ARQUIVOS DE ASMA, ALERGIA E IMUNOLOGIA


*Special Article*

# Starting an Allergy and Immunology practice. Part 2 – Standard Operating Procedure (SOP): What is it?

*Construindo o consultório do Alergista e Imunologista. Parte 2 – Procedimento Operacional Padrão (POP): o que é?*

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**ABSTRACT**

A standard operating procedure (SOP) is a structured organizational document that standardizes processes to ensure task planning and consistent quality in procedures. It provides a detailed description of a set of measures aimed at ensuring the quality and safety of care in medical offices through a descriptive manual. The SOP must be regularly reviewed, including all routine procedures, and updated whenever changes or alterations occur. Additionally, SOPs are subject to oversight by the Municipal Health Surveillance. This special article aimed to guide allergists on the necessary SOPs for their practice, according to the type of office, based on groups 1 to 3 as standardized by the Brazilian Federal Board of Medicine.

**Keywords:** Allergy, immunology, good practices, standard operating procedure.

**RESUMO**

O chamado POP (sigla para Procedimento Operacional Padrão) é um documento organizacional, padronizado, que uniformiza processos. O seu objetivo é garantir o planejamento de tarefa, assegurando uma qualidade consistente nos procedimentos a serem executados. Ele oferece uma descrição detalhada de um conjunto de medidas que visam à qualidade e segurança dos atendimentos prestados nos consultórios médicos, através de um manual descritivo, como está sendo proposto. O POP tem a necessidade de ser revisto constantemente, com toda a lista de rotina e, se necessário, atualizar o documento, diante de qualquer mudança ou alteração. Sendo assim, os POPs serão sempre cobrados pela Vigilância Sanitária Municipal. A proposta desse artigo especial é oferecer ao consultório do Alergologista um roteiro para ter orientação de quais POPS são necessários, conforme o tipo de consultório, baseado nos grupos 1 a 3, conforme padronização definida pelo Conselho Federal de Medicina.

**Descritores:** Alergia, imunologia, boas práticas, padrão operacional de procedimentos.

## Introduction

The Statute, Regulations, and Standards Committee of the Brazilian Association of Allergy and Immunology (CERN-ASBAI) presents the second part of the practical guide on how to start an Allergy and Immunology practice, this time with a focus on Standard Operating Procedures (SOPs).

SOPs are standard sets of instructions of Good Medical Practices, which are strongly recommended

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by the Brazilian Federal Board of Medicine (Conselho Federal de Medicina, CFM) and especially by the National Sanitary Surveillance Agency (Anvisa). These are subject to oversight by state or municipal health surveillance authorities, with municipal inspections being the most common. This guide includes recent updates regarding inspection requirements for private practices,[1] which are already in effect, as outlined in RDC Resolution No. 50, of February 21, 2002, issued by the Brazilian Ministry of Health. Other principles established in the ASBAI bylaws should also be considered.

Once an Allergy and Immunology practice is established, SOPs must be developed. But what are they, and why are they important?

An SOP is a document that describes, in detail, the steps necessary to adequately plan an activity, ensuring consistent quality in all tasks performed in the medical office. It serves as a standardized protocol that allows any trained individual to perform tasks efficiently and correctly. Such procedures may range from basic activities, such as adequate hand-washing techniques, to more complex ones, such as patient care and the performance of food or drug challenge tests.

With that in mind, CERN-ASBAI developed this second publication with the goal of guiding allergists on the key steps for establishing good clinical practices in the care of patients with allergic and/or immunological diseases in their office.

## Standard Operating Procedure

"SOP" is the most widely recognized and used term in health care organizations. It refers to detailed instructions outlined to achieve uniformity in the execution of tasks for a specific function.[1,2] SOPs are the final and fundamental document in the standardization process, describing the step-by-step sequence of a specific health care activity or procedure.

In the health care setting, the goal of an SOP is to maintain and ensure the smooth operation of a process through standardization and by minimizing deviations during the execution of a task. This guarantees that actions are performed as planned, correctly, and with the expected outcome.[1,3] SOPs regulate professional conduct and promote improvements that enhance the performance of the medical office by standardizing the tools and materials to be used, defining the individuals responsible for executing a task, outlining the correct way to perform a procedure, and establishing a schedule for periodic inspections of processes and equipment.

SOPs also aim to reduce the need for constant training, contributing to saving time and resources. Standardized processes can help reduce the time required for completing a task, resulting in greater productivity and reduced waste of resources.

SOPs can cover everything from cleaning protocols to patient care workflows. They include detailed instructions on how to consistently and safely perform specific tasks, helping ensure efficiency, safety, and regulatory compliance.[4] SOPs also serve as practical guides for new physicians or staff members, making it easier for them to understand how the office operates and helping resolve common day-to-day questions.

ISO 9001 does not mandate a specific format for SOPs, recognizing that each private practice has its own unique procedures. Nonetheless, SOPs should be concise, written in clear language, and based on technical and scientific knowledge. The sequence of steps must be logical and chronological, with prioritization based on the order in which each task should be performed.

State and municipal inspections of Allergy & Immunology offices[6] are conducted according to specific protocols developed for the specialty.

When drafting an SOP, the following elements should be considered[4,5]:

1. SOP number.
2. Date of creation.
3. Revision history.
4. Validation.
5. Implementation.
6. Title.
7. Names of individuals responsible for creating and validating the document.
8. Expected outcomes of the procedure.
9. List of required materials.
10. Description of main activities.
11. Description of how to manage the risks associated with the procedure and actions to be taken in case of noncompliance.

An SOP is considered valid when an individual is able to perform an activity using only the instructions provided. For this reason, SOPs should be simple, clear, and contain all necessary information for proper execution of the tasks.

Examples of SOPs include:

– SOP for hand hygiene.
– SOP for the use of Personal Protective Equipment (PPE).
– SOP for labeling disposable dispensing bottles.
– SOP for performing spirometry.
– SOP for cleaning office cabinets.
– SOP for cleaning office countertops, armchairs, and chairs.
– SOP for cleaning office windows, doors, and light switches.
– SOP for disinfecting the anthropometric scale.
– SOP for cleaning the office floor.

These SOPs are required for obtaining authorization to open a private practice or health care facility, for the issuance and/or renewal of a health permit, and even for affiliation with a health insurance provider, every 1 or 2 years.

As an example, Figure 1 illustrates the Municipal Health Surveillance Inspection Checklist used in city of Belo Horizonte, Brazil, for Allergy & Immunology offices.6 It includes several items that will be verified during the on-site inspection and must be supported by documentation proving compliance. Inspectors may even request a live demonstration of certain procedures. Items on the checklist are marked as: performed (Y), not performed (N), or not applicable (NA).

Figure 2 presents a standard SOP template, followed by instructions on how to properly complete each section of an SOP.

### *1.1 Company identification*

Enter the name of the company as it appears on the National Registry of Legal Entities (Cadastro Nacional de Pessoas Jurídicas, CNPJ) or, in the case of an individual, the full legal name. If applicable, the company logo may also be included.

### *1.2 SOP number*

Enter SOP number. For example: SOP No. 1, SOP No. 2, SOP No. 3, SOP No. 4.

Note: A separate SOP must be created for each work process.

### *1.3 Date of issuance/Effective date*

Enter the date the document was issued and its effective date.

Note: Set a review deadline for the SOP. If a new procedure is added, the SOP should be reviewed before the scheduled deadline.

### *1.4 Revision number*

Enter the current revision number of the document.

### *1.5 Procedure to be performed*

Enter the name of the procedure.

For example: Cleaning of materials, sterilization of instruments, cleaning of the procedure room, cleaning of bathrooms, etc.

### *1.6 Person(s) responsible*

Identify the employee(s) or team responsible for carrying out the activity.

### *1.7 Necessary materials and resources*

List all materials and supplies needed to perform the activity (eg, tools, soap/detergent, disinfectant, PPE).

### *1.8 Procedure description*

Provide a step-by-step description of the tasks required for performing the procedure, with prioritization based on the order in which they should be performed.

For example:

1. Hand washing as described in the Hand Hygiene SOP.
2. Donning PPE, according to the procedure's specific requirements (which should also be listed in the Materials section).
3. Gathering the materials and tools required for the procedure.
4. Executing each step of the procedure in the described order.

Note: Specify how often the procedure should be performed (frequency), taking into account its associated sanitary risks.

### *1.9 Observation*

List any precautions that should be taken when performing an activity to ensure the effectiveness of the process.

For example:

– In the presence of visible dirt, wash with soap and water to remove residues.
– Cleaning should always be performed from the cleanest area to the dirtiest.

**MUNICIPAL HEALTH DEPARTMENT**
**DIRECTORATE OF HEALTH SURVEILLANCE – DVSA/SMSA**

**INSPECTION CHECKLIST FOR ALLERGY & IMMUNOLOGY AND/OR PULMONOLOGY PRACTICES – Health Surveillance** **REVISION DATE: 03/03/2021**

**ID 390** **RVF_DVSA_73_VS** **EFFECTIVE DATE: 03/03/20**

| CBO/CNAE # | OCCUPATION NAME |
|---|---|
| 8640-2/99 | DIAGNOSTIC SUPPORT SERVICES |
| 2251/10 | ALLERGIST AND IMMUNOLOGIST |
| 2251/27 | PULMONOLOGIST |

| ITEM | DESCRIPTION | Y | N | NA | LAW[a] |
|---|---|---|---|---|---|
| | **INFRASTRUCTURE** | | | | |
| 1065 | IS THERE A WAITING ROOM FOR PATIENTS/ACCOMPANYING PERSONS? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 50/02, PART II, 3, UNID. FUNC. 1 - ATEND. AMB. AMB. APOIO |
| 7986 | IS THERE A RECEPTION AREA FOR PATIENT REGISTRATION? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 50/02, PART II, 3 - DIMENS. QUANT. E INST. PRED. UNID. FUNC. 1 - ATEND. AMB. AMB. APOIO |
| 11862 | IF DESENSITIZATION, INTRADERMAL, AND PROVOCATION TESTS ARE PERFORMED, DOES THE OFFICE HAVE:<br>* A ROOM COVERED WITH WATERPROOFING MATERIAL/PAINT OR TILE?<br>* A SINK WITH A COUNTER AND CABINET MADE OF SMOOTH, EASY-TO-CLEAN MATERIAL?<br>* A REFRIGERATOR WITH A MINIMUM / MAXIMUM THERMOMETER? | | | | LM 7031/96 ART. 97, SECTION II C/C RESOLUÇÃO 2153/2016 AND PORTARIA MS/GM 2048/02, ANNEX, ITEM 1.3 |
| 6573 | IS THERE A UTILITY/DISPOSAL ROOM? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 50/02, ART. 1, RT, PART II, 3 - DIMENS., QUANTIF. E INSTALAÇÕES PREDIAIS |
| 1068 | IF SO, IS THE UTILITY/DISPOSAL ROOM EQUIPPED WITH:<br>* TORNEIRA SOB PRESSÃO<br>* BRUSHES OF VARIOUS SIZES<br>* ILLUMINATED MAGNIFIER<br>* NEUTRAL OR ENZYMATIC DETERGENT<br>* COMPRESSED AIR<br>* HOT RUNNING WATER<br>* PLASTIC CONTAINERS FOR IMMERSION OF MEDICAL INSTRUMENTS | | | | LM 7031/96, ART. 97, SECTION II C/C REPUB. NOTIF. GER. COLEG. SUPERINT. VISA 202/2008 + LE nº 13317/99, ART. 81, SECTION I |
| 35 | DO THE TRASH CANS MEET THE FOLLOWING CRITERIA?<br>* MADE OF WASHABLE MATERIAL<br>* EQUIPPED WITH PLASTIC BAGS IN THE APPROPRIATE COLOR<br>* TOUCH-FREE<br>* CLEARLY LABELED WITH DESCRIPTIONS AND SYMBOLS<br>* SUFFICIENT IN QUANTITY<br>* IN GOOD CONDITION | | | | LM 7031/96 art. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM.3.2.1.1.7 + RDC 222/2018, ART. 11 |
| 11508 | ARE THE FLOOR, WALLS, AND CEILING EASY TO CLEAN, WITH MINIMAL GROOVES OR GAPS, AND IN GOOD CONDITION? | | | | LM 7031/96, ART. 69 C/C RDC 50/02, ART. 1, RT, PART 6.2, C.1 + RDC 063/2011, ART. 36 |

[a] This table lists specific Brazilian laws.
DF = Federal Decree; LE = State Law; LM = Municipal Law; NA = Accessibility Act; NTE = Technical Note; RT = Technical Standard.

**Figure 1**
Municipal Health Surveillance Inspection Checklist for Allergy & Immunology Offices – City of Belo Horizonte, state of Minas Gerais, Brazil.

| ITEM | DESCRIPTION | Y | N | NA | LAW[a] |
|---|---|---|---|---|---|
| | **INFRASTRUCTURE** | | | | |
| 11861 | IS PREVENTIVE AND CORRECTIVE MAINTENANCE OF THE BUILDING INFRASTRUCTURE PERFORMED (IN-HOUSE OR OUTSOURCED)? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 063/2011, ART. 23, INCISO VII AND IX + ART. 42 |
| 3084 | ARE VISIBLE ELECTRICAL INSTALLATIONS IN GOOD CONDITION? | | | | LM 7031/96, ART. 69 C/C PM 015/01, ART. 1, NTE 001/01, ANEX I, ITEM 3.12.6 C/C RDC 50/02, ART. 1, RT, PART III, 7 E RDC 63/2011, ART. 36 |
| 11316 | ARE LIGHTING AND VENTILATION ADEQUATE FOR THE ACTIVITIES PERFORMED? | | | | LM 7031/96, ART. 69 C/C RDC 063/2011, ART. 38 |
| XXXX | ARE ALL AREAS WELL-MAINTAINED, SAFE, ORGANIZED, AND CLEAN? | | | | LM 7031/96, ART. 69 C/C RDC 063/2011, ART. 56 |
| 9179 | ARE RESTROOMS AVAILABLE FOR STAFF AND PATIENTS/ ACCOMPANYING PERSONS? | | | | LM 7031/96, ART. 97, SECTION C/C RDC 50/02, ART. 1, RT, PART II, 3 - DIMENS., QUANT. E INST. PRED. |
| 1071 | ARE THERE APPROPRIATE RESTROOM FACILITIES FOR INDIVIDUALS WITH PHYSICAL DISABILITIES, ALLOWING WHEELCHAIR CIRCULATION, WITH OUTWARD-OPENING DOORS AND GRAB BARS POSITIONED 90 CM FROM THE FLOOR? | | | | RDC 50/02, ART. 1° RT, PART III, 4; ITEM 4.1 C/C PM 015/01 ART. 1, NTE 001/01, NA. III IT. 3 SUBIT. 3.1.10 + 3.1.11 AND NBR 9050/94 |
| 1512 | DO ALL DRAINS (EXCEPT THOSE CONNECTED TO THE STORM WATER SYSTEM) HAVE TRAPS AND FLIP-TOP COVERS? | | | | LM 7031/96, ART. 97, II C/C RDC 50/02, ART. 1, RT, PART III, ITEM 6.2, B.5 |
| 1195 | REGARDING OFFICE DIMENSIONS:<br>* DO CONSULTATION ROOMS HAVE A MINIMUM OF 7.5 $m^2$?<br>* ARE OFFICE DIMENSIONS COMPATIBLE WITH THE ACTIVITIES PERFORMED?<br>* DO THEY ALLOW FOR A RATIONAL WORKFLOW? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01, ART. 1°, NTE 001/01, ANEXO III, ITEM 3.1.6 OR RDC 050/02, PART II, 3, ATIVIDADE |
| 3625 | IS THERE A CLEANING SUPPLY STORAGE ROOM CONTAINING AT LEAST:<br>* A SINK OR BASIN<br>* ADEQUATE LOCATION (CABINET/SHELF) FOR STORING SUPPLIES<br>* A LIDDED PEDAL BIN WITH PLASTIC BAG<br>* DISPOSABLE HAND TOWELS<br>* LIQUID SOAP | | | | LM 7031/96 ART. 97, SECTION II C/C RDC 050/02 ART. 1°, RT, C/C PM 015/01 ART. 1, NTE 001/01, NA. ITEM 3 SUBIT. 3.1.12 |
| 7771 | IF THERE IS NO DESIGNATED CLEANING SUPPLY STORAGE ROOM, IS THERE ANOTHER APPROPRIATE PLACE FOR STORING CLEANING PRODUCTS AND EQUIPMENT? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART, 1°, NTE 001/01, ANEX III, ITEM 3.1.12 |
| 9330 | IS DRINKING WATER EASILY ACCESSIBLE TO PATIENTS AND STAFF, WITH NO RISK OF CONTAMINATION? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1°, NTE 001/01, ANEX III, ITEM 3.1.3 |
| 2858 | DO EXAMINATION ROOMS HAVE A WASHBASIN WITH SINK, RUNNING WATER, LIQUID SOAP AND/OR ANTISEPTIC SOLUTION, AND PAPER TOWELS? | | | | LM 7031, ART. 97, SECTION II C/C RDC 48/2000, ART. 1, ANEX, ROTEIRO B, ITEM 25, PM 015/2001 NTE 001/01 ANEX IV ITEM 3.28 + RDC 063/2011, ART. |

[a] This table lists specific Brazilian laws.
DF = Federal Decree; LE = State Law; LM = Municipal Law; NA = Accessibility Act; NTE = Technical Note; RT = Technical Standard.

**Figure 1** *(continued)*
Municipal Health Surveillance Inspection Checklist for Allergy & Immunology Offices – City of Belo Horizonte, state of Minas Gerais, Brazil.

| ITEM | DESCRIPTION | Y | N | NA | LAW[a] |
|---|---|---|---|---|---|
| | **EQUIPMENT / MEDICATIONS AND MATERIALS** | | | | |
| 3013 | ARE ONLY MEDICATIONS, ANTIGENS, SOLUTIONS, DISINFECTANTS, AND GERMICIDES USED THAT ARE:<br>* REGISTERED WITH THE APPROPRIATE REGULATORY AUTHORITY<br>* WITHIN BEYOND-USE DATE | | | | LM 7031/96 ART. 97.<br>SECTION X C/C RDC 063/2011, ART. 17 |
| 3566 | ARE MEDICATIONS AND MEDICAL SUPPLIES STORED:<br>* IN AN EXCLUSIVE AREA<br>* IN AN APPROPRIATE LOCATION<br>* IN A PLACE FREE FROM HUMIDITY<br>* IN A PLACE THAT IS EASY TO CLEAN<br>* IN A PLACE THAT IS EASY TO DISINFECT | | | | LM 7031/96, Art 97, SECTION II<br>C/C RDC 050/2002, PART II<br>3 UM. FUNC. 4 - AP. DIAG.TER.<br>ITEM 4.6 E RDC 063/2011,<br>ART. 36 |
| 5326 | ARE CONTROLLED SUBSTANCES KEPT IN A LOCKED CABINET/ROOM OR SECURED WITH ANOTHER SAFETY MECHANISM? | | | | LM 7031/96, Art 97, SECTION II<br>C/C Portaria MS/SVS 344/1998,<br>ART. 67 |
| 11863<br><br><br><br>11826 | IF DESENSITIZATION, PROVOCATION TESTS, OR IMMUNOTHERAPY FOR INHALANT/INSECT ALLERGY ARE PERFORMED, IS THE FOLLOWING AVAILABLE:<br><br>H2 ANTIHISTAMINE FOR IV USE (RANITIDINE) | | | | LM 7031/96 ART. 97, SECTION II<br>C/C RESOLUÇÃO 2153/2016 AND PORTARIA MS/GM 2048/02,<br>ANEX, ITEM 1.3 |
| 11864 | IF SENSITIZATION AND PROVOCATION TESTS WITH ANTIGENS AND LOCAL ANESTHESIA (WITHOUT SEDATION) ARE PERFORMED, PIS THE OFFICE EQUIPPED FOR EMERGENCY SITUATIONS WITH:<br>* ADRENALINE (EPINEPHRINE)<br>* DISTILLED WATER<br>* DEXAMETHASONE<br>* DIAZEPAM<br>* DIPYRONE<br>* DEXTROSE<br>* HYDROCORTISONE<br>* PROMETHAZINE<br>* SALINE SOLUTION | | | | LM 7031/96 art. 97, SECTION II<br>C/C RESOLUÇÃO 2153/2016<br>AND PORTARIA MS/GM 2048/02,<br>ANEX, ITEM 1.3 |
| 11865 | IF SENSITIZATION AND PROVOCATION TESTS WITH ANTIGENS AND LOCAL ANESTHESIA (WITHOUT SEDATION) ARE PERFORMED, IS THE OFFICE EQUIPPED FOR EMERGENCY SITUATIONS WITH:<br>* AUTOMATED EXTERNAL DEFIBRILLATOR<br>* OROPHARYNGEAL AIRWAYS (GUEDEL)<br>* OXYGEN SUPPLY WITH APPLICATOR MASK AND HUMIDIFIER<br>* PULSE OXIMETER<br>* AMBU BAG WITH RESERVOIR AND MASK<br>*SYRINGES, NEEDLES, AND IV INFUSION EQUIPMENT<br>* SCALP VEIN SETS/BUTTERFLY NEEDLES AND INTRAVENOUS CANNULAS (WITH ALL INSERTION MATERIALS)<br>* GAUZE, COTTON, CREPE BANDAGES, AND STERILE GLOVES | | | | LM 7031/96 ART. 97, SECTION II<br>C/C RESOLUÇÃO 2153/2016 AND PORTARIA MS/GM 2048/02,<br>ANEX, ITEM 1.3 |
| 2138 | IS THERE A DAILY LOG FOR TEMPERATURE CONTROL OF THE REFRIGERATOR USED FOR THERMOLABILE PRODUCTS AND IS THE TEMPERATURE MAINTAINED BETWEEN 2 °C AND 8 °C (MINIMUM AND MAXIMUM)? | | | | 7031/96 ART. 97 SECTION II<br>C/C LM RDC 36/2013, ANEX III - PROTOCOLO DE SEGURANÇA NA PRESCRIÇÃO, USO E ADMINISTRAÇÃO DE MEDICAMENTOS - ITENS 6.1.1 E |

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**Figure 1** *(continued)*
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| ITEM | DESCRIPTION | Y | N | NA | LAW[a] |
|---|---|---|---|---|---|
| **EQUIPMENT / MEDICATIONS AND MATERIALS** | | | | | |
| 1098 | ARE THE DISPENSING BOTTLES:<br>* SANITIZED<br>* LABELED<br>* MARKED WITH THE BOTTLING DATE<br>* WITHIN THE EXPIRATION DATE | | | | LM 7031/96 ART. 97 SECTION II C/C RDC 63/2011 ART. 57 |
| 10432 | ARE ALL PADDED FURNITURE, INCLUDING MATTRESSES AND CUSHIONS, COVERED IN WASHABLE, WATERPROOF MATERIAL, AND FREE OF HOLES, TEARS, GROOVES, OR INDENTATIONS? | | | | LM 7031/96, ART. 69 C/C RDC 063/2011, ART. 56 |
| 7532 | ARE ONLY SAFETY SYRINGES WITH RETRACTABLE NEEDLES USED IN PROCEDURES? | | | | LM 7031/96 ART. 97 SECTION II C/C LE 18797/10 ART. 1º |
| 2692 | ARE THERE SUFFICIENT QUANTITIES OF EQUIPMENT, MATERIALS, AND TOOLS FOR THE PROCEDURES PERFORMED, AND ARE THEY IN GOOD WORKING AND HYGIENIC CONDITIONS? | | | | LM 7031/96 ART. 97. SECTION X C/C RDC 063/2011, ART. 53 AND LM 7031/96, ART. 32, § ÚNICO |
| 1093 | IS THERE ENOUGH SUPPLY OF REUSABLE ITEMS? | | | | LM 7031/96 ART. 97. SECTION X C/C RDC 063/2011, ART. 53 + LM 7031/96, ART. 32, § ÚNICO |
| 2616 | IS THERE AN ADULT AND/OR PEDIATRIC STETHOSCOPE? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 3.2.1.1.1 |
| 4303 | IS THERE A DIGITAL THERMOMETER? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 3.2.1.1.2 AND RDC 145/2017, ART. 1º |
| 2617 | IS THERE AN EXAMINATION TABLE? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 3.2.1.1.3 |
| 1203 | IS THERE A SCALE FOR ADULTS AND/OR CHILDREN? | | | | LM 7031/96 ART 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 3.2.1.1.5 |
| 1204 | IS THERE A TABLE OR STAND FOR KEEPING MEDICAL DEVICES? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 3.2.1.1.8 |
| 1205 | IS THERE A SPHYGMOMANOMETER WITH CUFFS FOR BOTH ADULTS AND CHILDREN? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 3.2.1.10 |
| 1206 | IS THERE A NEGATOSCOPE? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 art. 1º, NTE 001/01, ANEX III, ITEM 3.2.1.10 |
| 1207 | ARE TONGUE DEPRESSORS DISPOSABLE? | | | | PM 015/01 ART. 1, NTE 001/01, ANEX III ITEM 3 SUBITEM 3.2.1.1.11 |
| 1198 | DO ALL APPLICABLE MEDICAL DEVICES HAVE REGISTRATION WITH ANVISA OR THE MINISTRY OF HEALTH, WHEN REQUIRED? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 3.2.2 |

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**Figure 1** *(continued)*
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| ITEM | DESCRIPTION | Y | N | NA | LAW[a] |
|---|---|---|---|---|---|
| | **PROCEDURES** | | | | |
| 1753 | ARE THERE ILLUSTRATIVE HAND HYGIENE INSTRUCTIONS, POSTED PREFERABLY IN A VISIBLE LOCATION NEAR WASHBASINS? | | | | LM 7031/96, ART. 97, II C/C RDC 63/2011, ART. 8º, II |
| 11507 | ARE THE NECESSARY SUPPLIES, PRODUCTS, AND EQUIPMENT MADE AVAILABLE TO ENSURE ADEQUATE HAND HYGIENE FOR WORKERS, PATIENTS, ACCOMPANYING PERSONS, AND VISITORS? | | | | LM 7031/96 ART 97 SECTION II C/C RDC 063/2011, ART. 59 |
| 6923 | ARE DISPENSERS FILLED WITH 70% ALCOHOL AVAILABLE IN ALL AREAS? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 042/2010, ART. 1º, ITEM X 063/2011, ART. 59 |
| 572 | IS 70% ETHYL ALCOHOL OR ANOTHER PROVEN DISINFECTANT USED TO DISINFECT EQUIPMENT, SURFACES, AND RECREATIONAL MATERIALS AFTER CLEANING? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 4.7.4 |
| 2673 | IS 1% SODIUM HYPOCHLORITE OR AN EQUIVALENT DISINFECTANT USED TO DISINFECT SURFACES? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART 1º, NTE 001/01, ANEX III, ITEM 4.7.3 |
| 1089 | FOR AREAS CONTAMINATED WITH BLOOD, SECRETIONS, OR EXCRETIONS, ARE THE FOLLOWING PROCEDURES FOLLOWED:<br>* WASHING WITH WATER AND SOAP<br>* DISINFECTION WITH 1% SODIUM HYPOCHLORITE OR ANOTHER PROVEN DISINFECTANT | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 4.7.2 |
| 1090 | REGARDING LINENS (SHEETS, GOWNS, PILLOWCASES, TOWELS, ETC.), WHEN NOT DISPOSABLE:<br>* ARE THEY REPLACED AFTER EACH PATIENT?<br>* ARE THEY PROPERLY LAUNDERED? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 4.7.7 |
| 8508 | ARE ALL CRITICAL ITEMS IN THE FACILITY STERILIZED? | | | | LM 7031/96, ART. 97, II C/C RDC 63/2011, ART. 57 |
| 1092 | ARE ALL MEDICAL DEVICES THAT COME INTO CONTACT WITH BODY FLUIDS, WHEN NOT DISPOSABLE, PROPERLY PROCESSED? | | | | LM 7031/96 ART. 32 |
| 11360 | DOES THE SERVICE ENSURE THE QUALITY OF DISINFECTION AND STERILIZATION PROCESSES FOR EQUIPMENT AND MATERIALS/ITEMS? | | | | LM 7031/96, ART. 97, II C/C RDC 63/2011, ART. 57 |
| 11535 | ARE THE SOLUTIONS USED FOR DISINFECTING MEDICAL DEVICES STORED IN SEALED AND LABELED PLASTIC CONTAINERS OR DISPENSERS WITH THE PRODUCT NAME, BOTTLING DATE, AND EXPIRATION DATE CLEARLY INDICATED? | | | | LM 7031/96 ART 34, ART. 97, SECTION II, C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 4.10 |
| 1199 | ARE DISINFECTED, STERILIZED, AND DISPOSABLE EQUIPMENT AND MATERIALS STORED IN CLEAN, CLOSED CABINETS OR DRAWERS? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART 1º, NTE 001/01, ANEX III, ITEM 4.11 |
| 9944 | IS THE PROHIBITION AGAINST EATING OR STORING FOOD IN PATIENT CARE AND TREATMENT AREAS STRICTLY OBSERVED? | | | | LM 7031/96, ART. 97, II C/C RDC 63/2011, ART. 64 |
| 4852 | ARE SUSPECTED CASES OF NOTIFIABLE DISEASES PROPERLY REPORTED TO THE RELEVANT HEALTH AUTHORITIES? | | | | LM 7031/96 ART. 97 SECTION II C/C RDC 063/2011, ART. 61 |
| 8502 | IF INVASIVE PROCEDURES ARE PERFORMED, DOES THE OFFICE HAVE AN INFECTION CONTROL TEAM? | | | | LM 7031/96, ART. 30 C/C LM 7031/96, ART. 97, SECTION II C/C RDC 063/2011, ART. 23, SECTION XV |

[a] This table lists specific Brazilian laws.
DF = Federal Decree; LE = State Law; LM = Municipal Law; NA = Accessibility Act; NTE = Technical Note; RT = Technical Standard.

**Figure 1** *(continued)*
Municipal Health Surveillance Inspection Checklist for Allergy & Immunology Offices – City of Belo Horizonte, state of Minas Gerais, Brazil.

| ITEM | DESCRIPTION | Y | N | NA | LAW[a] |
|---|---|---|---|---|---|
| | **HUMAN RESOURCES** | | | | |
| 11890 | IS THE OFFICE'S TECHNICAL SUPERVISOR BOARD-CERTIFIED IN ALLERGY AND IMMUNOLOGY BY THE REGIONAL MEDICAL BOARD (CRM) OF THEIR JURISDICTION? | | | | LM 7031/96, ART. 97, SECTION II C/C ANEX RESOLUTION CFM nº2.147/2016, ART. 9º, § 1º |
| 6403 | ARE COLLECTIVE PROTECTIVE EQUIPMENT (CPE) AND PERSONAL PROTECTIVE EQUIPMENT (PPE) AVAILABLE, AND IS THERE DOCUMENTATION CONFIRMING THEIR DISTRIBUTION TO STAFF? | | | | LM 7031/96, ART. 38, § ÚN. C/C PM 485/05, ART. 1, ANEX I - NR-32, ITEM 32.2.4.7 C/C RDC 63/11, ART. 47 C/C PM015/01 ART.1, NTE 001/01, ANEX III,4.12 E |
| 543 | DO STAFF MEMBERS RESPONSIBLE FOR CLEANING AND PROCESSING CONSISTENTLY AND UNDER SUPERVISION USE THE APPROPRIATE PPE WHEN NECESSARY, INCLUDING:<br>* LONG-CUFF RUBBER GLOVES<br>* WATERPROOF CLOSED-TOE SHOES<br>* WATERPROOF GOWN<br>* LONG-SLEEVED GOWN (FOR PROCESSING)<br>* PROTECTIVE GOGGLES (FOR PROCESSING) | | | | LM 7031/96, ART. 38, § ÚNICO C/C PM 485/05, ART.1, NA 1-NR- 32, ITEM 32.2.4.7 C/C RDC 63/11, ART. 47, NTE 001/01, ANEX III, 4.12 AND 4.15 |
| 656 | ARE THE PPE IN GOOD HYGIENIC CONDITION AND PROPERLY MAINTAINED? | | | | LM 7031/96 ART. 97 SECTION II C/C RDC 63/2011 ARTS. 17 AND 46 |
| | **DOCUMENTATION** | | | | |
| 6955 | DO THE ACTIVITIES LISTED ON THE OPERATING LICENSE AND REGISTRATION FORM MATCH THE ACTIVITIES ACTUALLY CARRIED OUT OR INTENDED TO BE CARRIED OUT AT THE SITE? | | | | LM 7031/96, ART. 20 C/C RDC 63/11 ART. 10 |
| 6549 | IS THERE A MANUAL OF POLICIES & PROCEDURES COVERING ALL WORK PROCESSES, INCLUDING TECHNICAL, ADMINISTRATIVE, AND HEALTH CARE ACTIVITIES, AS WELL AS RESPONSIBILITIES AND COMPETENCIES?? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 063/2011, ART. 51 |
| 9998 | DOES THE HEALTH SERVICE MAKE THE FOLLOWING AVAILABLE TO ALL STAFF:<br>* STANDARDS AND SAFETY PROTOCOLS RELATED TO BIOLOGICAL, CHEMICAL, PHYSICAL, OCCUPATIONAL, AND ENVIRONMENTAL HAZARDS?<br>* INSTRUCTIONS FOR THE USE OF PPE?<br>* INSTRUCTIONS IN CASE OF FIRE OR ACCIDENTS? | | | | LM 7031/96, ART. 97, II C/C RDC 63/2011, ART. 50, ITENS I - IV |
| 8254 | ARE THERE TRAINING RECORDS FOR STAFF MEMBERS, BOTH PRIOR TO BEGINNING THEIR DUTIES AND ON AN ONGOING BASIS, INCLUDING DATE, DURATION (HOURS), CONTENT, NAME AND CREDENTIALS OF THE INSTRUCTOR, AND NAMES AND ROLES OF PARTICIPANTS? | | | | LM 7031/96, ART. 97, II C/C RDC 63/2011, ART. 32 |
| 11509 | ARE THERE RECORDS CONFIRMING THAT THE TRAINING AND QUALIFICATIONS OF PROFESSIONALS ARE COMPATIBLE WITH THE FUNCTIONS PERFORMED? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 063/2011, ART. 31, § ÚNICO |

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**Figure 1** *(continued)*
Municipal Health Surveillance Inspection Checklist for Allergy & Immunology Offices – City of Belo Horizonte, state of Minas Gerais, Brazil.

| ITEM | DESCRIPTION | Y | N | NA | LAW[a] |
|---|---|---|---|---|---|
| | **D O C U M E N T A T I O N** | | | | |
| 531 | IS THERE PROOF OF WATER TANK CLEANING EVERY 6 MONTHS OR LESS? | | | | LM 7031/96, ART. 97, II C/C RDC 63/2011, ART. 39, § 1° C/C LM 6673/94, ART. 1, II |
| 7614 | ARE THERE RECORDS OF MICROBIOLOGICAL AND PHYSICOCHEMICAL ANALYSES OF POTABLE WATER QUALITY? | | | | LM 7031/96, ART. 97, II C/C RDC 63/2011, ART. 23, VI |
| 4200 | IF PEST CONTROL IS INCLUDED IN THE CLINIC'S INTEGRATED VECTOR CONTROL MANAGEMENT PLAN, IS THERE A VALID DISINFESTATION AND RODENT CONTROL CERTIFICATE ISSUED BY A SPECIALIZED COMPANY AND APPROVED BY THE MUNICIPAL HEALTH DEPARTMENT?<br>* DID THE MUNICIPAL HEALTH DEPARTMENT ISSUE A HEALTH PERMIT FOR THE COMPANY?<br>* IS THE CERTIFICATE WITHIN ITS VALIDITY PERIOD?<br>* DOES THE SERVICE COMPLY WITH INTEGRATED VECTOR CONTROL AND PEST MANAGEMENT STANDARDS? | | | | LM 7031/96 ART. 97, SECTION II C/C RDC 222/2018, ART. 1, ANEXO, ITEM 4.1.3 + RDC 63/11, ART. 63, § ÚNICO |
| 9322 | IS PREVENTIVE AND CORRECTIVE MAINTENANCE OF EQUIPMENT PERFORMED AND DOCUMENTED? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 063/2011, ART. 23, SECTION IX |
| 10237 | ARE OUTSOURCED SERVICES AND ACTIVITIES GOVERNED BY FORMAL SERVICE CONTRACTS PROPERLY REGISTERED WITH THE RELEVANT HEALTH AUTHORITY? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 063/2011, ART. 11 |
| 10010 | IS THERE A VACCINATION PROGRAM THAT INCLUDES GUIDANCE AND MECHANISMS FOR IMMUNIZATION AGAINST TETANUS, DIPHTHERIA, HEPATITIS B, AND OTHER BIOLOGICAL AGENTS TO WHICH WORKERS MAY BE EXPOSED? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 063/2011, ART. 43 AND PF 485/2005, NR 32, ITEM 32.3.1, ITEM e |
| 10387 | ARE MEDICAL RECORDS LEGIBLY COMPLETED, WITH SIGNATURE AND STAMP OF THE HEALTH CARE PROFESSIONAL DIRECTLY INVOLVED? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 063/2011, ART. 41 AND LM 7031/96, ART. 27 |
| 11704 | DO MEDICAL RECORDS INCLUDE DATA REGARDING PATIENT IDENTIFICATION AND ALL PROCEDURES PERFORMED? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 063/2011, ART. 41 AND LM 7031/96, ART. 26 |
| 9128 | ARE ALL MEDICAL RECORDS RELATED TO EACH PATIENT CONSOLIDATED INTO A SINGLE, UNIFIED RECORD, WITH LEGIBLE ENTRIES COMPLETED BY ALL PROFESSIONALS DIRECTLY INVOLVED IN THE PATIENT'S CARE, INCLUDING CLEAR IDENTIFICATION AND, FOR PHYSICAL RECORDS, THE PROFESSIONAL'S SIGNATURE AND STAMP? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 63/2011 ART. 26 |
| 3021 | DO MEDICAL RECORDS CONTAIN THE FOLLOWING INFORMATION:<br>* CLINICAL HISTORY?<br>* DIAGNOSIS?<br>* TEST RESULTS? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 63/2011 ART. 26 AND PM 015/01, ART. 1, NTE 001/01, ANEX I, ITEM 3.21.2 |
| 1283 | DO PRESCRIPTION FORMS INCLUDE THE PHYSICIAN'S NAME, LICENSE NUMBER, AND OFFICE ADDRESS? | | | | LM 7031/96 ART. 97, SECTION II C/C PM 015/01 ART. 1º, NTE 001/01, ANEX III, ITEM 4.3 |
| 1284 | ARE PRESCRIPTION FORMS AND MEDICAL DOCUMENTS WRITTEN LEGIBLY? | | | | LM 7031/96, ART. 97, II C/C RCFM 1246/88 CAPITULO III ART. 39 |

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**Figure 1** *(continued)*
Municipal Health Surveillance Inspection Checklist for Allergy & Immunology Offices – City of Belo Horizonte, state of Minas Gerais, Brazil.

| ITEM | DESCRIPTION | Y | N | NA | LAW[a] |
|---|---|---|---|---|---|
| | **D O C U M E N T A T I O N** | | | | |
| 1282 | ARE PRESCRIPTION FORMS FOR CONTROLLED SUBSTANCES COMPLIANT WITH REGULATORY REQUIREMENTS, AS DESCRIBED: TYPE “A” FORMS FOR A1, A2, AND A3 MEDICATIONS (ANNEX IX), TYPE “B” FORMS FOR B1 AND B2 MEDICATIONS (ANNEX X), SPECIFIC FORMS FOR SYSTEMIC RETINOIDS (C2 MEDICATIONS, ANNEX XII), AND SPECIFIC FORMS FOR THALIDOMIDE (C3 MEDICATIONS, ANNEX). | | | | LM 7031/96 ART. 97, SECTION II C/C PF 344/98, ART. 36, PARAGRAPH "a" to "m", ART. 52 |
| 10011 | ARE WORKERS REGULARLY ASSESSED FOR OCCUPATIONAL HEALTH, WITH THE APPROPRIATE RECORDS MAINTAINED? | | | | LM 7031/96, ART. 97, II C/C RDC 63/2011, ART. 44 |
| | **H C W M P** | | | | |
| 2925 | DOES THE CLINIC HAVE A HEALTH CARE WASTE MANAGEMENT PLAN (HCWMP)?<br>* IS THE HCWMP FILED WITH THE COMPETENT AUTHORITIES?<br>* IS THE HCWMP APPROVED BY THE COMPETENT AUTHORITIES?<br>* OR IS THERE A STATEMENT OF ZERO WASTE? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 063/2011, ART. 23, ITEM X |
| 9264 | IS THERE A CONTRACT OR PROOF OF SERVICE FOR EXTERNAL COLLECTION AND TRANSPORTATION OF WASTE BY A LEGALLY LICENSED COMPANY FOR THE TRANSPORT AND FINAL DISPOSAL OF HEALTH CARE WASTE? | | | | Law 7031/96 ART 22 C/C DM 16509/16 ART.1, NA 1 ITEM 2.6.2 |
| 2530 | IS THERE A RIGID CONTAINER FOR THE DISPOSAL OF SHARPS (NEEDLES, SCALPELS, ETC.), WITH ADEQUATE SUPPORT AND PLACED IN AN ADEQUATE LOCATION? | | | | LM 7031/96, ART. 97, SECTION II C/C RDC 222/2018, ART. 11 |
| 11336 | IS WASTE SEGREGATION CONDUCTED AT THE PLACE AND TIME OF ITS GENERATION? | | | | Law 7031/96 ART. 97 SECTION II C/C RDC 222/2018 ART. 11 |
| | **S M O K I N G** | | | | |
| 7055 | DOES THE OFFICE COMPLY WITH THE REQUIREMENT TO POST AND MAINTAIN SIGNS, POSTERS, OR NOTICES REGARDING THE PROHIBITION OF SMOKING, PLACED IN CLEARLY VISIBLE AREAS? | | | | LE 12.903/98 ART. 4 |
| 8503 | DOES THE OFFICE RESPECT THE PROHIBITION ON THE USE OF CIGARETTES, CIGARS, CIGARILLOS, PIPES, OR ANY SMOKING PRODUCT, WHETHER TOBACCO-DERIVED OR NOT, IN PUBLIC OR PRIVATE ENCLOSED SPACES THAT ARE ACCESSIBLE TO THE GENERAL PUBLIC OR DESIGNATED FOR COLLECTIVE USE, WHETHER FULLY OR PARTIALLY ENCLOSED? | | | | DF 8.262/14 ART. 3 |

[a] This table lists specific Brazilian laws.
DF = Federal Decree; LE = State Law; LM = Municipal Law; NA = Accessibility Act; NTE = Technical Note; RT = Technical Standard.

**Figure 1** *(continued)*
Municipal Health Surveillance Inspection Checklist for Allergy & Immunology Offices – City of Belo Horizonte, state of Minas Gerais, Brazil.

**SOP TEMPLATE**

<table>
<tr><td>(1.1) COMPANY IDENTIFICATION (Logo/Name)</td><td colspan="3">STANDARD OPERATING PROCEDURE – SOP</td></tr>
<tr><td>(1.2 ) SOP No.: _____</td><td>(1.3) Date of Issuance:<br>___ / ___ / ___</td><td colspan="2">(1.3) Effective Date:<br>___ / ___ / ___</td></tr>
<tr><td>(1.4) REV.: _____</td><td colspan="3">(1.5) PROCEDURE TO BE PERFORMED:</td></tr>
<tr><td colspan="4">(1.6) PERSON(S) RESPONSIBLE:</td></tr>
<tr><td colspan="4">(1.7) NECESSARY MATERIALS AND RESOURCES:</td></tr>
<tr><td colspan="4">(1.8) STEP-BY-STEP DESCRIPTION OF THE PROCEDURE:</td></tr>
<tr><td colspan="4">(1.9) OBSERVATIONS:</td></tr>
<tr><td colspan="4">(1.10) REFERENCES:</td></tr>
<tr><td>(1.11) PREPARED BY:</td><td>(1.11) REVIEWED BY:</td><td colspan="2">(1.11) APPROVED BY:</td></tr>
</table>

**Figure 2**
Standard SOP template

– Do not mix different cleaning or disinfectant products in the same solution.
– Follow the correct direction when cleaning.

### *1.10 References*

List the references consulted.

For example:

– BRAZIL. Agência Nacional de Vigilância Sanitária. Segurança do Paciente em Serviços de Saúde – Higienização das mãos. Brasília, 2009. Available from: www.gov.br. Accessed on May 21 2021.
– BRAZIL. Agência Nacional de Vigilância Sanitária. Segurança do Paciente em Serviços de Saúde – Limpeza e Desinfecção de Superfícies. Brasília, 2010. Available from: www.gov.br. Accessed on May 21 2021.
– Práticas Recomendadas SOBECC/Sociedade Brasileira de Enfermagem de Centro Cirúrgico, Recuperação Anestésica e Centro de Material e Esterilização. 5th ed. São Paulo: SOBECC; 2009.

### *1.11 Prepared by/Reviewed by/Approved by*

Enter the full name and signature of the professional(s) responsible for the preparation, review, and approval of the SOP.

Below are several SOPs approved by the Municipal Health Surveillance Agency of Belo Horizonte, provided as templates for the development of your practice's SOPs. It is important to note that each health care facility has its own procedures and protocols. These examples are meant to serve only as suggestions. Health inspectors will verify the accuracy of each SOP based on the practice's actual activities.

**SOP samples for CFM/ASBAI Group 3 Allergy & Immunology offices, drafted by the Coordinator of the Statute, Regulations, and Standards Commission of ASBAI in the city of Belo Horizonte, Minas Gerais, Brazil**

## SOP No. 1 – Date: __/__/__ – Revision: __/__/__

### Procedure

**Hand hygiene**.

### Person(s) responsible

All staff members.

### Objectives

– "Hand hygiene" refers to any action taken to clean the hands with the purpose of preventing the transmission of microorganisms and thereby reducing the risk of acute respiratory infections (ARIs) among patients and health care workers.

### Indications for hand hygiene

Hands must be cleaned at key points during patient care, in order to prevent ARIs caused by cross-transmission through hands.

– Before and after touching a patient, contaminated item, or surface.
– Before and after exposure to body fluids (eg, blood, secretions, or excretions).
– After contact between patients, between procedures, or whenever there is a risk of pathogen transfer.
– Between procedures on the same patient when there is a risk of cross-infection between different anatomical sites.
– Before and after using gloves.

### Necessary materials

– Sink suitable for hand hygiene.
– Liquid soap dispenser.
– Paper towel.
– Trash bin.

### Main activities

– Remove jewelry from hands and forearms, if worn.
– Turn on the tap and wet hands without touching the sink.
– Apply a sufficient amount of liquid soap to the palm.
– Lather hands by rubbing them together with the soap.
– Lather the back of each hand with the opposite palm.
– Lather between fingers.
– Rub back of fingers back and forth against the opposite palms.
– Rub each thumb clasped in opposite hand in a circular motion.
– Rub tips of fingers and nails in opposite palm in a circular motion.
– Rub each wrist with opposite hand in a circular motion.
– Rinse hands thoroughly to remove soap residue.
– Avoid direct hand contact with the faucet. Use a paper towel to turn it off.
– If the tap needs to be reopened, use a paper towel to do so.
– Dry hands with a paper towel, starting from the hands and moving to the wrists.
– Discard the paper towel in a trash bin for general waste.

### Observations

Use liquid soap and water when:

– Hands are visibly dirty, stained with blood or other body fluids, and after using the bathroom.
– When exposure to spore-forming pathogens is suspected or confirmed, including *C. difficile* outbreaks.
– In situations where alcohol-based hand sanitizer is unavailable.

The use of gloves does not replace hand hygiene. The hand-washing procedure must be performed both before and after glove use.

**References**

– Brazil. Ministério da Saúde. Protocolo para prática de higiene das mãos em serviços de saúde [Internet]. Elaborado pela Equipe técnica da ANVISA. Brasília, 2013. Available from: www.gov.br. Accessed on May 21 2021.

– Stacciarini TSG. Procedimentos Operacionais Padrão em Enfermagem. Uberaba: Universidade Federal do Triângulo Mineiro; 2011.

– Brazil. Ministério do Trabalho e Emprego. Portaria n° 485 de 11 de novembro de 2005. Norma Regulamentadora nº 32 (NR32): Segurança e Saúde no Trabalho em Estabelecimentos de Saúde. Available from: www.gov.br. Accessed on May 21 2021.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified)

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 2 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Hand rubbing with 70% alcohol gel**.

**Person(s) responsible**

All staff members.

**Objective**

– Remove transient skin flora, ensuring safe health care delivery for all patients.

**Necessary materials**

– 70% alcohol-based hand rub (ABHR) dispenser.

– A bottle of 70% alcohol (INPM).

**Indications for hand rubbing**

– Before touching a patient.

– Before an aseptic procedure.

– After body fluid exposure risk.

– After touching a patient.

– After touching a patient's surroundings.

**Main activities**

– Remove jewelry from wrists and forearms, if worn.

– Apply enough ABHR to cover all hand surfaces.

– Rub hands palm to palm.

– Rub back of each hand with palm of other hand with fingers interlaced.

– Rub palm to palm with fingers interlaced.

– Rub back of fingers with opposing palms with fingers interlocked.

– Rub each thumb clasped in opposite hand in a circular motion.

– Rub tips of fingers and nails in opposite palm in a circular motion.

– Rub each wrist with opposite hand in a circular motion.

– Rub until hands feel dry. Do not use paper towels.

**Observations**

– Hand rubbing should last 20 to 30 seconds for maximum effectiveness.

– Hand rubbing with 70% alcohol gel or ABHR may replace hand hygiene with soap and water when hands are not visibly dirty, when the procedure has a low risk of infection, and in emergency situations or when physical infrastructure is limited.

– All 70% alcohol containers must be labeled with the date of opening and expiration date according to the manufacturer.

**References**

– Brazil. Ministério da Saúde. Protocolo para prática de higiene das mãos em serviços de saúde. Elaborado pela Equipe técnica da ANVISA. Brasília, 2013. Available from: www.gov.br. Accessed on May 21 2021.

– Brazil. Ministério do Trabalho e Emprego. Portaria n° 485 de 11 de novembro de 2005. Norma Regulamentadora nº 32 (NR32): Segurança e Saúde no Trabalho em Estabelecimentos de Saúde. Available from: www.gov.br. Accessed on May 21 2021.
– Brazilian National Health Surveillance Agency – Anvisa. Medidas de Prevenção de Infecção Relacionada à Assistência à Saúde/Agência Nacional de Vigilância Sanitária – Brasília: Anvisa, 2017. Available from: www.gov.br. Accessed on May 21 2021.
– Higienização das Mãos em Serviços de Saúde (inclui preparação alcoólica). Portal Anvisa, 2017. Available from: www.portal.avisa.gov.br. Accessed on May 21 2021.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 3 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Use of Personal Protective Equipment (PPE).**

**Person(s) responsible**

Administrative assistant, general services assistant, receptionist, nurse, and physician.

**Objective**

– Ensure that all staff are adequately protected from workplace-related environmental and occupational hazards in situations where it is not possible to completely eliminate or reduce exposure.

**Necessary materials**

– Gown: protects clothing and skin.
– Cap: prevents hair and scalp exposure to organic matter and chemicals; also limits shedding into the environment.
– Surgical mask: protects the oronasal mucosa and prevents respiratory secretion contamination of the environment.
– Disposable or long-cuff gloves: protect skin from biological and chemical exposure. Long cuffs are required when forearm exposure is expected.
– Safety goggles: protect the ocular mucosa. Must be made of acrylic material that does not impair vision, fits well to the face, and provides lateral protection. Its use is recommended during mechanical cleaning of instruments and materials (disinfection).
– Closed-toe shoes: protect the skin in environments with moisture or significant amounts of infectious material (eg, operating rooms, waste disposal areas, sterilization centers, autopsy areas, and during environmental cleaning).

**Training and education**

**Frequency:**

– Every 6 months or when regulatory updates occur regarding PPE use.

**The employer must:**

– Train and educate staff in cleaning and disinfecting environments and instruments.
– Train and educate staff on appropriate PPE use based on needs and tasks.
– Promote employee awareness of the occupational risks to which they are exposed daily through accessible theoretical and practical training.

**The employee must:**

– Follow all training and instructions.

**Responsibilities**

***Employer***

– Provide employees only with PPE approved by the Ministry of Labor (PPE with Certificate of Approval).

– Instruct and train employees on the adequate use, storage, and maintenance of PPE.
– Maintain a sufficient stock of PPE to meet demand.
– Immediately replace PPE when damaged or missing.
– Provide and enforce the mandatory use of PPE during work activities.

***Employees***

– Use PPE only for its intended purpose.
– Take responsibility for the care, storage, and cleaning of their PPE.
– Notify the Technical Supervisor if the PPE becomes damaged or unsafe for use.
– Comply with all employer instructions on adequate PPE use.

**References**

– NR 6 - Equipamentos de proteção individual. Available from: www.gov.br. Accessed on October 2022.
– Oliveira AC. Infecções Hospitalares: epidemiologia, prevenção e controle. 1st ed. Rio de Janeiro: Guanabara Koogan; 2005. p.70-5.
– Posso MBS. Semiologia e Semiotécnica de Enfermagem. 2nd ed. São Paulo: Atheneu; 2005. p. 18-28.

**Actions in case of noncompliance**

– Report to the clinic's Technical Supervisor in case of inadequate use, damage, or need for replacement of PPE.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Technical Supervisor (Physician).

**SOP No. 4 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Labeling of disposable dispensing bottles**.

**Person(s) responsible**

Administrative assistant and nurse.

**Objective**

– Prevent contamination of fractionated solutions and ensure safe, harm-free care.

**Necessary materials**

– Alcohol dispensers.
– Labels for filling/expiration dates.
– Ballpoint pen.

**Main activities**

– Wash hands.
– Gather the alcohol dispensers to be used.
– Upon opening or refilling disposable dispensers:
– Label the dispenser with the substance name (70% alcohol) and the filling/opening date, using a ballpoint pen.
– The expiration period is 7 (seven) days from the date of filling or opening.
– Inspect all dispensers every Monday, checking expiration dates.
– If dispensers are expired and disposable, they must be discarded.

**Special measures**

– At the start of each workday, check all dispensers.
– The expiration period is 7 (seven) days from the date of filling or opening.

**Actions in case of noncompliance**

– If noncompliance is identified, immediately notify the clinic's Technical Supervisor.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Technical Supervisor (Physician).

**SOP No. 5 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Spirometry**.

**Person(s) responsible**

Nurse and physician.

**Definition**

Spirometry, also known as pulmonary function test or ventilatory function test, is a diagnostic test used to assess the volume and speed of airflow that a person can inhale and exhale using a spirometer.

**Objective**

– Spirometry is used to diagnose or monitor the progression of pulmonary diseases and evaluate the patient's lung capacity, indicating whether their air intake is sufficient to meet their physiological needs.

**Necessary materials**

– 70% ethyl alcohol (INPM).
– PPE (disposable gown, N95 mask, gloves).
– Disposable mouthpiece.
– Disposable pulmonary function filter.
– Paper towel.
– Bronchodilator (per medical prescription).
– Calibrated scale.
– Sphygmomanometer and stethoscope.
– Computer with spirometry software.
– Spirometer.
– Blue pen.
– Letterhead A4 paper.
– Printer.

**Procedure description**

1. Call the patient, confirm their name, and introduce and explain the procedure.
2. Check medical prescription.
3. Confirm that pretest instructions were followed.
4. Prepare and calibrate the spirometer (computer) and check parameters against technical standards (Brazilian Society of Pulmonology and Phthisiology).
5. Take anthropometric measurements.
6. Perform hand hygiene (per SOP No. 1).
7. Don gloves, disposable gown, and N95 mask.
8. Prepare and instruct the patient.
9. Have the patient sit for 5-10 minutes, then breathe into the mouthpiece attached to the spirometer.
10. Instruct the patient to breathe calmly for a short period.
11. Instruct the patient to breath in completely and exhale as forcefully and quickly as possible, then repeat the maneuver 3 times.
12. Administer the prescribed bronchodilator inhaler and have the patient wait 15 minutes at rest.
13. Repeat the spirometry test.
14. Deliver test results to the patient.
15. Dispose of used materials in the appropriate trash cans; reusable items should be sent for decontamination with enzymatic detergent.
16. Doff gloves and wash hands (per SOP No. 1)
17. Document the nursing notes and make a record of the procedure.
18. Keep the workspace clean and organized.

**Observations**

– The patient should rest for 5 to 10 minutes before the test.
– Fasting is not required.
– The patient must not drink tea or coffee during the 6 hours before the test.
– The patient must not drink alcohol during the 4 hours before the test.
– The patient must suspend use of short-acting (eg, salbutamol) and long-acting (eg, tiotropium) bronchodilators for 4 hours and 10 hours before the test, respectively.
– The patient must not smoke for at least 2 hours before the test.
– The patient should refrain from eating a large meal at least 1 hour before the test.

**References**

- Conselho Federal de Enfermagem. Resolução n° 545/2017. Anotação de Enfermagem e Mudança nas Siglas das Categorias Profissionais. Available from: http://www.cofen.gov.br/wp-content/uploads/2017/05/Resolu%C3%A7%C3%A3o-545-17.pdf. Accessed on Oct 5 2020.
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**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 6 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Cleaning of office cabinets**.

**Person(s) responsible**

General services assistant.

**Objective**

- Standardize the cleaning procedure for office cabinets, in order to prevent dirt accumulation and the proliferation of microorganisms.

**Necessary materials**

- PPE (gloves, mask, safety goggles, gown, neutral soap).
- Water.
- Quaternary ammonium solution.
- Procedure gloves.
- Bucket.
- 70% ethyl alcohol (INPM).
- Clean cloth.

**Procedure description**

- Wash hands.
- Don procedure gloves.
- Gather all required materials.
- Remove all items from inside the cabinet before starting.
- Wipe the cabinets with a damp cloth beforehand to make cleaning with water and neutral soap easier.
- Scrub the entire cabinet with a cloth soaked in quaternary ammonium solution.
- Use a clean cloth to remove excess disinfectant.
- Dry the entire cabinet with a clean cloth.
- Scrub the entire cabinet with 70% alcohol.
- Allow to air dry.
- Dispose of used cleaning cloths appropriately.
- Return items to the cabinet in an organized manner after drying.
- Doff gloves.
- Wash hands.
- Complete the cleaning log for record keeping.

**Special measures**

- Cleaning should be conducted once a week, or whenever necessary.
- All items must be removed from inside the cabinet before cleaning and only returned after completion.

**Actions in case of noncompliance**

- If the cleaning log is nearly full, notify the clinic's secretary to request more copies.
- For other instances of noncompliance, notify the clinic's Technical Supervisor so appropriate action can be taken.

**References**

– Brazil. Agência Nacional de Vigilância Sanitária. Segurança do paciente em serviços de saúde: limpeza e desinfecção de superfícies/Agência Nacional de Vigilância Sanitária. Brasília: Anvisa, 2010. Available from: www.gov.br. Accessed on May 21 2021.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Technical Supervisor (Physician).

**SOP No. 7 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Cleaning of office counters, armchairs, and chairs**.

**Person(s) responsible**

Receptionist, assistant, and general services assistant.

**Objective**

– Standardize the cleaning procedure for office counters, armchairs, and chairs, in order to prevent the proliferation of microorganisms.

**Necessary materials**

– Water.
– Liquid soap.
– Procedure gloves.
– Bucket.
– 70% ethyl alcohol (INPM).
– Disposable cleaning cloth.

**Main activities**

– Wash hands.
– Don procedure gloves.
– Gather all required materials.
– Remove all items from the counters before starting.
– Wipe down counters with a damp cloth to make cleaning easier.
– Rub all counters with a cloth dampened with liquid soap.
– Use a clean cloth to remove soap residue.
– Dry all counters with a clean cloth.
– Rub all counters with 70% alcohol in a unidirectional manner.
– Allow to air dry.
– Rub armchairs and chairs with 70% alcohol.
– Allow to air dry.
– Dispose of used cleaning cloths appropriately.
– Doff gloves.
– Wash hands.
– Complete the cleaning log for record keeping.

**Special measures**

– Cleaning should be performed at the end of each day, or whenever necessary.
– All items must be removed from the counters before cleaning and only returned after completion.

**Actions in case of noncompliance**

– Notify the clinic's Technical Supervisor.

**References**

– Brazil. Agência Nacional de Vigilância Sanitária. Segurança do paciente em serviços de saúde: limpeza e desinfecção de superfícies. Brasília: Anvisa, 2012.
– Fernandes AT. Infecção hospitalar e suas interfaces na área da saúde. São Paulo: Atheneu; 2000.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Technical Supervisor (Physician).

**SOP No. 8 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Cleaning of office windows, doors, and light switches**.

**Person(s) responsible**

General services assistant.

**Objective**

– Standardize the cleaning procedure for office windows, doors, and light switches, in order to prevent the proliferation of microorganisms.

**Necessary materials**

– Water.
– Neutral soap.
– Dedicated cleaning sponge.
– Two buckets.
– PPE (gloves, safety goggles, closed-toe shoes).
– Cleaning cloth.
– Quaternary ammonium solution.

**Main activities**

– Wash hands.
– Don PPE.
– Gather all required materials.
– Prepare the environment by moving furniture and equipment away from windows and walls.
– Fill both buckets halfway – one with clean water and the other with water and soap.
– Dampen a cloth with clean water, wring it out, and remove dust from surfaces using top-to-bottom and left-to-right motions.
– Dampen another cloth with soapy water, wring it, and clean glass surfaces, window and door frames, windowsills, and doorknobs.
– Use a third cloth dampened with clean water to remove any quaternary ammonium solution residue from windows and doors.
– Check if windows and doors are clean; if needed, repeat the process.
– Always dry windows and doors using a dry cleaning cloth.
– Remove any cloth placed beneath doors and windows.
– Return all furniture and equipment to their original positions.
– Clean all materials used and store them appropriately.

**Special measures**

– Cleaning should be conducted once a day, preferably at the end of the workday, or whenever necessary.
– All items must be moved before cleaning and only returned to their original place after completion.

**Actions in case of noncompliance**

– In case of noncompliance, notify the clinic's Technical Supervisor so appropriate action can be taken.

**References**

– Brazil. Agência Nacional de Vigilância Sanitária. Segurança do paciente em serviços de saúde: limpeza e desinfecção de superfícies. Brasília: Anvisa, 2012. Available from: www.gov.br. Accessed on May 21 2021.
– Fernandes AT. Infecção hospitalar e suas interfaces na área da saúde. 1st ed. São Paulo: Atheneu; 2000. 1706-21.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Technical Supervisor (Physician).

**SOP No. 9 – Date: __/__/__ Revision: __/__/__**

**Procedure**

**Disinfection of the anthropometric scale**.

**Person(s) responsible**

Receptionist, assistant, and general services assistant.

**Objective**

– Disinfect anthropometric scales to help prevent the spread of disease.

**Necessary materials**

– PPE (gloves, cap, safety goggles, and safety mask).
– 70% alcohol.
– Cleaning cloth.

**Main activities**

– Perform hand hygiene.
– Don listed PPE.
– Wipe the entire surface of the scale using a cloth soaked in 70% alcohol, using unidirectional movements.
– Allow to air dry.

**Observations**

– Disinfection of the anthropometric scale should be performed daily, or whenever necessary.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Technical Supervisor (Physician).

**SOP No. 10 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Cleaning of office floors**.

**Person(s) responsible**

Receptionist, assistant, and general services assistant.

**Objective**

– Standardize the cleaning procedure for office floors in order to prevent the proliferation of microorganisms.

**Necessary materials**

– Water.
– Neutral soap.
– Quaternary ammonium solution.
– Broom.
– Squeegee.
– Bucket.
– PPE (gloves, safety goggles, closed-toe shoes).
– Cleaning cloth.

**Main activities**

– Wash hands.
– Don PPE.
– Gather all required materials.
– Wash ceramic floors with water and neutral soap, using a broom to scrub the entire floor.
– Remove excess water and soap using a squeegee and damp cloth.
– Dry the floor using a clean cloth.
– Afterwards, use a cloth dampened with quaternary ammonium solution to clean the entire floor again to remove remaining dirt.
– Dry the floor using a dry cloth.
– Rinse the cloth in a bucket with clean water and reapply quaternary ammonium solution.

**Special measures**

– Cleaning should be performed once a day, preferably at the end of the workday, or whenever necessary.
– All items must be removed before cleaning and only returned after completion.

**Actions in case of noncompliance**

– In case of noncompliance, notify the clinic's Technical Supervisor so appropriate action can be taken.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Technical Supervisor (Physician).

**SOP No. 11 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Cleaning of waste bins**.

**Person(s) responsible**

Receptionist, assistant, and general services assistant.

**Objective**

– Standardize the cleaning procedure for waste bins in order to prevent the proliferation of microorganisms and maintain a safe work environment.

**Necessary materials**

– Water.
– Neutral soap.
– Cleaning sponge.
– PPE (gloves, safety goggles, gown, cap, and mask).
– Cleaning cloth.
– Quaternary ammonium solution.

**Main activities**

***General waste bin***

– Wash hands.
– Don PPE.
– Gather all required materials
– Begin cleaning with neutral soap, rubbing in a back-and-forth motion until the entire surface is clean.
– Rinse with water to remove all soap residue from the bin's surface.
– Disinfect the entire surface using quaternary ammonium solution, then wipe off the solution with a damp cloth.
– Rinse with a dry cloth and, once completely dry, insert a waste bag labeled for general waste.

***Biohazard waste bin***

– Wash hands.
– Don PPE.
– Gather all required materials.
– Pour quaternary ammonium solution into the interior of the bin and let it sit for 10 minutes.
– Begin cleaning with neutral soap, rubbing in a back-and-forth motion until the entire surface is clean.
– Rinse with water to remove all soap residue from the bin's surface.
– Disinfect the entire surface using quaternary ammonium solution, then wipe off the solution with a damp cloth.
– Rinse with a clean cloth and, once the bin is completely dry, insert a waste bag labeled for biological waste.

**Special measures**

– Cleaning should be conducted once a week, or whenever necessary.
– Waste must be removed before cleaning the bins.

**Actions in case of noncompliance**

– In case of noncompliance, notify the clinic's Technical Supervisor so appropriate action can be taken.

**References**

– Brazil. Agência Nacional de Vigilância Sanitária. Segurança do paciente em serviços de saúde: limpeza e desinfecção de superfícies. Brasília: Anvisa, 2012. Available from: www.gov.br. Accessed on May 21 2020.
– Fernandes AT. Infecção hospitalar e suas interfaces na área da saúde. 1st ed. São Paulo: Atheneu; 2000. p. 1706-21.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Technical Supervisor (Physician).

**SOP No. 12 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Cleaning of the refrigerator and cold box**.

**Person(s) responsible**

Receptionist.

**Objective**

– Standardize the cleaning procedure for the refrigerator and cold box, in order to prevent microbial proliferation and avoid potential contamination of biologics.

**Necessary materials**

– PPE (gloves, safety goggles, and mask).
– Neutral soap.
– 70% alcohol.
– Disposable cleaning cloth.
– Neutral detergent.
– Water.

**Main activities**

– Perform hand hygiene.
– Don listed PPE.

**Internal cleaning of the refrigerator**

– Turn off the equipment and unplug it.
– Remove gel packs and biologics from the refrigerator and place them in a cold box (as outlined in the specific SOP) until cleaning is complete.
– Carefully remove each drawer and place them in a clean, dry area.
– Use a dry, clean cloth only. No cleaning products should be used inside the refrigerator, as per the manufacturer's recommendations.
– Begin cleaning from the top to the bottom, using slow movements.
– Once complete, return the drawers, plug the refrigerator back in, and wait 30 minutes before returning the contents.
– Perform internal cleaning every 3 months, or whenever necessary.

**External cleaning of the refrigerator**

– Turn off the equipment and unplug it.
– Use a solution of water and neutral detergent only (do not use solvents or chemical products).
– Wipe down the exterior with a soft cloth dampened with the detergent solution, followed by a dry cloth to remove moisture.
– Remove drawers and shelves and clean them in the same manner.
– External cleaning should be performed every 3 months, or whenever necessary.

**Refrigerator disinfection**

– Switch off the main circuit and unplug the refrigerator.
– Follow the standard cleaning procedure as described above.
– Wipe all internal and external surfaces with a soft cloth dampened with 70% alcohol.
– Disinfection should be performed every 3 months, or whenever a spill of contaminated material occurs.

**Cleaning the cold box**

– Clean the cold box with neutral detergent.
– Rub the entire internal surface and remove detergent residue with a damp cloth, then dry using a clean disposable cloth.
– Always clean before and after each use.

**Observations**

– The refrigerator must be used exclusively for storing vaccines. It is strictly prohibited to store food, beverages, or any materials other than biologics.
– Vaccine vials and ampoules should preferably be placed in vial trays on shelves to allow for adequate cold air circulation.
– Store vaccines in their original packaging, leaving two-finger spacing between them and maintaining distance from the refrigerator wall to ensure airflow.
– Vaccines nearing expiration should be placed at the front to be used first.
– If a power failure occurs, take the necessary measures as quickly as possible to restore normal operation:
– Check the temperature immediately.
– If necessary, place biologics and gel packs in a cold box at +2 °C to +8 °C.
– Determine how long the refrigerator was off.
– If changes in temperature are found or vaccine integrity is compromised, segregate the affected vaccines and contact the regional health authority for guidance.
– In all the situations described above, notify the clinic's Technical Supervisor for adequate action.

**Note**

Refrigerator maintenance is performed every 3 months by a third-party service provider.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 13 – Date: __/__/__ Revision: __/__/__**

**Procedure**

**Disinfection of shared toys**.

**Person(s) responsible**

Receptionist, assistant, general services assistant.

**Objective**

– Disinfect shared toys to help prevent the spread of microorganisms.

**Necessary materials**

– PPE (gloves).
– Paper towel.
– 70% ethyl alcohol.
– Hair cap.
– Water and neutral soap.

**Main activities**

– Wash hands.
– Don listed PPE.
– If toys are visibly dirty, wash them with water and neutral soap.
– Soak a paper towel in 70% alcohol and rub the entire surface of each toy, repeating the motion 3 times over the entire area.
– Allow toys to air dry naturally.

**Observations**

– Toy disinfection should be performed at the end of each day, or whenever necessary.
– If the toy is visibly dirty, clean thoroughly with water and neutral soap, using a soft-bristle brush to scrub all surfaces.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 14 – Date: __/__/__ Revision: __/__/__**

**Procedure**

**Cleaning and disinfecting the peak flow meter**.

**Person(s) responsible**

Receptionist or assistant.

**Objective**

– Standardize the procedure for cleaning and disinfecting peak flow meters used in clinical examinations.

**Necessary materials**

– PPE (cap, mask, safety goggles, gloves, and gown).
– Diluted enzymatic detergent solution (per SOP No. 5).
– Cleaning brushes.
– Clean disposable cloth.
– Immersion container.
– 70% alcohol.

**Main activities**

– Wash hands.
– Don listed PPE.
– Collect the used peak flow meters from the examination rooms.

- Immerse the devices in the enzymatic detergent solution for 5 minutes, as per the manufacturer's recommendations.
- After soaking, manually clean the peak flow meters by brushing the lumen and the internal and external surfaces 3 times with a cleaning brush.
- Afterwards, rinse thoroughly under running water until all enzymatic detergent and visible dirt are removed.
- Use a clean cloth to assist with drying.
- Check if the peak flow meters are functioning and fully clean using a magnifying glass.
- Wipe the entire internal and external surfaces with a disposable cloth soaked in alcohol and allow to air dry naturally.
- After disinfection, place the cleaned peak flow meters in a labeled container with a lid marked "Clean material" and return them to the appropriate rooms.
- It is recommended to clean all peak flow meters once a week, even if they have not been used.

**Special measures**

- Used peak flow meters should be stored in lidded containers and collected twice daily (at 12:00 PM and 4:00 PM) for cleaning and disinfection.
- Before using in a patient, the physician should disinfect the cleaned device again with 70% ethyl alcohol across all surfaces.
- After use, the physician must place the peak flow meter into a transparent, lidded container labeled "Contaminated material."

**Actions in case of noncompliance**

- In case of noncompliance, immediately notify the clinic's Technical Supervisor.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 15 – Date: __/__/__ Revision: __/__/__**

**Procedure**

**Cleaning of air conditioning units**.

**Person(s) responsible**

General services assistant.

**Objective**

- Ensure compliance with occupational safety standards.
- Maintain the workspace clean and well-organized.

**Necessary materials**

- PPE (rubber gloves).
- Bucket with clean water.
- Bucket with water and neutral detergent.
- Clean cloths.
- Ladder.

**Main activities**

- Wash hands.
- Don listed PPE.
- Gather all required materials.
- Fully turn off the air conditioning unit and unplug it, if applicable.
- Remove the air filter. If the filter is torn or damaged, it must be replaced by the contracted maintenance company.
- Clean the air filter in the cleaning supply storage room by immersing it in water with detergent and performing manual cleaning, according to the manufacturer's recommendations (person responsible: contracted maintenance company).
- Clean the plastic front panel and visible external surfaces using a soft cloth lightly dampened with detergent solution (person responsible: general services assistant).

**Special measures**

- Cleaning should be performed once every 2 months, or whenever necessary.
- Never apply detergent, alcohol, or water directly onto the plastic front panel of the unit.
- Wait for the air filter to be completely dry before reinserting it into the unit.

– Do not plug the unit back in with wet or damp hands.
– This procedure does not replace preventive maintenance, which must be performed strictly according to the manufacturer's recommendations.

**Actions in case of noncompliance**

– In case of noncompliance, notify the clinic's Technical Supervisor so appropriate action can be taken.

For example:

Air conditioning company _____

Address: _____

Phone: _____

E-mail: _____

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 16 – Date: __/__/__ Revision: __/__/__**

**Procedure**

**Cleaning and disinfecting otoscope specula**.

**Person(s) responsible**

Physician, receptionist, and assistant.

**Objective**

– Standardize the procedure for cleaning and disinfecting otoscope specula used in clinical examinations.

**Necessary materials**

– PPE (cap, mask, safety goggles, gloves, and gown).
– Prime Clear Spray.
– Clean disposable cloth.
– Immersion container.
– Enzymatic detergent.
– 70% ethyl alcohol (INPM).
– Small brush suitable for internal cleaning of the specula.

**Main activities**

***Physician***

– Wash hands before and after the procedure.
– Don gloves.
– Spray Prime Clear on otoscope specula immediately after use and place them into the designated container.

***Receptionist and assistant***

– Wash hands.
– Don listed PPE.
– Collect used otoscope specula from the examination rooms.
– Immerse the specula in the enzymatic detergent solution for 5 minutes, according to the manufacturer's recommendations.
– After soaking, manually clean the specula by brushing the lumen and the internal and external surfaces 3 times with a cleaning brush.
– Afterwards, rinse thoroughly under running water until all enzymatic detergent and visible dirt are removed.
– Use a clean cloth to assist with drying.
– Check if the specula are functioning and fully clean.
– Wipe the entire internal and external surfaces with a disposable cloth soaked in alcohol and allow to air dry.
– After disinfection, place the cleaned specula in a labeled container with a lid marked "Clean material" and return them to the appropriate medical rooms.
– Specula should be cleaned once a week, even if they have not been used.

**Special measures**

– Used specula should be sprayed with Prime Clear immediately after use to prevent biofilm formation.
– Avoid prolonged skin contact with Prime Clear. Always wash and dry hands after use.

– Before using a clean speculum on a patient, the physician should disinfect it again with 70% ethyl alcohol over the entire surface.

**Actions in case of noncompliance**

– In case of noncompliance, immediately notify the clinic's Technical Supervisor.

**References**


– Brazil. Agência Nacional de Vigilância Sanitária. Segurança do paciente em serviços de saúde: limpeza e desinfecção de superfícies. Brasília: Anvisa, 2012. Available from: www.gov.br. Accessed on May 21 2021.
– Fernandes AT. Infecção hospitalar e suas interfaces na área da saúde. 1st ed. São Paulo: Atheneu; 2000. p.1706-21.
– Ficha Técnica do PRIME CLEAR. Solução pré-limpeza. Produto cadastrado na ANVISA: Processo: 25351.542696/2014-00. Empresa Indalabor Indaiá Laboratório Farmacêutico Ltda. Available from: www.indalabor.com.br. Accessed on May 23 2021.


**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 17 – Date: __/__/__ Revision: __/__/__**

**Procedure**

**Cleaning and disinfecting nasal specula**.

**Person(s) responsible**

Receptionist and assistant.

**Objective**

– Standardize the procedure for cleaning and disinfecting nasal specula used during clinical examinations.

**Necessary materials**

– PPE (cap, mask, safety goggles, gloves, and gown).
– Nasal speculum.
– Prime Clear Spray.
– Cleaning brushes.
– Enzymatic detergent.
– Clean disposable cloth.
– 70% ethyl alcohol.
– Immersion container.

**Main activities**

***Physician***

– Wash hands before and after the procedure.
– Don gloves.
– Spray Prime Clear on the nasal speculum immediately after use and place it into the designated container.

***Receptionist and assistant***

– Wash hands.
– Don listed PPE.
– Collect used nasal specula from the examination rooms.
– Immerse the specula in the enzymatic detergent solution for 5 minutes, according to the manufacturer's recommendations.
– After soaking, manually clean the specula by brushing the handle and internal and external surfaces 3 times with a cleaning brush.
– Afterwards, rinse thoroughly under running water until all enzymatic detergent and visible dirt are removed.
– Use a clean cloth to assist with drying.
– Check if the specula are functioning and fully clean.
– Wipe the entire internal and external surfaces and the handle with a disposable cloth soaked in alcohol and allow to air dry.
– After disinfection, place the cleaned specula in a labeled container with a lid marked "Clean material" and return them to the appropriate medical offices.
– Specula should be cleaned once a week, even if they have not been used.

**Actions in case of noncompliance**

– In case of noncompliance, immediately notify the clinic's Technical Supervisor.

**References**


– Brazil. Agência Nacional de Vigilância Sanitária. Segurança do paciente em serviços de saúde: limpeza e desinfecção de superfícies. Brasília: Anvisa, 2012. Available from: www.gov.br. Accessed on May 21 2021.
– Fernandes AT. Infecção hospitalar e suas interfaces na área da saúde. 1st ed. São Paulo: Atheneu; 2000. p.70-75.
– Ficha Técnica do Prime Clear. Solução pré-limpeza. Produto cadastrado na ANVISA: Processo: 25351.542696/2014-00. Empresa Indalabor Indaiá Laboratório Farmacêutico Ltda. Available from: www.indalabor.com.br. Accessed on May 23 2021.


**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 18 – Date: __/__/__ Revision: __/__/__**

**Procedure**

**Organize the cold box**.

**Person(s) responsible**

Nurse and physician.

**Objective**

– Maintain stable temperatures between +2 °C and +8 °C, ensuring the quality of stored products.

**Necessary materials**

– Digital thermometer.
– Cold box.
– Gel ice packs.
– Allergen extracts and biologics.
– Disposable cups.
– PPE (disposable gloves and mask).

**Main activities**

– Wash hands (per SOP No. 1).
– Don listed PPE.
– Remove gel packs from the freezer and place them at the bottom of the cold box.
– Insert the thermometer, or its probe, into the cold box, depending on the type used.
– Close the lid of the cold box.
– Wait until the internal temperature reaches between +2 °C and +8 °C.
– Place allergen extracts and biologics into new disposable cups and arrange the cups on top of the gel packs.
– Check the cold box's temperature every 4 hours.
– If variations in temperature occur, remove biologics and extracts immediately.

**Observations**

– Ensure consistent temperature monitoring and adhere strictly to the reading schedule.
– Significant temperature variations must be reported to the clinic's Technical Supervisor for immediate corrective action.
– Avoid leaving the cold box open for extended periods to prevent fluctuations in temperature.
– The cold box should only be used in case of refrigerator temperature fluctuations or during refrigerator cleaning.
– Disinfect the cold box with 70% alcohol before and after each use.

**References**


– Brazil. Ministério da Saúde. Secretaria de Vigilância em Saúde. Departamento de Vigilância Epidemiológica. Available from: www.gov.br. Accessed on May 21 2021.
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**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 19 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Immediate-reading skin test (prick test)**.

**Person(s) responsible**

Board-certified physician (AMB- and ASBAI-certified).

**Objective**

– The prick test is performed to assess whether a patient has an allergic reaction to a specific substance by applying it to the skin and then puncturing it.

**Necessary materials**

– Tray.
– Allergen extracts.
– Sharps disposal container.
– Disposable pointed instrument (needle, plastic or stainless steel lancet).
– Cotton ball.
– 70% alcohol.

**Main activities**

– Perform hand hygiene.
– Choose the appropriate application site.
– Clean the site with 70% alcohol and apply one drop of each allergen extract to be tested.
– Maintain a minimum distance of 2 cm between drops and then gently puncture the drops with a pointed instrument (needle or lancet).
– The number of extracts tested depends on the patient's clinical needs and forearm size; both forearms may be used if necessary.
– Always include one positive control and one negative control.
– After 15 to 20 minutes, read results and evaluate for the presence of wheal formation indicative of an allergic reaction.
– Document the procedure in the patient's medical record.

**Special measures**

– Allergens tested may include dust mites, fungi, insects, animal dander, feathers, foods, and latex.
– It is important to inform patients that antihistamines, topical corticosteroids, and other medications can suppress allergic responses, possibly leading to false-negative results. These medications should ideally be discontinued 1 week before the test.

**Actions in case of noncompliance**

– In case of noncompliance, immediately notify the clinic's Technical Supervisor.

**References**

– Heinzerling LM, Burbach GJ, Edenharter G, Bachert C, Bindslev-Jensen C, Bonini S, et al. GA(2)LEN skin test study I: GA(2)LEN harmonization of skin prick testing: novel sensitization patterns for inhalant allergens in Europe. Allergy. 2009;64(10):1498-506.
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**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 20 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Skin contact allergy test (patch test)**.

**Person(s) responsible**

Physician or nurse.

**Objective**

– The patch test is used to assess allergic responses to certain allergens (substances that may trigger allergies). The test aims to reproduce a mild allergic reaction by deliberately exposing the patient to a minimal amount of allergens.

**Necessary materials**

– Hypoallergenic tape.
– Pen.
– Paper filter or plastic chambers.
– Allergen extracts.
– Cotton balls.
– Alcohol-ether solution.

**Main activities**

– Perform hand hygiene.
– Cut a 30-cm strip of hypoallergenic tape – enough to accommodate the 30 allergens to be tested.
– Number each allergen to be tested.
– Attach paper filters opposite each number on the strip.
– Once the patch test is prepared, apply one drop of each allergen onto its respective paper filter.
– Choose the application site (external side of the arm or upper back).
– Clean the site with alcohol-ether solution and let it air dry.
– Afterwards, apply the patch, ensuring full contact between the paper panel and the skin.
– The patch test must remain in place for 48 to 72 hours before the reading.
– Provide the patient with all test instructions.
– The number of allergens tested varies according to each case.
– Document the procedure in the patient's medical record before and after reading the results.

***On the day of reading***

– After 48 to 72 hours, instruct the patient to remove the patch test and place it in a plastic bag without folding it, to be returned to the physician.
– After removal, the patient should expose the tested area to sunlight for 15 minutes (back or outer arm).

**Special measures**

– The patient must not wet the patch test area during the test.
– Shortly before returning to the clinic, the patient should remove the patch test and expose the tested area to sunlight for 15 minutes. If sunlight is not available, instruct the patient to stand 10 cm from a television screen for the same amount of time.
– Instruct the patient not to wash the test site until the physician has completed the reading.
– If the patient experiences intense itching, they must inform the physician. If the discomfort is tolerable, they may wait until the scheduled consultation; otherwise, contact the clinic for guidance.
– It is important to inform patients that antihistamines, topical corticosteroids, and other medications can suppress allergic responses, possibly leading to false-negative results.

**Actions in case of noncompliance**

– In case of noncompliance, immediately notify the clinic's Technical Supervisor.

**References**

– Nettina SM. Brunner: prática de enfermagem. Vol. II. 7th ed. Rio de Janeiro: Guanabara Koogan; 2003.
– Smeltzer SC, Bare BG. Brunner & Suddarth: tratado de enfermagem médico-cirúrgica. Vol. III. 9th ed. Rio de Janeiro: Guanabara Koogan; 2002.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 21 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Monitoring of refrigerator temperature**.

**Person(s) responsible**

Receptionist and nurse.

**Objective**

– Maintain a stable temperature and ensure the quality and safety of stored products.

**Necessary materials**

– Digital refrigerator thermometer.
– Temperature monitoring spreadsheet (USB/digital format).

**Main activities**

– Review the temperature monitoring spreadsheet monthly.
– Check and record the refrigerator's temperature daily at 8:00 AM and 5:00 PM.
– Avoid keeping the refrigerator door open for extended or unnecessary periods.
– Maintain an internal temperature between +2 °C and +8 °C.

**Observations**

– **Significant temperature fluctuations must be reported to the clinic's Technical Supervisor for immediate corrective action.**
– Avoid leaving the refrigerator open for extended periods to avoid fluctuations in temperature.
– The refrigerator is equipped with an audible alarm that activates during temperature fluctuations. It also sends automatic alerts to the Clinic Administrator.
– The refrigerator has internal backup batteries with extended autonomy in case of power outages. In such situations, avoid opening the refrigerator and keep a cold box prepared with gel packs and a digital thermometer (+2 °C to +8 °C) for emergency use if needed.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 22 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Preventive and corrective maintenance of the refrigerator and automated external defibrillator (AED)**.

**Person(s) responsible**

Nurse, clinic administrator, and/or physician.

**Objectives**

– Ensure adequate functioning of critical clinic equipment (refrigerator and AED).
– Establish a maintenance schedule in partnership with equipment suppliers (attached).
– Maintain direct communication channels with the maintenance team for immediate support.

**Necessary materials**

– Maintenance service agreement.
– Maintenance scheduling calendar.
– Communication channels with maintenance teams (email, phone, messaging apps).
– Maintenance checklist.

**Main activities**

– Conduct scheduled preventive maintenance and corrective maintenance as needed.
– Contact the service provider for corrective maintenance if any functional issues arise.
– Complete the maintenance checklist.

**Procedure description**

– Welcome the technician upon arrival.
– Check if the visit is aligned with the scheduled date.
– Accompany the technician during the procedure.
– Request that the technician completes the maintenance form.
– Request preventive and/or corrective maintenance, including repairs or replacement of parts if necessary, ensuring prior quotation of both service and materials is provided.
– Request that the technician affix a maintenance label to the equipment (including the date of service, the technician's name, and the next scheduled maintenance date) and provide the invoice for the service performed.

**References**

– Brazil. Ministério da Saúde. Secretaria de Vigilância em Saúde. Departamento de Vigilância das Doenças Transmissíveis. Manual de Rede de Frio do Programa Nacional de Imunizações / Ministério da Saúde, Secretaria de Vigilância em Saúde, Departamento de Vigilância das Doenças Transmissíveis. 5th ed. Brasília: Ministério da Saúde, 2017. Available from: www.gov.br. Accessed on May 21 2021.

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**Observations: examples of contact information.**

1) Refrigerator manufacturer/maintenance:

_____

a) Address: _____

b) Telephone: _____

c) E-mail: _____

2) AED manufacturer/maintenance:

_____

a) Address: _____

b) Telephone: _____

c) E-mail: _____

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 23 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Crash cart and automated external defibrillator (AED) check.**

**Person(s) responsible**

Nurse and/or physician.

**Objectives**

– Organize medications, medical supplies, and the AED in the crash cart.
– Check all medications, supplies, and AED pads and properly discard any expired items.
– Check AED battery status weekly.
– Ensure patient safety during urgent and emergency situations.

**Necessary materials**

– Crash cart.
– Medications and medical supplies.
– AED and pads.
– Crash cart checklist.
– Ballpoint pen.

**Main activities**

– Organize medications, medical supplies, and the AED in the crash cart.
– Write down all medications on the checklist, including the beyond-use date and quantity.
– Highlight on the checklist any medications nearing expiration.
– Perform a full check monthly.

**Procedure description**

– Perform hand hygiene.
– Clean the crash cart and related equipment using nonsterile gauze soaked in 70% alcohol.
– Test laryngoscope and blades.
– Test the AED.
– Check all items against the checklist.
– Organize all supplies inside the crash cart according to clinic standards.

- Seal the crash cart after inspection.
- Label the seal with the date, time, seal number, and name of the inspector.
- Perform hand hygiene.
- Keep the workspace well-organized.
- Ensure the AED battery charger remains plugged into a power outlet, according to the manufacturer's recommendations.
- Recheck the checklist anytime the seal is broken.
- Open the crash cart and conduct a comprehensive check of the expiration dates and batch numbers of all materials and medications, either when a medication is to be used or during routine inspections.

### General observations (per Resolution RDC 44/2009)

- All medications must be stored in an organized manner, according to the manufacturer's recommendations, and under conditions that maintain their identity, integrity, quality, safety, efficacy, and traceability.
- The storage area must be spacious enough to allow organized storage of different medication categories.
- The storage area must be kept clean and protected from direct sunlight, humidity, and heat to preserve the chemical, physical, and microbiological integrity of the products, ensuring their quality and safety.
- Products should be stored on shelves, in drawers, or equivalent supports, kept off the floor, walls, and ceiling to allow for proper cleaning and inspection.
- Disposal of such products must follow specific health care waste management legislation, including any applicable state or municipal regulations.
- Medications must be stored in areas with restricted access to staff. Public access to these areas is strictly prohibited.

### AED observations

- The AED battery has a shelf life of five (5) years and must be kept charged.
- When the low battery indicator is triggered, the battery still holds enough charge for approximately 15 shocks or 30 minutes of monitoring.
- To replace the battery:
  1. Turn off the AED.
  2. Flip the AED upside down.
  3. Press the battery latch and remove the old battery pack.
  4. Insert the new battery until a "click" is heard.
  5. Turn the device back on and wait for the voice and display instructions until the message "Place the electrodes on the patient's chest" appears.
  6. Check the battery status on the bar graph indicator.
  7. Turn off the AED.
  8. Keep the charger connected to the AED and plugged into a power source until the AED is needed for use.

### Corrective maintenance

- The AED performs routine self-checks and alerts the operator if maintenance is required by displaying a warning and emitting voice prompts, as shown in Figure 3.

| Message | Required action |
|---|---|
| "Maintenance required. **Low battery**." | **Recharge** or **replace** the battery. |
| "Maintenance required. **Hardware failure**." | **Restart** the system. If the problem persists, **contact authorized technical support**. |

**Figure 3**
Warning messages for maintenance of the crash cart and AED

### Preventive maintenance

- The AED performs periodic self-checks, even when powered off. If the battery charge falls below 20% of its maximum capacity, the device emits an audible beep and visual warning, accompanied by voice and text prompts indicating the need for maintenance.

***AED cleaning***

- The AED and all its accessories must be cleaned after each use or when visibly dirty. All cleaning procedures should be performed at room temperature.
- Disconnect the battery charger from the power outlet.
- Gather the device and battery charger for cleaning.
- Use one cloth slightly dampened with neutral liquid soap and water, and another with 70% ethanol.
- Do not use abrasive agents, organic solvents, chlorine, or hydrocarbon-based products.
- Do not remove or damage the labels on the AED, accessories, or charger – they are essential for identification and safety.
- Wipe the external surface of the device and charger using the soapy cloth.
- Disinfect the same surfaces with the ethanol-soaked cloth.
- Use a dry washcloth to clean the display or, if necessary, a lightly dampened cloth to remove dust and debris.

***AED testing***

- Turn on the AED.
- Check the battery level on the display. If it is low, recharge immediately.
- Wait for the voice and display instructions until the message “Place the electrodes on the patient’s chest” appears.
- Turn off the AED.
- Keep the charger connected to the AED and plugged into a power source.

***AED calibration***

- The AED must be sent to an authorized technical service every 12 months for preventive maintenance and calibration.

**References**


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- Brazil. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução RDC nº 44, de 17 de agosto de 2009. Aprova o “Regulamento técnico sobre Boas Práticas Farmacêuticas para o controle sanitário do funcionamento, da dispensação e da comercialização de produtos e da prestação de serviços farmacêuticos em farmácias e drogarias e dá outras providências”. Available from: www.gov.br. Accessed on May 28 2021.


**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic’s Technical Supervisor (Physician).

**SOP No. 24 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Inventory check of medications and disposal of expired medications**.

**Person(s) responsible**

Receptionist or assistant.

**Objectives**

- Organize medication samples and other clinic medications.
- Check medication inventory and adequately discard expired items.

**Necessary materials**

- Medication samples and other clinic medications.
- Locked cabinet used exclusively for medication storage.
- Medication inventory checklist.
- Ballpoint pen.

**Main activities**

- Gather all sample medications.

– Write down all medications on the checklist, including the medication name, manufacturer (lab), lot number, beyond-use date, and box quantity.
– Store medications in a restricted-access cabinet, preferably in alphabetical order or according to the physician's preferences, ensuring easy visibility.
– Place medications nearing expiration at the front of the cabinet.
– Perform a full check every month.
– Separate expired medications by laboratory and return them to the respective representative upon their next visit. Alternatively, send them for incineration or dispose of them in a designated facility. Do not dispose of medications in regular trash, infectious waste, or via the sewage system.

**Observation**

– Until collection by the lab representative or appropriate disposal, expired medications must be stored in a clearly labeled bag or box ("Expired medication – Awaiting disposal") and kept in a separate area from active medical supplies.

**General observations (per Resolution RDC 44/2009)**

– All medications must be stored in an organized manner, according to the manufacturer's recommendations, and under conditions that maintain their identity, integrity, quality, safety, efficacy, and traceability.
– The storage area must be spacious enough to allow organized storage of different medication categories.
– The storage area must be kept clean and protected from direct sunlight, humidity, and heat to preserve the chemical, physical, and microbiological integrity of the products, ensuring their quality and safety.
– For medications requiring refrigeration or specific temperature conditions, follow the storage instructions on the package. The temperature must be monitored and logged daily.
– Medications should be stored on shelves, in drawers, or equivalent supports, kept off the floor, walls, and ceiling to allow for proper cleaning and inspection.
– Clinics dispensing controlled substances must use a secure cabinet or designated locked room under the supervision of a licensed health care professional (pharmacist, nurse, or physician).
– Medications that are expired, tampered with, suspected of being counterfeit, adulterated, or altered must be stored securely away from active inventory, clearly labeled, and segregated to prevent dispensing.
– Disposal of such products must follow specific health care waste management legislation, including any applicable state or municipal regulations.
– Medications must be stored in areas with restricted access to clinic staff. Public access to these areas is strictly prohibited.
– Do not store medications in cardboard boxes, shoeboxes, or any container other than the original packaging.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 25 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Inventory check of vaccines and biologics and disposal of expired medications**.

**Person(s) responsible**

Physician and nurse.

**Objectives**

– Ensure the safe administration of vaccines and biologics according to the manufacturer's recommendations.

**Necessary materials**

– Tray.
– Vaccine.
– Sharps disposal container.

- Prefilled syringe or immunization device.
- Needle (13 × 4.5 or 25 × 7).
- Cotton ball.
- 70% ethyl alcohol (INPM).

**Main activities**

- Correctly and courteously identify the patient to receive the vaccine.
- Record the date of administration, dose, batch number, and vaccinator's name in the vaccination record card and the clinic's online control system (NetVacinas).
- Document the applied dose in the daily log (according to standard procedures) and enter vaccination information into the internal electronic system and the National Immunization Program Information System (SI-PNI).
- Review the patient's current vaccination status. Schedule the next dose (written in pencil) on the vaccination record card and in the clinic's online control system (NetVacinas), considering the recommended intervals between doses and additional vaccines, according to the national immunization schedule.
- Provide guidance by informing the patient about the importance of vaccination, next appointments, and how to manage possible adverse events.
- Verify the vaccine/biologic to be administered against the vaccination record card and/or medical prescription. Observe its appearance, integrity, and beyond-use date.

**Administration of vaccines/biologics**

- Perform hand hygiene before the procedure.
- Select the appropriate syringe and needle; if necessary, attach the needle to the syringe, keeping it capped. Use single-dose devices containing the vaccine, as recommended by the manufacturer.
- Follow the manufacturer's recommendations for route and dosage.
- Inspect the vaccine/biologic for appearance, packaging condition, batch number, and beyond-use date.
- Prepare the product according to the manufacturer's recommendations.
- Keep the needle capped until administration.
- Immediately return multi-dose vials to the refrigerator after drawing the dose.
- Administer according to specific techniques for each product.
- Do not recap the needle.
- Discard syringes/needles and ampoules in the sharps disposal container.
- Dispose of glass vials in rigid, clearly labeled toxic waste containers.
- Perform hand hygiene after the procedure.
- Document the procedure.

**Special measures**

- Antisepsis of the patient's skin is not routinely recommended unless it is visibly dirty. In such cases, clean with soap and water or 70% alcohol. Wait 30 seconds for drying if alcohol is used.
- When the sharps disposal container is full, it should be sealed, labeled "Biological waste," and disposed of properly.
- For administration of monoclonal antibodies (Xolair®, Fasenra®, Nucala®, etc.):
  a) Properly identify the patient and check the medical prescription.
  b) Wash hands before and after the procedure.
  c) Prepare the monoclonal antibody according to the manufacturer's recommendations: dilute and gently homogenize using rotational movements, then allow it to rest for approximately 15 minutes before administration.
  d) Inform the patient about the procedure and instruct them to report any adverse symptoms following administration.
  e) Don PPE (gloves and lab coat).
  f) Administer the monoclonal antibody subcutaneously using a 13 × 4.5-mm needle and a 3-mL syringe, following the prescribed number of doses according to the medical prescription and the manufacturer's recommendations.
  g) Monitor vital signs for 1 hour after the injection and report any changes.

h) Discharge the patient after observation and make all relevant notes and documentation.

i) Wash hands.

**Receiving vaccines**

– Wash hands and clean the workspace.

– Upon delivery, check packaging and record box temperature on the delivery note. Do not accept if the temperature is not within the +2 °C to +8 °C range.

– Check quantity and beyond-use date of each package.

– Store as instructed.

– Sign the delivery receipt and retain the invoice for entry in NetVacinas and the SI-PNI system.

**Records**

– Log doses daily in NetVacinas, the patient's electronic medical record, and the vaccination record card.

– Report applied doses and monthly inventory in the Ministry of Health's National Immunization Program Information System (SI-PNI) as instructed by the State Health Department.

**Actions in case of noncompliance**

– Do not accept vaccines that are outside the recommended temperature range or whose integrity is compromised.

**References**

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**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 26 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Activities in the vaccination room**.

**Person(s) responsible**

Physician and nurse.

**Objectives**

– Standardize the procedure for administering biologics in the vaccination room.

– Properly complete the vaccination record card and update the SI-PNI system.

– Organize the vaccination room.

**Necessary materials**

– Tray or emesis basin.

– Vaccines

– Sharps disposal container.

– Pedal-operated bin.

– Disposable syringe.

– Disposable needle.

– Cotton balls.

– PPE (gloves, lab coat, and mask).

– Liquid soap and 70% ethyl alcohol.

– Vaccination record card.

– Computer with Internet access.

**Main activities**

***Procedure steps***

– Check beyond-use date after opening a multi-dose vial, according to the National Immunization Program recommendations.

– Surround the interior of the daily-use cold box with gel packs after the "fog" disappears and temperature stabilization is confirmed (approximately +1 °C).

– Measure the internal temperature of the cold box with a long-probe thermometer, ensuring it is between +2 °C and +8 °C (ideally +5 °C) before placing vaccines inside. Position the thermometer probe in the center of the box.

– Place vaccines and diluents in the cold box once the recommended temperature is reached.

– Remove the vaccines from the refrigerator and separate the corresponding diluents in quantities required for the day's scheduled appointments and walk-in demand.

– Remove gel packs from the refrigerator and leave them on the sink or counter until the surface "fog" dissipates.

– Perform hand hygiene.

– Note: When cold box use is necessary (eg, high volume of administrations, power outage, refrigerator malfunction, or during refrigerator cleaning):

– Arrange forms and office supplies neatly on the worktable.

– Check that refrigerator temperature is between +2 °C and +8 °C.

– Ensure the vaccination room is clean and organized.

***Room organization***

– The vaccination room must be organized and visibly clean for patients.

– It must always be ready to receive patients.

***Patient care***

– Greet the patient courteously.

– Check the patient's current vaccination status.

– Gather health information to assess indications, precautions, and contraindications for vaccine administration.

– Educate the patient about the importance of vaccination and completing the immunization schedule according to their target group, based on the current schedule of the National Immunization Program and the Brazilian Society of Immunizations.

– Open all vaccination record documents (vaccination record card, SI-PNI, NetVacinas, and electronic medical record). If the immunization system is computerized, register the patient in both the clinic's and the Ministry of Health's electronic system.

– Keep the environment clean and instruct accompanying persons not to place personal items (eg, bags, cell phones, or vaccination record cards) on the preparation counter.

***Documentation***

– Review the patient's vaccination history to identify vaccines to be administered if returning.

– Record the date of application, dose, batch number, health care facility where the vaccine was administered, and the vaccinator's name in the vaccination record card and online control system (NetVacinas).

– Document the applied dose in the daily log (according to standard procedures) and enter vaccination information into the electronic system (both SI-PNI and NetVacinas).

– Schedule the next dose (written in pencil) on the vaccination record card and in the online control system (NetVacinas), considering the recommended intervals between doses and additional vaccines, according to the national immunization schedule and Brazilian Society of Immunizations guidelines.

– Provide guidance by informing the patient about the importance of vaccination, next appointments, and how to manage possible adverse events.

– Verify the vaccine to be administered against the vaccination record card and/or the medical prescription.

***Vaccine administration***

– Perform hand hygiene before the procedure.

– Select the appropriate syringe and needle; if necessary, attach the needle to the syringe, keeping it capped.
– Confirm the correct administration route and dosage.
– Inspect the vaccine for appearance, packaging condition, batch number, and beyond-use date.
– Prepare the vaccine.
– Keep the needle capped until administration.
– Immediately return multi-dose vials to the cold box after drawing the dose.
– Administer the vaccine according to specific techniques.
– Discard syringes/needles in the sharps disposal container.
– Perform hand hygiene after the procedure.
– Recommendations: After opening, the vaccine solution should be kept in the original vial.
– Only draw the dose immediately before administration.
– Never store prefilled syringes in the daily-use cold box.
– Observation: Antisepsis of the patient's skin is not routinely recommended unless it is visibly dirty. In such cases, clean with soap and water or 70% alcohol and wait 30 seconds for the skin to dry.
– Attention: For BCG vaccine, do not disinfect the skin with alcohol or any product – use only a dry cotton ball.
– Wearing gloves does not exempt from hand washing before and after the procedures.
– Special attire is not required for parenteral vaccine administration.
– Fill out the vaccination record card, provide guidance to the patient, and discharge them.

***End of day***

– Record the number of discarded vials (expired, broken, etc.) in the SI-PNI registration form to support the assessment of biologic stock movement and losses.
– Clean the cold box after use and wait for it dry before storing it.
– Complete all digital vaccine administration documents (SI-PNI, NetVacinas, and internal Excel® spreadsheets).
– Ensure refrigeration equipment is functioning properly.
– Leave the vaccination room clean and organized.

***Disposing of the sharps container***

– When full, the sharps disposal container must be replaced and collected by an authorized waste management company.

***Vaccine orders***

– Check vaccine stock.
– Notify the clinic administration to restock when necessary.

***Receiving vaccines***

– Wash hands and clean the workspace.
– Upon delivery, check packaging and record box temperature on the delivery note. Do not accept if the temperature is not within the +2 °C to +8 °C range.
– Fill out a noncompliance report if needed and refuse the vaccines.
– Quickly check quantity and beyond-use dates.
– Store vaccines immediately in the appropriate refrigerated space.
– Sign and keep the delivery receipt.

**Special measures**

– During vaccine administration, request the assistance of the child's guardian to help immobilize the child if necessary. The success of the procedure depends on this support and not solely on the vaccinator. If the guardian is uncomfortable doing so, reschedule the appointment for safety reasons.
– In case of an adverse event following immunization (AEFI), complete the appropriate online form and notify the Health Department. Correctly identify the patient and the vaccine, completing the AEFI form in full. Provide clinical support to the patient.
– The AEFI form is available from: http://pni.datasus.gov.br/Download/Eapv/Ficha_EAPV_ PNI070411.pdf.

**Actions in case of noncompliance**

– In case of noncompliance, immediately notify the clinic's Technical Supervisor.
– In case of refrigerator malfunction or power outage, follow the Contingency Plan.

**References**

– Potter PA, Perry AG. Guia Completo de Procedimentos e Competências de Enfermagem. Rio de Janeiro: Elsevier; 2012. p.308-14.
– Brazil. Ministério da Saúde. Secretaria de Vigilância em Saúde. Departamento de Vigilância das Doenças Transmissíveis. Manual de Normas e Procedimentos para Vacinação / Ministério da Saúde, Secretaria de Vigilância em Saúde, Departamento de Vigilância das Doenças Transmissíveis. Brasília: Ministério da Saúde, 2014. Available from: www.gov.br. Accessed on May 21 2021.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 27 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Urgent and emergency care**.

**Person(s) responsible**

Physician and nurse.

**Objectives**

– Provide immediate care to patients in urgent and emergency situations.

**Necessary materials**

– Crash cart.
– Automated external defibrillator (AED).
– Pulse oximeter.
– Rigid spine board.
– PPE (lab coat, glove, and mask).

**Main activities**

– Ensure the scene is safe.
– Check patient's responsiveness.
– Call for help.
– Simultaneously check for a central pulse and breathing or gasping.
– Bring the crash cart near the patient.
– Don PPE (lab coat, glove, and mask).
– Start cardiopulmonary resuscitation (CPR) with chest compressions if there is no pulse.
– Begin positive pressure ventilation using a bag valve mask (Ambu bag) connected to oxygen. For patients with no advanced airway, use a compression-to-ventilation ratio of 30:2. For patients with an advanced airway, provide continuous compressions with ventilations at a rate of 1 breath every 6 seconds (10 breaths per minute).
– Monitor the patient using pulse oximetry.
– Connect the AED as quickly as possible and check rhythm. If a shockable rhythm is detected (ventricular fibrillation/pulseless ventricular tachycardia), follow the AED's instructions, ensure everyone is clear, deliver a shock, and immediately resume CPR (5 cycles or 2 minutes).
– In the case of a refractory shockable rhythm: administer 300 mg of amiodarone IV as a bolus, followed by 150 mg if necessary.
– If the rhythm is non-shockable (asystole/PEA), immediately resume CPR (5 cycles or 2 minutes).
– Establish venous access.
– Administer medications as ordered by the physician, flush with 20 mL of normal saline, and elevate the venous access limb.
– Keep syringes with medications clearly labeled.
– Track the timing of medication administration (eg, adrenaline) every 3 to 5 minutes and notify the physician/team leader.

– Rotate professionals performing compressions and ventilation every 2 minutes.
– Continue CPR while indicated, reassessing rhythm and carotid or femoral pulse every 2 minutes.
– Maintain chest compressions.
– Minimize the frequency and duration of interruptions in chest compressions.
– Prepare orotracheal intubation equipment (laryngoscope with blades, endotracheal tube appropriate for patient's age); proceed with intubation, verify placement, and secure the tube.
– Perform post-resuscitation care.
– Discard used materials properly.
– Doff gloves.
– Perform hand hygiene.
– Call EMS and notify the patient's health insurance provider.
– Maintain patient support and monitoring until transfer.
– Document the incident in detail in the patient's medical record.

**Special measures**

– Ensure high-quality CPR, avoiding interruptions.
– Perform chest compressions in the lower half of the sternum, at a depth of 5–6 cm, allowing complete recoil of the chest after each compression, at a rate of 100 compressions per minute.
– Seal the bag-mask tightly around the patient's face. Deliver 2 breaths every 30 compressions. If using an advanced airway, deliver 1 breath every 6 seconds and perform continuous compressions for 2 minutes.
– Check for a central pulse for no more than 10 seconds every cycle or every 2 minutes.
– Emergencies related to severe allergies, anaphylaxis, or other conditions require the presence of a physician, immediate use of crash cart medications, and, if needed, transfer to a hospital facility.
– In case of an acute reaction following vaccination, provide initial support, identify the vaccine administered, fill out the AEFI report, and send it to the Health Department.

**Documentation**

– Document all actions in detail in the patient's electronic medical record.
– Complete the crash cart medication control form and restock medications.
– Complete the AEFI report form, if applicable.

**References**

– Aehlert B. ACLS: Suporte avançado em cardiologia. Emergências em Cardiologia. 4th ed. Rio de Janeiro: Elsevier; 2013.
– Hazinski MF, Schuster M, et al. Destaques da American Heart Association 2015: Atualização das Diretrizes de RCP e ACE. American Heart Association, 2015. Available from: https://cpr.heart.org/. Accessed on Apr 28 2021.
– Neumar RW, Shuster M, et al. Parte 1: sumario executive: 2015 American Heart Association Guidelines Updade for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2015;132(suppl):18.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 28 – Date: __/__/__ – Revision: __/__/__**

## Procedure

**Administration of allergen-specific sublingual immunotherapy**.

## Person(s) responsible

Physician and nurse.

## Objectives

– Establish standardized procedures for the administration of the first dose of allergen-specific sublingual immunotherapy. Standardizing the administration method and prescription improves the safety of allergen immunotherapy practices.

## Necessary materials

– Informed Consent Form for immunotherapy administration.
– Necessary resources and prior preparation.
– Immunotherapy administration record sheet.
– Evaluation before and after immunotherapy administration; and dispensing of immunotherapy vial for home treatment.

## Activities

– The administration schedule for sublingual immunotherapy is described in Figure 4.

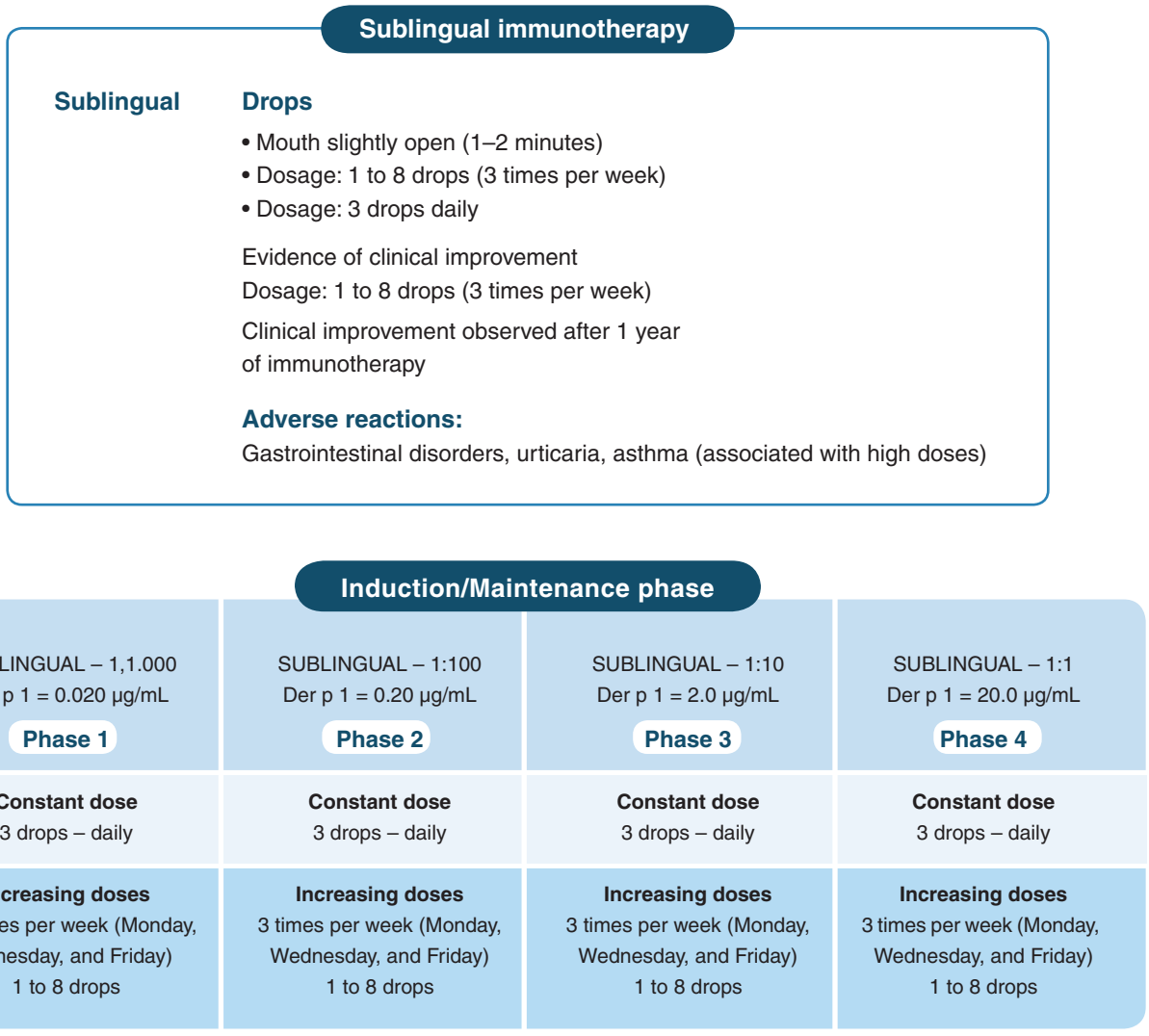


**Figure 4**
Administration of allergen-specific sublingual immunotherapy

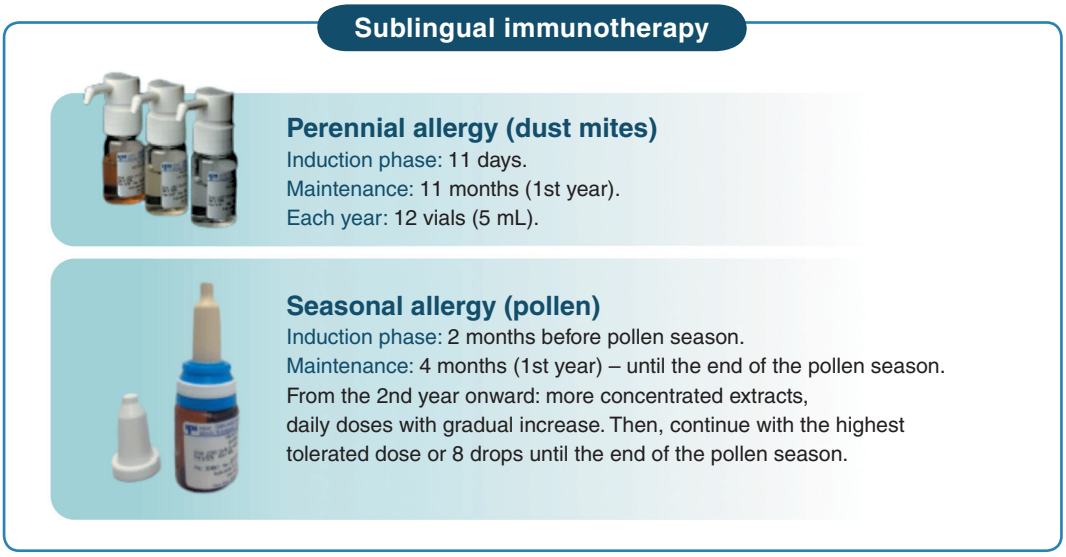


**Figure 4** *(continued)*
Administration of allergen-specific sublingual immunotherapy

**Documentation**

- Document the procedure in the patient's medical record.
- The Informed Consent Form and immunotherapy administration sheet are attached to this document.

**Adverse reactions**

- In case of adverse reactions, immediately contact the physician in charge.

**Special measures**

- Instruct the patient to store the allergen vial in the refrigerator after dilution.
- Instruct the patient to correctly fill out the immunotherapy administration sheet and bring it to each follow-up appointment.

**References**


- Brazil. Conselho Federal de Medicina, CFM. Resolução nº 1.794/2006, publicada no Diário Oficial da União (D.O.U.) 11 de agosto de 2006, Seção I, pg. 127. Available from: www.sistemas.cfm.org.br. Accessed on Apr 28 2021.
- Anvisa – Resolução da Diretoria Colegiada RDC Nº 233, de 17 de agosto de 2005, publicada no Diário Oficial da União (DOU) em 22 de agosto de 2005. Available from: www.bvsms.saude.org.br. Accessed on Apr 28 2021.
- Anvisa – Resolução da Diretoria Colegiada RDC Nº 67, de 08 de outubro de 2007, publicado no Diário Oficial da União (DOU). Available from: www.bvsms.saude.org.br. Accessed on Apr 28 2021.
- Anvisa – Resolução da Diretoria Colegiada RDC N° 54, de 10 de dezembro de 2013, publicada no Diário Oficial da União (DOU) nº 240, de 11 de dezembro de 2013. Available from: www.gov.org.br. Accessed on Apr 28 2021.


**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 29 – Date: __/__/__ – Revision: __/__/__**

### Procedure

**Administration of allergen-specific subcutaneous immunotherapy**.

### Person(s) responsible

Physician and nurse.

### Objectives

– Establish standardized procedures for the injection of allergen-specific subcutaneous immunotherapy. Standardizing the administration method and prescription improves the safety of allergen immunotherapy practices.

### Necessary materials

– Informed Consent Form for immunotherapy administration.
– Necessary resources and prior preparation.
– Immunotherapy administration record sheet.
– Pre- and post-application evaluation of immunotherapy.

### Activities

– The protocol for the administration of allergen-specific subcutaneous immunotherapy is described in Figure 5.

### Documentation

– Document the procedure in the patient's medical record.
– The Informed Consent Form and the immunotherapy administration record sheet are attached to this document.

### Administration

– Wash hands.
– Don gloves.
– Correctly identify the patient and medication.
– Disinfect the vial cap with 70% ethyl alcohol and aspirate the medication.
– Explain the procedure to the patient.
– Disinfect the application site with 70% alcohol.
– Administer immunotherapy subcutaneously, rotating application sites.

**Induction phase: Standardized extract**

| Phase 1 | Phase 2 | Phase 3 | Phase 4 |
|---|---|---|---|
| **1:10,000<br>0.0005 µg** | **1:1,000<br>0.005 µg** | **1:100<br>0.05 µg** | **1:10<br>0.5 µg** |
| 0.10 mL | 0.10 mL | 0.10 mL | 0.10 mL |
| 0.20 mL | 0.20 mL | 0.20 mL | 0.20 mL |
| 0.30 mL | 0.30 mL | 0.30 mL | 0.30 mL |
| 0.40 mL | 0.40 mL | 0.40 mL | 0.40 mL |
| 0.50 mL | 0.50 mL | 0.50 mL | 0.50 mL |

**Figure 5**
Administration of allergen-specific subcutaneous immunotherapy

- Instruct the patient to report any abnormalities.
- Properly dispose of gloves and syringe without recapping the needle.
- Wash hands.
- Complete forms and release the patient.

**References**


- Conselho Federal de Medicina, CFM. Resolução nº 1.794/2006, publicada no Diário Oficial da União (D.O.U.) 11 de agosto de 2006, Seção I, pg. 127. Available from: www.sistemas.cfm.org.br. Accessed on Apr 28 2021.
- Anvisa – Resolução da Diretoria Colegiada – RDC Nº 233, de 17 de agosto de 2005, publicada no Diário Oficial da União (DOU) em 22 de agosto de 2005. Available from: www.bvsms.saude.org.br. Accessed on Apr 28 2021.
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**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 30 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Subcutaneous administration of medication**.

**Person(s) responsible**

Physician and nurse.

**Objectives**

- Administer medications via the subcutaneous route.

**Necessary materials**

- Tray.
- Allergen extract.
- Sharps disposal container.
- Syringe (1 mL).
- Needle (13 × 4.5).
- Cotton balls.
- 70% ethyl alcohol (INPM).

**Main activities**

- Perform hand hygiene.
- Don gloves.
- Check prescription.
- Ensure the patient's privacy by closing curtains, placing screens, or closing doors.
- Choose the application site on the body, rotating sites appropriately.
- Clean the site with a cotton ball soaked in 70% alcohol: position the cotton ball in the center of the area and clean outward in a circular motion covering approximately 5 cm.
- Open the syringe packaging and attach the needle, maintaining asepsis.
- Draw the medication from the ampoule or vial.
- Remove the needle cap with the nondominant hand using a direct motion.
- Pinch the subcutaneous fold of the area with the thumb and index finger.
- Hold the syringe between the thumb and index finger of the dominant hand.
- Hold the syringe like a dart, palm facing down.
- Insert the needle at a 45° to 90° angle (90° for obese patients).
- Inject the medication slowly (1 mL/10 seconds).
- Withdraw the needle at the same angle of insertion, applying a cotton ball or dry gauze.
- Do not recap the needle.
- Discard the syringe in a sharps disposal container.
- Perform hand hygiene.
- Document the procedure in the patient's medical record.

**Special measures**

- The subcutaneous route can accommodate 0.5 to 1.0 mL.
- Avoid the periumbilical region.
- Palpate the selected site for nodules, redness, or pain and inspect the skin surface for bruises, inflammation, or edema. Avoid sites showing these conditions.
- Since puncturing a blood vessel through this route is very rare, aspiration before medication administration is not necessary.

**Actions in case of noncompliance**

- In case of noncompliance, immediately notify the clinic's Technical Supervisor.

**References**


- Potter PA, Perry AG. Fundamentos de enfermagem. Rio de Janeiro: Elsevier; 2009. p.686-754.
- Luvas cirúrgicas e luvas de procedimentos: Considerações sobre seu uso. Boletim Informativo de Tecnovigilância. Brasília, n.2, abr-jun, 2011.
- Conselho Regional de Enfermagem de Minas Gerais. Uso de luvas de procedimento para a administração de medicamentos. Fev, 2010.
- Potter PA, Perry AG. Guia Completo de Procedimentos e Competências de Enfermagem. Rio de Janeiro: Elsevier; 2012. p. 308-14.


**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 31 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Pharmacovigilance – Adverse reactions**.

**Person(s) responsible**

Physician and nurse.

**Objectives**

- Standardize the management of adverse reactions and support analyses and statistical studies for the recognition of new adverse reactions, identification of predisposing factors for side effects, and the ongoing prevention of adverse reactions to immunotherapy.

**Necessary materials**

- Notification form.
- Standardized questionnaire (pharmacovigilance form).

**Activities**

- Complete the designated form (Figure 6).

**Local reaction**

- Local reactions are classified by measuring the largest diameter of the reaction.
- Immediate reactions with a diameter smaller than 5 cm and delayed reactions smaller than 10 cm are considered clinically irrelevant.
    1. Induration, itching, or edema at the injection site: apply ice or topical corticosteroid if the reaction exceeds 10 cm in diameter, and administer oral antihistamines. Assess the need to adjust the dosage regimen in case of more intense reactions.
    2. Itching and/or swelling of the lips, tongue, or oropharynx during sublingual administrations: administer oral antihistamines and/or systemic corticosteroids, depending on the severity of the reaction. Assess the need to adjust the dosage regimen in case of more intense reactions.

**Systemic reaction**

- Signs and/or symptoms away from the injection site.
- Systemic reactions usually begin a few minutes after vaccine administration and rarely occur after 30 minutes. They can be classified as:
    1. Mild systemic reactions: localized urticaria, rhinitis or mild asthma, nausea, or slight abdominal pain.

| CLINIC LOGO | **QUESTIONNAIRE – IMMUNOTHERAPY PHARMACOVIGILANCE** |
|---|---|

Spontaneous report of suspected adverse reactions

| Dilution batch | |
|---|---|

## Patient information

| Patient (initials) | Date of birth | Age | Sex ( ) Male ( ) Female |
|---|---|---|---|
| | | | |

Diagnosis of allergic disease

( ) Asthma ( ) Rhinitis ( ) Atopic dermatitis ( ) Hymenoptera venom allergy ( ) Allergy to hematophagous arthropod bites ( ) Others

## Information about the allergen extract (suspected)

Allergen(s) used: ( ) Mite ( ) Epithelium ( ) Pollens ( ) Fungi ( ) Hematophagous insects ( ) Hymenoptera venom

Extract source laboratory name:

Batch: Beyond-use date:

| Treatment number: | Beyond-use date: | Date of reaction: |
|---|---|---|
| | | |

Concentration/dilution:

( ) 1:1,000.000 ( ) 1:100,000 ( ) 1:10,000 ( ) 1:1,000 ( ) 1:100 ( ) 1:10 ( ) 1:1

Route of administration:

( ) Subcutaneous, aqueous solution, dose _____ mL ( ) Subcutaneous, depot system, dose _____ mL

( ) Sublingual, dose _____ gotas ( ) Sublingual, dose _____ sprays

Time elapsed between administration and reaction

( ) Within the first 30 minutes

( ) After 30 minutes but before 1 hour

( ) ___ hours after administration

Local reaction

( ) Edema ( ) Erythema ( ) Papule larger than 10 mm

( ) Itching ( ) Papule smaller than 10 mm

( ) Possible reaction to aluminum hydroxide (depot)

Systemic reaction

( ) Grade I – Nonspecific (malaise, headache, lethargy, likely not IgE-mediated)

( ) Grade II – Mild (mild rhinitis and/or asthma)

( ) Grade III – Moderate (urticaria, angioedema, severe asthma) – immediate treatment required

( ) Grade IV – Severe (anaphylactic shock or anaphylaxis) – Immediate treatment required

**Figure 6**
Questionnaire – "Spontaneous report of suspected adverse reactions"

Other adverse reactions and symptoms:

Possible causes of the adverse reaction:

( ) Incorrect dosage ( ) New vial
( ) Asthma symptoms ( ) Medication use (eg, beta-blockers, etc.)
( ) Period of exacerbation ( ) Other causes – Specify: _____

| Did the reaction disappear after immunotherapy suspension? | Did the reaction reappear after immunotherapy reintroduction? |
|---|---|
| ( ) Yes ( ) No ( ) Not applicable | ( ) Yes ( ) No ( ) Not applicable |

Outcome attributed to the event

( ) Death ( ) Life-threatening ( ) Hospitalization ( ) Significant medical event ( ) None of the above

## Concomitant medications

| Medication name | Dose and route of administration | Date of administration |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |

## Physician information

Prior to administration, the patient:

( ) Was evaluated by the physician, was well, and not experiencing an allergy attack.
( ) Applied immunotherapy elsewhere without possibility of physician evaluation.
( ) _____

Was the report sent to health authorities?

( ) Yes ( ) No

Relationship to immunotherapy:

( ) Unrelated ( ) Remote relation ( ) Possible relation ( ) Probable relation

Name: _____
Address: _____
City: _____
State: _____
ZIP code: _____
Medical license #: _____

Date and physician's signature:

Reserved for entity/company use

| Date received: | Received by: |
|---|---|
| Manufacturer: | Importation/compounding: |

***Important: Filling out this report does not necessarily imply that the product caused the adverse reaction.***

**Figure 6** *(continued)*
Questionnaire – "Spontaneous report of suspected adverse reactions"

2. Moderate systemic reactions: slow onset (>15 minutes) of generalized urticaria and/or moderate asthma, vomiting, diarrhea, or severe abdominal pain.
3. Severe systemic reactions: rapid onset (<15 minutes) of generalized urticaria, angioedema, or severe asthma.
4. Anaphylactic shock: rapidly progressing reaction characterized by skin itching, erythema, generalized urticaria, laryngeal stridor (angioedema), asthma, and hypotension, possibly leading to loss of consciousness. Following a systemic reaction, the physician should carefully weigh the benefit-risk ratio of continuing or discontinuing immunotherapy treatment.

**Management of severe systemic allergic reactions (anaphylaxis)**

1. Immediate treatment is required to halt the progression of anaphylaxis.
2. Administer intramuscular adrenaline (epinephrine) at a 1/1,000 dilution:
   – Adults: 0.3 to 0.5 cc.
   – Children: 0.01 mg/kg/dose, up to a maximum of 0.3 cc (for children under 40 kg).
   – This dose can be repeated every 5 to 15 minutes, if necessary, up to a total of 3 applications.
3. Administer intramuscular antihistamine (promethazine). For example: 2 mg for adults or 0.025 mg/kg/dose for children (may also be administered intravenously); alternatively, hydroxyzine 25 mg for adults or 1 mg/kg/dose for children.
4. Deliver oxygen at a flow rate of 6 to 8 L/min via nasal cannula or face mask.
5. Establish venous access.
6. Administer intravenous corticosteroids (eg, methylprednisolone 125 mg for adults or 1–2 mg/kg for children; or hydrocortisone 200 mg for adults or 4 mg/kg/dose for children) to prevent delayed symptoms. If venous access cannot be established, corticosteroids may be administered orally or intramuscularly.
7. Administer intravenous fluids or plasma expanders, if necessary.
8. In case of bronchospasm, also administer inhaled salbutamol (via nebulizer or pressurized aerosol).

**Documentation**

– Document the incident in the patient's medical record.
– Notify relevant authorities.

**References**

– Conselho Federal de Medicina, CFM. Resolução nº 1.794/2006, publicada no Diário Oficial da União (D.O.U.) 11 de agosto de 2006, Seção I, pg. 127. Available from: www.sistemas.cfm.org.br. Accessed on Apr 28 2021.
– Brasil - Agência Nacional de Vigilância Sanitária - Anvisa. Resolução da Diretoria Colegiada – RDC Nº 233, de 17 de agosto de 2005, publicada no Diário Oficial da União (DOU) em 22 de agosto de 2005. Available from: www.bvsms.saude.org.br. Accessed on Apr 28 2021.
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**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 32 – Date: __/__/__ – Revision: __/__/__**

### Procedure

**Dispensation of allergen-specific immunotherapy vial for sublingual administration**.

### Person(s) responsible

Physician.

### Objectives

– Establish procedures for the dispensation of immunotherapy vials for sublingual administration following the application of the first dose of allergen-specific immunotherapy. Standardizing the method of administration and prescription improves the efficacy and safety of allergen immunotherapy practices.

### Necessary materials

– Informed Consent Form for immunotherapy administration.
– Necessary resources and prior preparation.
– Immunotherapy administration record sheet.
– Provide instructions and dispense the sublingual vial for home treatment. Reinforce guidance about possible adverse reactions.

### Activities

– Request the patient to sign the Informed Consent Form for immunotherapy administration.
– Deliver the vial and the dose administration record sheet to the patient, along with information about the vaccine and potential reactions.
– Provide guidance on the adequate storage of the vial.

### Documentation

**INFORMED CONSENT FORM (ICF) AFTER IMMUNOTHERAPY INFORMATION SESSION**

Patient _____

***General information***

Allergen immunotherapy is a treatment used worldwide for respiratory allergies (such as allergic rhinitis and asthma) and insect bite allergies. It consists of the administration of increasing doses of an allergen (the agent causing the allergy) via the sublingual or subcutaneous route to increase the individual's "resistance" or develop tolerance to that specific allergen.

***How is treatment performed?***

The indication for allergen immunotherapy is based on the patient's medical history and results from skin tests or blood tests. Increasing doses of the allergen extract are administered either sublingually or subcutaneously. The complete treatment duration is up to 3 years.

***Possible side effects during immunotherapy***

General symptoms occur in approximately 0.1% of all cases and may include: red patches (urticaria) over the body, eye and throat itching, nasal congestion, throat or chest tightness, cough, wheezing, shortness of breath, dizziness, nausea, and vomiting. Severe reactions (anaphylaxis) are very rare. In the vast majority of cases, reactions resolve with appropriate medications.

I am aware that I may suspend the treatment at any time without it causing any embarrassment or affecting my medical care in any way. My physician remains available to continue my treatment under any circumstances.

I declare that I have read all the information above and clarified all my doubts with the physician responsible for the treatment. I understand all the risks and benefits of allergen-specific immunotherapy and agree to the treatment and all terms outlined in this informed consent form. I am signing this document freely and voluntarily, in joint decision with my physician.

_____ _____

Signature of patient or guardian | Responsible physicians

City _____ , Date: ___/___/ ____

– Attached: dose administration record sheet.

**References**

– Conselho Federal de Medicina, CFM. Resolução nº 1.794/2006, publicada no Diário Oficial da União (D.O.U.) 11 de agosto de 2006, Seção I, pg. 127. Available from: www.sistemas.cfm.org.br. Accessed on Apr 28 2021.
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**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 33 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Dispensation of allergen-specific immunotherapy vial for injectable administration**.

**Person(s) responsible**

Physician.

**Objectives**

– In special cases, such as patients who live too far away to attend weekly appointments or patients who are unable to attend due to professional activities, vials of injectable immunotherapy will be dispensed and delivered to the patient for administration at another location.

**Necessary materials**

– Informed Consent Form for immunotherapy administration.
– Necessary resources and dose administration record sheet for the person responsible for the injection (for administration in a facility equipped for emergency treatment). Patient must sign to acknowledge receipt of the vial.
– Provide instructions and dispense the vial for treatment outside the facility. Reinforce guidance about possible adverse reactions.

**Activities**

– Request the patient to sign the Informed Consent Form for immunotherapy administration.
– Deliver the package containing the vial and the dose administration record sheet and provide information about the vaccine and possible adverse reactions.
– Provide instructions on the correct storage of the vaccine (keep it in the refrigerator door).

**Documentation**

**INFORMED CONSENT FORM (ICF)**
**AFTER IMMUNOTHERAPY**
**INFORMATION SESSION**

Patient: _____

***General information***

Allergen immunotherapy is a treatment used worldwide for respiratory allergies (such as allergic rhinitis and asthma) and insect bite allergies. It consists of the administration of increasing doses of an allergen (the agent causing the allergy) via the sublingual or subcutaneous route to increase the individual's "resistance" or develop tolerance to that specific allergen.

***How is treatment performed?***

The indication for allerge immunotherapy is based on the patient's medical history and on skin or

blood tests (such as the RAST test). Increasing doses of the allergen extract are administered either sublingually or subcutaneously. The complete treatment duration is up to 3 years.

***Possible side effects during immunotherapy***

General symptoms occur in approximately 0.1% of all cases and may include: red patches (urticaria) over the body, eye and throat itching, nasal congestion, throat or chest tightness, cough, wheezing, shortness of breath, dizziness, nausea, and vomiting. Severe reactions (anaphylaxis) are very rare. In the vast majority of cases, reactions resolve with appropriate medications.

I am aware that I may suspend the treatment at any time without it causing any embarrassment or affecting my medical care in any way. My physician remains available to continue my treatment under any circumstances.

I declare that I have read all the information above and clarified all my doubts with the physician responsible for the treatment. I understand all the risks and benefits of allergen-specific immunotherapy and agree to the treatment and all terms outlined in this informed consent form. I am signing this document freely and voluntarily, in joint decision with my physician.

_____ _____

Signature of patient or guardian | Responsible physicians

City _____ , Date: ___/ ___ / ____

– Attached: dose administration record sheet.

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 34 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

## Confidentiality and privacy of patient medical records.

**Person(s) responsible**

Receptionist, assistant, administrative assistant, and administrative staff.

**Objectives**

– Ensure the confidentiality and integrity of patient information documented in medical records.

**Important**

– Article 69 of the Medical Code of Ethics: "It is prohibited for the physician to fail to create a medical record for each patient."

– A medical record (patient record) is a set of standardized, organized, and concise documents intended to record all information related to medical and paramedical care provided to the patient.

– The medical record is a permanent document maintained by physicians and health care facilities (CFM Resolution No. 1331/89). It may later be used by interested parties as legal evidence until the expiration of the statute of limitations for lawsuits, which is twenty (20) years.

**Necessary materials**

– Patient's medical record

– Digital storage for medical records in a recognized cloud-based system using a secure database solution (ProDoctor Cloud). The software is hosted in internationally recognized data centers that ensure, beyond information security, compliance with the Brazilian GDPR and Federal Board of Medicine (Resolution 2.299/2021) requirements.

– A Confidentiality and Privacy Agreement for patient record information.

**Activities**

1. Explain the concept and importance of patient records.
2. Emphasize the need to store records in a restricted area protected against moisture.
3. Explain the legal requirement for storing patient records for the mandatory period.
4. Explain that all notes in the medical record are confidential.
5. Require employees to sign the Confidentiality and Privacy Agreement, committing not to disclose any patient information contained in the medical record.

**References**

1. Conselho Federal de Medicina, CFM. Código de Ética Médica. Resolução CFM nº 1.931, de 17 de setembro de 2009. Brasília: CFM; 2010. p. 70.

**Annex**

**CONFIDENTIALITY AND PRIVACY AGREEMENT**

By this instrument, and in accordance with applicable law, the Employee: _____

_____,

and the Clinic: _____

_____.

agree as follows:

Given that proper and diligent performance of activities in the medical office requires discretion regarding the technical and confidential information contained in patient records:

The employee hereby agrees to:

I) Maintain confidentiality, refraining from using such confidential information for personal or third-party gain.

II) Use such information solely for the purpose of properly performing their professional duties at the clinic.

III) Protect confidential information disclosed to them with the same degree of care used to protect the clinic's own records.

The employee may only disclose patient information to a third party with prior written consent from the clinic or under judicial order, in which case the employee must immediately inform the physician in writing.

The employee is expressly prohibited from producing copies or backups of patient records without prior authorization from the physician.

By signing this agreement, the employee acknowledges and accepts the obligation to maintain the confidentiality of patient information. Failure to comply with any of the confidentiality provisions set forth herein will subject the employee to disciplinary and administrative actions by the employer.

Executed in two (2) counterparts of equal form and content, signed before two witnesses.

City: _____ , on _____

of _____ , 20____ .

_____

Employee/Secretary

_____

Physician

Witnesses:

Name: _____

CPF (Taxpayer Identification Number): _____

Name: _____

CPF (Taxpayer Identification Number): _____

**Prepared by:** Registered Nurse (COREN-certified).

**Reviewed by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 35 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Cleaning the vaccination room**.

**Person(s) responsible**

Receptionist, assistant, and general services assistant.

**Objective**

– Prevent cross-infection, provide comfort and safety to patients and staff, and maintain a clean and comfortable environment.

**Necessary materials**

– Bucket.
– Closed-toe shoes.
– Disinfectant (quaternary ammonium solution or bleach).
– Hand brush, sponge.
– Cleaning gloves.
– Floor cloth (clean), cleaning cloth, dustpan, squeegee.
– Appropriate clothing for cleaning (apron).
– Soap.
– Waste disposal bags.
– Natural bristle broom.
– PPE (safety goggles, long-cuff gloves, mask, and cap).

**Main activities**

– For concurrent cleaning of the vaccination room, employees must:
  • Wear appropriate clothing and closed-toe shoes.
  • Gather all necessary cleaning materials (bucket, disinfectant solution, squeegee, floor cloth or mop, cleaning gloves, dustpan).
  • Wash hands with soap and water and/or use alcohol gel.
  • Don gloves before starting cleaning.
  • Prepare the disinfectant solution for cleaning, adding 1/50 parts of water.
– Note: the agent used to disinfect the vaccination room is preferably quaternary ammonium solution.
– Wash floors with water and neutral soap, using a broom to scrub the entire floor.
– Remove excess water and soap using a squeegee and damp cloth.
– Dry the floor using a clean cloth.
– Afterwards, use a cloth dampened with quaternary ammonium solution to clean the entire floor again to remove remaining dirt.
– Dry the floor using a dry cloth.
– Rinse the cloth in a clean water bucket and reapply quaternary ammonium solution until the floor is fully clean.
– Gather any debris from the floor into a dustpan using a mop or a damp cloth wrapped around the mop head.
– Empty the waste basket, closing the bag correctly.

**Terminal cleaning procedures**

– For terminal cleaning of the vaccination room, employees must:
  • Wash hands before and after cleaning the room and/or sanitize them with 70% alcohol gel.
  • Don gloves before starting cleaning.
  • Gather all necessary cleaning materials.
  • Prepare the disinfectant solution for cleaning, adding 1/50 parts of water.

***Note 1***

– For powder laundry detergent, use one tablespoon of detergent per 5 liters of water.
– Gather any debris from the floor into a dustpan using a natural bristle broom with a damp cloth wrapped around the broom head.
– Empty the waste basket, closing the bag correctly.

***Note 2***

– Waste bags are disposable and should never be reused.
– Wipe down the waste baskets with a damp cloth that has been soaked in the disinfectant solution.
– Start cleaning from the ceiling, using a natural bristle broom with a dry cloth wrapped around the broom head.

- Clean the light fixtures by removing any detachable parts, washing them with soap, and then drying them.
- Wipe down windows, stained glass, and frames with a cloth soaked in the disinfectant solution, followed by a damp cloth, and finally a dry cloth.
- For the exterior of windows, stained glass, and frames, use a natural bristle broom (or brush) and the disinfectant solution to wash, and then rinse them.
- Clean tiled walls with a cloth soaked in the disinfectant solution, then wipe with a damp cloth and finish with a dry cloth.
- Clean the light switches with a damp cloth and then dry them.
- Wash the sink and faucet as follows:
  - For stainless steel sinks, use a sponge and the disinfectant solution.
  - For porcelain sinks, use a sponge, water, and a cream cleaner.
  - Rinse all sinks and wipe them down with a cloth dampened with the disinfectant solution.
- Clean the floor using a natural bristle broom with a cloth dampened with the disinfectant solution wrapped around the broom head, and then wipe it with a dry cloth.

***Note 3***

- Avoid sweeping the floor to prevent dust from spreading around the room.
- Clean from the farthest point of the room toward the exit, repeating as needed until the area is clean (at least three times).

**Special measures**

- The vaccination room is cleaned daily at the end of each work shift, and whenever necessary.
- Once a week the floor is washed with soap and water and then disinfected with a disinfectant solution. A more thorough cleaning takes place every two weeks, when the ceiling, walls, windows, light fixtures, lamps, and doors are cleaned.

**Observations**

- Concurrent cleaning of the vaccination room should be conducted at least twice daily at scheduled times or as needed. Terminal cleaning involves thorough cleaning and disinfection of all surfaces (horizontal, vertical, internal, and external) and equipment within the room. Terminal cleaning of the vaccination room should be conducted every 15 days, including a comprehensive cleaning of the floor, ceiling, walls, doors, windows, furniture, light fixtures, lamps, and air-conditioning filters.

**Prepared by:** Registered Nurse (COREN-certified).

**Revised by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 36 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Cleaning in case of spillage of bodily fluids (urine, feces, vomit, and secretions)**.

**Person(s) responsible**

Receptionist, assistant, and general services assistant.

**Objective**

- Standardize the cleaning routine within the clinic in case of spillage of bodily fluids (urine, feces, vomit, and other secretions) in order to prevent the spread of microorganisms and maintain a clean and comfortable environment.

**Necessary materials**

- Water.
- Neutral soap.
- Quaternary ammonium solution.
- 70% ethyl alcohol.
- Squeegee.
- Bucket.
- PPE (gloves, safety goggles, mask, gown, and closed-toe shoes).
- Cleaning cloth.
- Paper towel.

**Main activities**

– Wash hands before and after the activity.
– Don PPE.
– Gather all required materials.

**Disinfection technique for organic matter**

1. Remove any organic matter, such as bodily fluids (urine, feces, vomit, secretions) or blood spills (even small ones or splashes), from all affected surfaces using a paper towel or cloth, discarding it in the infectious waste bin immediately.
2. Proceed with disinfection as described below.

***For floors and walls***

Use quaternary ammonium solution: first, clean the surface to be disinfected with soap or detergent using a squeegee. Rinse and dry. After cleaning, moisten a clean cloth with the pure solution and apply it to the area where the organic matter has been removed, leaving it to act for 10 minutes. If necessary, rinse and dry.

***For furniture***

Use 70% alcohol: first, clean the surface to be disinfected with soap or detergent using furniture cloths. After cleaning the furniture, rub it with 70% alcohol until it evaporates completely, repeating this step three consecutive times.

**Special measures**

– Cleaning should be conducted whenever necessary.
– Cleaning should be conducted as soon as possible.
– If an outsourced company handles cleaning, provide their name.

**References**

– Brazil. Ministério da Saúde. Segurança do paciente em serviços de saúde: Limpeza e Desinfecção de Superfícies. Anvisa; 2012.
– Ferreira AM, de Andrade D, Rigotti MA, de Almeida MTG, Guerra OG, Santos Junior AG. Avaliação da desinfecção de superfícies hospitalares por diferentes métodos de monitoramento. Rev Latino-Am Enfermagem. 2015;23(3):466-74.

**Prepared by:** Registered Nurse (COREN-certified).

**Revised by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 37 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Mandatory reporting.**

**Person(s) responsible**

Physician and nurse.

**Objective**

– Standardize the routine practice for mandatory reporting of diseases, conditions, and health events.

**Necessary materials**

– Computer with Internet access.
– Patient's complete sociodemographic and clinical data.
– Belo Horizonte City Hall access link for mandatory reporting (http://notificacao.pbh.gov. br/individual.php).

**Main activities**

– Conduct a thorough clinical evaluation if any notifiable disease is suspected.
– Request tests or referral to a specialist if necessary.
– Gather all the required data to complete the mandatory reporting form accurately:
  • Date of first symptoms.

- Patient's name.
- Sex.
- Date of birth.
- Age.
- Mother's name.
- Contact telephone number.
- City of residence.
- Full address.
- District.
- Reference point.
- E-mail.

– Report any strong suspicion and/or confirmed cases (through a report or corroborating examination) to your city's municipal system.

– Provide appropriate guidance to the patient.

The flowchart of the mandatory reporting process and the content of the reporting form used by the Belo Horizonte City Hall are illustrated in Figures 7 and 8.

**Special measures**

– The communication of the occurrence of specific diseases or health conditions to public health authorities, whether by health professionals or any citizen, is termed "reporting" and must be kept confidential.

– Suspected cases must be reported without waiting for confirmation to ensure timely implementation of necessary prevention and control measures.

– According to Anvisa's guidelines, both monitoring and mandatory reporting of diseases can be facilitated through the City Hall's Portal (http://notificacao.pbh.gov.br/individual.php).

**Annex**

– Contact telephone numbers and addresses:

– Municipal Regional Health Authority:
Address:
Phone:

– Municipal Health Department:
Address:
Phone:

– Epidemiological Surveillance Management Unit (GVIGE - central level)

**References**

– Belo Horizonte City Hall [website]. Available from: https://prefeitura.pbh.gov.br/saude/informacoes/vigilancia/vigilancia-epidemiologica.

– Belo Horizonte City Hall [website]. Available from: https://prefeitura.pbh.gov.br/saude/informacoes/vigilancia/vigilancia-epidemiologica/fichas-de-notificacao-compulsoria.

– Brazil. Ministério da Saúde. Secretaria de Vigilância em Saúde. Coordenação-Geral de Desenvolvimento da Epidemiologia em Serviços. Guia de Vigilância em Saúde: volume único [recurso eletrônico] / Ministério da Saúde, Secretaria de Vigilância em Saúde, Coordenação-Geral de Desenvolvimento da Epidemiologia em Serviços. 3rd ed. Brasília: Ministério da Saúde, 2019. Available from: https://prefeitura.pbh.gov. br/sites/default/files/estrutura-de-governo/saude/ Guia%20de%20Vigil%C3%A2ncia%20em%20 Sa%C3%BAde%202019.pdf. Accessed on May 2024.

**Notifiable diseases/events**

– Serious workplace accidents
– AIDS (patients aged 13 years or older)
– AIDS (patients under 13 years of age)
– Venomous animals
– Human anti-rabies
– Botulism
– Cholera
– Pertussis
– HIV-exposed children
– Dengue-Chikungunya
– Diphtheria
– Acute Chagas disease
– Work-related illness/Work-related cancer
– Work-related illness/Occupational dermatoses
– Work-related illness/RSI/MSD
– Work-related illness/NIHL
– Work-related illness/Pneumoconioses
– Work-related illness/Work-related mental disorders
– Febrile exanthematous diseases/Measles/Rubella
– Epizootic

- Sporotrichosis
- Schistosomiasis
- Exposure to biological material
- Yellow fever
- Spotted fever
- West Nile fever
- Typhoid fever
- HIV-positive pregnant women
- Hansen's disease
- Hantavirus disease
- Viral hepatitis
- Exogenous intoxication
- American tegumentary leishmaniasis
- Visceral leishmaniasis
- Leptospirosis
- Malaria
- Meningitis
- Acute flaccid paralysis/Poliomyelitis
- Plague
- Human rabies
- Rotavirus
- Acquired syphilis
- Congenital syphilis
- Syphilis in pregnant women
- Congenital rubella syndrome
- Severe acute respiratory syndrome
- Outbreaks
- Outbreak - FBD
- Accidental tetanus
- Neonatal tetanus
- Tuberculosis
- Complicated varicella
- Interpersonal/self-directed violence

**For questions:**

- Epidemiological Surveillance Management Unit (GVIGE - central level)

  +55 (31) 3277.7767/7768
- Out of Hours CIEVS service - 98835.3120
- Municipal Health Department

  Address: 2336 Afonso Pena Ave - Funcionários, Belo Horizonte, MG, Brazil

  Opening hours: 8am to 6pm

  Phone: +55 (31) 3277.7722

**Prepared by:** Registered Nurse (COREN-certified).

**Revised by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

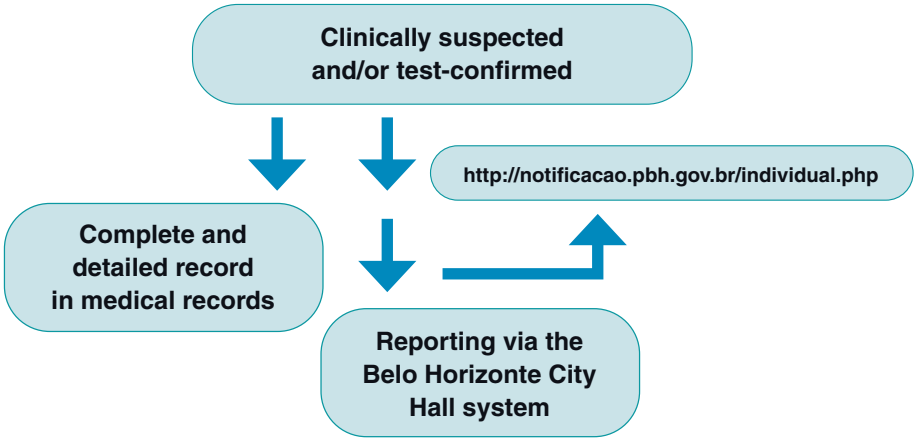


**Figure 7**
Flowchart of the mandatory reporting process

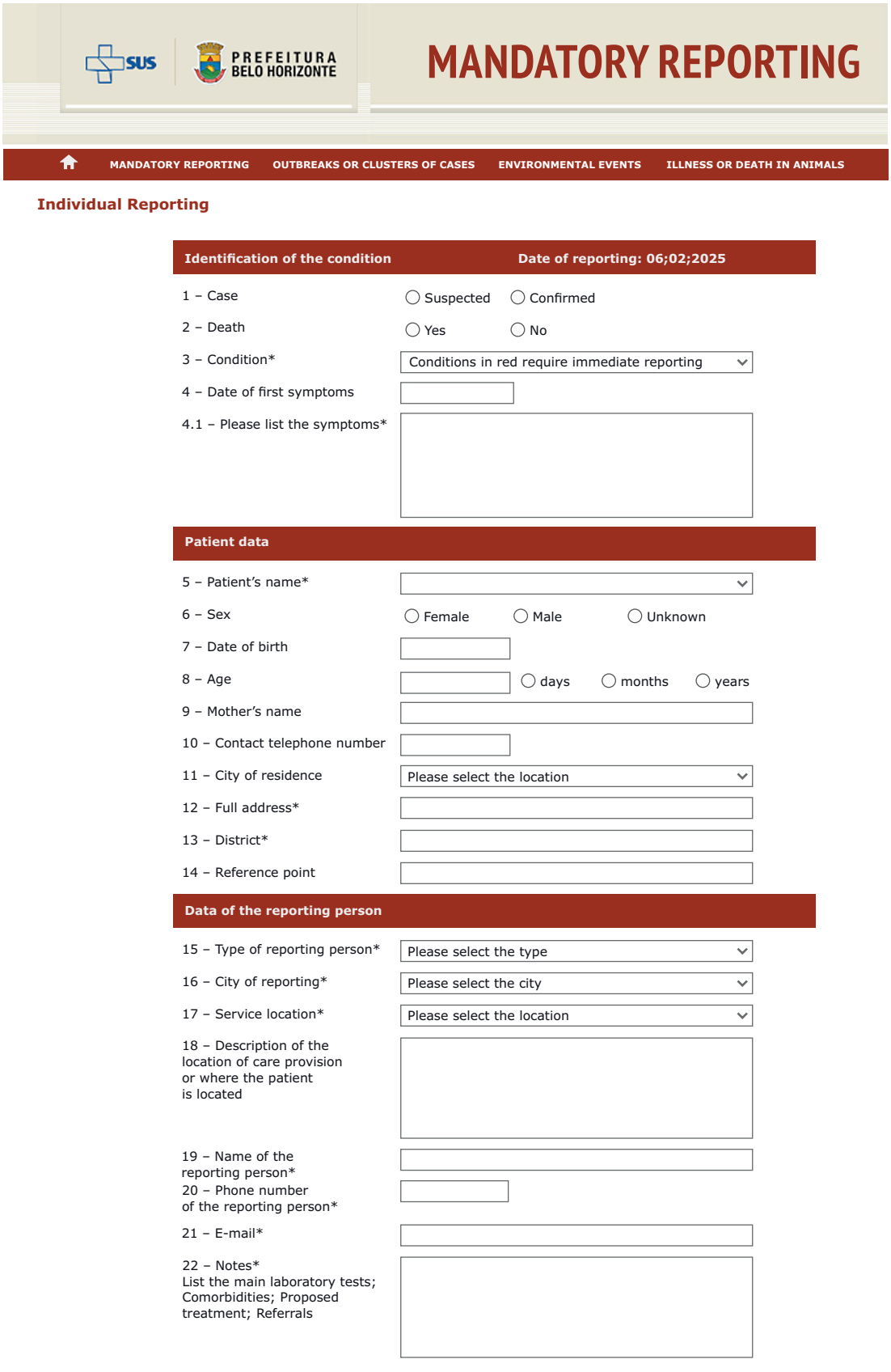


**Figure 8**
Belo Horizonte City Hall electronic form for mandatory reporting

**SOP No. 38 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Calibration of sphygmomanometers**.

**Person(s) responsible**

Secretary, physician, and nurse.

**Objective**

– Standardize the calibration routine for sphygmomanometers within the clinic to ensure they function correctly and maintain the quality of the care provided.

**Necessary materials**

– Sphygmomanometers.

**Main activities**

– Send devices for calibration according to the attached schedule (secretaries).
– Report any changes in a device's functioning (physicians and nurses) so that it can be sent for corrective maintenance when needed.
– Store devices in a suitable place to maximize their lifespan.

**Special measures**

– Upon delivery after calibration and/or maintenance, devices should be evaluated to check for any damage or malfunction.
– The sphygmomanometer cuff should be cleaned with cotton soaked in 70% ethyl alcohol after each use. If it becomes excessively dirty, it should be washed with soap and water as necessary.

**References**

– Portaria Inmetro nº 24, de 22 de fevereiro de 1996, Regulamento Técnico Metrológico que estabelece as condições a que devem satisfazer os esfigmomanômetros mecânicos do tipo aneroide, destinados a aferir a pressão arterial.

**Calibration schedule**

– Annual calibration in the month of _____. Mention where the calibration is conducted and have the validity seal.

**Prepared by:** Registered Nurse (COREN-certified).

**Revised by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 39 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Infection control**.

**Person(s) responsible**

Physician, nurse, administrative staff, and secretary.

**Objective**

– The office or clinic does not have inpatients. It provides diagnostic and treatment services for patients with allergic diseases, as well as vaccination and immunobiological agent administration.
– A license from the competent health authority is a mandatory requirement for operation. Failure to possess this license would constitute a breach of current legal and regulatory standards.
– It is the responsibility of everyone at the clinic to monitor and adhere to the cleaning and disinfection protocols outlined in the SOPs to prevent the spread of diseases and contamination.
– The use of PPE is critical to safeguarding the health of all clinic personnel.
– The 5 moments for hand hygiene is a measure adopted and recommended by the Ministry of Health.
– Soap and 70% alcohol dispensers should be available throughout the facilities for common use by employees and patients.
– Environmental disinfection should be performed using a quaternary ammonium solution.
– To ensure proper and compliant disposal, waste should be kept under supervision following the guidelines established in the Health Care Waste Management Plan.
– All diagnostic, therapeutic, and auxiliary utensils and instruments used in the clinic that may come into contact with biological agents must be disposable.

– The clinic is responsible for the periodic checking and calibration of all equipment and devices, in accordance with current legislation.
– All patients must have a computerized record containing their data, as well as their illness, ensuring easy access to information on an individual basis.

**Actions in case of noncompliance**

– For other instances of noncompliance, notify the clinic's Technical Supervisor so appropriate action can be taken.

**Reference**

– Brazil. Agência Nacional de Vigilância Sanitária. Segurança do paciente em serviços de saúde: limpeza e desinfecção. Brasília: Anvisa, 2012. Available from: https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/servicosdesaude/publicacoes/manual-de-limpeza-e-desinfeccao-desuperficies.pdf/view. Accessed on May 5 2021.

**Prepared by:** Registered Nurse (COREN-certified).

**Revised by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 40 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Power outage contingency plan – Refrigerators**.

**Person(s) responsible**

Physician, nurse, administrative staff, and secretary.

**Objective**

– Safeguard immunobiological agents and their quality should the refrigerator fail for any reason.

**Necessary materials**

– Contingency Plan Flowchart.
– Contact telephone numbers.

**Main activities**

– In the event of a power interruption or equipment malfunction, it is crucial to keep the refrigerator closed and monitor the internal temperature closely.
– For example, the Indrel RW22D® refrigerator has an autonomy of 48 hours, provided the doors remain closed, according to the manual.
– The internal temperature must be strictly checked every 10 minutes using an external digital thermometer.
– The refrigerator system is programmed to contact up to three designated telephone numbers in case of a breakdown, temperature fluctuation, or power outage. It will automatically dial these numbers and play a pre-recorded message to alert users of any issues.
– If there is an unscheduled power outage, contact the energy provider to ascertain the estimated restoration time.
– If the equipment malfunctions, notify the equipment maintenance department immediately to explore potential solutions.
– If power restoration is not expected, the equipment issue cannot be resolved promptly, or the internal temperature approaches 7 °C, immediately transfer the immunobiological agents to a cooler, ensuring the temperature remains between +2 and +8 °C (SOP 41 – Cooler assembly).
– The clinic must have reusable ice packs readily available for use when storing immunobiological agents in coolers.
– When transferring vaccines to a cooler, ensure they are packaged to prevent mechanical shocks (do not leave them loose inside the cooler).

**Actions in case of noncompliance**

– In all cases, the nurse should develop educational activities to address the issue, ensuring the correction and application of this SOP.

**Prepared by:** Registered Nurse (COREN-certified).

**Revised by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 41 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Cooler assembly**.

**Person(s) responsible**

Physician, nurse, administrative staff, and secretary.

**Objective**

– Ensure immunobiological agents are kept at a standardized temperature between 2 and 8 °C to maintain their immunizing potential.

**Necessary materials**

– Reusable ice packs.
– Polyurethane cooler.
– Maximum and minimum thermometer.

**Coolers**

– Coolers are typically made from thermal materials such as polyurethane or expanded polystyrene (e.g. Styrofoam, Insonor), with the latter being the most common for transporting immunobiological agents between laboratories and vaccination rooms.
– Each cooler must be capable of maintaining a storage temperature between +2 and +8 °C for a specific duration.
– Before use, inspect the cooler for any cracks or holes, and ensure the lid is in good condition.
– After each use, thoroughly wash and dry the coolers. Store them without the lid until they are completely dry. Once dry, replace the lid and store them in a suitable location (Figure 9).

**Cooler assembly**

***Special measures***

– Maintain the internal temperature between +2 and +8 °C. Monitor this using an extension cable thermometer, preferably, or a linear thermometer. Replace the recyclable ice packs as needed to stay within the temperature range.
– Use recyclable ice packs that have been stored in the refrigerator freezer. Allow them to acclimatize before use, as their temperature in the freezer can reach approximately -7 °C.
– When arranging the immunobiological agents inside the cooler, ensure they are surrounded (islanded) by recyclable ice. For the cooler mentioned above, this typically involves using three to five 500 mL recyclable ice packs.
– Always keep the cooler out of direct sunlight and away from any heat sources, such as stoves or heaters.

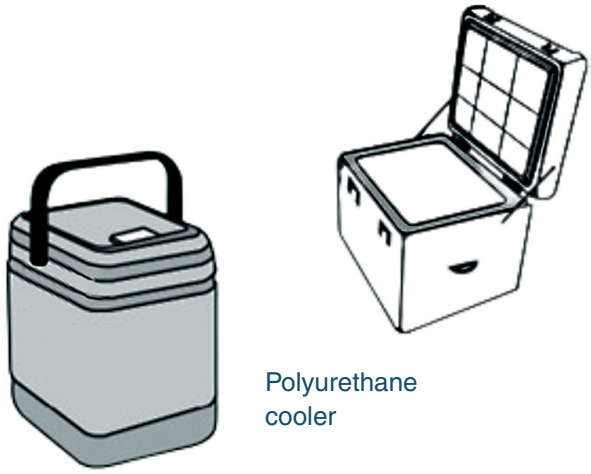


**Figure 9**
Polyurethane cooler

**Cooler assembly**

– Ice pack acclimatization: remove the reusable ice packs from the refrigerator and place them on sinks or countertops that have been previously cleaned with 70% alcohol. Leave the ice packs in place until the “fog” that typically covers their frozen surface has dissipated.
– Simultaneously, take one ice pack and place it on an insulating material, such as the lid of a Styrofoam box. Position the bulb of a thermometer with an extension cable underneath this ice pack, to monitor when the packs reach the minimum required temperature of 0 °C.

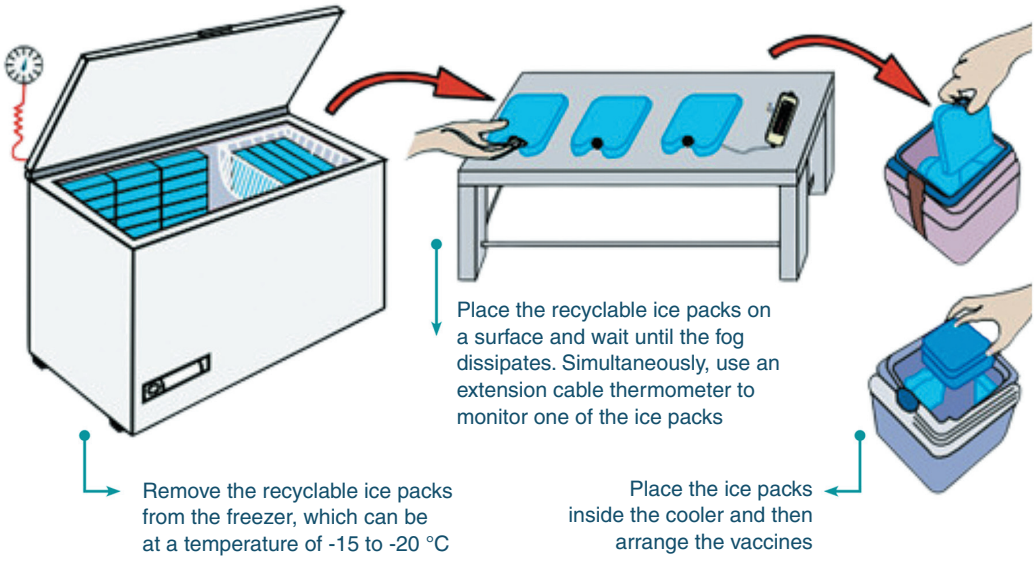


**Figure 10**
Cooler assembly

– Once the "fog" has dissipated and a positive temperature is confirmed by the extension cable thermometer located underneath one of the packs, arrange the items in the coolers as shown in Figure 10.
– Meanwhile, prior to placing the vaccines inside, it is recommended to use the extension cable thermometer to measure and confirm the internal temperature of the cooler.

### Actions in case of noncompliance

– In all cases, the nurse should develop educational activities to address the issue, ensuring the correction and application of this SOP.

**Prepared by:** Registered Nurse (COREN-certified).

**Revised by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 42 – Date: __/__/__ – Revision: __/__/__**

### Procedure

**Patient identification**.

### Person(s) responsible

All staff members.

### Objective

– Ensure that every patient receives the intended care (procedure or treatment) by verifying their identity before any action is taken.

### Necessary materials

– Patient's medical record.

### Required actions

– Call the patient by their full name.

– Verify the patient's identity by cross-referencing their name and date of birth with the information in their medical record.

**Observation**

– Even if the health care professional is familiar with the patient, it is crucial to follow these identification protocols to ensure the correct patient receives the correct care.

**Reference**

– Ministério da Saúde. Portaria N° 529: Portaria Nº 529, de 1º de Abril de 2013. Available from: https://bvsms.saude.gov.br/bvs/saudelegis/gm/2013/prt0529_01_04_2013.html. Accessed on Sep 13 2022.

**Prepared by:** Registered Nurse (COREN-certified).

**Revised by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 43 – Date: __/__/__ – Revision: __/__/__**

**Procedure**

**Fall prevention**.

**Person(s) responsible**

All staff members.

**Objective**

– Enhance patient safety by preventing, minimizing, or eliminating any fall risks during their treatment period.

**Necessary materials**

– Patient's medical record.

**Required actions**

– Identify and document each patient's fall risk on their care form and/or medical records.
– Clearly mark any steps or uneven surfaces with visible signage.
– Pay close attention to patients' footwear, advising them to avoid shoes that may increase the risk of slipping and falling.
– Provide clear instructions to both the patient and their family members on effective fall prevention strategies.

**Observations**

***1. The following situations are considered falls:***

– Finding a patient on the floor.
– A patient being supported during a fall, even if they do not reach the floor.
– A patient slipping from a chair, armchair, or toilet onto the floor.

***2. Factors that can increase the risk of falling***

– Altered mental state (confusion or agitation).
– Neurological disorders.
– Impaired gait and balance.
– Underlying health conditions and chronic diseases.
– Sensory impairments affecting hearing, vision, and touch.
– A history of previous falls.
– Pregnancy.
– Obesity.
– Use of medications that affect the central nervous system.
– Age (those aged > 60 years and children).
– Urinary or bowel urgency.

A fall risk is considered to be present if one or more of these risk factors are identified.

***3. Reporting and actions in the event of a fall***

– Transport the patient on a stretcher and notify the attending physician for evaluation and a physical examination.
– If the attending is not immediately available, the staff member should request an evaluation from another physician or arrange for a referral to the emergency department.
– Document the circumstances of the fall and the medical actions taken in the patient's medical record.

**Reference**

– Ministério da Saúde. Portaria Nº 529, de 1º de Abril de 2013. Available from: https://bvsms.saude.gov.br/bvs/saudelegis/gm/2013/prt0529_01_04_2013.html. Accessed on Sep 13 2022.

**Prepared by:** Registered Nurse (COREN-certified).

**Revised by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

**SOP No. 44 – Date: __/__/__ – Revision: __/__/__**

## NURSING REGULATIONS AT THE CLINIC:

### Introduction

The Clinic _____
is located at _____ ,
_____
registered under CNPJ number _____ , and is private in nature. Its main activity is to provide care for patients within the specialty of Allergy and Immunology. You can contact the clinic by phone:
_____
or _____ ,
via e-mail: _____
or through our Instagram page: _____

The health insurance plans accepted at the clinic include:
_____
_____ .

### Objective

Define and outline the objectives of nursing professionals within the clinic.

### Duties and responsibilities

The Nursing Technical Supervisor holds responsibility for the following tasks:

- Planning, supervising, and monitoring all health care activities.
- Actively participating in the clinic management process through effective collaboration with support sectors, including administration, reception, and offices.
- Implementing and overseeing the systematization of patient care protocols.
- Updating and disseminating the internal nursing regulations on an annual basis, while also providing support to medical directors.
- Developing and revising SOPs annually and whenever new activities are introduced.
- Ensuring adequate health care coverage in the vaccination room, spirometry services, and skin testing procedures.
- Monitoring audits conducted by health surveillance and other regulatory agencies, and implementing necessary adjustments to maintain compliance.
- Participating in the recruitment, interviewing, and onboarding processes for new nursing staff members.
- Overseeing the maintenance, preservation, and inventory control of all nursing-related assets and equipment.
- Identifying and addressing any maintenance requirements, coordinating with the relevant support services to resolve these needs.
- Conducting regular assessments of material and equipment needs and collaborating with the administrative department to develop a purchasing schedule.
- Providing training to nursing staff under their supervision during onboarding, transitions to new roles or departments, and whenever there are updates to processes and procedures, as well as encouraging and facilitating their team's participation in institutional events.
- Developing and managing the nursing quality process (manuals, regulations, SOPs, and protocols).
- Monitoring and supervising the temperature of vaccine and medication refrigerators, ensuring accurate recording on designated forms.
- Maintaining oversight of the emergency cart.
- Conducting daily functionality checks of the AED and documenting these checks on the appropriate form.
- Performing activities related to the clinic's Infection Control service.
- Executing tasks that are specifically designated as exclusive to nurses.

**Staff and requirements**

– Requirements for the positions listed below:

***II - Nursing Technical Supervisor***

– COREN-certified, with jurisdiction in the area where the practice will take place;
– At least 2 years of proven professional experience.

**Working hours and shifts**

The Clinic _____

operates from Monday to Friday, between ____ : ____

AM and _____ : _____ PM.

All clinic employees are required to be in uniform and report to work at their scheduled time as specified in their employment contract.

The medical director has the authority to modify work hours as necessary, and any such changes will be communicated to the affected employee in advance.

The standard work schedule is as follows:

– Physicians: Monday to Friday, from xx:xx to xx:xx, with a break from xx:xx to xx:xx.
– Nurses: Tuesday and Thursday, from xx:xx to xx:xx.
– Administrative assistant: Monday to Friday, from xx:xx to xx:xx.
– Secretary I: Monday to Friday, from xx:xx to xx:xx.
– Secretary II: Monday to Friday, from xx:xx to xx:xx.

**General Provisions**

These regulations are to be followed by all employees of the Clinic _____ .

The nursing SOPs will be accessible as PDF files in a shared folder on the server and also available in print within the room (where they must be stored). Employees should refer to these documents if they have any questions. The SOPs will be updated annually or whenever their content requires changes.

These regulations may be subject to amendments due to the adoption of new relevant legislation, the implementation or discontinuation of units or services within the clinic, or at the discretion of the board of directors.

Any proposed changes to these regulations must be submitted to the medical board for their approval.

Situations not explicitly addressed in these regulations will be resolved through collaboration between the medical team, nursing staff, and administration.

These internal regulations will be made available to all clinic employees following approval by the board of directors. They will be reviewed/updated biannually or when their content is modified.

**Prepared by:** Registered Nurse (COREN-certified).

**Revised by:** Registered Nurse (COREN-certified).

**Approved by:** Clinic's Technical Supervisor (Physician).

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**Conclusions**

The implementation of SOPs in allergists' offices will help organize and standardize daily tasks and procedures. This will ensure that every team member follows the same protocols, which is crucial for maintaining patient safety and the efficient operation of the clinic. Furthermore, these SOPs will assist us in complying with the health regulations and standards set forth by regulatory bodies such as the Brazilian Federal Board of Medicine and National Health Surveillance Agency.

**Recommended reading**

– Agência Nacional de Vigilância Sanitária - Anvisa. Segurança do Paciente em Serviços de Saúde – Higienização das mãos [Internet]. Available from: https://bvsms.saude.gov.br/bvs/publicacoes/seguranca_paciente_servicos_saude_higienizacao_ maos.pdf.
– Agência Nacional de Vigilância Sanitária – Anvisa Segurança do Paciente em Serviços de Saúde – Limpeza e Desinfecção de Superfícies [Internet]. Available from: https://www.gov.br/anvisa/ptbr/centraisdeconteudo/publicacoes/servicosdesaude/publicacoes/manual-de-limpeza-e-desinfeccao-desuperficies.pdf.

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