POLICY TITLE: U.S. Export Controls and Sanctions	SYSTEM POLICY AND PROCEDURE MANUAL
POLICY #: 800.24	**CATEGORY:** Compliance & Ethics
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Prepared by: Office of Corporate Compliance	**Notations:** Supersedes: GR103, Export Controls in Research

GENERAL STATEMENT of PURPOSE

The purpose of this policy is to describe the background and general management of Northwell Health activities that may be subject to United States ("U.S.") export control and sanctions laws, regulations and associated executive orders.

POLICY

It is the policy of Northwell Health to comply with U.S. export control and sanctions laws, regulations and associated executive orders. The objective of export control and sanctions regulations is to protect national security by preventing certain physical commodities, software, technology and funds from being acquired by parties adverse to the interests of the U.S. The governing framework for U.S. export controls and sanctions consists of statutes, executive orders, and regulations from the U.S. Departments of Commerce, State and the Treasury. Export control laws restrict certain types of physical commodities, software and technology from being shipped or transmitted overseas to individuals, including U.S. citizens, being re-exported or transferred between two non-U.S. countries, or being made available to foreign nationals on U.S. soil. The sanctions laws most relevant to a U.S. entity generally prohibit U.S. persons from engaging in business dealings with restricted persons or in restricted locations. Violation of U.S. export control and sanctions laws can result in severe civil and criminal penalties and fines as well as sanctions or removal of exporting privileges. Therefore, every Northwell Health employee, officer, director, student and agent shares responsibility for ensuring that Northwell Health complies with U.S. export controls and sanctions laws, regulations and associated executive orders.

SCOPE

This policy applies to all Northwell Health employees, as well as medical staff, volunteers, students, trainees, physician office staff, contractors, trustees and other persons performing work for or at Northwell Health; faculty and students of the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell or the Hofstra Northwell School of Nursing and Physician

Assistant Studies conducting research on behalf of the Zucker School of Medicine on or at any Northwell Health facility.

DEFINITIONS

"Bureau of Industry and Security (BIS)": A bureau under the U.S. Department of Commerce which administers and enforces the Export Administration Regulations (EAR).

"Commerce Control List (CCL)": Located at Supplement No. 1 to Part 774 of the Export Administration Regulations (EAR), the CCL is a list of items (i.e., commodities, software, and technology) under the export control jurisdiction of the U.S. Department of Commerce's BIS that are assigned an Export Controls Classification Number (ECCN) and corresponding export restrictions.

"Directorate of Defense Trade Controls (DDTC)": The U.S. Department of State's Directorate of Defense Trade Controls administers the International Traffic in Arms Regulations (ITAR).

"Export Administration Regulations (EAR)": Govern and impose controls relating to the export, re-export or transfer of certain items due to various national interests, including national security, nonproliferation of weapons, regional stability, crime control, human rights and anti-terrorism. The EAR also places limitations on exporting, re-exporting or transferring commercially available items that have a military component known as dual use. Although the EAR impose only limited controls on the export of services, the regulations do place controls on technology that could be transmitted while providing services relating to EAR-controlled items.

"**EAR99**": Items subject to the EAR but not listed on the CCL or assigned an Export Control Classification Number (ECCN), are classified as EAR99, the lowest level of control for items subject to the EAR.

"Export Control Classification Number (ECCN)": A five-character alphanumeric entry used in the CCL that describes the item, indicates licensing requirements, and provides reasons for control. The CCL is divided into ten categories which include:

- 0 – Nuclear Materials Facilities & Equipment (and Miscellaneous Items)
- 1 – Materials, Chemicals, Microorganisms, and Toxins
- 2 – Materials Processing
- 3 – Electronics Design Development and Production
- 4 – Computers
- 5 (Part 1) – Telecommunications
- 5 (Part 2) – Information Security
- 6 – Sensors and Lasers
- 7 – Navigation and Avionics
- 8 – Marine
- 9 – Aerospace and Propulsion

These categories are broken down further into the following product groups:

- A –End Items, Equipment, Accessories, Attachments, Parts, Components, and Systems
- B – Test, Inspection, and Production Equipment
- C – Materials
- D – Software
- E – Technology

"Export": includes an actual shipment or transmission of items, services, or technical data, subject to U.S. export controls, out of the U.S. or the release of technology or software source code (under EAR), or technical data (under ITAR), to a non-U.S. person within the U.S.

Technology, software, or technical data can be considered "released" for export through:

1. Visual inspection by a foreign national of U.S.-origin equipment and facilities;

2. Oral or written exchanges of information in the U.S. or abroad;

3. Transfer or shipment via any means (physical or electronic) to a foreign entity; or

4. Provision of a service, or the application to situations abroad of personal knowledge or technical experience acquired in the U.S.

    - A "**deemed export**" is the release of controlled technology or source code to a foreign national physically located in the U.S. This release is "deemed" to be an export, as if exporting to the country of the foreign national.

    - A "**re-export**" is an actual shipment or transmission of items subject to export regulations from one foreign country to another foreign country.

    - A "**transfer**" is a change in end use or end user of an item within the same foreign country.

"Fundamental research": Basic or applied research in science, mathematics and engineering where the resulting information is ordinarily published, shared broadly in the scientific community and no sponsor publication or access restrictions have been accepted. Fundamental research is generally excluded from export controls. This exclusion can apply to the dissemination of research results, data and information, but generally not to the transmission of controlled physical goods, software or equipment or technology.

- ***Under the EAR*** (15 CFR §734.8), research conducted by or supported by The Feinstein Institutes for Medical Research ("Feinstein Institutes") normally will be considered fundamental research unless Feinstein Institutes or its researchers accept sponsor restrictions on the publication of scientific and technical information resulting from the project or activity. The EAR specifically permit limited prepublication reviews by research sponsors to prevent the inadvertent divulging of proprietary information provided to the researcher by the sponsor or to ensure that publication will not compromise the patent rights of the sponsor.

- ***Under the ITAR*** (22 CFR §120.11(8)), only research in science and engineering at accredited institutions of higher learning in the U.S. can qualify as fundamental. Feinstein Institutes research will not qualify as fundamental research under ITAR if: (1) Feinstein Institutes or its researchers accept any restrictions on the publication of scientific or technical information resulting from the project or activity; or (2) the research is federally funded and specific access and dissemination controls protecting information resulting from the research have been accepted by Feinstein Institutes or the researcher.

"International Traffic in Arms Regulations (ITAR)": U.S. regulations that restrict and control, for the purpose of safeguarding U.S. national security, the export of defense and military related technologies. Regulations prohibit the export, re-export, or transfer of "defense articles" (items identified on the U.S. Munitions List ("USML"), including technical data) or "defense services" (defined at 22 CFR § 120.9 as furnishing of assistance, including training, to foreign persons in the U.S. or abroad). The ITAR restrict the export of design, development, engineering manufacture, production, assembly, testing, repair, maintenance, modification, operation, demilitarization, destruction, processing or use of defense articles or related technical data without prior authorization such as a license, license exception, or a regulatory exemption.

A **license** is prior written authorization from one or more U.S. Government agencies that may be required to carry out certain sponsored research or other activities involving specified technologies or certain destinations/recipients, if an exception, exemption, or exclusion is not available. Licenses may be general (available for use by any qualified exporter under certain enumerated scenarios) or specific (personal to the requestor for a specified export scenario of specific goods or technology).

"Office of Foreign Assets Controls (OFAC)": Under the U.S. Department of Treasury, OFAC administers and enforces economic and trade sanctions against a number of countries, individuals and entities to support national security goals against targeted foreign countries, regimes, or individual persons or entities. OFAC regulations generally apply to U.S. citizens and permanent resident aliens wherever they are located; individuals and entities physically located in the U.S. (regardless of citizenship or country of residence); and corporations organized under U.S. law, including their foreign branches, agencies, and representative offices. Certain sanctions also apply to foreign subsidiaries of U.S. entities.

"Restricted Party Lists (**RPL)":** Lists maintained by the U.S. Government of individuals, entities, and countries with which one may not conduct business or engage in specified activities without obtaining a valid license. Commercial providers and the website www.trade.gov/export-solutions offer search tools that combine relevant RPLs.

"Technology Control Plan (TCP)": A document used to safeguard material or information restricted under the ITAR, EAR, or other relevant laws and regulations. The TCP lays out a security plan and training, and identifies responsible parties. A TCP must be approved by an authorized Northwell Health official before restricted material or information can be brought onto campus.

"Technical Data":

- ***Under ITAR*** (22 CFR § 120.10), (1) information, other than software defined in §120.10(a)(4), which is required for the operation, repair, testing, maintenance or modification of defense articles (this includes information in the form of blueprints, drawings, photographs, plans, instructions or documentation); (2) Classified information relating to defense articles and defense services on the U.S. Munitions List and 600-series items controlled by the Commerce Control List; (3) Information covered by an invention secrecy order; and (4) Software (*see* § 120.45(f)) directly related to defense articles. This definition does not include information concerning general scientific, mathematical, or engineering principles commonly taught in schools, colleges, and universities, or information in the public domain as defined in § 120.11 or telemetry data as defined in note 3 to Category XV(f) of part 121 of this subchapter. It also does not include basic marketing information on function or purpose or general system descriptions of defense articles.
- ***Under EAR*** (15 CFR § 772.1), included in its definition of Technology, which is Information necessary for the "development," "production," "use," operation, installation, maintenance, repair, overhaul, or refurbishing (or other terms specified in ECCNs on the CCL that control "technology") of an item.

"United States Munitions List (USML)": A list administered by the DDTC that defines defense articles and defense services that are subject to licensing. The list is contained in Part 121 of ITAR.

"U.S. Person": includes any individual who is a U.S. citizen, non-U.S. citizen who is a lawful permanent resident of the U.S., a protected individual as defined by 8 U.S.C. 1324b(a)(3) (generally including specific immigration status such as certain refugees and recipients of asylum), an entity organized under the laws of the U.S. or any jurisdiction within the U.S. (including foreign branches), and any person physically located in in the U.S. A person not meeting the above qualifications is considered a foreign person or foreign national.

PROCEDURE

Activities Subject to Export Controls Review

Northwell Health will not authorize any activities that are prohibited under U.S. export control or sanctions laws or regulations. Export control laws and regulations apply to certain activities at Northwell Health that may or may not involve research. Export control and sanctions regulations may apply whether or not the research is funded by or subject to a grant, contract, clinical trial, or other agreement, and apply whether or not the EAR, ITAR, or OFAC regulations are cited in the research award document. In general, export controls impose licensing obligations on the export, re-export, or in-country transfer of physical commodities, software, and technology. Further, export control restrictions follow an item that is subject to U.S. export controls and can impose licensing obligations and prohibitions on third parties, regardless of whether they are U.S. persons. In addition, if a researcher accepts export-controlled technology or information from a government agency or from industry, the researcher is subject to ITAR or EAR-related compliance obligations. Before engaging in any export-controlled research related activity, or to determine whether research is subject to export controls, Northwell Health researchers, employees, students and contractors must contact the Office of Compliance at exportcontrols@northwell.edu for help in determining potential compliance requirements.

The following activities may require prior export controls review by Compliance:

- Engaging in research that involves controlled materials, technical data and biological agents (e.g., select agents, hazardous or infectious materials, military or defense articles or services or NASA-related research) or dual-use technologies (e.g., technologies capable of use for both civilian and military applications);
- Shipping or transferring controlled items, software or technology/technical data outside of the U.S. or to a foreign national in the U.S. or abroad depending on the item, destination, recipient and end-use;
- Teaching, receiving funding from, researching or collaborating with foreign nationals or entities in the U.S. or abroad;
- Providing consulting services abroad;
- Sharing research results or protected intellectual properties with foreign individuals or entities;
- Providing training to foreign nationals that may include access to export-controlled data or technology, including taking foreign nationals on tours through research areas that may be restricted; or
- Traveling to or working in foreign countries, particularly if traveling with controlled materials, technical data and/or technology.

Sanctioned and Embargoed Countries, Entities and Individuals

The U.S. imposes economic and trade sanctions against certain identified individuals, groups, and entities that are designated on various lists, including OFAC's Specially Designated Nationals and Blocked Persons List (SDN List). OFAC sanctions bar most transactions by U.S. persons with individuals or entities on the SDN List without an OFAC license. In addition, any entity that is 50% or more owned, individually or in the aggregate, by one or more individuals or entities on the SDN List is considered also blocked, even if that owned entity is not itself listed on the SDN List. Prohibitions include transactions, importation, exportation, and re-exportation of goods and services, whether direct or indirect. U.S. sanctions also prohibit U.S. persons from facilitating transactions with sanctioned entities or individuals.

The U.S. also imposes economic and trade sanctions on countries and regions. Currently, the U.S. has comprehensive sanctions against Cuba, Iran, North Korea, Syria, and the Crimea, Donetsk, and Luhansk regions of Ukraine. The U.S. also maintains enhanced sanctions programs that relate to Venezuela and Russia. In addition, there are targeted sanctions programs and embargoes for other countries, regions, entities and individuals that are updated frequently and are available online:

- The U.S. Department of Treasury Office of Foreign Assets Control: https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx
- The U.S. Department of State: https://www.state.gov/economic-sanctions-policy-and-implementation/
- The U.S. Department of Commerce: https://www.bis.doc.gov/index.php/documents/regulation-docs/420-part-746-embargoes-and-other-special-controls/file

OFAC regulations generally apply to U.S. persons wherever they are located; individuals and entities located in the U.S.; and corporations organized under U.S. law, including their foreign branches, agencies, and representative offices. Certain sanctions also apply to foreign subsidiaries of U.S. entities. As a U.S.-based entity, Northwell Health must comply with U.S. sanctions.

The practical application of U.S. sanctions is that a U.S. person may not engage in transactions that involve a restricted individual or entity or an individual or entity in an embargoed country or region if the transaction is not covered under an exception or license. As such, Northwell employees must contact the Office of Corporate Compliance if they have any reason to believe such a person, entity, country or region may be involved.

If any activities involve comprehensively sanctioned countries, countries subject to enhanced sanctions program, or sanctioned entities, or individuals, further review by the Office of Corporate Compliance is required.

Export Controls Review and Restricted Party Screening

Screening is conducted prior to executing contracts or agreements, onboarding individuals, and engaging in international activities, and monitored thereafter for all existing counterparties. Each Northwell business unit or department involved in facilitating contracts, agreements, onboarding or international activities is responsible for ensuring that: (1) export control reviews are conducted for any activities that may involve controlled items, software, or technology; and (2) screening is conducted for any third parties with which Northwell conducts business or research, to determine whether the third party is on the RPL or located in a restricted country or region.

The following activities may trigger an export controls review/screening:

- Grants and Research Agreements submitted through the Grants Management Office when funding proposals are entered into the Grants Management System (GMS). If responses indicate a review is required, an Ancillary Review is requested directly through the GMS. Agreements that appear to be inconsistent between the answers given and the content of the submission, contract or agreement will trigger clarification questions to the Principal Investigator.

- Clinical Trial Agreements (CTAs) that require an export control review are reviewed by the Clinical Trials Office. The Clinical Trials Office engages the Office of Research Compliance to determine whether the third party is listed on an RPL.

- Material Transfer Agreements, Confidentiality Agreements, Inter-Institutional Agreements, Institutional Approval, Research Collaboration Agreements, Consulting Agreements, License Agreements and Patent Applications submitted through the Office of Technology Transfer and/or Office of Legal Affairs may be escalated for an export controls review/screening.

- Requests for Remote Educational Consultations from individuals located outside of the United States as well as any proposal to engage or otherwise do business with individuals or entities located outside of the U.S. submitted through Northwell's Center for Global

Health, International Services and/or Office of Legal Affairs may be escalated for export controls review/screening.

Screening of individuals will be conducted in the following manner:

- New hires, visiting scientists/scholars, volunteers/interns, partners, vendors, employees of startup companies leasing space on campus, international recipients of shipments remuneration and services (e.g., telemedicine and educational consultations), and other third parties must be screened against the RPLs as part of the onboarding, contracting or other business process. In addition, non-U.S. employees, vendors and other third parties must be screened. Non-U.S. students must also be screened prior to admission .

- Visitors to sensitive areas designated in TCPs must also be screened prior to access.

If a potential third party is listed on a RPL or consolidated screening list for which the U.S. Government maintains restrictions on certain activities, the matter must be escalated to the appropriate management, Human Resources or the Office of Corporate Compliance personnel for further guidance, and no transactions may take place until cleared. Please contact the Office of Corporate Compliance at exportcontrols@northwell.edu for inquiries against the RPL or consolidated screening list.

Procedures Regarding Exports

If an export license is required, the Office of Corporate Compliance will work with the Office of Legal Affairs and coordinate the application process. Obtaining an export license may take anywhere from one to six months or more, and there is no guarantee that a license will be issued. No export or deemed export activity requiring a license can take place until the required export license is obtained.

It is the responsibility of the Office of Corporate Compliance, working with the employee and department, to determine the licensing requirements for exporting any item (e.g., materials, equipment, software, technology, information) to destinations outside the U.S. or to foreign nationals within the U.S. Determining the license requirements of an item can be a complicated process requiring proper classification of the item or technical data and verification and clearance of the target destination, end use, and end users. The EAR contains a number of end-user and end-use based controls.

Dual-use items controlled under the EAR and items found on the Commerce Control List (CCL) may require a license before exporting. Commercial items that are usually considered low-technology (e.g., consumer goods) generally do not require a license. However, such items may be classified as EAR99. According to the Bureau of Industry and Security (BIS), an EAR99 item exported to an embargoed country, to an end-user of concern or in support of a prohibited end-use, may require you to obtain a license before exporting. Items and services listed on the USML require a license to import and export and require registration with the DDTC. For certain activities involving sanctioned countries or parties, a specific license may be required from OFAC.

Exports, re-exports, and transfers require a license when the exporter has reason to know that the item will be used in certain nuclear and ballistic missiles, UAV/drones, chemical and biological

weapons, maritime nuclear propulsion end-uses, certain activities involving semiconductors and supercomputers, and certain end-uses in specified countries that qualify as military in nature. Exports, re-exports, and transfers to military end-users in certain countries can also require a license. While it can be difficult to identify these end-uses or end-users, any red flags or concerns related to these end-uses must be raised to the Office of Corporate Compliance. The U.S. Government also has a number of lists of proscribed parties. Any export of items subject to the EAR to an individual or entity on any of these lists of proscribed parties may require a license. These lists must be included in the screening described above.

For assistance in determining whether your item is found on the Commerce Control List (CCL) or the USML, please contact the Office of Corporate Compliance.

The final determination of whether an item requires an export license, qualifies for a license exemption or exception, or can be exported as "No License Required" will be made and documented by the Office of Corporate Compliance in collaboration with the requesting individual(s).

Restrictions Relevant to Travel, Destinations, Entities, and Persons

In certain instances, Northwell Health may host researchers or other professionals from embargoed/comprehensively sanctioned countries and territories (e.g., Cuba, Iran, North Korea, Syria and the Crimea, Luhansk, and Donetsk regions of Ukraine) or from countries subject to enhanced sanctions programs in compliance with U.S. sanctions regulations. In such a case, the department's administration will work with Human Resources and the Office of Legal Affairs to prepare a visiting agreement to ensure that all requirements of the U.S. sanctions are met.

Travel to or working on projects involving a country subject to comprehensive or enhanced sanctions may involve significant restrictions or require a license. For instance, consulting or teaching services may require a license, even for non-technical topics. Furthermore, when traveling to sanctioned countries, hand-carrying certain items, including laptops, GPS, hand-held devices, phones etc., may require a license. If you are traveling to any country subject to comprehensive or enhanced sanctions, you must obtain approval from your department head, and for any destinations requiring a license you must work with the Office of Corporate Compliance in order to ensure compliance with all sanctions and export control regulations.

Prior to traveling with any portable electronic devices, please check with your department administration and IT to determine if a loaner laptop is available. For more information about international travel, please refer to the Northwell IT Security Guidelines When Traveling Internationally, and other resources on the Export Controls Compliance intranet page.

Before agreeing to provide funding or employment involving country subject to comprehensive or enhanced sanctions on behalf of the organization, the appropriate Northwell Health offices involved in facilitating the agreements and funding must conduct restricted party screening (RPL) and consult the Office of Corporate Compliance for assistance in identifying potential restrictions on the transaction or required licenses. Refer to *Northwell Health Policy #100.075 International Travel* for more information on international travel requirements.

Accepting, Working with, and Creating Export-Controlled Items; Technology Control Plans (TCPs)

Before accepting, working with, or creating any export-controlled or potentially export-controlled items, software, technology or information, Northwell Health researchers, employees, students, and contractors must contact the Office of Corporate Compliance for help in determining potential compliance requirements.

If a project or class involves the receipt or creation of export-controlled items, software, or technology, the researcher or other responsible person will be required to complete a TCP in collaboration with the Office of Corporate Compliance before any work or research can begin. The TCP will outline the specific procedures and safeguards that will be implemented by the employee to ensure compliance with U.S. export controls. The TCP will need to be reviewed periodically and updated as necessary.

All Northwell Health researchers, employees, students, and contractors receiving or creating export-controlled information or items will be asked to sign the "Acknowledgement of Technology Control Plan" acknowledging their receipt and/or creation of export-controlled items and their understanding of their responsibilities and duties regarding the safe handling and use of the items.

Marking

Documents containing information relating to products, software, or technology subject to export controls must contain an export control legend informing the recipient of the handling requirements. Marking will be completed in accordance with the relevant TCP.

Exclusions

U.S. export controls have several exceptions and exclusions that can apply in specific situations. Certain exclusions bear significant importance to the activities of Northwell Health: fundamental research, educational activities, public domain, and informational materials.

- Fundamental Research Exclusion (FRE)

Most Northwell Health research activities and associated technology and technical data are excluded from export controls because of a general exception for fundamental research under the EAR and the ITAR. By not accepting any restriction on publication, Northwell Health's dissemination of research results, data and information is protected by the fundamental research exclusion and therefore, in most situations, no license would be needed. The fundamental research exclusion (FRE) does not apply by default; its use must be documented through a review of the circumstances and parties around the transfer of the material or information in question. The application of the FRE to the transmission of export-controlled information, materials, or items outside of the U.S. must be evaluated separately.

- Educational Activities Exclusion

General scientific, mathematical, and engineering principles commonly taught in universities are excluded from control under the EAR and the ITAR. In addition, information that has already been

published and is considered publicly available (as defined) may be exempt from export control. The sanctions programs also contain exclusions for information and informational materials (as defined).

If you seek to rely on any of the above exclusions or exceptions, you must consult with the Office of Corporate Compliance to determine if the exclusion or exception applies or if a license will be necessary prior to undertaking any activity that may be covered by an exclusion or exception.

Records Retention and Availability

Export control records must be retained for five years from the latest date of export, re-export or expiration date. This includes records from the date of export or date of license expiration as per regulatory requirements. Records must be made available to a regulatory authority upon request.

Education and Training

An educational course in export controls is offered through the Collaborative Institutional Training Initiative (CITI) Program. Training may also be facilitated by the Office of Corporate Compliance if needed. Courses are required for anyone who is involved in certain export control activities requiring a license or personnel who are part of a TCP. The required training course must be completed prior to initiating any export-controlled activity and must be renewed before the expiration of three years, as long as the export-control activity continues.

Auditing and Monitoring

The Office of Corporate Compliance or Internal Audit may conduct periodic routine auditing and monitoring. It is the responsibility of all employees to conduct themselves in compliance with this policy. Employees may report incidents of non-compliance via the Corporate Compliance Help Line 1-800-894-3226 or by web-based reporting at www.northwell.ethicspoint.com.

Enforcement

Non-compliance with this policy may lead to disciplinary action, up to and including termination of employment.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

- U.S. Department of State, Directorate of Defense Trade Controls (DDTC) – International Traffic in Arms Regulations (ITAR) 22 CFR parts 120-130
- U.S. Department of Commerce, Bureau of Industry and Security (BIS) – Export Administration Act (EAR) 15 CFR parts 700-799
- U.S. Department of the Treasury, Office of Foreign Asset Control (OFAC) 31 CFR parts 500-599
- Northwell Health Policy #800.05, Screening of Federal and State Exclusion Lists
- Northwell Health Policy #100.075, International Travel
- Northwell Health Policy #GR081 Visiting Scientists and Visiting Scholars for Research

CLINICAL REFERENCES/PROFESSIONAL SOCIETY GUIDELINES
N/A

ATTACHMENTS
N/A

FORMS
N/A

APPROVAL:	
Northwell Health Policy Committee	5/21/2024
System PICG/Clinical Operations Committee	6/20/2024

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