

## Twenty-five years later: has ISBT 128 fulfilled its promise?

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Traceability is essential to any quality program for medical products of human origin (MPHO). Standardized terminology, coding, and labeling systems that include key elements for traceability support electronically readable information on product labels and improve the accuracy and efficiency of data collection. ISBT 128 is such a system. The first specification for ISBT 128 was published 25 years ago, and since that time it has become the global standard for labeling and information transfer for MPHO. Additionally, standardization of granular product description codes has supported hemovigilance and other activities that depend on aggregated data. This review looks back over the development, current status, and potential future applications of the ISBT 128 Standard.

In 1994 the first specification for ISBT 128, the international standard for terminology, identification, coding, and labeling of medical products of human origin (MPHO), was published. Initially intended simply as a replacement for the ABC Codabar blood labeling standard, its developers saw a broader purpose for the information standard. The new standard was to be truly international, ensuring that each product would be labeled in a way that would be globally unique for 100 years. The standard would be far-sighted so that products created by processes that were totally unforeseen in 1994 could be easily accommodated in the product coding system by simple additions to a table. More types of relevant information (e.g., red blood cell [RBC] or platelet antigens) were to be encoded. Finally, the standard would accommodate other MPHO, such as cellular therapy and tissues.

During the past 25 years, ISBT 128 has grown in both scope and usage. It has played a significant role in supporting and improving traceability, while internationally standardized

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**ABBREVIATIONS:** ABC = American Blood Commission; DIN = donation identification number; DMSO = dimethyl sulfoxide; FIN = facility identification number; HPCs = hematopoietic progenitor cells; ICCBBA = International Council for Commonality in Blood Bank Automation; INNs = international nonproprietary names; ISBT = International Society of Blood Transfusion; ISO = International Organization for Standardization; MPHO = medical products of human origin; OIDs = object identifiers; PDCs = product description codes; RFID = radio-frequency identification; TAG = technical advisory group; USANs = United States adopted names; WHO = World Health Organization; WPIT = Working Party on Information Technology.

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product codes are playing an increasing role in biovigilance and other analyses of aggregated data. The development, current status, and potential future applications of ISBT 128 will be reviewed.

Traceability, as defined by the AABB Standards,<sup>1</sup> is the ability to follow the history of a product or service by means of a recorded identification. Traceability, therefore, requires the capture and storage of information related to the MPHO donors, products, and recipients, often over long periods of time as defined by regulators. Accuracy in collection and storage of such information is greatly enhanced by automated systems.

Electronically readable information such as bar code symbols and radio-frequency identification (RFID) tags on product labels provide a convenient and accurate means of gathering data. Information within the electronically readable symbols and tags is generally in a coded format to reduce the number of characters, and hence label space, needed. Therefore, a coding system is needed to present information in an electronically readable format.

Because MPHO products are transferred between and among health care facilities, the codes used within electronically readable information must be standardized so that a facility that receives a product can accurately interpret encoded information and does not have to relabel it in accordance with the requirements of its own computer system. Further, because some MPHO, most notably cellular therapy products, may be shipped internationally, such coding must be internationally standardized. The product identifier (the donation identification number) must be globally unique to ensure traceability across national boundaries.

Recognizing the importance of traceability to the safety of MPHO, the World Health Organization (WHO) has urged member states “to encourage the implementation of globally consistent coding systems to facilitate national and international traceability.”<sup>2</sup> A 2012 international transplantation workshop convened by WHO to consider global traceability recognized that ISBT 128 was a well-established initiative to ensure global traceability of MPHO that met the WHO recommendation for a globally consistent coding system.<sup>3</sup>

## HISTORY (ADOPTION OF ISBT 128)

### ABC Codabar, the first widely used system for barcoded blood labels

Beginning in the late 1970s, some blood products were being labeled with bar codes using a system developed by the American Blood Commission (ABC). The system was called ABC Codabar because it was a variation of the Codabar bar code symbology. By the 1980’s, ABC Codabar had become widely used globally. However, after about a decade of use, shortcomings of the system became apparent. Some of the more critical flaws were:

- Units of blood and blood components were not uniquely identified—the exact same donation identifiers were used

in different countries, within the same country, and even, over time, within a given blood collection or pooling facility. Products had to be relabeled with new identifiers that were unique within a facility if they were received from a source other than the primary supplier because of a potential for duplicate identifiers. Further, this potential for duplicate identifiers presented a major obstacle to centralized testing.

- Product codes (the codes used to identify products in an automated system) were five characters long and structured such that a given character in a particular position within the code had a specific meaning. This severely limited the number of different products that could be coded within the system and caused the system to become inadequate as new products were developed.
- Reading errors were found. During a 1997 US Food and Drug Administration (FDA) Blood Product Advisory Committee meeting,<sup>4</sup> it was noted: “One of the disadvantages of code-a-bar (sic) is the susceptibility to substitution errors, and the lack of space to incorporate a check character to reduce the likelihood of such an error.”
- Perhaps most significantly, there were no provisions for ongoing management or support of ABC Codabar. The ABC’s workgroup was disbanded after developing the initial ABC Codabar guidance, apparently in the mistaken belief that the work was completed. There was no one to address the subsequent problems that occurred. Additionally, when new methods of processing blood were developed that were not addressed in the original guideline, there was no organization responsible for creating new internationally standardized product codes to accommodate these products. This lack of control over product codes resulted in the loss of standardization, as each country (and sometimes an individual facility) developed its own solutions. Further, lack of user support for facilities implementing the standard was a major challenge, especially for early implementors.

In its 1997 report to the Blood Products Advisory Committee,<sup>4</sup> the US Department of Defense discussed how it had contracted with numerous civilian blood suppliers to ship blood to the Persian Gulf during Desert Shield/Desert Storm. A variety of significant shortcomings in the use of ABC Codabar, many of which affected traceability, were described.

### Development of ISBT 128

Because of these flaws, in 1989 the International Society of Blood Transfusion (ISBT) asked its Working Party on Automation and Data Processing, later renamed Working Party on Information Technology (WPIT), to develop a new standard to replace Codabar. The ISBT WPIT completed the first specification for ISBT 128 (the number 128 reflects the 128 characters of the American Standard Code for Information Interchange seven-bit character set that the standard uses) in 1994, and it was approved by the ISBT board that same year.

Also, that year the International Council for Commonality in Blood Bank Automation (ICCBBA) was designated as the organization to manage the standard. By designating ICCBBA as the organization to manage the ISBT 128 standard, its ongoing development and maintenance, as well as user support, were addressed.

The ISBT 128 standard corrected other deficiencies of ABC Codabar as well:

- Each donation is uniquely identified for a period of 100 years. This is done by creating a 13-character donation identification number (DIN) comprising three sections: a five-character facility identification number (FIN), a two-character year code, and a six-character serial number. ICCBBA assigns a unique FIN to each facility registered to use ISBT 128 that is used within a DIN, ensuring that no two organizations that use ISBT 128 will assign the same DIN to a collection. ICCBBA maintains the FIN assignments in a database that is made available to all registered users. Each facility is responsible for assigning the six-character serial number and ensuring that it was unique for a given year code. Thus, no two collections from a given facility would have the same identifier for a 100-year period (Fig. 1).
- Product description codes (PDCs) are sequentially assigned. To support coding of many different types of MPHOS, the first one or two characters of the five-character PDC represents the category of product. For example, codes beginning with E are blood products, codes beginning with S are cellular therapy products, and codes beginning with T are tissue products. See Table 1 for code assignments. However, these are the only positions within the five-character code that have been assigned a meaning. Because both letters and numbers may be used in the code, and the code is not structured beyond the assignment of the characters indicating category of MPHOS, the number of potential codes is enormous. ICCBBA assigns PDCs and maintains the codes and their corresponding product descriptions in a database that is made available to all registered users of ISBT 128.

The five-character PDC is the first portion of an eight-character product code. The three additional characters encode divisions of a component (e.g., an RBC product that has been divided into multiple products for pediatric use). For blood and cellular therapy products, the type of collection (e.g., allogeneic, autologous, directed) is also encoded within these three characters (Fig. 2). For other MPHOS, all three additional characters are

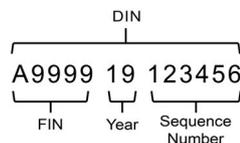


Fig. 1. ISBT 128 donation identification number (DIN).

**TABLE 1. First character(s) of product description codes**

Character(s)	Category of MPHOS
E	Blood
H	MPHOS with INN or USAN
M0	Human milk
M9	Topical products of human origin (e.g., serum eye drops)
N0	Organs for transplant
P	Regenerated tissue products
R0	Reproductive tissue
S	Cellular therapy
T	Tissues
V	Ocular tissue
W0	Fecal microbiota
X0	Plasma derivatives for which ABO is significant (e.g., solvent detergent plasma)
X5	In vivo diagnostic MPHOS (e.g., radiolabeled diagnostic red cells)
A, B, C, and D	Nationally or locally assigned codes

INN = international nonproprietary name; MPHOS = medical products of human origin; USAN = United States adopted name.

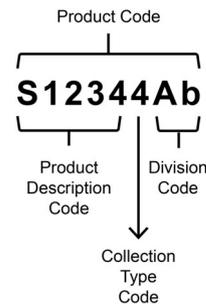


Fig. 2. Product code structure for blood, cellular therapy, regenerated tissue products, fractionated plasma, and MPHOS with INN or USAN.

used to identify divisions and the type of donation is encoded within the product description code (Fig. 3).

Code 128, the linear bar code symbology used with ISBT 128, has fewer misreads than Codabar. The final data character in each Code 128 symbol (the character immediately preceding the stop character) is a check character. Its value is determined by an algorithm performed on the other data characters in the symbol. The check character contributes greatly to the reliability of Code 128, virtually eliminating errors. This internal check

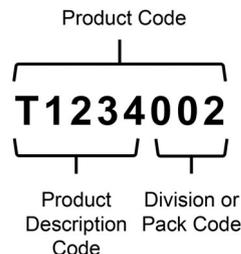


Fig. 3. Product code structure for other MPHOS.

character aids in the detection of errors when the bar codes are electronically scanned. In addition, while it is intended that DINs be entered into computer systems via scanning, another check character (printed within a box following a DIN) is used to verify DINs that are entered via a keyboard.

Once ISBT 128 was successfully implemented for blood products, it was recognized that traceability requirements for other MPHO were very similar. It was subsequently adapted for cellular therapy and then for tissue (including ocular, reproductive, and regenerated), organs, human milk, fecal microbiota, and topical products (e.g., serum eye drops).<sup>5</sup>

## HOW IT WORKS

### ISBT 128 PDCs

PDCs are the heartbeat of the ISBT 128 system. Approximately 10 times each year, ICCBBA adds new codes to the product description code database (the database has over 12,000 codes) and releases an updated version of the Standard Terminology for Medical Products of Human Origin,<sup>6</sup> the document that lists terms used in the product descriptions and their definitions. The frequency of updates reflects the constant development of new products, especially in leading-edge fields such as cellular therapy and regenerative medicine.

The process of developing internationally standardized product descriptions begins with identifying appropriate terminology. Without agreement on the meaning of the terms used to describe a product, a code could have different meanings to different organizations.

For each of the major categories of the MPHO Standard (Blood, Cellular Therapy, Tissues, Ocular Tissue, Organs, Reproductive Medicine, Regenerated Tissues, and Human Milk), a technical advisory group (TAG) comprising volunteer experts from around the world is established. Members of these groups often represent professional organizations within the field (see Table 2 for professional organizations participating in ICCBBA TAGs). Regulators participate as observers on most of the TAGs and provide important guidance on regulatory requirements. The TAGs, with appropriate public consultation, are responsible for determining the terminology to describe products.

Terminology includes class names for products (e.g., RBCs or hematopoietic progenitor cells [HPCs], apheresis) and attributes that describe the product in greater detail (e.g., leukoreduced or CD34 enriched). Attributes are arranged in groups of mutually exclusive options (variables). For blood products, an additional level of description, a modifier, also exists. Each product description includes the class name and usually one or more attributes (and for blood, modifiers). All terminology, definitions, and abbreviations that are used in the PDC database are listed in the Standard Terminology for Medical Products of Human Origin.<sup>6</sup> Products are then described by selecting a class name and adding appropriate attributes (and/or modifiers for blood).

**TABLE 2. Organizations and regulators participating in ICCBBA technical advisory groups**

AABB
American Association of Tissue Banks (AATB)
American Dental Association (ADA)
American Red Cross
American Society for Apheresis (ASFA)
American Society for Reproductive Medicine (ASRM)
American Society for Transplantation and Cellular Therapy (ASTCT, previously ASBMT)
America's Blood Centers (ABC)
Asia Pacific Association of Surgical Tissue Banking (APASTB)
Asia Pacific Blood and Marrow Transplantation (APBMT)
Association of Eye Banks of Asia (AEBA)
Biotherapeutics Association of Australasia (BAA)
Canadian Blood Services
Danish Patient Safety Authority
European Association of Tissue Banks (EATB)
European Blood Alliance (EBA)
European Commission (DG SANTE)
European Eye Bank Association (EEBA)
European Milk Bank Association (EMBA)
European Society for Blood and Marrow Transplantation (EBMT)
European Society of Human Reproduction and Embryology (ESHRE)
Eye Bank Association of America (EBAA)
Eye Bank Association of Australia and New Zealand (EBAANZ)
Eye Bank Association of India (EBAI)
Foundation for the Accreditation of Cellular Therapy (FACT)
Global Medical Device Nomenclature (GMDN) Agency
GS1
Health Canada
Héma-Québec
Human Milk Banking Association of North America (HMBANA)
International Society for Cell Therapy (ISCT)
International Society of Blood Transfusion (ISBT)
Joint Accreditation Committee ISCT-Europe & EBMT (JACIE)
Latin American Blood and Marrow Transplantation Society (LABMT)
National Marrow Donor Program (NMDP)
Pan American Association of Eye Banks (APABO)
Swedish Health and Social Care Inspectorate
Tissue Engineering & Regenerative Medicine International Society (TERMIS)
US Department of Defense (DoD)
US Department of Veterans Affairs
US Food and Drug Administration (US FDA)
World Marrow Donor Association (WMDA)
World Union of Tissue Bank Associations (WUTBA)
ICCBBA = International Council for Commonality in Blood Bank Automation.

For the purpose of the PDC database, the classes, attributes, and modifiers describing a product are listed in a very structured (and abbreviated) way to allow computers to be able to manage the information.<sup>7,8</sup> For example, an HPC, marrow, collected in citrate, thawed and stored at refrigerator temperatures, and containing 10% dimethyl sulfoxide [DMSO], a blood product from a third-party donor (neither the donor nor the recipient), and additives, is described in the database as HPC, MARROW|Citrate/XX/refg|10% DMSO|3rd Party Comp: Yes|Other Additives:Yes|Thawed.

The PDC assigned to this product description in the ISBT 128 database is S1378. This code appears on the product label in an electronically readable format and in all electronic and manual records pertaining to the product.

## New terminology and PDCs

Given the need for constant updates as new products are developed, a robust system to address new products is essential. As TAG members are actively working in the field, they often directly address the need for new terminology.

The stimulus may also come from users. When a facility needs a code for a product they produce, they begin by searching the PDC database using an online look-up tool on the ICCBBA Web site ([www.iccbba.org](http://www.iccbba.org)). They enter the description of their product choosing from the class names and attributes (and modifiers, if applicable) available. If the database does not contain the product description they need, they complete an online form to request a new product code from ICCBBA. When they can describe their new product using existing terminology, ICCBBA will issue a new product code meeting their needs on the next database update. If the terminology to describe the product does not exist, the request is channeled through the appropriate advisory group for development of new terminology. Depending on the complexities or potential controversies involved, this process may take several months. Once new terminology is approved, it is added to the PDC database and the Standard Terminology for Medical Products of Human Origin,<sup>6</sup> making it available for use in new product descriptions.

## Other information conveyed by ISBT 128 codes

A great deal of other information, beyond the DIN and product code, can be conveyed using ISBT 128 codes. This includes various dates (collection/procurement, expiration, manufacture, time of death for ocular tissue, etc.), ABO/D and non-ABO/D RBC antigens, platelet antigens, infectious marker results, product consignment information, and the like. Descriptions of data structures conveying this additional information is found in the ISBT 128 Standard Technical Specification.<sup>5</sup>

While such information is often conveyed using linear or two-dimensional symbols (bar codes) on a product label, the ISBT 128 codes may also be used in electronic messaging or in an RFID tag. Some codes, such as infectious marker testing results, are complex and too long for conveying information by linear bar codes on product labels and should be conveyed by electronic messaging.

## Traceability using ISBT 128

Within ISBT 128, traceability is achieved primarily through the use of the DIN and the product code. When the number of divisions needed exceeds the capacity of the product code, as happens with some product categories, a separate code may be used for divisions. If used, this division code is also required for traceability. Additionally, for some tissue products, the identity code of the processing facility may also be required for traceability.

The DIN uniquely identifies the collection and product codes (in combination with a separate division code, if used)

uniquely identify each product from a collection. The DIN and product code (and separate division code or processing facility code, if applicable) are linked to both the donor and recipient records.

Because all codes and definitions are standardized, any organization handling a product can efficiently scan the labels (or receive electronic messages utilizing ISBT 128 codes) and interpret them exactly as the organization labeling the product (or sending the electronic message) intended.

## CURRENT STATUS OF ISBT 128

While ISBT 128 was initially created as a replacement for ABC Codabar, it has far exceeded it. Differences include:

- ISBT 128 is not just a blood labeling standard; it addresses terminology, identification, coding, and labeling of MPHO (including blood, cellular therapy, tissues, reproductive cells, human milk, and organs).
- ISBT 128 was developed and is maintained by international committees of experts and reflects the needs of many countries.
- ISBT 128 has robust mechanisms to address new developments.
- ISBT 128 has the degree of standardization needed for use in disparate computer systems, but with enough flexibility to support different practices around the world.
- ABC Codabar was strictly for blood products, while ISBT 128 is designed for many MPHO. Table 1 lists product categories that are supported by the ISBT 128 standard. Products regulated as medical devices that include a human donor component (exact products in this category vary by country) may also use ISBT 128. Further, it can be used to label products with international non-proprietary names (INNs) and United States adopted names (USANs) if the product contains a human donor component.
- It is widely used. As of January 2019, there were 5300 facilities in 89 countries on six continents registered to use the ISBT 128 standard.
- With many users worldwide using a single standard, aggregated data can be analyzed to support hemovigilance, research, and business needs.
- Operational efficiency has resulted from label, software, and equipment vendors able to standardize across many MPHO facilities and multiple countries.
- Globally unique identification supports resource sharing and centralized testing.
- There are 35 data structures intended for uses that go far beyond the labeling of blood. In addition to what has already been mentioned, information specific to medical devices and the Single European Code can be encoded in ISBT 128 data structures.
- Not limited to a single bar code symbology, ISBT 128 coding can be used to transfer information with Code

128, Data Matrix (a two-dimensional symbol), RFID, and electronic messaging.

Organizations such as the FDA and the Centers for Disease Control and Prevention are finding the ISBT 128 standardized product codes of a granularity that makes them very useful in vigilance. In an abstract<sup>9</sup> by FDA staff, it was noted that "... using the ISBT-128 (sic) coding system is feasible and well-captured within the BEST EHR [Biologics Effectiveness and Safety Electronic Health Record] databases. Incorporation of ISBT-128 (sic) codes into the CBER blood surveillance system can enhance hemovigilance activities and will afford FDA the ability to actively monitor blood component utilization and transfusion-related adverse events." Additionally, America's Blood Centers has found the standardized coding of products useful in its data warehouse.

ICCBBA manages the standard so that it continues to meet the needs of users. Through its TAGs and board of directors, it anticipates future needs in time to adapt the ISBT 128 standard before actual need. It supports users by:

- Having an international board of directors and TAGs with expertise in many fields to ensure sensitivity to a wide variety of global practices;
- Updating the PDC and FIN databases approximately 10 times per year;
- Providing user support via a help desk staffed with trained individuals and by publishing many standards and implementation guidance documents (currently there are 12 standards documents and 27 implementation guidance documents);
- Maintaining the ICCBBA Web site ([www.iccbba.org](http://www.iccbba.org)) with updated technical and administrative information;
- Managing 11 TAGs with expertise in the various fields of MPHO to review and suggest changes to the ISBT 128 standard, as well as develop new terminology addressing the needs of each field;
- Maintaining relationships with many professional and governmental organizations, including being a non-governmental organization in official relations with WHO, to ensure that ISBT 128 is compatible with external requirements;
- Supporting infrastructure and education in developing countries by financial donations;
- Being an issuing agency under International Organization for Standardization (ISO) 15459.<sup>10</sup> This means that ISO has recognized ICCBBA as an organization able to issue globally unique identifiers following its rules ensuring codes issued are truly unique; and
- Supporting new initiatives, such as collaborating with the World Marrow Donor Association to create and manage globally unique identifiers for donors and potential donors of cellular therapy products<sup>11</sup> and the European Commission to harmonize ISBT 128 with the Single European Code for cell and tissue products.<sup>12</sup>

## FUTURE

The ICCBBA board of directors, TAGs, and staff work diligently to ensure ISBT 128 continues to meet the needs of its users. While developing new terminology is the bulk of the work for TAGs, they also report developing trends in each field to the ICCBBA board of directors.

New applications for the ISBT 128 standard will be developed. For example, the INN and USAN are both terminology systems, but they are not coding systems. Alone, they do not provide the means to encode information into electronically readable symbols. The ISBT 128 standard is able to provide the means to encode product information for INN and USAN MPHO supporting electronically readable labels.<sup>13</sup>

Electronic messages (direct communication between computer systems) and the use of ISBT 128 within these messages are likely to become more prevalent. In anticipation of this, ICCBBA provides a table assigning unique object identifiers (OIDs) to data elements and data structures.<sup>5</sup> A new OID for an MPHO unique identifier has been created by combining existing ISBT 128 data elements. This is a single globally unique identifier for any MPHO and provides a key for identifying a product in electronic messages.

Health Level 7,<sup>14</sup> an international standard development organization, manages a messaging standard to enable disparate health care applications to exchange key sets of clinical and administrative data. Once of its specifications, Fast Healthcare Interoperability Resources, is rapidly gaining support, and ISBT 128 data elements and data structures may be used within this system.

As more facilities adopt ISBT 128, more organizations collecting and analyzing data for vigilance, research, and business purposes will undoubtedly find the granularity of ISBT 128 standardized product codes useful.

ICCBBA will continue to work with other regulatory and professional organizations, perhaps providing a coding system for other standard terminologies. For example, standard terminology to code target receptors of genetically modified T-cell products exists,<sup>15</sup> but as yet there is no way to encode the terms electronically. An opportunity might exist for ICCBBA to be able to provide a supporting data representation with associated OID for this type of terminology.

At an individual facility level, many organizations implemented ISBT 128 at its most basic level, utilizing only the most basic data structures: DIN, ABO/D, product code, expiration date/time, and special testing (cytomegalovirus, hemoglobin S, etc.). At the time, it was believed that other data structures, such as other RBC antigens and platelet antigens, as well as such features as the manufacturer's data file, could be implemented after initial adoption deadlines were met. However, often these optional improvements to process control were never implemented. Additional educational efforts are now needed to remind users that there are more ways in which ISBT 128 can improve process control

and for users, as well as their software developers, to consider implementing these features.

In the broader perspective, there are a number of challenges to international standardization that will continue to be obstacles. In the authors' experiences, these include:

- Mistrust of an organization based in another country;
- Suspicion over the motivation of the organization;
- The belief that standards should be “free”; and
- The unwillingness of regulators and international organizations to select a single standard because of concerns about being seen as unfair.

However, global standardization requires common commitment to a single standard.

## CONCLUSION

Has ISBT 128 fulfilled its promise? It solved the original problems of ABC Codabar and much more. It has become a truly global standard, allowing products collected by a facility in one country to be shipped to a facility in another country with standardized electronically readable labels ensuring common understanding of the characteristics of the product and traceability. Beyond the 1994 expectations of ISBT 128, the standardization of terminology and coding supports the collection and analysis of large amounts of aggregated data needed for such purposes as vigilance, research, and business analysis.

Computers are a part of our daily lives. For MPHO, realizing the full power of automation requires global standardization of terminology, identification, coding, and labeling. Over the past 25 years, ISBT 128 has proven to be a reliable system that has constantly evolved to meet the needs of its global users, supporting traceability for MPHO and vigilance programs. It is used in more than 89 countries across six continents and disparate health care systems.

## CONFLICT OF INTEREST

Paul Ashford is an employee of ICCBBA; Pat Distler is a former employee of ICCBBA and is now retired.

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