delays along the cold chain are inevitable. Traceability allows for detection of these interruptions. These interruptions must be reacted quickly to maintain the desired product characteristics. Chaudhuri, et al. provided an in-depth literature review regarding data that can be collected along the cold chain and how it can be employed for responsive decision-making [21]. For instance, the management of vaccine cold chain logistics warrants precise coordination between all involved processes to ensure product efficacy. Such coordination is achieved through data collection (e.g., temperature monitoring) and up-to-date records for traceability that must be effectively communicated in an ad hoc or routine-based manner [22]. This communication can be achieved using emerging IoT technologies, whose successful utilization is highly dependent on effective local and global standardization [2]. Nevertheless, in the impermanent environment of the cold chain networks, integration, and standardization remain open challenges.

2.2 Context-awareness of the cold chain

Context-awareness is an important aspect that provides the necessary adjustment of the system to the changes in the external context. Dey, et al. defined context as "any information that can be used to characterize the situation of an entity. An entity is a person, place, or object that is considered relevant to the interaction between a user and an application, including the user and applications themselves". Context-awareness is the ability of the system to "use context to provide relevant information and/or services to the user, where relevancy depends on the user's task" [23].

In the cold chain domain, context has been proposed for optimizing cold chain logistics. Many researchers investigated this possibility and suggested variety of solutions. Mejjaouli and

Babiceanu provided a decision-support system that considered context information including transportation conditions and location collected by radio Frequency Identification (RFID) and Wireless Sensor Networks (WSN) [12]. Another group of authors developed an Internet of Things (IoT) enabled rerouting model that could assess the overall cold chain profit and make adjustments to the transportation and storage plans [13]. Li et al. developed a context-aware cold chain management framework that provides support for risk management, logistics distribution, and product traceability [10].

2.3 Business context notion

As pointed out in Section 2.1 standardization and integration remain open challenges in the cold chain domain. Recently, business context has been investigated for its potential to improve standardization and integration efforts [14]. Novakovic in his research study defined business context as "any information that can be used to characterize the situation of an entity within a scope where business operates. An entity is a person, place, or object that is considered relevant to the execution of a business process in a business environment, including the business process and business environments themselves" [24]. The Core Component Technical Specification (CCTS) uses the notion of the business context to define business intent of the message standard [25]. According to CCTS, business context can be described using eight context categories, which may not be exhaustive (e.g., geo-political location, industry, business process activity, business process role). Recent studies have shown that newly developed computational method and model added on top of the CCTS business context may enhance effectiveness and efficiency in development and usage of message standards [3]. In other words, business context can be employed as a metadata and driver for development of message standard components and their profiles. Profile is a message standard component restricted for a particular integration use case (e.g., restricted data formats, cardinalities, semantics, etc.) [3]. In another paper, the authors investigated business context for its potential to measure the ability of existing message standards to cover intended integration use cases [26]. As a result, two business context-based measures were defined—completeness of coverage and effectiveness.

2.4 Express Packs: Benefits and a Challenge

Express Pack (EP) refers to a collection of message profiles designed to provide a simpler starting point for addressing specific industry integration use cases. An EP is derived from a full message standard specification, and it is usually defined within a common business process model in which such profiled messages are intended to be exchanged between the process actors. For example, OAGi has defined an Express Pack for the Order-to-Cash end-to-end business process, which includes Purchase Order, Invoice, Shipment Notice and other messages [27]. The messages were profiled to reflect common data exchange requirements present at Small and Medium Enterprises.

Because an EP provides a collection of profiles of messages that correspond to common data exchange requirements, such EP makes a standards-based integration a more efficient process in comparison with the situation where companies have to start from the original, typically very large standard.

However, even with an EP, there remains a challenge to manage integration efforts at the level of profile usage by the partners' systems. To see this, consider an ideal situation, where each EP message profile would have one and only one type definition for each data element of the message profile. Yet, in reality, each system will necessarily have its data exchange interfaces built on some non-standard data elements that are absent from the EP, which makes the ideal integration situation realistically infeasible. Over time, there will be many such proprietary, non-standard decisions made by system implementors, which means that the EP eventually needs to accommodate multiple choices for a specific element and data exchange requirements, which would then also depend on a specific system implementation. (In Section 4, within the validation use case, we adopt an example of *Country Code* element, which has multiple formatting choices within the EP.) Therefore, even in the case where an industry adopts an EP to support a collection of integration scenarios, there still exists the need to manage usage of the EP's profiles because of inherent variations in requirements from business priorities, and regulations, to name a few. Conceptually, this is no different in managing standards-based integration when there is no EP; the difference is, however, in scale, which is a key factor in accomplishing systems integration.

3. AUTOMATED SUPPLY CHAIN PARTNER ONBOARDING

According to Novakovic, *external* and *internal* context can be distinguished [24]. In the cold chain domain, the *external context* refers to the one that can be detected using various physical sensors (e.g., RFID, WSN, IoT, QR, etc.) that enable traceability of the cold chain. The *internal context* also referred to as *business context*, is detected using logical sensors.

As investigated in [10,12,13], the *external context* causes certain adjustments in the cold chain operation that could necessitate adjustments to workflow or business process execution. In other words, a business process model instance needs to be adaptable to changes in the *external context*. Authors in [31] formulated the business process adaptation requirement as a dynamic composition of business process activities problem and proposed a framework to address such problem. The framework assumed that electronic communications between business systems were pre-setup based on a traditional integration approach. However, such an assumption limits the agility needed in cold chain for biopharma. In addition, pre-setup electronic communications may no longer work at the moment needed if business processes or systems have changed. A more responsive systems integration approach is needed.

As described in Section 2.3, past works have shown that business context could lend itself to an adaptive systems integration approach by automating message standard profiling based on the integration use case. Fig. 1 illustrates the scenario in which the automatic message profiling occurs in step 3 driven by step 1 and 2. These two steps are where the external context triggers the identification of new cold chain partners leading to the adjustment to the business process execution. They were addressed in earlier research papers [10,12,13]. In this paper, the detail of step 3 will be discussed.

Step 3.1 and Step 3.2 identify a business system and respectively message type based on the new supply chain partner determined in Step 2. The identified business system has an associated *business context*. Based on the business context and the message type, the required message profile can be automatically created in Step 3.3. In that step, the *business context* is employed to filter components in the standard message specification corresponding to the message type. The filtering reflects the integration requirements of the identified business system. Consequently, a new supply chain partner can be automatically onboarded.

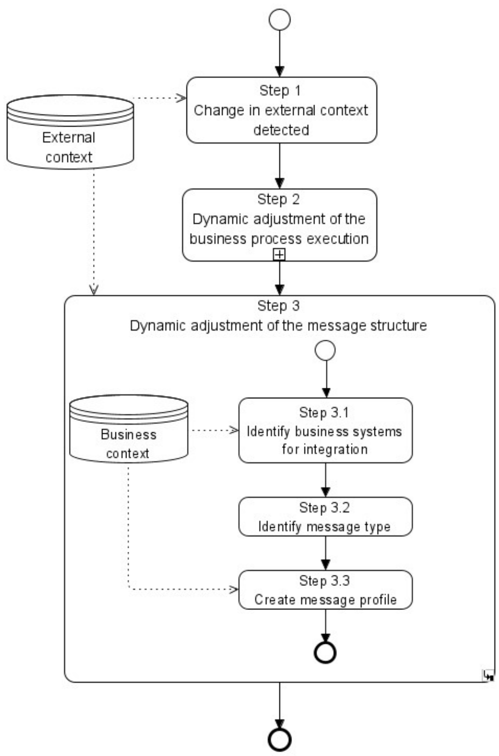

Fig 1: AUTOMATED SUPPLY CHAIN ONBOARDING

4. USE CASE

A simplified biopharmaceutical use case requiring cold chain adaptation is used for evaluating the automatic message profile creation and ultimately the automatic supply chain onboarding. Recently, Open Application Group Inc. (OAGi) developed an OAGIS Express Pack for Real-Time Release of Raw Materials (RTRRM) with predefined message profiles for the biopharmaceutical industry [4]. The Shipment (i.e., Advanced Shipping Notice - ASN) is one of the messages from the Express Pack; and it will be used for the evaluation.

In Fig. 2. the biopharmaceutical raw materials distribution is illustrated. The materials need to be delivered in a low-temperature environment to the factory for the purpose of the production of biopharmaceutical products. However, if the transport temperature is rising above the maximum allowed temperature (e.g., the refrigerator stopped working), the materials need to be urgently transferred to a conforming storage at the nearest warehouse to preserve the required raw material quality.

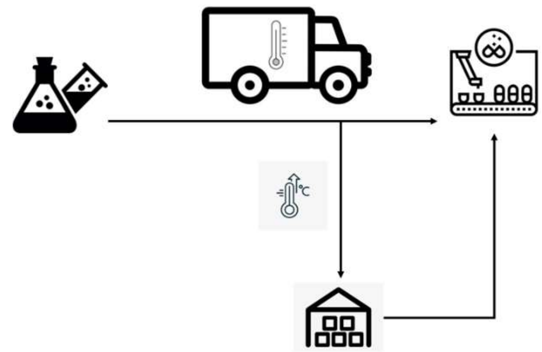

Fig 2: DISTRIBUTION OF BIOPHARMACEUTICAL RAW MATERIALS

Step 1: Change in external context detected. Here we will assume that sensors that are able to monitor the *external context* as well as the decision-support system that is able to interpret the *external context* are available as envisioned in [10].

Step 2: Dynamic adjustment of the business process execution. When an undesirable condition in the *external context* is detected, the decision-support system locates the nearest warehouse and makes necessary adjustments of the underlying business process. In Fig. 3 a simplified shipment business process is presented. If external conditions are as expected, the *Supplier* delivers raw materials to the *Biopharmaceutical factory* for the vaccine production purposes. However, if a transport temperature increases over an allowed limit, the execution of the business process adjusts to reroute raw materials to the nearest *Warehouse*, identified by the decision-support system. Gray activities in Fig. 3 represent an example of the business process execution adjustment.

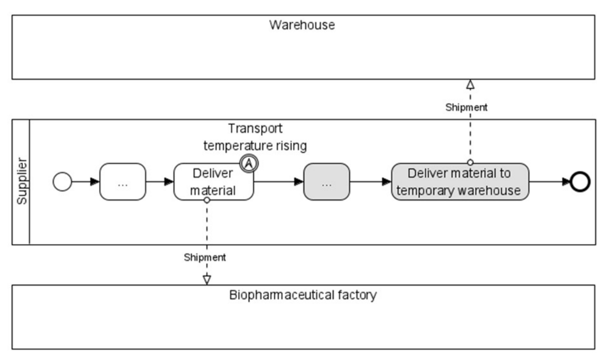

Fig 3: SHIPMENT BUSINESS PROCESS

Step 3.1: Identify business systems for integration. Once the warehouse is selected in step 2, the *Automatic message profile creation* starts. The first step towards this is to gather *business context* information about the warehouse by identifying its business system. Let's say that two warehouses are detected, and that their warehouse order management business systems are identified. These business systems have *business contexts* as presented in Table 1. The first warehouse operates in BC_A, while the second warehouse operates in a *business context* denoted as BC_B.

Table 1: Business Contexts of available warehouses.

	Business context	
Context Category	BC_A	BC_B
Business process role	Warehouse manager	Warehouse manager
Geo-political	France	Spain
Industry	Pharmaceutical	Pharmaceutical
Activity	Receive Shipment	Receive Shipment

Step 3.2: Identify message type. After, the business system (i.e., warehouse order management) is identified, the next step is to identify a message type, *Shipment*, that needs to be exchanged, based on the dynamically chosen business process activity as described in Step 2. In Fig. 4, a simplified structure of the *Shipment* message from the RTRRM Express Pack is presented.

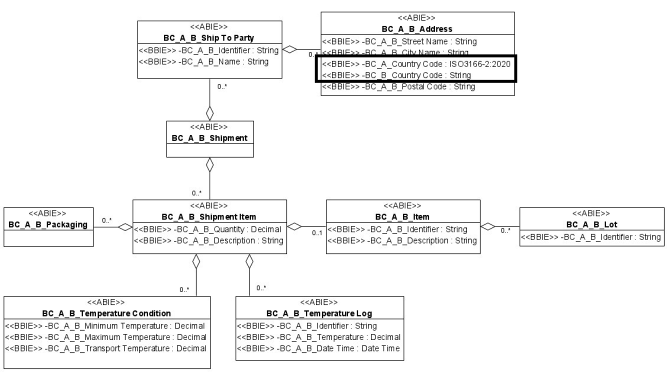

Fig 4: SHIPMENT MESSAGE – AN EXCERPT

As previously emphasized, the Express Pack was completely developed using Score platform. Score incorporates CCTS concepts [32], so the main building blocks of the message are Aggregate Business Information Entities and their properties – Basic and Association Business Information Entities (ABIE, BBIE and ASBIE, respectively). Each building block is associated with one or more business contexts that encodes integration use case(s) for which the building block is valid. In Fig. 3 each building block is prefixed with an appropriate *business context* from Table 1 (e.g., *BC_A_B_Temperature Condition*). For simplicity reasons, all building blocks are valid for both *business contexts*, except *Country Code* that uses different value domains—ISO3166-2:2020 [33] or String— depending on a *business context*. According to [34], there are countries (e.g., Spain is one of them) that due to "business practice and legal requirements" do not use ISO3166-2 region codes. Differences like this one are important and need to be accounted for in order to achieve systems integration.

Step 3.2: Create message profile. The final step is to create a profile of the identified message type based on the *business context* of a dynamically selected business system (i.e., warehouse). This step follows an approach to "Assemble message schema profile" that was proposed in [3]. For that purpose, an *Effective business context* needs to be calculated for each building block. According to [3], it is calculated as an intersection of a *business context* associated to each building block (Assigned business context) in Fig. 4 and a *Requested business context* which in this case is the business context associated with the business system with whom the integration needs to be achieved. Those building blocks, for which the *Effective business context* is computed to be an empty set, are not relevant for the given business system in the use case. Details about the calculation of the *Effective business context* and its interpretation can be found in [3].

Table 2 presents a portion of the *Shipment* message building blocks along with their assigned and *Effective business contexts*.

Table 2: Effective business context calculation.

Building block	Assigned BC	Effective BC	
		Requested BC = BC_A	Requested BC = BC_B
Ship to Party	BC_A_B	BC_A	BC_B
Address	BC_A_B	BC_A	BC_B
Street Name: String	BC_A_B	BC_A	BC_B
City Name: String	BC_A_B	BC_A	BC_B
Country Code: ISO3166-2:2020	BC_A	BC_A	Ø
Country Code: String	BC_B	Ø	BC_B

Fig. 5 represents the resulting *Shipment* message profiled for the first selected warehouse whose *Requested business context* is BC_A.

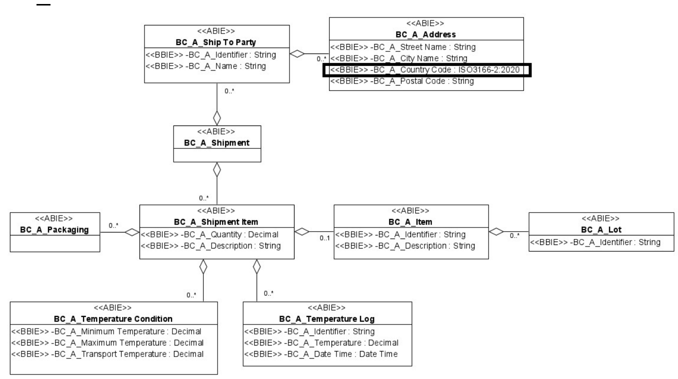

Fig 5: SHIPMENT MESSAGE PROFILED FOR BC_A

Based on the *Effective business context* calculation it is obvious that *Address* will be described with a different set of properties depending on a *Requested business context* (i.e., business system with whom the integration needs to be achieved). In this case, the *Address* is described using *Country Code: ISO3166-2:2020* property.

5. DISCUSSION AND FUTURE WORK

Our preliminary evaluation of the business context approach to automatic onboarding of supply chain partners shows promising results, but certain gaps are identified. First, there are various technologies that enable detection of the *external context*, but detection of the *business context* remains an open issue. To the best of our knowledge, there is no research paper that addresses this issue. Future research will address this issue by developing Web services to detect various aspects (i.e., categories) of a *business context*.

Second, the assumption made in the evaluation scenario is that systems in the cold chain network are using OAGIS Express Pack for Real-Time Release of Raw Materials. Based on an analysis presented in [26], it is unlikely to expect that such centrally developed message specification is capable of covering all variabilities in the biopharmaceutical integration use cases. Our most recent research efforts are looking into addressing this challenge by developing a distributed standardization approach that would be able to collect the requirements of all participating business systems. Such an approach would ensure that a library of standard components is complete and capable of supporting data exchanges for required variations in a cold chain domain.

Third, the validation was conducted using a simplified biopharmaceutical use case where one adjustment of the underlying business process was presented – rerouting of the raw materials to the nearest warehouse. However, more complicated situations would be required in reality. Let's say that the materials were exposed to an extremely high temperature over a long period. In that case, it would not make sense to reroute materials to the nearest warehouse. Instead, the materials would be returned to a supplier with an appropriate message type exchanged (e.g., OAGIS Item Nonconformance message type). In a situation like this one, the business system and message type that needs to be exchanged are dynamically determined and have to be addressed through an appropriate profiling process. Further validation of the proposed conceptual solution for on-the-fly systems integration will consider a collection of real integration use cases in a cold chain domain.

6. CONCLUDING REMARKS

The paper pointed out that due to sensitivities of raw materials and products transported through the cold chains and the lack of traceability, the risks associated with quality and waste problem in cold chains are significant. While many approaches to improve the effectiveness of cold chains have been proposed, the standardization and interoperability remain open challenges. Based on the analysis of previous efforts in the cold chain domain, the notion of *external context* is recognized. In addition, the paper introduced the notion of *business context* which is proposed as a basis for a novel approach to achieve agile supply chain via automatic supply chain partner onboarding. The paper presented an initial investigation into applying the approach to a simplified biopharmaceutical use case requiring adaptive cold chain. The results of the investigation showed that, with identified improvements, the approach has a potential to achieve the automatic onboarding of supply chain partners. To that end, several future works have been identified.

DISCLAIMER AND ACKNOWLEDGEMENT

Certain commercial systems and applications identified in this paper are not intended to imply recommendation or endorsement by the National Institute of Standards and Technology, nor is it intended to imply that they are necessarily the best available for the purpose.

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