



ISBT 128 STANDARD

Global Registration Identifier for Donors: ION Database and GRID Rules

Version 3.3.0

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Table of Contents

1	Intro	oduction	4
	1.1	Purpose	4
	1.2	Scope	4
	1.3	Intended Audience	4
	1.4	Normative Reference	4
	1.5	Other References	5
	1.6	Background	5
	1.7	Changes in this Version	6
2	For	mat and Purpose of ION	7
3	GR	ID Issuing Organization Database	8
4	ION	Assignment and Maintenance	.10
	4.1	Contact Information	.10
	4.2	Obtaining an ION	.10
	4.3	Updating Information Associated with an ION	.10
	4.4	Inactivating an ION	.10
	4.5	Reactivating an ION	.10
	4.6	Merging/Acquisition of GRID Issuing Organizations	.11
	4.7	IONs Reserved for Validation Purposes	.11
	4.8	Reassignment of IONs	.11
5	GRI	D Allocation Rules	.12
	5.1	Allocating a GRID	.12
	5.2	Calculating the Checksum	.12
	5.3	Eye-readable presentation of the GRID	.15
	5.4	Electronic encoding of GRID	.16
	5.5	Using the checksum to verify a GRID	.17
6	Info	rmation for Software Developers	.18
	6.1	Database	.18
	6.2	Use of the ION within the GRID	.18
	6.3	The GRID Checksum	.18

Table

Table 1	GRID Issuing Organization Database Structure [RT059]	9
Table 2	Version Table (ION Database) [RT060]	9
Table 3	Character to ISO/IEC 7064 Check Values [RT061]1	3

1 Introduction

1.1 Purpose

The purpose of this document is to provide:

- specifications for the structure of the Global Registration Identifier for Donors (GRID) and the Issuing Organization Number (ION);
- information on how to obtain and update an ION; and,
- rules on the use of the GRID.

Throughout this document where the word "shall" is used, it represents a requirement; where the word "should" is used, it represents a recommendation; and where the word "may" is used, it represents an option.

1.2 Scope

This standard provides information on the structure of the GRID Issuing Organization Database as well as instructions on how to obtain an ION, how to update the ION information within the database, and how to use a GRID for hematopoietic progenitor cell (HPC) donors and potential donors.

1.3 Intended Audience

The intended audience of this document is WMDA and its members, ICCBBA, and organizations that will assign GRIDs.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

ISO 3166-1 Country Codes http://www.iso.org/iso/country_codes/country_codes

ISO/IEC 7064:2003(E): Information technology—Security techniques—Check character systems

ISO/IEC 15417: 2007(E): Information technology—Automatic Identification and data capture techniques—Code 128 bar code symbology specification

ISO/IEC 15459-4-2014(E): Information technology – Automatic identification and data capture techniques – Unique Identification—Part 4 Individual products and product packages

ISO/IEC 16022:2024(E): Information technology—Automatic identification and data capture techniques — Data Matrix bar code symbology specification

1.5 Other References

ICCBBA Website (<u>www.isbt128.org</u>)

1.6 Background

The WMDA and ICCBBA work together to maintain the GRID Issuing Organization Database. WMDA determines which organizations will be listed in the database and collects the required information from these organizations. It shares this information with ICCBBA.

ICCBBA maintains the database that contains the names and locations of GRID Issuing Organizations linking them to their assigned ION. The full list of organizations is made available to organizations actively listed in the ION database, WMDA, and, upon request, competent authorities.

WMDA and ICCBBA have jointly developed the rules for the GRID.

1.7 Changes in this Version

The following table indicates the major changes between Version 3.2.0 and Version 3.3.0 of this document. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print, while changes to formatting or organization, or additional guidance, are in regular print. If changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

	Version 3.2.0 of ST-015	Version 3.3.0 of ST-015		
	Chapter, Section, Table, or Figure	Chapter, Section, Table, or Figure	Change	Rationale
1.	Throughout	Throughout	Replaced www.iccbba.org with www.isbt128.org.	To reflect the official website address.
2.	Throughout	Throughout	Replaced iccbba@iccbba.org with support@isbt128.org.	To reflect the official help desk e-mail address.
3.	Throughout	Throughout	Updated the reference to ISO 16022 with the updated version of 16022:2024.	An updated version was published by ISO.
4.	Copyright	Copyright	Provided an updated copyright statement.	Per legal recommendations.
5.	ICCBBA Standards Committee	ICCBBA Standards Committee	Updated the Standards Committee list with its current members.	New members.
6.	WMDA Board	WMDA Board	Updated the list of Board members with its current members.	New members.
7.	1.4	1.4	Added hyperlinks to the referenced ICCBBA publications.	User friendliness.
8.	5.3	5.3	Added additional specification for how the GRID shall be printed on forms and reports.	To remove ambiguity of the GRID on documents.
9.		End of Document	Added a reference page for internal ICCBBA use only.	To facilitate document control.

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1011	J.Z.U	v ə.	1011	υ.	υ.	υ

2 Format and Purpose of ION

The ION identifies organizations that issue GRIDs and is assigned by ICCBBA in its role as an issuing agency under ISO 15459. A unique random ION is assigned to each issuing organization.

The ION is a 4-digit number between 1000 and 9999. It shall be encoded and interpreted by reference to the ICCBBA GRID Issuing Organization Database published and maintained by ICCBBA on the ICCBBA Website.

The ION shall be used as the first 4 characters within a GRID to create global uniqueness and may also be used for other purposes (e.g., databases) to identify organizations that assign GRIDs.

3 GRID Issuing Organization Database

This Microsoft Excel® spreadsheet contains the names and locations of all GRID Issuing Organizations. It is published on the ICCBBA Website and is called:

GRID Issuing Organizations – xlsx

It contains the fields shown in Table 1.

An XML file and its associated XML Schema are also available on the ICCBBA Website:

GRID Issuing Organizations Data File – xml GRID Issuing Organizations XML Schema – xsd

Note: The XML data file contains IONs that have an "Active" status only while the Excel spreadsheet provides both "Active" and "Inactive" IONs.

The information about each organization held in the ICCBBA database is provided by the WMDA at the time of registration of the ION. It is the responsibility of the Issuing Organization to ensure that it remains accurate by notifying WMDA of any changes. WMDA will, in turn, notify ICCBBA of changes.

Version number related information is also provided in the XML file; it contains the fields as shown in Table 2.

A two-level system is employed to distinguish versions of the database.

- The first level shall tie the database to the controlling version of the *ISBT 128 Standard*, *Global Registration Identifier for Donors: ION Database and GRID Rules* (ST-015). That is, if ST-015 is version 3.x.x, the first digit of the database version is 3.
- The second level shall commence at 1 and be incremented each time a new version of the database is released under the same version of the standard document.

Field Name	Maximum Data Length	Field Description
ION	4	GRID Issuing Organization Number* between 1000 and 9999
Issuing Organization Name	255	Name of GRID Issuing Organization
Shortened Name	100	Shortened name of GRID Issuing Organization
ISO Country Code	2	Code for country as assigned in ISO 3166-1
Date Registered by ICCBBA	10	Date organization registered by ICCBBA
Status	8	Indicator of whether an organization is currently issuing GRIDs. Values will be "Active" or "Inactive"
WMDA_ID	7	Identifier assigned by WMDA

Table 1	GRID Issuing	Organization	Database	Structure	[RT059]
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*10 IONs, 9990-9999, have been set aside for validation purposes. ICCBBA has used the userdefined country code of XA (as allowed by ISO 3166-1) for these IONs.

Field Name	Maximum Data Length	Field Description
Version Number	10	The version number of the ION database
Date	10	The date issued. The format is YYYY-MM-DD
Issued By	6	Organization assigning the ION
Issuer Website	50	Website of the organization assigning the ION
Related Document	255	URL for the "Related Document"
Related-Document Comment	255	Explains that there is a related document that contains both "Active" and "Inactive" IONs

Table 2 Version Table (ION Database) [RT060]

4 ION Assignment and Maintenance

4.1 Contact Information

Organizations may contact

- WMDA by emailing mail@wmda.info
- ICCBBA by emailing the ICCBBA help desk at <u>support@isbt128.org</u>

4.2 Obtaining an ION

Organizations wishing to assign GRIDs shall contact WMDA.

WMDA shall notify ICCBBA of organizations that will issue GRIDs and ICCBBA shall assign each of these organizations an ION.

Organizations shall use their assigned ION when creating a GRID in order to achieve global uniqueness that is essential in identifying potential donors/products for cell and gene therapy.

4.3 Updating Information Associated with an ION

The information about each organization held in the GRID Issuing Organization Database is provided by the WMDA at the time of registration of the ION at ICCBBA. It is the responsibility of the Issuing Organization to ensure that it remains accurate by notifying WMDA of any changes. WMDA will, in turn, notify ICCBBA of changes.

While Chapter 3 describes the information from the GRID Issuing Organization Database that is published, additional information is maintained by WMDA and ICCBBA in the full database to identify not only the organization and its location, and contact information for individuals within the organization.

Issuing Organizations shall notify WMDA when any information shown on Table 1 or contact information for the organization changes.

4.4 Inactivating an ION

If an ION is no longer needed (i.e., the organization no longer assigns GRIDs), the ION may be inactivated. The inactivated ION will continue to be included in the ION database, but the "Status" field will indicate the organization is inactive.

Organizations wishing to inactivate their ION shall contact the WMDA office.

4.5 Reactivating an ION

If the activities of an organization with an inactivated ION change such that they will again assign GRIDs, they may request their previous ION. If criteria are met, WMDA and ICCBBA may reactivate the ION. Contact the WMDA office for more information.

4.6 Merging/Acquisition of GRID Issuing Organizations

If two GRID Issuing Organizations merge, or if one organization acquires another, the new organization may choose to (1) retain one of the IONs and inactivate the other or (2) request a new ION and inactivate the previous two IONs. Contact the WMDA office for more information.

4.7 IONs Reserved for Validation Purposes

A range of IONs has been reserved for purposes of validation testing. This range is 9990 through 9999. Facilities should use IONs within this range when performing validation testing. This range may also be used for example labels when the use of an actual ION is not recommended (e.g., examples of GRIDs in published papers).

4.8 Reassignment of IONs

Once assigned, an ION shall not be reassigned to another organization.

5 GRID Allocation Rules

5.1 Allocating a GRID

The GRID is a nineteen character identifier composed of three elements: a four digit ION; a thirteen character Registration Donor Identifier (RDI) assigned by the Issuing Organization; and a two digit checksum.

Global Re	egistration Identifier for Donors (G	RID)
9991	0120 7043 3201	632
lssuing Organization Number (ION)	Registration Donor Identifier	Checksum

An organization issuing a GRID shall always use a GRID commencing with their assigned ION.

RDI's shall be controlled in such a manner that they uniquely identify a single donor.

RDI's shall be numeric, or alphanumeric using only upper case alpha characters. (Linear bar code length increases as alpha characters are used)

Checksums shall be calculated as indicated in section 5.2 below.

Once assigned a GRID shall never be reassigned.

5.2 Calculating the Checksum

The checksum is based on the ISO 7064 Mod 37-2 algorithm. This section shows how the checksum shall be calculated for any given GRID. The calculation is based on the first seventeen data characters of the GRID (the ION followed by the RDI).

Global Registration Identifier for Donors (GRID)



Data used to calculate checksum Checksum

The steps in the process are as follows:

- 1. For each character in the seventeen character string, determine its check value as required by ISO 7064 from Table 3 (e.g., character F has value 15);
- 2. For each character in the seventeen character string, determine its weighted check value by multiplying the check value from Table 3 by the nth power of 2 where n is the position of the character from the right-hand end of the string;
- 3. Sum the weighted check values from step 2;
- 4. Find the modulus 37 value of the sum from step 3;
- 5. Subtract the value obtained in step 4 from 38;
- 6. Find the modulus 37 value of the result of step 5;
- 7. If the value from step six is a single digit add a leading zero.
- 8. The calculated value is the modulo 37-2 checksum.

Table 3 Character to ISO/IEC 7064 Check Values [RT061]

Character	0	1	2	3	4	5	6	7	8	9	Α	В	С
Value	0	1	2	3	4	5	6	7	8	9	10	11	12
Character	D	Е	F	G	н	Т	J	к	L	м	Ν	0	Ρ
Value	13	14	15	16	17	18	19	20	21	22	23	24	25
Character	Q	R	s	Т	U	V	w	х	Υ	Ζ			
Value	26	27	28	29	30	31	32	33	34	35			

Example of Checksum Calculation

	STEP 1	n	2 ⁿ	STEP 2
Character in the string	ISO 7064 check value (a)	Position of the character from the right	(b)	Weighted check value (a x b)
9	9	17	131072	1179648
9	9	16	65536	589824
9	9	15	32768	294912
1	1	14	16384	16384
0	0	13	8192	0
1	1	12	4096	4096
2	2	11	2048	4096
0	0	10	1024	0
7	7	9	512	3584
0	0	8	256	0
4	4	7	128	512
3	3	6	64	192
3	3	5	32	96
2	2	4	16	32
0	0	3	8	0
1	1	2	4	4
6	6	1	2	12

ION+Registration Donor Identifier is 99910120704332016

Step 3: sum of last column = 2093392

Step 4: modulo 37 of 2093392= 6

Step 5: 38 – 6 = 32

Step 6: modulus 37 of 32 = 32

Step 7: Add leading zero if single digit. = 32

Thus, the mod 37-2 checksum is 32.

9991 0120 7043 3201 632

5.3 Eye-readable presentation of the GRID

When printed in an eye-readable format, the GRID shall be divided into five blocks of 4,4,4,4,3 to assist manual transcription.

Spacing between the blocks shall be sufficient to ensure the blocks are clearly separated.

The GRID shall be printed in a font that allows differentiation between similar letters and digits (i.e., 0 and 0, 1 and I)

An example of the full GRID eye-readable format is shown below.



When printed on a medical product label, the GRID shall be preceded with the uppercase letters GRID and a colon (i.e. GRID:).

GRID: 9991 0120 7043 3201 632

When the GRID is printed on forms and reports, spacing between blocks of characters shall be included if space permits. The preceding 'GRID:' is required if the form or report design does not clearly identify the position as a GRID. The data identifier characters (&:) shall not be included in an eye-readable presentation of the GRID.

5.4 Electronic encoding of GRID

When the GRID is represented in automatic identification and data capture (AIDC) solutions, it shall be encoded as Data Structure 039 in the ISBT 128 Standard.

Purpose: Data Structure 039 shall specify a globally unique identifier for HPC donors or potential donors.

Element	Length	Туре
&	1	data identifier, first character
:	1	data identifier, second character
nnnn	4	numeric {0–9}, first character shall not be 0
aaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa	13	alphanumeric {A–Z; 0–9} Where alpha characters are used they must be uppercase.
bb	2	two-digit checksum {00–36}

Structure: &:nnnnaaaaaaaaaaabb

The data content string shall be 19 characters and shall be encoded and interpreted as follows:

nnnn	GRID Issuing Organization Number (ION) that shall be encoded and interpreted by reference to the GRID Issuing Organizations Database published on the ICCBBA Website.
aaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa	Registration Donor Identifier that shall uniquely identify a donor, or potential donor, within the registration organization. (Note: Alpha characters in the RDI will increase the length of a linear bar code.)
bb	Two-digit modulus 37-2 checksum. Section 5.2 describes how the checksum is calculated.

If the GRID is to be represented in a linear bar code, Code 128 shall be used and comply with ISO/IEC 15417: 2007: Information technology—Automatic identification and data capture techniques—Code 128 bar code symbology specification.

If the GRID is to be represented in a 2-D symbol, Data Matrix shall be used and comply with ISO/IEC 16022:2024(E): Information technology—Automatic identification and data capture techniques — Data Matrix bar code symbology specification.

The GRID may be combined with additional information in the 2-D symbol as part of an ISBT 128 Compound Message. Additional information about the Compound Message

data structure and requirements for the use of Code 128 and Data Matrix may be found in the *ISBT 128 Standard Technical Specification* (ST-001).

5.5 Using the checksum to verify a GRID

The integrity of a GRID can be verified by performing a checksum calculation on the first seventeen characters of the GRID and ensuring that the resulting checksum matches the last two characters.

Such a verification should be performed each time a GRID is received by a computer system either by manual entry or electronic transfer from another system.

If the verification fails appropriate action shall be taken to ascertain the point at which the GRID became corrupted.

6 Information for Software Developers

6.1 Database

The GRID Issuing Organization Database is available both as a Microsoft Excel® spreadsheet and as an XML file. The database is updated when new organizations are added or when changes to existing organizations occur when this information is provided to ICCBBA. A version control sheet is issued with each new version of the database and, along with the database, is posted on the ICCBBA Website.

6.2 Use of the ION within the GRID

The ION in the GRID is present as a means of ensuring global uniqueness across multiple organizations. However it is not intended to be parsed as a data item in its own right in order to identify the organization with which the donor is associated.

Where it is necessary to transmit the identity of this organization the ION should be used in a data field specifically designed for the purpose.

6.3 The GRID Checksum

The GRID contains an integral checksum calculated as indicated in section 5.2. Whenever a system receives a GRID, either via manual input or electronic messaging, it should verify the GRID as indicated in section 5.5.

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