هيئة تنمية البحث والتطوير والابتكار
Research Development and Innovation Authority

رؤية VISION 2030
المملكة العربية السعودية
KINGDOM OF SAUDI ARABIA

National Procurement Guidelines for RDI Materials

A National Guideline for Procurement of Material for Research Development and Innovation Use into Saudi Arabia

Developed by the Research Development and Innovation Authority (RDIA)

August 2024

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Introduction

In support of the Kingdom of Saudi Arabia's Vision 2030, the Research, Development, and Innovation Authority (RDIA) plays a critical role in progressing scientific advancements and innovation. Effective planning and management of research materials are crucial for the seamless execution of scientific projects and the achievement of the Kingdom's RDI strategic goals in the four priority domains of:

- Health and Wellness
- Sustainability and Essential Needs
- Energy and Industrials
- Economies of the Future

RDIA aims to enhance the efficiency and productivity of research activities while optimizing resource utilization and minimizing waste by ensuring that researchers have timely access to the necessary high-quality RDI materials supporting the researchers and innovators in the Kingdom, fostering a well-organized and efficient research environment. This guideline document is designed to provide researchers across the Kingdom with general guidance on the procurement processes required to import materials for RDI use. It also offers guidance on strategies for:

- Determining the types and quantities of RDI material needed for their research activity
- Managing inventory for these materials
- Providing general guidelines on the safe use, management, storage, and waste control of these materials

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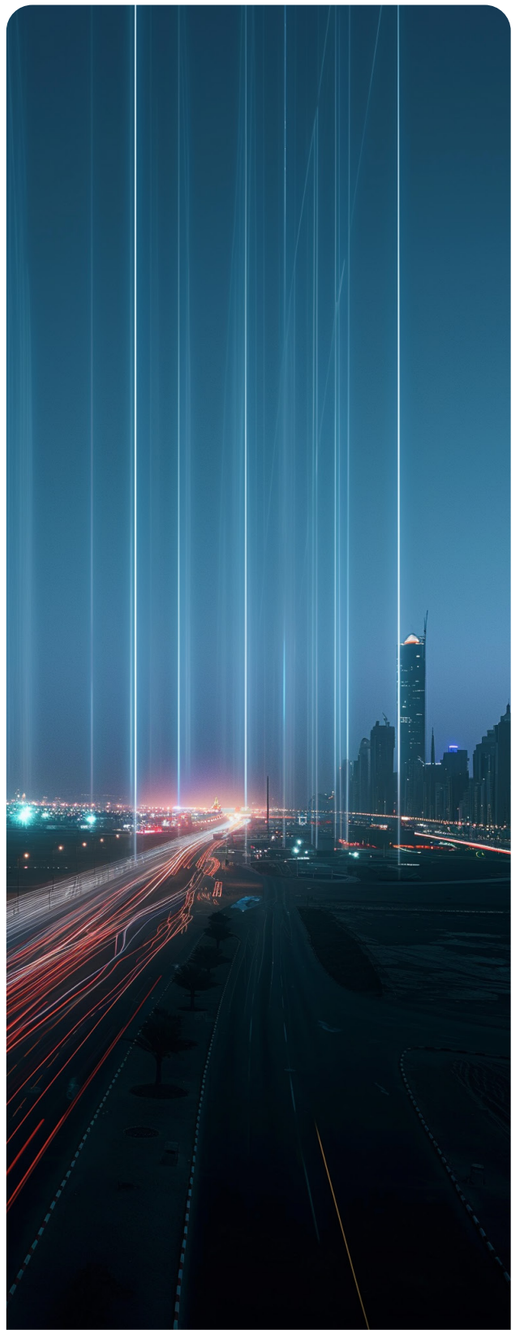
Purpose and Scope



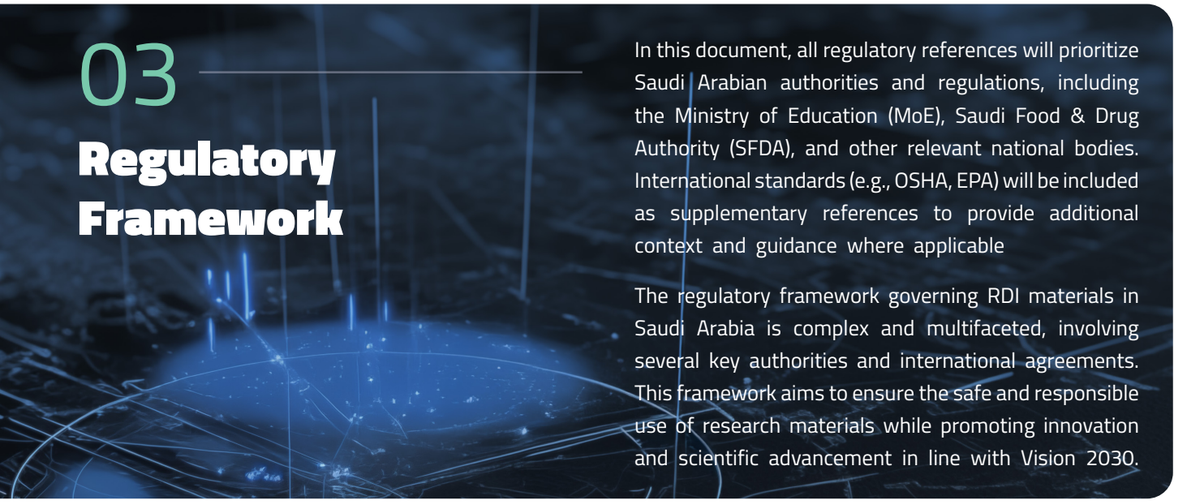
The purpose of this guideline paper is to offer researchers, directors of Research Materials Units, and RDI Units in universities and research centers throughout the Kingdom full guidance on:

- Efficient planning and management of research materials
- Determining appropriate types and quantities of materials for various research projects
- Navigating the procurement and importation processes for RDI materials
- Implementing effective inventory management techniques
- Ensuring compliance with safety regulations and environmental requirements
- Establishing best practices for the safe use, storage, and disposal of research materials

The recommendations are intended to enable the implementation of the RDI strategic goals specified in Saudi Arabia's Vision 2030 and to assist researchers in optimizing resource use and research output.

Disclaimer

Consider this document as a guideline to provide you with general informational purposes only and is not intended as legal advice. Researchers and research institutions are encouraged to consult with legal experts before engaging in activities involving the import, use, or management of RDI materials. **This document does not cover all aspects of legal and regulatory compliance related to research materials and should not be relied upon as a sole source of guidance.** The Research, Development, and Innovation Authority (RDIA) assumes no responsibility for errors or omissions in the contents of this document.



03 Regulatory Framework

In this document, all regulatory references will prioritize Saudi Arabian authorities and regulations, including the Ministry of Education (MoE), Saudi Food & Drug Authority (SFDA), and other relevant national bodies. International standards (e.g., OSHA, EPA) will be included as supplementary references to provide additional context and guidance where applicable

The regulatory framework governing RDI materials in Saudi Arabia is complex and multifaceted, involving several key authorities and international agreements. This framework aims to ensure the safe and responsible use of research materials while promoting innovation and scientific advancement in line with Vision 2030.

Overview of Relevant Authorities and Key Stakeholders

The regulatory framework and implementation of RDI material management in Saudi Arabia involve collaboration among several key entities:

Ministry of Education (MoE): oversees the governance of research activities and material procurement within educational institutions. This includes reviewing and approving import applications for research materials used in university settings. The MoE's Research Material Committee assesses these applications to ensure they meet regulatory requirements and align with national research priorities.

Research, Development, and Innovation Authority (RDIA): While not a regulatory body, RDIA plays a significant role in advancing scientific research and innovation, aligning with Vision 2030 goals. It provides guidelines and support for researchers in navigating the regulatory landscape.

Saudi Food & Drug Authority (SFDA): Monitors the safety and efficacy of chemicals used in food and drug-related research, and medical centers as well as Medical Devices and In Vitro Diagnostics reagent that import for research purposes. Its responsibilities include:

- Issuing import permits for pharmaceutical and clinical research materials
- Ensuring compliance with safety standards for these materials
- Collaborating with other regulatory bodies to develop expedited review processes for critical research materials, particularly those relevant to public health emergencies

Ministry of Interior: Through the High Commission for Industrial Security (HCIS), the General Directorate of Narcotics Control, and the General Directorate of Civil Defense, ensures the security and regulatory compliance of these materials.

Ministry of Environment, Water, and Agriculture: Oversees environmental compliance aspects of research material management, particularly concerning waste disposal and environmental impact.

Zakat, Tax and Customs Authority: Manages the taxation and customs clearance processes for imported research materials.

Nuclear and Radiological Regulatory Commission: Oversees materials related to nuclear research and radiology to meet stringent safety and security standards.

Universities and Research Institutions: End-users of this guideline, responsible for implementing the recommended practices in their day-to-day operations.

Private Sector Research Entities: Align their research material management practices with national standards and regulations.

Compliance Requirements

While international standards such as those from OSHA and EPA are referenced for additional guidance, researchers must ensure compliance with the primary regulations set forth by Saudi Arabian authorities, including the MoE, SFDA, and other relevant national bodies

- **Import Licensing:** Researchers must obtain appropriate licenses and permits before importing materials. This often involves submitting detailed applications to the MoE, SFDA, or HCIS depending on the nature of the requested materials.
- **Safety and Handling Protocols:** Strict adherence to safety protocols is mandatory, especially for hazardous materials. This includes proper storage, handling, and disposal procedures
- **Inventory Management:** Accurate record-keeping of all research materials, particularly controlled substances, is required. This includes tracking usage, storage conditions, and disposal
- **Personnel Training:** Researchers and staff handling RDI materials must undergo appropriate training, especially for hazardous or sensitive materials
- **Waste Management:** Proper disposal of research waste in compliance with environmental regulations is crucial. This often requires detailed disposal plans and the use of licensed disposal services
- **Reporting:** Regular reporting to relevant authorities on the status and use of controlled substances is typically required

International Standards and Agreements

Saudi Arabia adheres to several international agreements that influence its RDI material regulations. These international standards supplement the primary regulations established by Saudi Arabian authorities. As a signatory to various international agreements, Saudi Arabia incorporates these standards into its RDI material regulations:

- **Chemical Weapons Convention (CWC):** This impacts the handling and reporting of certain chemicals that could potentially be used in chemical weapons
- **Basel Convention:** Governs the transboundary movements of hazardous wastes and their disposal, affecting how research waste is managed and disposed of
- **Stockholm Convention on Persistent Organic Pollutants:** Influences the regulation of certain organic pollutants in research settings
- **Montreal Protocol:** Affects the use and importation of substances that deplete the ozone layer, some of which may be used in research
- **International Air Transport Association (IATA):** Dangerous Goods Regulations: These govern the international transport of hazardous materials, including many research chemicals

Furthermore, Saudi Arabia often aligns its practices with international standards such as:

- ISO/IEC 17025 for testing and calibration laboratories
- Good Laboratory Practice (GLP) principles
- Biosafety levels (BSL) guidelines from the World Health Organization

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RDI Material Procurement Process

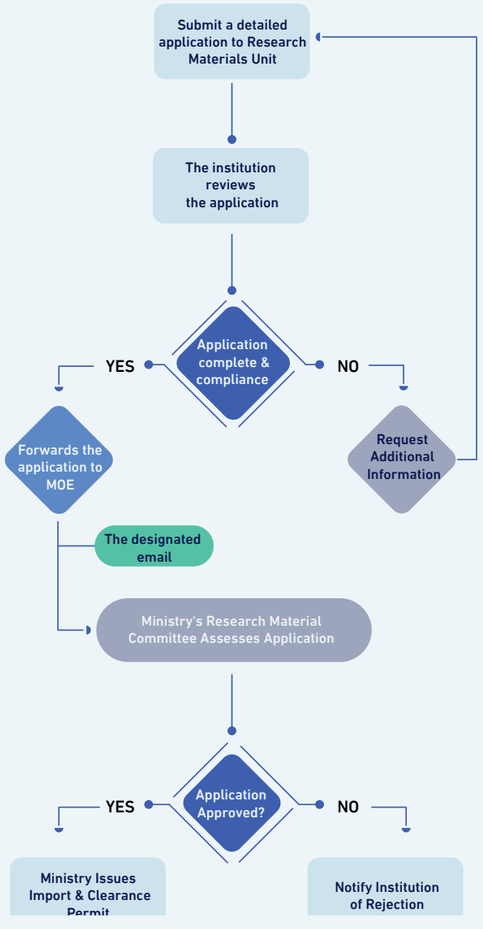

Figure 1: Flowchart of the Application Process for Importation of Research Materials in Saudi Arabia

The procurement of research, development, and innovation (RDI) materials in Saudi Arabia involves a structured process overseen by multiple governmental bodies to ensure safety, compliance, and efficient resource utilization.

Application Procedure

1. Researchers must submit a detailed application to their institution's Research Development and Innovation Unit (RDIU) or Research Materials Unit. The application should include:
   - A comprehensive description of the required materials (See appendix B)
   - Justification for the research purpose
   - Quantity needed
   - Safety Data Sheet (SDS) for chemical materials
   - A disposal plan for the materials after use
2. The institution reviews the application for completeness and compliance with internal policies
3. Upon approval, the institution forwards the application to the Ministry of Education's Research Material Committee via the designated email (chemunit@moe.gov.sa).
4. The Committee assesses the application to ensure alignment with regulatory requirements.
5. If the material belongs to the ninth list, list of un-restricted material, the application is then approved by the Ministry of Education and all necessary import and clearance permits are issued.
6. If the requested material belongs to the first or third list, explosive or explosives and chemical precursors respectively, the application will then be routed to the appropriate responsible authority, in this case, the HCIS (see appendix C). If the requested material belongs to the second list of material, chemical precursors, the application is then routed to the SFDA.
7. Table 1 below serves as a reference for applicants requesting the importation of RDI chemical materials into Saudi Arabia. It categorizes chemical materials based on their classification, list number, and the corresponding restrictions or prohibitions associated with each material. The table also specifies the authorities that are responsible for reviewing, approving, and issuing the necessary import and clearance documents for each category, ensuring that each application is handled appropriately, enhancing compliance and efficiency in the importation process.

Category	List	Classification	Responsible Authority
List of prohibited and restricted chemicals	First	Explosive	Ministry of Interior – High Commission For Industrial Security
	Second	Chemical precursors	Ministry of Interior (Including: General Directorate of Narcotics Control, General Administration of chemical Precursors and Laboratories, General Authority for Food and Drug Administration
	Third	Explosives and chemical precursors	Ministry of Interior – High Commission For Industrial Security
Lists of chemicals banned according to international agreements	Fourth	1998 Rotterdam Convention - Hazardous chemicals and pesticides	National Center for Environmental Compliance
	Fifth	2001 Stockholm Convention – Persistent organic pollutants	National Center for Environmental Compliance
	Sixth	1987 Montreal Convention – Substances that deplete the ozone layer	National Center for Environmental Compliance
	Seventh	The Convention on the Prohibition of the Development, Production and Use of Chemicals issued by Royal Decree No. M/57 and its Executive Regulations	Ministry of Foreign Affairs
	Eighth	Chemical materials whose clearance and import procedures fall in accordance with the Explosives and Crackers Regulations – issued by Royal Decree No. M38 dated and its executive regulations	Ministry of Interior
List of chemical that is neither prohibited nor restricted	Ninth	Substances that are not included in any of the prohibited or restricted lists	Ministry of Education

Table 1: Classification and Regulatory Authorities for RDI Chemical Materials: This table categorizes various chemical materials needed for Research, Development, and Innovation (RDI) in Saudi Arabia, delineating their classification, list number, and associated restrictions or prohibitions. It also identifies the responsible authority for reviewing, approving, and issuing the necessary import and clearance documents for each category of chemicals, from explosives to environmental hazards.

Import Regulations

Import regulations vary based on the type of material:

- **Chemical Materials:** Categorized into nine lists, each with specific restrictions and responsible authorities. For instance, the first list of material, material elements of explosive compounds, are regulated by HCIS, while material list nine cover non-restricted chemicals fall under the Ministry of Education's purview.
- **Biological Materials:** Require adherence to biosafety guidelines, particularly for BSL3 and BSL4 materials. Importation involves strict protocols for handling, storage, and disposal.
- **Radioactive Materials:** Subject to regulations set by the Nuclear and Radiological Regulatory Commission, requiring specialized handling and storage procedures.
- **Living Organisms:** The importation of living organisms, including animals, bacteria, cells, and tissues, is subject to strict regulations to ensure biosafety and compliance with ethical standards. Researchers must obtain appropriate permits from the Ministry of Environment, Water, and Agriculture and the Saudi Food & Drug Authority (SFDA). Detailed documentation is required, including the species, quantity, purpose of research, and expected duration of use. For animals, approval from the Institutional Animal Care and Use Committee (IACUC) is necessary. Microorganisms require information on type, strain, and biosafety level, while cells and tissues need details on origin and storage requirements. All imports must comply with international standards such as the OIE Terrestrial Animal Health Code and WHO guidelines for the transport of infectious substances.
- Specialized Equipment: May require additional permits depending on their nature and potential dual-use applications.

Researchers must comply with international agreements such as the Chemical Weapons Convention, Basel Convention, and IATA Dangerous Goods Regulations.

Procurement Process Enhancement

To optimize the efficiency and safety of the procurement process, implement the following measures:

- **Integrated Classification:** Incorporate international systems (e.g., GHS, NFPA 704) into the MRP database for proper material storage and handling.
- **Inventory Management:**
  - Track expiration dates and special storage conditions for sensitive materials.
  - Integrate MRP with Laboratory Information Management Systems (LIMS) for accurate inventory records and streamlined experiment planning.
  - Automatically update stock levels as materials are consumed.
- **Safety Monitoring:**
  - Track cumulative exposure levels for researchers, with automated alerts for approaching regulatory limits.
  - Link MRP with waste management systems to forecast waste generation and automate disposal manifest creation.
  - Include emergency procedures in the MRP system for quick access during incidents.
- **Advanced Tracking:**
  - Implement RFID or barcode systems for real-time tracking of high-risk materials.
  - Set up periodic reconciliation processes for controlled substances.
- **Predictive Analytics:**
  - Forecast degradation rates of unstable compounds.
  - Implement a first-expired, first-out (FEFO) system for critical materials.
- **Safety Data Management:**
  - Maintain an up-to-date database of SDSs linked to inventory items.
  - Set up automatic notifications for SDS updates.
- **Compatibility Management:** Integrate databases to alert users of potential reactions during material requisition or storage assignment.

Proposed Expedited Process for Critical Research Materials

To address the need for accelerated procurement of essential materials for urgent pharmaceutical and clinical studies, the following expedited review system is under consideration:

- **SFDA Collaboration:** It is proposed that the Saudi Food & Drug Authority could play a key role in developing this expedited review process, leveraging their expertise in pharmaceutical and clinical material regulation.
- **Critical Request Identification:** A system could be implemented where researchers clearly flag urgent requests for pharmaceutical or clinical study materials, potentially using a standardized "Critical Research Material" designation on application forms.
- **Eligibility Criteria:** Specific criteria may be established to determine which requests qualify for expedited review. These could include:
  - Direct relevance to public health emergencies
  - Time-sensitive clinical trials
  - Research addressing critical national health priorities
- **Streamlined Processing:** The proposed expedited process would aim to significantly reduce review times compared to standard procedures. This could potentially be achieved through:
  - Dedicated fast-track review teams
  - Parallel processing of multi-agency approvals
  - Implementation of digital workflow systems for real-time application tracking
- **Application Transfer:** For applications requiring further evaluation or specific considerations, a system could be developed to transfer the application to the appropriate responsible authority as detailed in Table 1.
- **Regular Review:** If implemented, it is recommended that the process be regularly reviewed by relevant authorities to ensure its effectiveness and make necessary adjustments.

Proposed Transportation of Research Materials

The safe and secure transportation of research materials, especially during periods of high temperatures and over long internal distances, is crucial for maintaining the integrity of research projects. To address this concern, the following recommendations are proposed for all RDI materials, including chemical, radioactive, and biological materials:

- **Licensing Transportation Companies:** It is recommended that transportation companies be licensed specifically for the transport of research materials. This licensing should take into account:
  - The ability to maintain appropriate temperature control during transport.
  - Security measures to protect sensitive research materials.
  - Proper handling procedures for potentially hazardous materials.
- **Consulting Relevant Ministries:** The Ministry of Interior and the Ministry of Transport should be consulted to develop and implement appropriate licensing and regulatory frameworks for companies transporting research materials.
- **Use of Licensed Services:** Research institutions and individual researchers should only use licensed and approved transportation services when moving research materials between locations.
- **Database of Approved Providers:** A database of approved transportation providers should be maintained and made available to all research institutions and researchers.
- **Regular Audits and Inspections:** Regular audits and inspections of licensed transportation companies should be conducted to ensure ongoing compliance with safety and security standards.

05 Material Needs Planning

Effective material needs planning is crucial for the success of any RDI project. It involves accurately estimating the quantities of materials required and ensuring their availability at the right time.

Standardized Research Material Request Form

To streamline the process of requesting materials for scientific research and to improve resource management across the Kingdom, the following system will be implemented:

- **Unified Request Form**

  A standardized form for requesting chemical research materials has been developed by RDIA and will be distributed to all research institutions in the Kingdom. The form includes the following key information:

  - Researcher's details (name, ID/Iqama number, title, contact information)
  - Research entity and department
  - Work address and lab details
  - RDIA Research Proposal Reference Number (if applicable)
  - Brief description of chemical material use in research
  - Detailed list of requested materials, including:
  - Chemical Material Name
  - Quantity and Unit
  - Chemical Abstracts Services (CAS) Registry Number (if available)
  - Additional attachments such as CAS, Formula, SDS, or other relevant documents

The form aims to help stakeholders identify if the material request is associated with research funded by RDIA through the proposal number, facilitating an easier or expedited clearance process.

Researchers are required to certify that the information provided is correct and that the imported materials will be used for research purposes only, adhering to safe use, management, and proper waste disposal guidelines.

- **Disposal Planning:**
  - Import applications must include a detailed disposal plan for the research materials
  - The disposal plan should outline the methods and procedures for safely disposing of the materials once they are no longer needed
  - The plan should also identify the licensed disposal services that will be used

While not mandatory, using this standardized form can streamline the application process and potentially expedite approvals from relevant authorities such as the Saudi Food & Drug Administration (SFDA), the Ministry of Education (MoE), and the High Commission for Industrial Security (HCIS).

Researchers are encouraged to use this form as it provides a comprehensive overview of the requested materials and their intended use, which can be beneficial for both the applicants and the reviewing authorities.

- **Integration with RDIA Database:**
  - The completed forms will be linked to the RDIA's central database.
  - This integration will allow for comprehensive tracking of research materials from request to disposal.
- **Material Management:**
  - The system will help in identifying consumed materials, procurement methods, and optimal disposal procedures after use.
  - It will assist in determining initial quantity requirements and may facilitate the provision of materials from existing inventory.
- **Demand-Based Scheduling:**
  - The system will enable scheduling of requests based on actual needs and demand.
- **Benefits:**
  - Improved resource allocation and reduced waste
  - Enhanced tracking of research materials throughout their lifecycle
  - Better forecasting of material needs across the Kingdom's research ecosystem
  - Potential for cost savings through bulk purchasing and inventory optimization

Unified Procurement for Frequently Used Research Materials

To address the need for efficient spending and streamlined procurement processes:

- **Strategy Objectives:**
  - Identify commonly used research materials across institutions.
  - Establish a centralized procurement system for these materials.
  - Standardize suppliers to achieve economies of scale.
  - Implement bulk purchasing to reduce costs.
  - Ensure quality control and consistency of materials across institutions.
- **System Design:**
  - Simplify the ordering process for researchers.
  - Reduce administrative burden on individual institutions.
  - Leverage collective buying power to negotiate better prices.
  - Ensure timely delivery of materials to researchers.

- **Benefits:**
  - Improved resource allocation and reduced waste.
  - Enhanced tracking of research materials throughout their lifecycle.
  - Better forecasting of material needs across the Kingdom's research ecosystem.
  - Potential for cost savings through bulk purchasing and inventory optimization.

Repurposing Industrial and Service Materials Policy

To address the need for efficient utilization of materials across industries and research:

- This policy should aim to:
  - Identify materials from industrial and service sectors that have potential research applications.
  - Establish protocols for the safe transfer and repurposing of these materials.
  - Create a database of available materials that researchers can access.
  - Ensure compliance with safety and environmental regulations when repurposing materials.
- Researchers interested in utilizing repurposed materials should indicate this in their research proposals and material requests.

Advanced Procurement Process Management

To enhance the efficiency, safety, and compliance of the procurement process for RDI materials, the following advanced management strategies should be implemented:

- **Integrated Classification Systems:**
  - Incorporate international classification systems (e.g., GHS, NFPA 704) into the MRP database to ensure proper storage and handling of materials.
  - Use this integration to automatically flag materials requiring special handling or storage conditions.
- **Expiration and Storage Tracking:**
  - Implement features to track expiration dates and special storage conditions for sensitive materials.
  - Utilize predictive analytics to forecast degradation rates of unstable compounds and implement a first-expired, first-out (FEFO) system for critical materials.
- **Laboratory Information Management System (LIMS) Integration:**
  - Integrate MRP with LIMS to maintain accurate inventory records and streamline experiment planning.
  - Use this integration to automatically update stock levels as materials are consumed in experiments.
- **Safety and Compliance Monitoring:**
  - Implement a feature to track cumulative exposure levels for researchers, with automated alerts for approaching regulatory limits.
  - Maintain an up-to-date database of Safety Data Sheets (SDS) linked directly to inventory items, with automatic notifications for SDS updates.
- **Waste Management Integration:**
  - Link MRP with waste management systems to forecast waste generation and automate disposal manifest creation.
  - Use this integration to ensure compliance with waste disposal regulations and optimize waste management processes.
- **Emergency Preparedness:**
  - Include emergency procedures directly in the MRP system for quick access during incidents.
  - Integrate real-time inventory data of neutralizing agents and spill control materials for immediate response to emergencies.
- **High-Risk Material Tracking:**
  - Implement RFID or barcode systems for real-time tracking of high-risk materials.
  - Set up periodic reconciliation processes for controlled substances to ensure accurate inventory and prevent misuse.
- **Compatibility Management:**
  - Integrate compatibility databases to alert users of potential reactions during material requisition or storage assignment.
  - Use this feature to prevent accidental mixing of incompatible materials and enhance overall laboratory safety.

Sample Size Determination

Sample size determination can vary depending on the stage of research and the type of data being collected. For instance:

- **During the proof of concept (PoC) stage,** a smaller sample size is often sufficient to demonstrate potential efficacy or highlight major flaws in the proposed concept.
- **In the validation stage** following a successful PoC, a larger sample size is required to confirm findings and refine effect size estimates with greater precision
- **Statistical Principles:** The key statistical principles involved in sample size calculation include:
  - **Confidence Level:** Typically set at 95% or 99%, this represents the probability that the true population parameter falls within the confidence interval.
  - **Margin of Error:** The acceptable range of error in the results, often expressed as a percentage.
  - **Effect Size:** The magnitude of the difference or relationship being studied.
  - **Power:** The probability of detecting a true effect, typically set at 80% or 90%.
  - **Population Variance:** The variability in the population being studied.
- **When determining sample size, researchers should also consider:**
  - **The nature of the data:** Whether the study involves attribute (categorical) or continuous variables can affect the sample size calculation approach.
  - **The specific research question and study design:** Different study types (e.g., superiority trials, non-inferiority trials, equivalence trials) may require different sample size considerations

The sample size calculation can be expressed using the following general formula:

$$n = \frac{Z^2 \sigma^2}{E^2}$$

(Ref: National Institutes of Health, 2021)

Where:

- n = Sample size
- Z = Z-score (e.g., 1.96 for 95% confidence level)
- σ = Population standard deviation
- E = Margin of error

Note: Calculators based on Chapters 5 and 6 of Designing Clinical Research (4th Edition) and available on the UCSF CTSI Sample Size website.

For **comparing two groups,** the formula expands to:

$$n = \frac{2(Z\alpha/2 + Z\beta)^2\sigma^2}{d^2}$$

(Ref: National Institutes of Health, 2021)

Where:

- Zα/2 = Z-score for desired significance level
- Zβ = Z-score for desired power
- d = Minimum expected difference between the two groups

Note: Calculators based on Chapters 5 and 6 of Designing Clinical Research (4th Edition) and available on the UCSF CTSI Sample Size website.

These formulas are based on the central limit theorem and assume a normal distribution.

Practical Examples and Tools

Researchers can use various tools to calculate sample size:

- G*Power: A free software that performs sample size calculations for various study designs.
- NIH Sample Size Calculator: An online tool provided by the National Institutes of Health for quick sample size estimations.
- R packages: Such as 'pwr' for power analysis and sample size calculation.

Example: For a study with a 95% confidence level, 5% margin of error, and population standard deviation of 0.5, the sample size would be:

$$n = \frac{(1.96^2 x 0.5^{2)}}{0.05^2} \approx 384$$

This calculation provides a starting point, which should be adjusted based on practical considerations such as resource availability and expected response rates.

Material Requirements Planning (MRP)

- **Process Overview:** MRP is a system for calculating the materials and components needed to manufacture a product. In the context of RDI, it helps manage the procurement and inventory of research materials. The MRP process typically involves:
- **Identifying Material Requirements:** Based on research plans and project timelines.
- **Checking Current Inventory Levels:** To determine what materials are already available.
- **Determining Additional Materials Needed:** To meet the project's requirements.
- **Scheduling Orders:** To ensure timely availability of materials.
- **Implementation Guidelines:** To implement an effective MRP system for RDI:
  - Integrate with Project Management Systems: Align material needs with research timelines.
  - Use Forecasting Techniques: Predict material requirements for upcoming projects.
  - Implement a Robust Inventory Management System: With real-time tracking.
  - Establish Safety Stock Levels: For critical materials to prevent stockouts.
  - Regularly Review and Update Lead Times: For material procurement.
  - Consider Just-In-Time (JIT) Approach: For perishable or expensive materials.
  - Use Specialized Software Solutions: Such as Laboratory Information Management Systems (LIMS) for managing research materials.

Integration of MRP and Sample Size Determination

- Researchers should include detailed sample size calculations in their research grant proposals to aid in planning material quantities.
- The calculated sample size should be used as input for Material Requirements Planning (MRP) systems to determine the exact quantities of materials needed for the study.
- This integration helps optimize resource utilization and minimizes waste by ensuring that sufficient materials are available without overstocking

Here's how this integration works:

- **Use Sample Size Calculations as Input for MRP:** Once researchers determine their required sample size, this information can be fed into the MRP system to calculate the exact quantities of materials needed for the study.
- **Forecasting Material Needs:** MRP systems can use historical data on sample sizes and material consumption to forecast future needs for similar studies.
- **Inventory Management:** MRP can help manage inventory levels based on planned sample sizes for upcoming studies, ensuring that sufficient materials are available without overstocking.

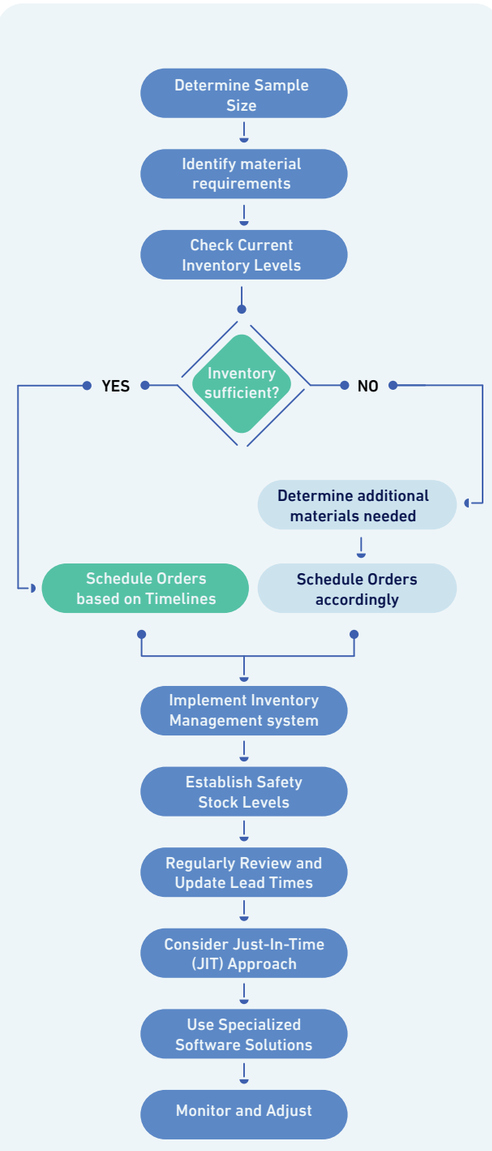

Figure 2: flowchart to illustrate the integration of Material Requirements Planning (MRP) with Sample Size Determination in the context of research material management

Practical Example

Let's consider a pharmaceutical research project studying the efficacy of a new drug:

- **Sample Size Determination:** Using G*Power software, researchers calculate that they need 128 participants for their study to achieve 80% power with a medium effect size (0.5) at a 0.05 significance level.
- **Material Requirements: Each participant requires:**
  - 30 doses of the drug (1 dose per day for 30 days)
  - 5 blood collection tubes
  - 1 urine collection kit
- **MRP Integration:** The MRP system calculates the total materials needed:
  - Drug doses: 128 × 30 = 3,840 doses
  - Blood collection tubes: 128 × 5 = 640 tubes
  - Urine collection kits: 128 × 1 = 128 kits
- **Inventory Check:** The MRP system checks current inventory:
  - 2,000 drug doses in stock
  - 300 blood collection tubes in stock
  - 50 urine collection kits in stock
- **Order Scheduling:** The MRP system schedules orders for:
  - 1,840 additional drug doses
  - 340 additional blood collection tubes
  - 78 additional urine collection kits
- **Safety Stock:** The system maintains a safety stock of 10% for each item to prevent stockouts.

Research-specific MRP Challenges

Implementing MRP in research environments comes with unique challenges, such as dealing with highly variable demand, managing materials with short shelf lives, and handling specialized equipment needs. Addressing these challenges requires:

- **Adaptable Forecasting Models:** Use flexible forecasting models that can adjust to the dynamic nature of research projects.
- **Shelf-Life Management:** Implement strict protocols for managing materials with short shelf lives to prevent waste (World Health Organization, 2020).
- **Specialized Equipment Needs:** Ensure that MRP systems can handle the procurement and maintenance schedules for specialized research equipment (ISO 55000:2014).

Integration with Regulatory Compliance

Given the strict regulatory environment for research materials, especially in fields like pharmaceuticals or biotechnology, integrating MRP with regulatory compliance processes is essential. This includes:

- **Compliance Tracking:** Use MRP systems to track compliance with local and international regulations (FDA, 2022).
- **Documentation Management:** Maintain detailed records of all regulatory documents and approvals within the MRP system (ISO 9001:2015).
- **Audit Preparedness:** Ensure that MRP systems can generate reports and documentation required for regulatory audits (OECD, 1998).

Risk Management in MRP

Research often involves high-value or hazardous materials. MRP can be used to manage risks associated with these materials by:

- **Stockout Prevention:** Establish safety stock levels to prevent stockouts of critical materials (ISO 9001:2015).
- **Overstock Management:** Use predictive analytics to avoid overstocking and reduce waste (Syntetos et al., 2016).
- **Degradation Monitoring:** Implement systems to monitor the degradation of materials and ensure they are used before they become obsolete (WHO, 2020).

Sustainability Considerations

As sustainability becomes increasingly important in research, MRP can be used to minimize waste and improve resource efficiency by:

- **Waste Reduction:** Implement strategies to reduce waste through better inventory management and material usage planning (ISO 14001:2015).
- **Resource Efficiency:** Use MRP to optimize the use of resources and reduce the environmental impact of research activities (United Nations, 2015).
- **Sustainable Procurement:** Source materials from suppliers that adhere to sustainable practices (ISO 20400:2017).

MRP in Multi-site Research

Many research projects involve collaboration across multiple sites. Implementing MRP in these complex, multi-site scenarios can be achieved by:

1. Use a centralized MRP system that can coordinate material needs across multiple sites (Umble et al., 2003).
2. Ensure seamless data integration between different sites to maintain accurate inventory records (ISO/IEC 17025:2017).
3. Implement collaboration tools within the MRP system to facilitate communication and coordination between sites (Project Management Institute, 2017).

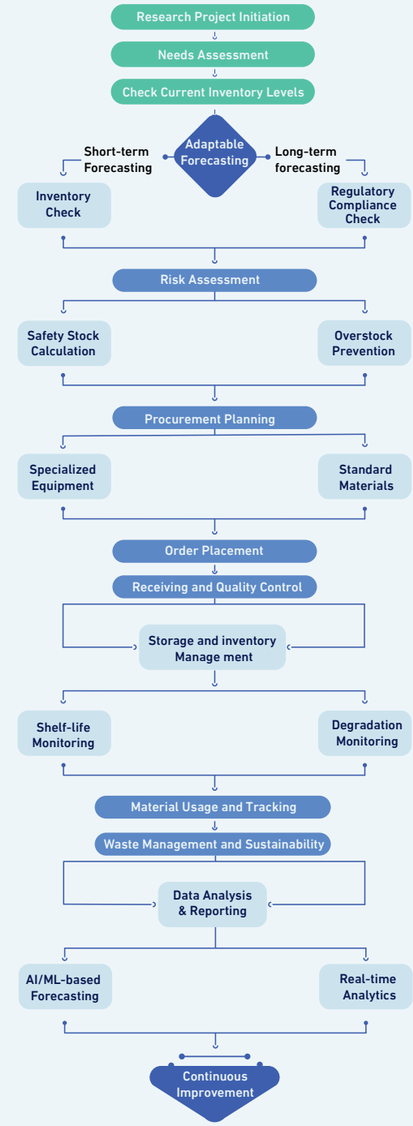

Figure 3: Material Requirements Planning (MRP) Process

06 Safety and Handling Protocols

Safety protocols in this section are based on both Saudi Arabian regulations and supplementary international standards. Researchers must prioritize compliance with local regulations while using international guidelines as additional resources.

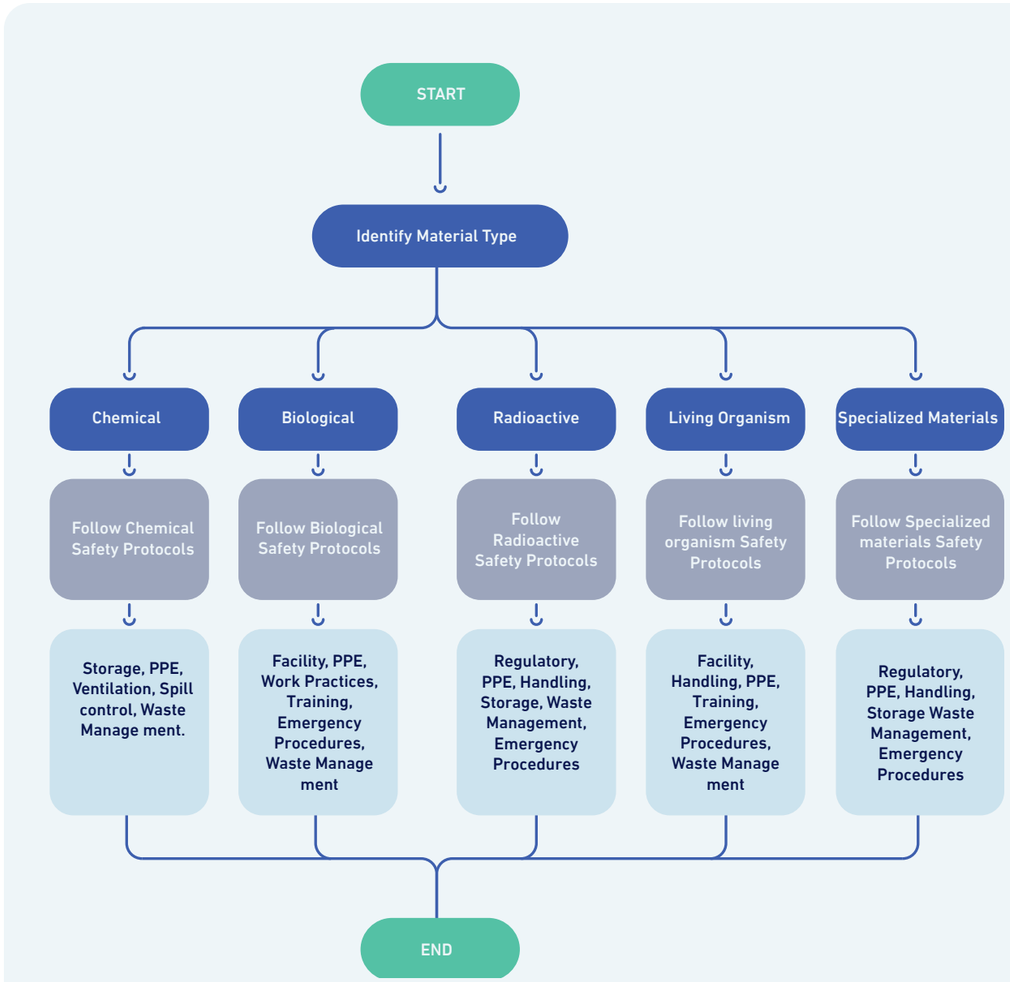

Figure 4: Figure 1: Safety Protocol Decision Tree for Determining Appropriate Safety Measures Based on Material Type

Chemical Materials

Effective management of laboratory chemicals and reagents, such as acids, bases, solvents, buffers, and enzymes, is critical for maintaining safety and compliance with regulatory standards. Adhere to Material Safety Data Sheets (MSDS) for each chemical, which provide essential information on handling, storage, and emergency measures. Implement a Chemical Hygiene Plan (CHP) as outlined by OSHA's Laboratory Standard (29 CFR 1910.1450) to enhance laboratory safety. This includes protocols for proper labeling, safe storage, and disposal of chemicals to minimize exposure risks and prevent accidents.

- **Storage:**
  - Use approved safety cabinets with a minimum 1-hour fire rating for flammable and combustible liquids (NFPA 30, 2021)
  - Maintain separate storage areas for acids and bases, with acid-resistant shelving for acid storage (OSHA 1910.106, 2022)
  - Store oxidizers in a dedicated, fire-resistant cabinet at least 7.6 meters (25 feet) away from flammable and combustible materials (NFPA 400, 2019).
  - Ensure refrigerators used for chemical storage are explosion-proof or laboratory-safe models (NFPA 45, 2019).
- **Ventilation:**
  - Maintain a minimum of 6 air changes per hour in laboratories handling hazardous chemicals (ANSI/AIHA Z9.5, 2012).
  - Ensure fume hoods provide a face velocity of 80120- feet per minute (ASHRAE Standard 110, 2016).
  - Install local exhaust ventilation systems for processes generating toxic vapors or dusts (ACGIH, 2022).
- **Personal Protective Equipment (PPE):**
  - Use gloves with the appropriate chemical resistance rating for the hazardous materials being handled [OSHA 1910.138, 2022].
  - Wear safety goggles meeting ANSI Z87.1 standards when handling corrosive or reactive chemicals [ANSI/ISEA Z87.1, 2020].
  - Use respiratory protection with the correct cartridge type for specific chemical hazards when engineering controls are insufficient [OSHA 1910.134, 2022
- **Spill Control:**
  - Maintain spill kits appropriate for the types and quantities of hazardous materials present [EPA 40 CFR 264.52, 2022].
  - For laboratories with large quantities of acids or bases, install safety showers and eyewash stations that meet ANSI Z358.1 standards [ANSI/ISEA Z358.1, 2014].
- **Waste Management:**
  - Use UN-approved containers for hazardous waste storage, selecting container material compatible with the waste [DOT 49 CFR 173, 2022].
  - Do not fill liquid waste containers beyond 80% capacity to allow for vapor expansion [EPA 40 CFR 265.173, 2022].
  - Label all hazardous waste containers with the full chemical name(s), associated hazards, and accumulation start date [OSHA 1910.1200, 2022].
  - Follow specific disposal procedures for different types of chemicals, such as acids, bases, solvents, and reactive materials, in accordance with local and international regulations.

Biological Materials (including BSL3 and BSL4)

Handling biological materials, including cells, tissues, proteins, and DNA, requires special attention to safety and contamination prevention. Adherence to the Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines ensures a safe framework for managing these sensitive materials. When working with pathogenic strains, use higher biosafety levels (BSLs) and specific containment equipment to avoid cross-contamination and exposure. Techniques like aseptic handling in laminar flow cabinets and the use of personal protective equipment (PPE) are essential practices to maintain the integrity of biological samples and protect laboratory personnel.

- **Facility Requirements**
  - BSL3: Use a dedicated negative pressure laboratory with controlled access and a hands-free sink near the exit [Centers for Disease Control and Prevention (CDC), 2009].
  - BSL4: Employ either a Cabinet Laboratory or a Suit Laboratory with complete sealing of the facility, dedicated air supply, and decontamination protocols for all materials leaving the area [World Health Organization (WHO), 2004].
- **Personal Protective Equipment (PPE)**
  - BSL3: Wear double gloves, solid-front wraparound gowns, scrub suits, or coveralls, and respiratory protection such as a fitted N95 respirator [CDC, 2009].
  - BSL4: Use a positive pressure suit with a dedicated air supply or a Class III Biological Safety Cabinet [WHO, 2004].
- **Work Practices**
  - Conduct all procedures involving infectious materials within a certified Biological Safety Cabinet (BSC) or other approved containment devices [CDC, 2009].
  - Decontaminate all waste before removal from the facility using validated methods (e.g., autoclaving) [WHO, 2004].
  - Implement a comprehensive occupational health program including medical surveillance and available immunizations for specific agents handled [CDC, 2009].
- **Training and Documentation**
  - Provide extensive, specialized training for all personnel working with BSL3 and BSL4 agents [CDC, 2009].
  - Maintain detailed records of all experiments, personnel access, and potential exposures [WHO, 2004].
- **Emergency Procedures**
  - Develop and regularly practice specific emergency response plans for potential incidents or exposures [CDC, 2009].
  - Install eyewash stations and decontamination showers within the containment area [ANSI/ISEA Z358.1, 2014].
- **Waste Management**
  - Autoclave biohazardous waste before disposal to ensure decontamination [WHO, 2004].
  - Use biohazard bags and containers for the collection and storage of biological waste [CDC, 2009].
  - Dispose of biological waste through licensed biomedical waste disposal services [EPA, 2022].
  - Maintain records of all biological waste disposal activities

Radioactive Materials

- **Regulatory Compliance:**
  - Adhere to regulations set by the Nuclear and Radiological Regulatory Commission of Saudi Arabia [Nuclear and Radiological Regulatory Commission, 2023].
  - Implement a radiation safety program that includes ALARA (As Low As Reasonably Achievable) principles [International Atomic Energy Agency (IAEA), 2018].
- **Facility Design:**
  - Use shielding materials appropriate for the type and energy of radiation (e.g., lead for gamma, concrete for neutrons) [National Council on Radiation Protection and Measurements (NCRP), 2005].
  - Install radiation monitoring equipment at key locations within the facility [International Commission on Radiological Protection (ICRP), 2007].
- **Personal Protective Equipment:**
  - Use appropriate PPE based on the type of radiation, including lead aprons, thyroid shields, and radiation-attenuating gloves when necessary [World Health Organization (WHO), 2016].
  - Wear personal dosimeters (e.g., film badges, thermoluminescent dosimeters) to monitor radiation exposure [United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), 2008].
- **Handling and Storage:**
  - Store radioactive materials in locked, shielded containers within secure, designated areas [U.S. Nuclear Regulatory Commission (NRC), 2020].
  - Use remote handling tools (e.g., tongs, forceps) to minimize direct contact with radioactive sources [Health Physics Society, 2019].
- **Waste Management:**
  - Segregate radioactive waste by half-life and type of radiation [International Atomic Energy Agency (IAEA), 2009].
  - Store short-lived isotopes for decay before disposal as regular waste [U.S. Environmental Protection Agency (EPA), 2021].
  - Use licensed radioactive waste disposal services for long-lived isotopes [World Nuclear Association, 2022].

Hazardous Materials Management

When handling hazardous materials in research settings, adhere to the following technical specifications:

- **Storage Requirements:**
  - Use approved safety cabinets with a minimum 1-hour fire rating for flammable and combustible liquids (NFPA 30: Flammable and Combustible Liquids Code)
  - Maintain separate storage areas for acids and bases, with acid-resistant shelving for acid storage (OSHA 1910.106: Flammable Liquids)
  - Store oxidizers in a dedicated, fire-resistant cabinet at least 25 feet away from flammable and combustible materials (NFPA 400: Hazardous Materials Code)
  - Ensure refrigerators used for chemical storage are explosion-proof or laboratory-safe models (NFPA 45: Standard on Fire Protection for Laboratories Using Chemicals)
- **Ventilation Specifications:**
  - Maintain a minimum of 6 air changes per hour in laboratories handling hazardous materials (ANSI/AIHA Z9.5: Laboratory Ventilation

- Ensure fume hoods provide a face velocity of 80120- feet per minute (ASHRAE Standard 110: Method of Testing Performance of Laboratory Fume Hoods)

- Install local exhaust ventilation systems for processes generating toxic vapors or dusts (ACGIH: Industrial Ventilation: A Manual of Recommended Practice)

- **Personal Protective Equipment (PPE):**

  - Use gloves with the appropriate chemical resistance rating for the hazardous materials being handled (OSHA 1910.138: Hand Protection)

  - Wear safety goggles meeting ANSI Z87.1 standards when handling corrosive or reactive chemicals (ANSI/ISEA Z87.1: Occupational and Educational Personal Eye and Face Protection Devices)

  - Use respiratory protection with the correct cartridge type for specific chemical hazards when engineering controls are insufficient (OSHA 1910.134: Respiratory Protection)

- **Spill Control:**

  - Maintain spill kits appropriate for the types and quantities of hazardous materials present (EPA 40 CFR 264.52: Contingency Plan and Emergency Procedures)

  - For laboratories with large quantities of acids or bases, install safety showers and eyewash stations that meet ANSI Z358.1 standards (ANSI/ISEA Z358.1: Emergency Eyewash and Shower Equipment)

Living Organisms (including animals, bacteria, cells, and tissues)

- **Facility Requirements:**
  - Maintain species-appropriate housing for research animals that allows for natural behaviors and minimizes stress [Guide for the Care and Use of Laboratory Animals, National Research Council, 2011].
  - Use appropriate biosafety level laboratories for work with microorganisms, based on risk assessment [WHO Laboratory Biosafety Manual, 2020].
- **Handling and Care:**
  - Implement protocols for humane handling and care of research animals, including appropriate nutrition, veterinary care, and environmental enrichment [AAALAC International, 2021].
  - Use aseptic techniques when handling cell cultures and microorganisms to prevent contamination [American Society for Microbiology, 2019].
- **Personal Protective Equipment (PPE):**
  - Use appropriate PPE based on the type of organism and level of containment required, such as gloves, lab coats, and respiratory protection when necessary [CDC Biosafety in Microbiological and Biomedical Laboratories, 2020].
  - Wear additional protective equipment when handling animals, such as bite-resistant gloves for certain species [OSHA, 2022].
- **Training and Documentation:**
  - Provide comprehensive training on animal handling, ethics, and welfare for all personnel involved in animal research [Federation of European Laboratory Animal Science Associations, 2020].
  - Maintain detailed records of all experiments, animal care procedures, and any adverse events [AAALAC International, 2021].
- **Emergency Procedures:**
  - Develop and regularly practice emergency response plans for potential incidents such as animal escapes or exposure to infectious agents [IACUC, 2022].
  - Install appropriate containment and alarm systems to prevent and detect escapes of research organisms [WHO Laboratory Biosafety Manual, 2020].
- **Waste Management:**
  - Follow specific protocols for the disposal of animal carcasses and tissues, including incineration or other approved methods [EPA, 2022].
  - Decontaminate all waste from work with microorganisms before disposal, typically through autoclaving [CDC, 2020].
- **Ethical Considerations:**
  - Adhere to the 3Rs principle (Replacement, Reduction, Refinement) in animal research to minimize animal use and suffering [NC3Rs, 2022].
  - Obtain appropriate ethical approvals and informed consent for research involving human-derived cells or tissues [WHO, 2020].
- **Import Request Process:**
  - Submit a detailed request to the Research Development and Innovation Unit (RDIU) of your institution.
  - Include specific information:
    - For animals: species, number, purpose of research, expected duration of use
    - For microorganisms: type, strain, quantity, biosafety level
    - For cells/tissues: type, origin, quantity, storage requirements
  - Provide documentation of approval from the Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), or equivalent ethics board.
  - Obtain necessary permits from relevant authorities such as the Ministry of Environment, Water, and Agriculture, and the Saudi Food & Drug Authority (SFDA).
- **Regulatory Compliance:**
  - Ensure compliance with international standards:
    - World Health Organization (WHO) guidelines [WHO, 2020]
    - Centers for Disease Control and Prevention (CDC) protocols [CDC, 2020]
    - OIE Terrestrial Animal Health Code for international transport [OIE, 2021]
    - Adhere to local regulations:
    - Saudi National Committee of Bio and Medical Ethics guidelines
    - Ministry of Environment, Water, and Agriculture regulations
    - SFDA requirements for medical and pharmaceutical research materials
- **Documentation Requirements:**
  - Detailed description of the living organisms or biological materials to be imported
  - Comprehensive justification for their use in research

- Risk assessment and management plan
- Ethical approval documentation
- Material Transfer Agreements (MTAs) if applicable

- **Transportation and Storage:**
  - Follow international guidelines for the safe transport of biological materials [IATA, 2023]
  - Ensure appropriate temperature control and containment during transportation
  - Implement a robust inventory management system for stored materials
  - Regularly audit storage facilities for compliance with safety and quality standards
- **End-of-Life Considerations:**
  - Develop clear protocols for euthanasia of research animals that align with international standards [AVMA, 2020]
  - Establish procedures for the safe and ethical disposal of biological materials at the end of research
  - Consider options for rehoming animals or repurposing biological materials when appropriate and possible
- **Reporting and Compliance Monitoring:**
  - Submit regular reports to the RDIU and relevant authorities on the status of imported organisms and materials
  - Conduct periodic internal audits to ensure ongoing compliance with all regulations and guidelines
  - Cooperate fully with any external inspections or audits by regulatory bodies
- **Specific Considerations for Medical and Health Applications:**
  - **For animals used in medical testing:** Implement stringent quality control measures to ensure reliability of test results
  - Develop protocols for long-term monitoring of animals used in chronic disease studies
  - **For live and preserved tissues:**
  - Establish strict protocols for collection, preservation, and storage to maintain sample integrity
  - Implement a robust tracking system to ensure traceability of all tissue samples
  - **For laboratory specimens:**
  - Develop standardized procedures for collection, processing, and analysis
  - Implement quality assurance measures to ensure accuracy and reproducibility of results
  - **For biological materials and living cells:**
  - Establish protocols for maintaining cell line authenticity and preventing cross-contamination
  - Implement measures to ensure the stability and viability of biological materials during long-term storage

Specialized Materials (including explosive materials, radioactive substances, and specialized batteries)

- **Regulatory Compliance and Permissions:**
  - Obtain necessary permits from relevant authorities:
    - ◊ High Commission For Industrial Security for explosive material or explosives and chemical precursors material.
    - ◊ Nuclear and Radiological Regulatory Commission for radioactive substances.
    - ◊ Ministry of Energy for specialized batteries and energy storage devices.
  - Comply with international regulations such as the International Air Transport Association (IATA) Dangerous Goods Regulations
  - Adhere to the Chemical Weapons Convention (CWC) guidelines for applicable materials
- **Import Request Process:**
  - Submit a detailed request to the Research Development and Innovation Unit (RDIU) of your institution, including:
    - ◊ Precise chemical composition and physical properties of the material.
    - ◊ Quantity required and justification for the amount.
    - ◊ Intended use in research, including experimental protocols.
    - ◊ Safety measures and containment procedures.
    - ◊ Disposal plans.
  - Provide documentation of approval from the Institutional Safety Committee or equivalent
  - Include a comprehensive risk assessment and management plan
- **Transportation and Handling:**
  - Use specialized transportation services certified for handling dangerous goods
  - Ensure proper packaging and labeling according to UN recommendations on the Transport of Dangerous Goods
  - Implement a chain of custody documentation for the entire transportation process.
  - Utilize GPS tracking for high-risk materials during transit
- **Storage and Security:**
  - Maintain dedicated, secure storage facilities with:
    - ◊ Restricted access control systems.
    - ◊ 247/ surveillance
    - ◊ Environmental controls (temperature, humidity, etc.)
    - ◊ Appropriate shielding for radioactive materials
  - Implement inventory management systems with real-time tracking
  - Conduct regular audits and reconciliations of material stocks
- **Handling and Usage Protocols:**
  - Develop and strictly adhere to Standard Operating Procedures (SOPs) for each material
  - Use appropriate Personal Protective Equipment (PPE) as specified for each material
  - Conduct all procedures involving these materials in designated containment areas.
  - Implement a buddy system for high-risk procedures
  - Maintain detailed logs of material usage, including amounts and purposes
- **Waste Management and Disposal:**
  - Develop specific disposal protocols for each type of material in compliance with environmental regulations
  - Use certified waste disposal services for hazardous materials

- Maintain detailed records of all disposal activities
- Implement decontamination procedures for all equipment and areas exposed to these materials

- **Emergency Response and Contingency Planning:**
  - Develop and regularly update emergency response plans for potential incidents
  - Install specialized safety equipment (e.g., chemical showers, radiation detectors)
  - Conduct regular emergency drills and simulations
  - Establish direct communication channels with local emergency services
- **Training and Certification:**
  - Provide comprehensive, material-specific training for all personnel involved
  - Ensure all researchers handling these materials have up-to-date certifications
  - Conduct regular refresher courses and assessments
  - Maintain detailed training records for all personnel
- **Reporting and Documentation:**
  - Submit regular reports to the RDIU and relevant authorities on the status and use of these materials
  - Maintain a centralized database of all research activities involving these materials
  - Document any incidents or near-misses, however minor, and conduct thorough investigations
- **Collaboration and Information Sharing:**
  - Establish protocols for secure information sharing with collaborating institutions
  - Implement strict confidentiality agreements for all personnel involved.
  - Participate in national and international networks for best practices in handling specialized research materials
- **Ethical Considerations:**
  - Ensure all research involving these materials undergoes rigorous ethical review
  - Consider dual-use potential and implement safeguards against misuse
  - Regularly review and update ethical guidelines in line with international standards

Equipment and Instruments

- **Maintenance and Calibration:**
  - Develop and adhere to a regular maintenance schedule for all laboratory equipment [ISO 17025:2017].
  - Calibrate instruments according to manufacturer specifications and relevant ISO standards [National Institute of Standards and Technology (NIST), 2019].
  - Maintain detailed logs of all maintenance and calibration activities [Clinical and Laboratory Standards Institute (CLSI), 2020].
- **Training:**
  - Provide comprehensive training to all users on the proper operation of equipment and instruments [Occupational Safety and Health Administration (OSHA), 2022].
  - Ensure that only trained and authorized personnel operate specialized equipment [American Chemical Society (ACS), 2021].
- **Safety Features:**
  - Regularly inspect and test safety features such as emergency shut-offs, interlocks, and alarms [National Fire Protection Association (NFPA), 2019].
  - Ensure all equipment is properly grounded and protected against electrical hazards [Institute of Electrical and Electronics Engineers (IEEE), 2018].
- **Decontamination:**
  - Develop and follow protocols for decontaminating equipment used with hazardous materials [Centers for Disease Control and Prevention (CDC), 2020].
  - Use appropriate disinfectants or decontamination methods based on the type of contamination [World Health Organization (WHO), 2020].
- **Disposal:**
  - Follow manufacturer guidelines and local regulations for the disposal of obsolete or non-functional equipment [U.S. Environmental Protection Agency (EPA), 2022].
  - Ensure proper decontamination of equipment that has been exposed to hazardous materials before disposal or transfer [European Commission, 2021].

07

Storage and Inventory Management

Best Practices

- Implement a robust inventory management system to track all materials from procurement to disposal (ISO 9001:2015).
- Maintain accurate records of material usage, storage conditions, and expiration dates to ensure compliance and safety (ISO 9001:2015).
- Maintain comprehensive records of all waste disposal activities, including the type and quantity of waste, disposal methods, and dates.
- Provide documentation of disposal activities to relevant regulatory authorities as required.

Tracking Systems

- Implement a tracking system to monitor the lifecycle of waste materials from generation to final disposal.
- Use barcode or RFID systems to track the movement and usage of materials in real-time (GS1, 2021).
- Integrate inventory management systems with laboratory information management systems (LIMS) for seamless data sharing and tracking (ISO/IEC 17025:2017).

Quality Control

Conduct regular audits and inspections to ensure that storage conditions and inventory records meet regulatory standards (ISO 9001:2015).

Implement a quality control program that includes regular testing and validation of materials to ensure their integrity and suitability for research purposes (Good Laboratory Practice (GLP) guidelines).

Storage Time Calculation

It is essential to consider factors such as material stability, expiration dates, and storage conditions. Here are some guidelines:

- **Material Stability:**
  - Assess the stability of materials under various storage conditions (temperature, humidity, light exposure) [International Conference on Harmonisation (ICH) Q1A(R2), 2003].
  - Conduct stability studies to determine the shelf life of materials.
- **Expiration Dates:**
  - Follow manufacturer guidelines for expiration dates.
  - Use a first-expired, first-out (FEFO) system to manage inventory [ISO 9001:2015].
- **Storage Conditions:**
  - Ensure that storage conditions meet the specific requirements for each material (e.g., temperature-controlled environments for perishable items) [ISO 9001:2015].
  - Regularly monitor and document storage conditions to ensure compliance [ISO/IEC 17025:2017].
  - Based on the factors mentioned, , use the below approach to estimating storage time:

Storage Time (T) = Base Shelf Life (BSL) * Stability Factor (SF) * Environmental Factor (EF)

Where:

1. Base Shelf Life (BSL): The manufacturer's recommended shelf life under ideal conditions.
2. Stability Factor (SF): A value between 0 and 1 that represents the material's inherent stability.
   - SF = 1 for highly stable materials
   - SF < 1 for less stable materials
3. Environmental Factor (EF): A value between 0 and 1 that accounts for storage conditions.
   - EF = 1 for ideal storage conditions
   - EF < 1 for suboptimal conditions

The equation can be expressed as:

T = BSL * SF * EF

For example:

- If a material has a base shelf life of 24 months (BSL = 24)
- It's moderately stable (SF = 0.8)
- Stored in good but not ideal conditions (EF = 0.9)

The estimated storage time would be:

T = 24 * 0.8 * 0.9 = 17.28 months

Note: This equation is a simplification and should be used as a general guide. Actual storage time calculations should consider:

1. Specific material properties
2. Detailed stability data from studies [ICH Q1A(R2), 2003]
3. Precise environmental conditions (temperature, humidity, light exposure)
4. Any applicable regulatory requirements

08 Research Equipment and Associated Materials

To ensure the effective selection, procurement, and management of research equipment and associated materials, the following guidelines should be adhered to:

Guidelines for Selecting and Procuring

- **Criteria for Selection:** Evaluate equipment based on research needs, compatibility, and future scalability.
- **Vendor Assessment:** Consider vendor reliability, service support, and warranty terms.
- **Budget Considerations:** Align equipment procurement with budget constraints and funding availability.

Procedures for Acquiring Materials Necessary for Equipment Operation

- **Material Identification:** Identify all consumables and accessories required for equipment operation.
- **Procurement Process:** Follow standardized procurement procedures for necessary materials, ensuring timely availability to avoid operational delays.

Standards for Equipment Calibration and Maintenance

- **Calibration:** Calibrate equipment according to manufacturer specifications and relevant ISO standards (e.g., ISO 17025:2017).
- **Maintenance Schedule:** Develop and adhere to a regular maintenance schedule for all laboratory equipment.
- **Documentation:** Maintain detailed logs of all maintenance and calibration activities.

Protocols for Ensuring Equipment Reliability and Accuracy

- **Quality Control:**
  - Implement quality control measures to monitor the performance and accuracy of research equipment.
  - Conduct periodic performance evaluations and document the results.
- **Troubleshooting:**
  - Develop troubleshooting protocols to address common equipment issues and minimize downtime.
  - Provide training for researchers and technical staff on troubleshooting techniques.

Guidelines for Proper Storage and Handling of Equipment and Associated Materials

- **Storage Conditions:**
  - Ensure that research equipment and materials are stored in appropriate conditions to prevent damage and degradation.
  - Use climate-controlled storage facilities for sensitive equipment and materials.
- **Handling Procedures:**
  - Establish standard operating procedures (SOPs) for the safe handling of research equipment and materials.
  - Provide training for staff on proper handling techniques to prevent accidents and equipment damage.

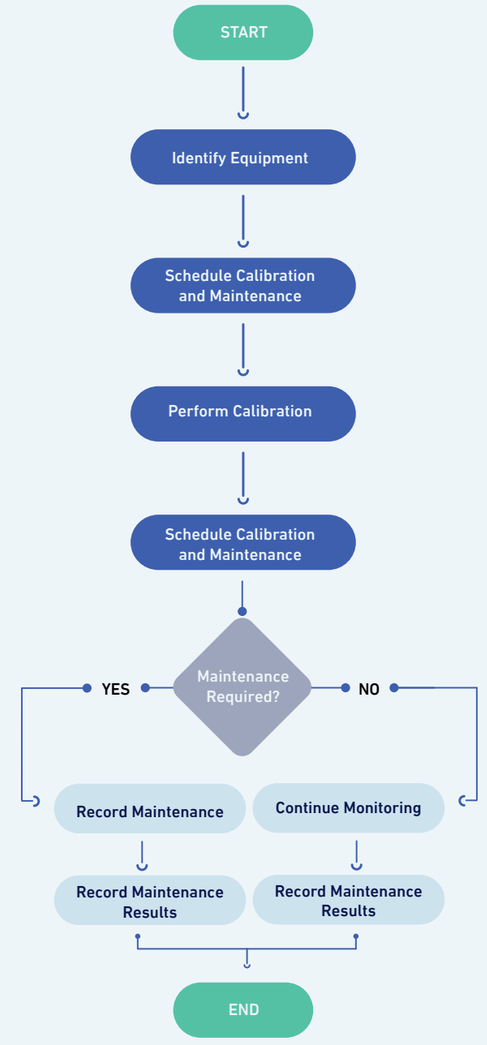

Figure 5: Equipment Calibration and Maintenance Process Flowchart

09 Emergency Response and Risk Management

Effective emergency response and risk management are critical components of laboratory safety. This section outlines key protocols for spill control, exposure management, and evacuation procedures.

Spill Control

- **Maintain appropriate spill kits:**
  - Keep spill kits readily accessible in all areas where hazardous materials are used or stored [EPA 40 CFR 264.52, 2022].
  - Ensure spill kits are appropriate for the types and quantities of hazardous materials present in the laboratory.
- **Implement spill response procedures:**
  - Develop and regularly update written spill response procedures for different types of materials (chemical, biological, radioactive) [OSHA 1910.120, 2022].
  - Train all laboratory personnel in spill response techniques and the use of spill kits [CDC, 2009].
- **Install safety equipment:**
  - For laboratories with large quantities of acids or bases, install safety showers and eyewash stations that meet ANSI Z358.1 standards [ANSI/ISEA Z358.1, 2014].
  - Ensure clear access to safety equipment at all times.
- **Fire Extinguisher Types and Placement:**
  - Install appropriate fire extinguishers (e.g., Class D for combustible metals) within 50 feet of hazardous material storage areas.
  - Ensure that all fire extinguishers are regularly inspected and maintained.
- **Eyewash Stations and Decontamination Showers:**
  - Install eyewash stations and decontamination showers within the containment area.
  - Ensure these stations are easily accessible and regularly maintained to meet safety standards.

Exposure Protocols

- **Develop exposure response plans:**
  - Create detailed protocols for responding to different types of exposures (chemical, biological, radioactive) [CDC, 2009].
  - Include procedures for immediate first aid and subsequent medical follow-up.
- **Implement decontamination procedures:**
  - Install and maintain decontamination showers within containment areas for BSL3 and BSL4 facilities [WHO, 2004].
  - Develop specific decontamination protocols for different types of exposures.
- **Medical surveillance:**
  - Implement a comprehensive occupational health program including medical surveillance and available immunizations for specific agents handled [CDC, 2009].
  - Maintain detailed records of all potential exposures and follow-up actions.

Evacuation Procedures

- **Develop evacuation plans:**
  - Create clear, written evacuation procedures for various emergency scenarios (fire, chemical spill, biological release) [OSHA 1910.38, 2022].
  - Clearly mark emergency exits and evacuation routes throughout the facility.
- **Conduct regular drills:**
  - Regularly practice emergency response plans and evacuation procedures [CDC, 2009].
  - Document all drills and use feedback to improve procedures.
- **Install emergency systems:**
  - Implement alarm systems to alert personnel of emergency situations.
  - Ensure emergency lighting is in place to guide evacuation in case of power failure.
- **Designate assembly points:**
  - Establish and clearly communicate designated assembly points outside the building for use during evacuations.
  - Ensure assembly points are at a safe distance from the facility and do not impede emergency responders.

General Emergency Preparedness

- **Emergency response team:**
  - Establish and train a dedicated emergency response team for the facility [OSHA 1910.120, 2022].
  - Ensure team members are trained in handling various types of emergencies specific to the laboratory's activities.
- **Communication protocols:**
  - Develop clear communication protocols for different types of emergencies.
  - Maintain up-to-date emergency contact lists, including internal personnel and external emergency services.
- **Equipment and supplies:**
  - Regularly inspect and maintain emergency equipment such as fire extinguishers, first aid kits, and personal protective equipment [NFPA, 2019].
  - Ensure adequate supplies are available for various emergency scenarios.
- **Documentation and review:**
  - Maintain detailed documentation of all emergency incidents and responses.
  - Regularly review and update emergency procedures based on incidents, drills, and changing laboratory conditions.

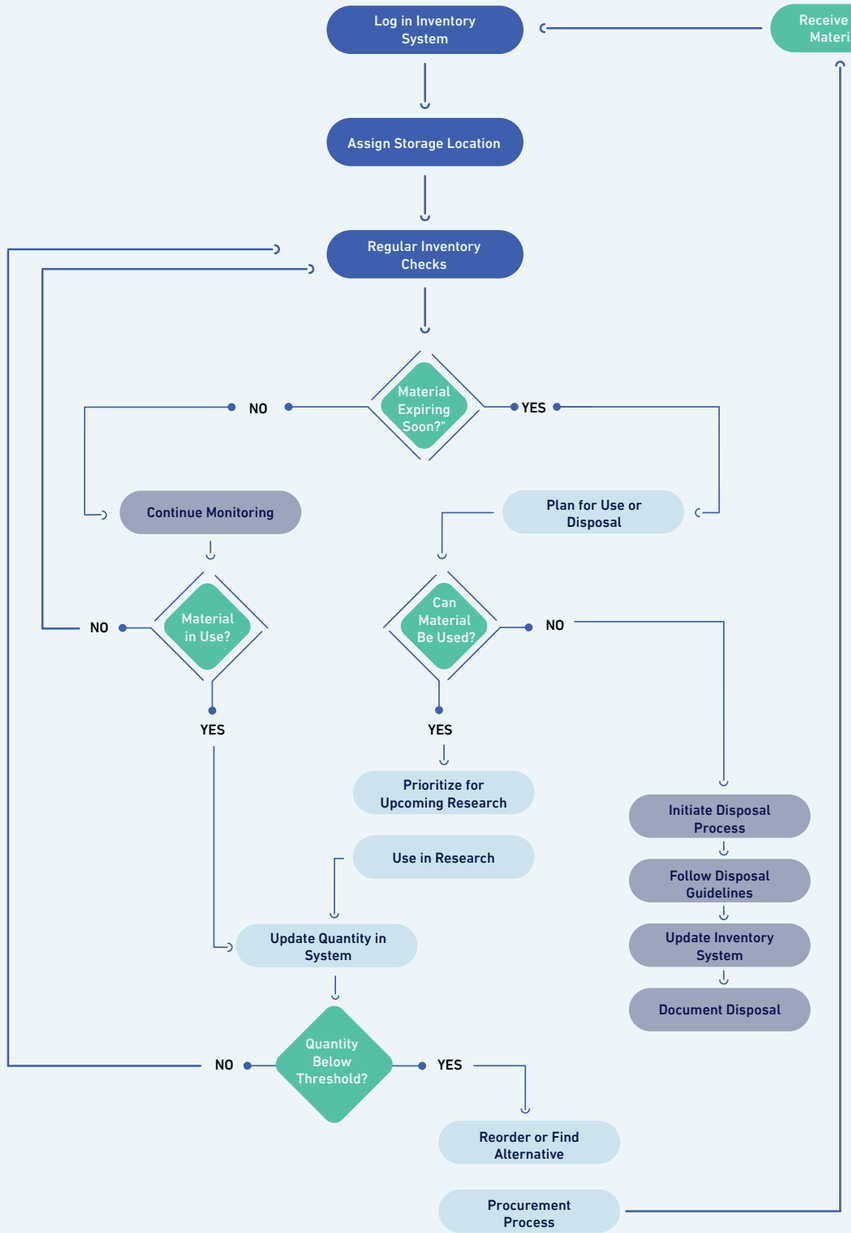

Figure 6: Emergency Response Protocols for Hazardous Materials Flowchart

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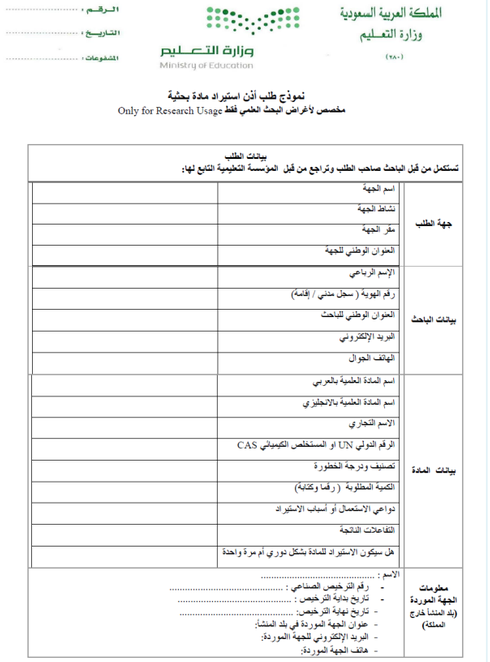
11 Attached Appendix

- Appendix A: Ministry of Education Import Application Form
- Appendix B: Chemical Research Material Import Certification Form
- Appendix C: High Commission For Industrial Security Related Material Request Forms

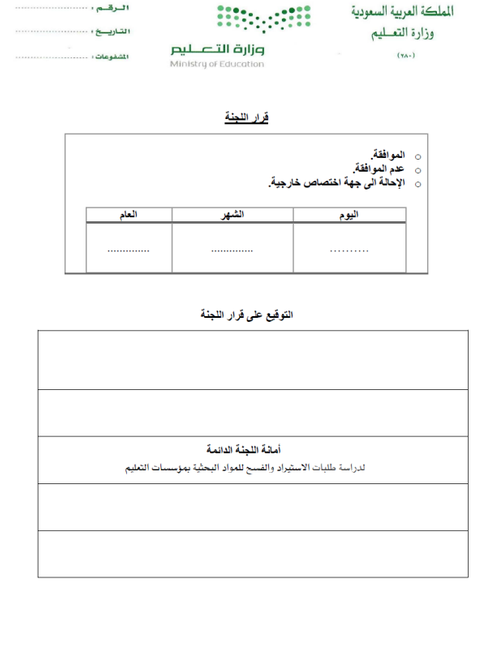
Appendix A: Ministry of Education Import Application Form



المملكة العربية السعودية
وزارة التعليم
(٢٨٠)
وزارة التعليم
Ministry of Education
الرقم :
التاريخ :
المشفوعات :

نموذج طلب أذن استيراد مادة بحثية
Only for Research Usage **مخصص لأغراض البحث العلمي فقط**

بيانات الطلب **تستكمل من قبل الباحث صاحب الطلب وتراجع من قبل المؤسسة التعليمية التابع لها:**		
جهة الطلب	اسم الجهة	
	نشاط الجهة	
	مقر الجهة	
	العنوان الوطني للجهة	
بيانات الباحث	الإسم الرباعي	
	رقم الهوية (سجل مدني / إقامة)	
	العنوان الوطني للباحث	
	البريد الإلكتروني	
	الهاتف الجوال	
بيانات المادة	اسم المادة العلمية بالعربي	
	اسم المادة العلمية بالانجليزي	
	الاسم التجاري	
	الرقم الدولي UN او المستخلص الكيميائي CAS	
	تصنيف ودرجة الخطورة	
	الكمية المطلوبة (رقما وكتابة)	
	دواعي الاستعمال أو أسباب الاستيراد	
	التفاعلات الناتجة	
	هل سيكون الاستيراد للمادة بشكل دوري أم مرة واحدة	
معلومات الجهة الموردة (بلد المنشأ خارج المملكة)	الاسم : ..... - رقم الترخيص الصناعي : ..... - تاريخ بداية الترخيص : ..... - تاريخ نهاية الترخيص: ..... - عنوان الجهة المورد في بلد المنشأ: - البريد الإلكتروني للجهة المورد: - هاتف الجهة المورد:	



المملكة العربية السعودية
وزارة التعليم
(٢٨٠)
وزارة التعليم
Ministry of Education
الرقم :
التاريخ :
المشفوعات :

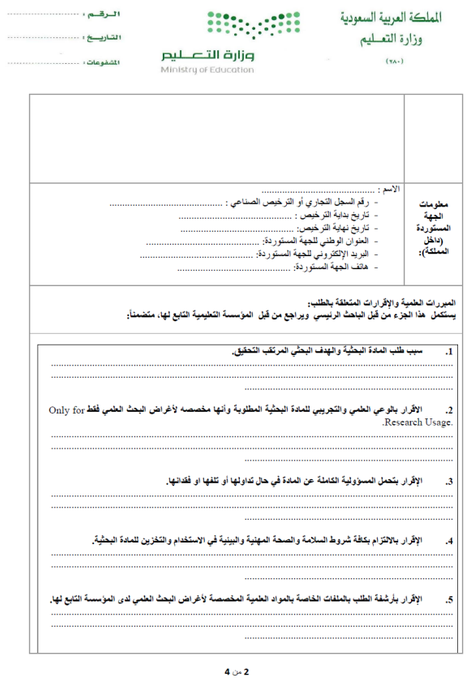
قرار اللجنة

- الموافقة.
- عدم الموافقة.
- الإحالة الى جهة اختصاص خارجية.

اليوم	الشهر	العام
.....	.....	.....

التوقيع على قرار اللجنة

أمانة اللجنة الدائمة لدراسة طلبات الاستيراد والفسح للمواد البحثية بمؤسسات التعليم

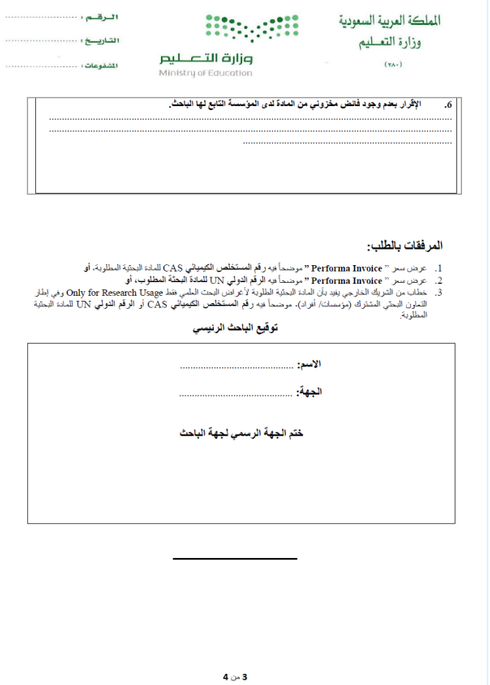


المملكة العربية السعودية
وزارة التعليم
(٢٨٠)
وزارة التعليم
Ministry of Education
الرقم :
التاريخ :
المشفوعات :

معلومات الجهة المستوردة (داخل المملكة):	الاسم : ..... - رقم السجل التجاري أو الترخيص الصناعي : ..... - تاريخ بداية الترخيص : ..... - تاريخ نهاية الترخيص: ..... - العنوان الوطني للجهة المستوردة: ..... - البريد الإلكتروني للجهة المستوردة: ..... - هاتف الجهة المستوردة: .....

المبررات العلمية والإقرارات المتعلقة بالطلب:
يستكمل هذا الجزء من قبل الباحث الرئيسي ويراجع من قبل المؤسسة التعليمية التابع لها، متضمناً:

1. **سبب طلب المادة البحثية والهدف البحثي المرتقب التحقيق.**
.....
.....
.....
2. **الإقرار بالنوعي العلمي والتجريبي للمادة البحثية المطلوبة وأنها مخصصه لأغراض البحث العلمي فقط** Only for Research Usage.
.....
.....
.....
3. **الإقرار بتحمل المسؤولية الكاملة عن المادة في حال تداولها أو تلفها او فقدانها.**
.....
.....
.....
4. **الإقرار بالالتزام بكافة شروط السلامة والصحة المهنية والبيئية في الاستخدام والتخزين للمادة البحثية.**
.....
.....
.....
5. **الإقرار بإرشفة الطلب بالملفات الخاصة بالمواد العلمية المخصصة لأغراض البحث العلمي لدى المؤسسة التابع لها.**
.....
.....
.....



المملكة العربية السعودية
وزارة التعليم
(٢٨٠)
وزارة التعليم
Ministry of Education
الرقم :
التاريخ :
المشفوعات :

6. **الإقرار بعدم وجود فائض مخزوني من المادة لدى المؤسسة التابع لها الباحث.**
.....
.....
.....

المرفقات بالطلب:

1. عرض سعر " **Performa Invoice** " موضحاً فيه رقم المستخلص الكيميائي CAS للمادة البحثية المطلوبة، أو
2. عرض سعر " **Performa Invoice** " موضحاً فيه الرقم الدولي UN للمادة البحثة المطلوب، أو
3. خطاب من الشريك الخارجي يفيد بأن المادة البحثية المطلوبة لأغراض البحث العلمي فقط Only for Research Usage وفي إطار التعاون البحثي المشترك (مؤسسات/ افراد)، موضحاً فيه رقم المستخلص الكيميائي CAS أو الرقم الدولي UN للمادة البحثية المطلوبة.

توقيع الباحث الرئيسي

الاسم: .....

الجهة: .....

ختم الجهة الرسمي لجهة الباحث

Chemical Research Material Import Certification Form

RESEARCH, DEVELOPMENT, AND INNOVATION AUTHORTIY (RDIA)

ID: GCO-FRM-001
Status: Effective
Version: V1.0
Date: 11-08-2024

Appendix B: Controlled Research Chemical Substance Import Certification Form

Importer Instructions:

1) Complete this form if you intend to import a chemical material into the Kingdom of Saudi Arabia for research use.
2) Forward a completed copy of this form along with a Purchase Order to the foreign vendor/shipper for inclusion with the shipment (if applicable) to be submitted to the Ministry of Education and to be available to the Saudi Customs upon entering the country.
3) Retain a copy of this form and other accompanying shipping papers for record keeping and quality purposes.

NOTE: If you are importing the restricted chemical through a supplier distributor, they will take responsibility for submitting the import certification.

Shipment Contents:

Chemical materials imported into the Kingdom of Saudi Arabia may be accompanied by this certification form indicating that the chemical material will be used for research purposes **only** and that the shipment is in compliance with the laws and regulations of the *Saudi Food & Drug Administration (SFDA), the Ministry of Education (MoE), and the High Commission for Industrial Security (HCIS), and any other responsible authority in Saudi Arabia.*

This shipment contains the following controlled chemical substances:

Chemical Material Name	Quantity	Unit	Chemical Abstracts Services (CAS) Registry Number (If available)

Attach additional sheets that identify the chemical materials to be shipped. Include the following information (if available):

☐ CAS ☐ Formula ☐ SDS ☐ Other (Specify: .....)

Information of Person Using the Requested Material			
Full Name			
Saudi National ID/Iqama Number			
Title			
Mobile Number			
Research Entity Name – Department	*(e.g., King Saud University – Chemical Engineering Department)*		
Work Address – Lab Using Controlled Chemical Substance	*(Note: Please include Lab Room Number)*		
RDIA Research Proposal Reference Number (If applicable)			
Brief Description of Chemical Material Use in Research			
☐ I certify that all information entered are correct to the best of my knowledge, and that the imported material highlighted in this document will be used for research purposes only, and that I will adhere to the safe use and management of the requested chemical materials, as well as proper waste disposal. I acknowledge that I am responsible for any misuse of these materials that violates local or international laws in accordance with the Saudi Food & Drug Administration (SFDA), the Ministry of Education (MoE), and the High Commission for Industrial Security (HCIS), and any other responsible authority in Saudi Arabia.			
Date (DD/MM/YYYY)		**Signature**	

Appendix C: High Commission For Industrial Security Related Material Request Forms (1 / 2)

نموذج (١)
تخزين مواد كيميائية

بيانات المادة :

الأسم الكيميائي للمادة			
عربي		انجليزي	
الرقم الدولي للمادة (UN)		المستخلص الكيميائي (CAS)	
وزنها	رقماً	تصنيف الخطورة	
	كتابة		
تاريخ تخزينها			

اسم المسئول عن المستودع :
التوقيع :

ملاحظة : ١- يطبع على ورق الشركة / المؤسسة ويحفظ في الملفات لدى إدارة المستودع وصورة لدى الشركة / المؤسسة.
٢- تسجل لكل مادة كيميائية واحدة بيان مستقل .

٥٣

نموذج رقم (٢)

تعهد

نتعهد نحن ....
سجل تجاري أو ترخيص صناعي رقم ....
وتاريخ / / ١٤هـ ومقرها بمنطقة ....
ومدينة .... صندوق بريد .... رمز بريدي .... الهاتف
.... الفاكس ....

الالتزام بالاتي :

١- نظام استيراد المواد الكيميائية وإدارتها ولائحته التنفيذية .
٢- أن تتضمن البيانات الإيضاحية المدونة على شحنه المادة الكيميائية الآتي الاسم العلمي باللغة العربية والانجليزية والرقم الدولي ورقم التسجيل في دائرة المستخلصات الكيميائية CAS أو احدهما وعلامة الخطورة التحذيرية .
٣- أن تستخدم المواد الكيميائية في المجال الذي استوردت من اجله .
٤- تزويد الجهة المختصة لإذن الاستيراد والرئاسة العامة للأرصاد وحماية البيئة بصفة دورية ببيان يوضح فيه الكميات المتراكمة .
٥- تزويد الجهة المانحة لاذن الاستيراد بأي تعديل في بيانات المنشأة .
٦- تعتبر الجهة المستوردة مسئولة مسئولية كاملة عن جميع الممارسات والنشاطات في إدارة المواد الكيميائية عند وقوع حوادث لحماية العاملين والجمهور والبيئة مع توفير المعدات الشخصية الواقية ووضع قواعد داخلية للوقاية.
٧- أن يكون الوارد الفعلي من الشحنات المطلوبة لا يتجاوز الكميات المحددة في اذن الاستيراد.

اسم مدير الجهة أو المفوض : تصديق الغرفة التجارية الصناعية
التوقيع المعتمد والتاريخ :
الختم :

ملاحظة هامة : يعد على أوراق الجهة المستوردة وتعبأ البيانات طباعة ولا يسمح بخط اليد .

شعار الجهة

نموذج رقم (٣) إذن استيراد مواد كيميائية تدخل في تركيب المتفجرات

PERMITION NUMBER: رقم الإذن:

Date of Issue: تاريخ الإصدار:
Date of Expiry: تاريخ الانتهاء:
Permeation Request Number: رقم وارد طلب الإذن:
Page: 1/1 صفحة: ١/١

تعليمات الإذن:

Importer			المستورد
Address			عنوانه
For			المرسل إليه
Address			عنوانه
Manuf			الصانع
Address			عنوانه
Exporter			المصدّر
Address			عنوانه

Item	Substance or Preparation	General Name	Quantity

توقيع مدير الجهة

الختم

نموذج (٢)
صرف مواد كيميائية

بيانات المادة

ملاحظة : تسجل بيانات كل مادة في بيان مستقل .

٥٤

نموذج رقم (٤)
طلب إذن استيراد مواد كيميائية تدخل في تركيب المتفجرات

نموذج رقم (١)
طلب إذن استيراد سلائف كيميائية

شعار الجهة

نموذج رقم (٥) إذن استيراد سلائف كيميائية

PERMITION NUMBER: رقم الإذن:

Date of Issue: تاريخ الإصدار:
Date of Expiry: تاريخ الانتهاء:
Permeation Request Number: رقم وارد طلب الإذن:
Page: 1/1 صفحة: ١/١

تعليمات الإذن:

Importer			المستورد
Address			عنوانه
For			المرسل إليه
Address			عنوانه
Manuf			الصانع
Address			عنوانه
Exporter			المصدّر
Address			عنوانه

Item	Substance or Preparation	General Name	Quantity

توقيع مدير الجهة

الختم

Appendix C: High Commission For Industrial Security Related Material Request Forms (2 / 2)

نموذج رقم (٦)

طلب إذن استيراد مواد كيميائية تدخل في تركيب المتفجرات وصنع المخدرات

شعار الجهة

نموذج رقم (٧) إذن استيراد مواد كيميائية تدخل في تركيب المتفجرات وصنع المخدرات

PERMITION NUMBER:	رقم الإذن:

Date of Issue: تاريخ الإصدار:

Date of Expiry: تاريخ الانتهاء:

Permeation Request Number: رقم وارد طلب الإذن:

Page: 1/1 صفحة: ١/١

تعليمات الإذن:

Importer			المستورد
Address			عنوانه
For			المرسل إليه
Address			عنوانه
Manuf			الصانع
Address			عنوانه
Exporter			المصدر
Address			عنوانه

	Substance or Preparation	Trade Name	Quantity

توقيع مدير الجهة

الختم

نموذج رقم (٨)

طلب إذن استيراد مواد كيميائية غير مقيدة أو غير محظورة

شعار الجهة

نموذج رقم (٩) إذن استيراد مواد كيميائية غير مقيدة أو غير محظورة

PERMITION NUMBER:	رقم الإذن:

Date of Issue: تاريخ الإصدار:

Date of Expiry: تاريخ الانتهاء:

Permeation Request Number: رقم وارد طلب الإذن:

Page: 1/1 صفحة: ١/١

تعليمات الإذن:

Importer			المستورد
Address			عنوانه
For			المرسل إليه
Address			عنوانه
Manuf			الصانع
Address			عنوانه
Exporter			المصدر
Address			عنوانه

	Substance or Preparation	Trade Name	Quantity

توقيع مدير الجهة

الختم

نموذج رقم (١٠)

طلب إذن فسح مواد كيميائية صادر لها إذن استيراد رقم ( ) وتاريخ (/ / ١٤هـ)

رقم الصادر ....

تاريخ الصادر ....

نموذج رقم (١١)

إذن فسح مواد كيميائية رقم ( ) وتاريخ ( )

نسخة للرئيس العام للأرصاد وحماية البيئة

نسخة للرئيس التنفيذي للهيئة العامة للغذاء والدواء/ قطاع الدواء

مدير عام الجمارك/ جمرك ....

نسخة لمدير عام الدفاع المدني

نسخة لمدير عام مكافحة المخدرات/ الإدارة العامة للسلائف والمختبرات

نسخة لمدير شرطة منطقة .... / الأسلحة والمتفجرات

السلام عليكم ورحمة الله وبركاته :

الإشارة : إذن الاستيراد الصادر من هذه الإدارة برقم ( ) وتاريخ ( )

الموضوع : الموافقة على طلب (جهة حكومية أوشركة أو مؤسسة أو مصنع) .... باستيراد المواد التالية :

م	اسم المادة باللغة العربية	اسم المادة باللغة الإنجليزية	الكمية (وزن (كجم) أو حجم (لتر)

الصانع : .... المصدر: ....

الفاتورة رقم:.......................وتاريخ: ....

بوليصة شحن رقم : ....وتاريخ :.......................

المرسل إليه : .... عنوانه: ....

الإفادة : لا مانع لدينا من فسح المواد الموضحة أعلاه مع التقيد بما ورد بنظام استيراد المواد الكيميائية وإدارتها الصادر بالمرسوم الملكي الكريم رقم (م/٣٨) وتاريخ (١٤٢٧/٦/١٦هـ) ولائحته التنفيذية

المطلوب : نأمل بعد الإطلاع إكمال اللازم بموجبه ولكم تحياتنا

- يتم طباعة الإذن على الأوراق الرسمية للجهة المختصة.
- تزويد الهيئة العامة للغذاء والدواء بنسخة من إذن الفسح لمواد الجدول (٢) و(٣).
- تزويد المديرية العامة لمكافحة المخدرات بنسخة من إذن الفسح لمواد الجدولين (١) و (٢).

اسم مديـــر الجهة المختصة وتوقيعه

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