



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUN 04 2018

ADMINISTRATIVE ORDER

No. 2018 – 0016

SUBJECT: Revised Guidelines in the Implementation of the One-Stop Shop Licensing System

I. RATIONALE/BACKGROUND

Administrative Order (A.O.) No. 2007-0021, known as, “Harmonization and Streamlining of the Licensure System for Hospitals” was issued on June 6, 2007, to harmonize and streamline the systems and processes that will make health regulation more rational and client responsive. The One-Stop Shop (OSS) Licensing System was adopted, and entailed transaction with one regulatory office in the Department of Health (DOH), a unified inspection team, and issuance of a single license for hospitals which covered their ancillary services and other health facilities/services. The application of the OSS Licensing System expanded to include non-institution based health facilities with ancillary services, such as Medical Facilities for Overseas Workers and Seafarers (MFOWS), Ambulatory Surgical Clinics (ASC), Dialysis Clinics, based on A.O. No. 2008-0027, known as “One-Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital-Based Dialysis Clinics and Non-Hospital-Based Ambulatory Surgical Clinics with Ancillary Services.”

Recent changes, such as the passage of Republic Act. No. 9711 or the Food and Drug Administration (FDA) Act of 2009, necessitated transfer of the then DOH Bureau of Health Devices and Technology (BHDT) to Alabang, Muntinlupa, when it became the FDA-Center for Device Regulation, Radiation Health and Research (CDRRHR). Consequently, the filing of application and payment of fees for radiation facilities are now received at the FDA main office. Moreover, the varied modes of payment (direct to DOH Central/Regional Cashier, online bank payments), the separate schedules for inspection, and the different processing timelines being followed by the concerned regulatory offices are no longer in consonance with the OSS Licensing System, and contributed further to the delay in the issuance of the DOH-License to Operate (DOH-LTO) or DOH-Certificate of Accreditation (DOH-COA).

Cognizant of the situation and the need for a more efficient and harmonized system in the issuance of DOH-LTO and DOH-COA, the OSS Licensing System is to be adopted once again. As a refinement to the current regulatory scheme and to create more impact by making the licensing process timely, easy and convenient to the clients, the concerned regulatory offices shall accept and process applications online through the Online Licensing and Regulatory System (OLRS). Furthermore, this is in support of the President’s directive to streamline all government processes including regulation.

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The implementation of the OSS Online Licensing System shall also cover the other health facilities with ancillary services, such as non-hospital-based MFOWS, non-hospital-based ASCs, non-hospital-based Dialysis Clinics, Infirmaries and Birthing Homes.

II. OBJECTIVE

This Order sets the revised guidelines in the implementation of the One-Stop Shop Licensing System using the Online Licensing and Regulatory System (OLRS) for the licensure of hospitals and licensure and accreditation of other health facilities with ancillary services.



III. SCOPE

This Order shall apply to the following DOH offices involved in the enforcement of regulatory standards in all government and private hospitals and other health facilities namely: the Health Facilities and Services Regulatory Bureau (HFSRB), the Regional Office-Regulatory, Licensing and Enforcement Division (RO-RLED) and the Food and Drug Administration (FDA), which involves the Regional Field Office (RFO) and the Center for Device Regulation, Radiation Health and Research (CDRRHR).

IV. DEFINITION OF TERMS AND ACRONYMS


1. Applicant – the natural or juridical person who is applying for a License to Operate or Certificate of Accreditation of a hospital or any other health facility
2. Certificate of Compliance (COC) – a form of authorization/permission granted by the Food and Drug Administration which serves as proof of the facility's compliance to the set technical requirements. It is a prerequisite for the issuance of the Department of Health-License to Operate.
3. CDRR – refers to the Center for Drug Regulation and Research of the FDA
4. CDRRHR – refers to the Center for Device Regulation, Radiation Health and Research of the FDA
5. Certificate of Registration – refers to the certificate issued by CDRRHR to compliant Magnetic Resonance Imaging (MRI) facilities
6. DOH – refers to the Department of Health
7. Department of Health-Certificate of Accreditation (DOH-COA) – refers to the formal authorization issued by DOH to an individual, partnership, corporation or association to operate a health facility. It refers to compliance to standards set for a particular purpose such as, but not limited to, HIV testing, drug testing, water analysis, issuance of medical fitness certification to overseas work applicants, and performance of kidney transplant. These standards cover input/structural, process and outcome/output standards.
8. Department of Health-License to Operate (DOH-LTO) – a formal authority issued by DOH to an individual, agency, partnership or corporation to operate a hospital or other health facility. It is a prerequisite for accreditation of a health facility (regulated by HFSRB) by any DOH-recognized accrediting body for

Quality Management System, such as International Organization for Standardization (ISO).

9. FDA – refers to the Food and Drug Administration
10. Health Facility – refers to institution, whether stationary or mobile, land based or otherwise, that provides healthcare and other health-related establishment which provides diagnostics, therapeutic, rehabilitative, palliative and/or related health care services except medical radiation facilities and hospital pharmacies.
11. Health Facility Evaluation and Review Committee (HFERC) – refers to the committee that reviews all applications for Department of Health-Permit to Construct (DOH-PTC) with respect to compliance with the guidelines in planning and design of health facilities.
12. Health Facilities and Services Regulatory Bureau (HFSRB) – the Bureau of DOH in charge with the implementation of these rules and regulations.
13. Hospital – a place devoted primarily to the maintenance and operation of health facilities for the diagnosis, treatment and care of individuals suffering from illness, disease, injury or deformity or in need of obstetrical or other surgical, medical and nursing care. It shall also be construed as any institution, building or place where there are installed beds, cribs or bassinets for twenty-four hour use or longer by patients in the treatment of diseases.
14. Initial Applications – refer to applications by newly constructed health facilities, changes in the circumstances of the facility, such as, but not limited to, change of ownership, transfer of site, and increase in bed and major alterations or renovations.
15. One-Stop Shop (OSS) Licensing System – a strategy of the DOH to harmonize the licensure of hospitals, their ancillary and other health facilities including, but not limited to, the clinical laboratory, HIV testing, drinking water analysis and drug testing; blood bank, blood collection unit and blood station; dialysis clinic; ambulatory surgical clinic; pharmacy; and medical x-ray facility; but excluding hospital-based Medical Facilities for Overseas Workers and Seafarers (MFOWS), hospital-based Drug Abuse Treatment and Rehabilitation Center, hospital-based Stem Cell Facility, facilities for kidney transplantation, and facility using radioactive material that are currently regulated by the Philippine Nuclear Research Institute (PNRI). The OSS shall also apply to non-hospital-based Medical Facilities for Overseas Workers and Seafarers, non-hospital-based Ambulatory Surgical Clinics, non-hospital-based Dialysis Clinics, Infirmaries and Birthing Homes.
16. Recommendation Letter (RL) – a form of authorization/permission granted by the RFO and CDRRHR of the Food and Drug Administration to facilities with waived inspection but have proven compliance to documentary requirements. These facilities shall be subject to Post Licensing Inspection (PLI) prior to the issuance of the Certificate of Compliance. 
17. RFO – refers to the Regional Field Office of the FDA
18. RO-RLED – Regional Office-Regulation Licensing and Enforcement Division 

V. IMPLEMENTING MECHANISMS

A. General Guidelines

1. All hospitals and other health facilities must secure a DOH-LTO or DOH-COA, whichever is applicable, and must be compliant at all times with the licensing standards and requirements set forth by HFSRB and FDA.
2. The Certificate of Need (CON), when applicable, issued by the Regional Office and the Department of Health-Permit to Construct (DOH-PTC), issued by the HFSRB or the RO-RLED, are prerequisites for the issuance of the DOH-LTO or DOH-COA.
3. The guidelines for the OSS implementation shall be strictly followed at the central and the regional levels of the involved DOH regulatory offices.
4. The HFSRB shall be responsible for the initial and renewal of DOH-LTO of levels 2 and 3 general hospitals and specialty hospitals, non-hospital-based MFOWS, non-hospital-based ASCs and non-hospital-based dialysis clinics.
5. The RO-RLED shall be responsible for the initial and renewal of DOH-LTO of birthing homes, infirmaries, and level 1 hospitals and their add-on facilities, for example, dialysis clinic in a level 1 hospital.
6. All applications, whether for initial or renewal, for DOH-LTO or DOH-COA shall be processed through the Online Licensing and Regulatory System (OLRS), once the system is fully functional.
7. The HFSRB/RO-RLED and FDA (RFO and CDRRHR) shall assign OSS evaluators for the assessment of all submitted applications and corresponding documentary requirements.
8. At the Central Office, the Director IV, or in his/her absence or unavailability or when delegated, the Director III of HFSRB, shall approve the issuance of the DOH-LTO or DOH-COA of the health facility.
9. At the Regional Office, the Director IV, or in his/her absence or unavailability or when delegated, the Director III of the RO-RLED, shall approve the issuance of the DOH-LTO or DOH-COA of the health facility.
10. A single DOH-LTO or DOH-COA shall be issued to the health facility, and shall include:
 - a) Category of the facility;
 - b) Authorized bed capacity (when applicable);
 - c) Ancillary services and other regulated health facilities regardless of ownership, beyond the requirement for the category of that particular health facility; and
 - d) Validity period 

11. The OSS Licensing System shall be applicable to all health facilities and ancillary services within the hospital premises, except for the following health facilities, which shall require a separate application for DOH-COA:
 - a) Medical Facilities for Overseas Workers and Seafarers (MFOWS);
 - b) Drug Abuse Treatment and Rehabilitation Center (DATRC);
 - c) Human Stem Cell and Cell-based or Cellular Therapy Facility; and
 - d) Facilities for Kidney Transplantation
12. Sanctions for violations meted out for ancillary services and other health facilities, regardless of ownership, shall be borne by the hospital or health facility where they are located.
13. A database of all licensed health facilities under the OSS shall be integrated into the OLRs.

B. Specific Guidelines

1. Licensing or Accreditation Process – Initial Application (See **Annex A** for the Process Flow of Initial Application)
 - a) Filing of application for initial DOH-LTO/DOH-COA shall be from the start of the working day of the year to November 15.
 - b) Initial applicants shall create an account at the OLRs webpage. The user name and password shall be safeguarded by the client, and shall be used to register for all transactions.
 - c) Once registered, the applicant may log in to access and fill out the application forms. The corresponding fees for the applied health facilities/services shall be shown to guide the client in the computation of fees due to each agency. The applicant shall then encode and/or upload the documentary requirements including scanned copy of the proofs of payment for HFSRB/RO-RLED and FDA.
 - d) The non-refundable application fee shall be paid to the corresponding regulatory offices: for HFSRB to the DOH cashier, for the RO-RLED to the RO Cashier and for RFO and CDRRHR through FDA cashier or bank payments specified by the FDA. Applicant shall provide proofs of payment, such as scanned copy of the official receipt and deposit slip/on-coll payment slip.
 - e) The application will not proceed if there are incomplete entries and lacking documentary requirements.
 - f) Once the application is accepted into the system, the assigned OSS evaluators shall assess the technical correctness of the documentary requirements submitted including proofs of payment. A technically correct application means that the required documents, as specified in the application checklist of HFSRB/RO-RLED and FDA, have been submitted. The timeline from acceptance to approval of application is three (3) days. *nd*

- g) If the application was evaluated to be technically incorrect, a system generated email will be sent automatically to the applicant, and the status of the application shall appear as "WITH DEFICIENCY". A STOP-CLOCK shall be observed and the client shall be given thirty (30) days to correct the documentary requirements. Failure to do so shall result in the DISAPPROVAL and forfeiture of payment.
- h) If the application was evaluated to be technically correct, HFSRB/RO-RLED and FDA shall organize a team of inspectors and shall implement joint inspections of health facilities whose priority are those under the One-Stop Shop Licensing System. From the time of approval of the application, the inspection teams from HFSRB/RO-RLED, RFO and CDRRHR/RFO shall be given twenty (20) days to inspect the facility.
- i) Inspection maybe waived by RFO, who shall then automatically issue a Recommendation Letter (RL) for pharmacy and schedule a post licensing inspection. Nevertheless, if deemed necessary, the RFO may conduct an inspection of the pharmacy and shall then transmit the COC online to HFSRB/RO-RLED, if compliant. A copy of the Inspection Report shall be issued to the facility. The list of facilities found to be non-compliant during the post licensing inspection shall be forwarded to HFSRB/RO-RLED.
- j) If found non-compliant during inspection, the inspection team from the concerned offices shall notify the applicant of their deficiencies and the facility shall be given time to comply within the prescribed timeline (maximum of 30 days).
- k) The counting of days for the HFSRB/RO-RLED to process the application shall be stopped ("STOP-CLOCK") until all deficiencies have been complied with.
- l) Failure to complete the compliance within the timeline given shall mean disapproval of the application and forfeiture of payment. The client shall then be notified through e-mail, and shall have to re-apply.
- m) For compliant health facilities, the following documents shall be transmitted online to HFSRB/RO-RLED:

- i. For Hospital, Infirmary

From CDRRHR/RFO: COC for Levels I, II and III diagnostic x-ray facilities, dental x-ray facilities, interventional and specialized x-ray facilities; Certificate of Registration for Magnetic Resonance Imaging (MRI) facilities; and LTO for Transportable X-ray Facility and for Therapeutic X-ray Facility Utilizing Medical Linear Accelerator (LINAC) x-ray machines

From RFO: RL/COC for pharmacy

- ii. For Birthing Home, ASC, MFOWS, Dialysis Clinic

From CDRRHR/RFO: COC for diagnostic radiology

From RFO: RL/COC for pharmacy

- n) The assigned OSS evaluators from HFSRB/RO-RLED, after receiving the transmitted RL/COC from RFO, and COC, COR or LTO from CDRRHR/RFO, shall then recommend to the Director IV of HFSRB/RO Director, or in his/her absence or unavailability or when delegated, the Director III of HFSRB/RO, the approval of the issuance of the DOH-LTO or DOH-COA.
 - o) The Director IV of HFSRB/RO Director, or in his/her absence or unavailability or when delegated, the Director III of HFSRB/RO, shall approve the issuance of the DOH-LTO or DOH-COA.
 - p) The system will then generate a hard copy of the DOH-LTO or DOH-COA on a security paper with QR (quick response) code, to be picked up by the applicant or be delivered by courier, depending on the chosen method of delivery.
 - q) Once licensed, applicant shall be assigned a National Health Facility Registry Code as its new username and a system generated password for DOH-LTO/DOH-COA renewal and shall be transmitted via email.
 - r) The timeline from complete compliance after inspection to the issuance of DOH-LTO/DOH-COA shall be seven (7) days.
 - s) The timeline for the issuance of the initial DOH-LTO or DOH-COA shall be within thirty (30) days from acceptance of complete application.
 - t) If due to force majeure or any unforeseen events, the RL/COC/COR/LTO from FDA and DOH-LTO or DOH-COA were not issued within the 30-day period from receipt of the complete application, the DOH-LTO or DOH-COA shall automatically be issued, but a post licensing inspection shall be undertaken by the concerned offices.
2. Renewal of the License or Accreditation (See **Annex B** for the Process Flow of Renewal Application)
- a) The renewal period for DOH-LTO or DOH-COA shall be from October 1 to December 15 of the current year. A 10% discount shall be given to those who filed complete renewal applications from October 1 to November 30 of the current year.
 - b) Application to HFSRB/RO-RLED and FDA (RFO and CDRRHR) shall be through the OLRs, using the National Health Facility Registry code assigned to the licensed health facility as username and the system generated password.
 - c) The timeline for automatic renewal shall be fifteen (15) days from acceptance into the system of the complete application forms, together with the other documentary requirements and the uploaded scanned copy of the proofs of payment for each office, to the issuance of DOH-LTO/DOH-COA. *all*

- d) Eligible for automatic renewal:
- i. facilities with no sanctions, violations or deficiencies;
 - ii. facilities which have corrected/complied to the noted violations at the time of application; and
 - iii. facilities which submitted/participated in the Online Health Facility Statistical Reporting System (OHFSRS)
- e) Automatic renewal shall only apply to hospitals.
- f) The DOH-LTO or DOH-COA of those facilities with sanctions, violations or deficiencies shall be renewed only after serving out their sanction/penalty or corrected their violations, or completed their deficiencies. If compliance was met after the expiration of the DOH-LTO/DOH-COA, the date of validity of the new DOH-LTO/DOH-COA shall start from the date of full compliance.
- g) HFSRB shall conduct monitoring visits and FDA (RFO and CDRRHR) may carry out Post Licensing Inspection on those facilities which renewed their DOH-LTO/DOH-COA automatically, and those with previous sanctions or violations.
- h) Whenever there are changes in the circumstances of the facility, such as, but not limited to, change of ownership, transfer of site, and increase in bed, the health facility shall go through the same process in the issuance of initial DOH-LTO or DOH-COA.
- i) Sanctions for late filing of application for renewal of DOH-LTO or DOH-COA shall be in accordance with the existing rules and regulations of the concerned bureau/agency.

VI. VALIDITY OF DOH-LTO OR DOH-COA

- a) The DOH-LTO for the hospitals, birthing homes and infirmaries shall be valid for one (1) year.
- b) The DOH-LTO for non-hospital-based dialysis clinics and non-hospital-based ambulatory surgical clinics shall be valid for three (3) years.
- c) The DOH-COA for the non-hospital-based medical facilities for overseas workers and seafarers shall be valid for three (3) years.

VII. SCHEDULE OF FEES

- a) The DOH-LTO or DOH-COA fee shall follow the Schedule of Fees currently prescribed by the DOH and FDA.
- b) The applicant, upon filing the application, shall pay the corresponding fee to the DOH/RO Cashier and FDA Cashier or any authorized banks for pharmacy and diagnostic radiology and radiation oncology.

VIII. PENALTY

Imposable penalties for violations hereof shall be in accordance with A.O. No. 2007-0022 titled "Violations under the One-Stop Shop Licensure System for Hospitals", A.O. No. 2008-0027 known as "One-Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital-Based Dialysis Clinics and Non-Hospital-Based Ambulatory Surgical Clinics with Ancillary Services", and related issuances or guidelines.

IX. APPEAL

Any hospital or other health facility aggrieved by the decision of the Director IV of HFSRB/RO Director, or in his/her absence or unavailability or when delegated, the Director III of HFSRB/RO, or FDA Director-General may, within ten (10) days after receipt of the notice of decision file a notice of appeal to the Head of the Office for Health Regulation (OHR). All pertinent documents and records of the applicant shall then be elevated by the HFSRB or RO to the OHR. The decision of the Head of the OHR if still contested maybe brought on a final appeal to the Secretary of Health whose decision shall be final and executory.

X. TRANSITORY PROVISIONS

1. Implementation of the online licensing system shall be done by phase.
 - a. Phase 1 shall start on July 2018, and shall cover :
 - i. initial DOH-LTO of hospitals (HFSRB)
 - ii. initial DOH-LTO/DOH-COA of other health facilities (HFSRB)
 - b. Phase 2 shall start on July 2019, and shall cover:
 - i. initial and renewal DOH-LTO of hospitals (HFSRB/selected regional offices)
 - ii. initial and renewal of the DOH-LTO/DOH-COA of other health facilities (HFSRB/selected regional offices)
 - c. Phase 3 (full implementation) shall start on July 2020, and shall cover:
 - i. initial and renewal of the DOH-LTO/DOH-COA of all health facilities under the OSS Licensing System (HFSRB/all regional offices)
2. The OSS Licensing System shall be implemented even while the online system is being developed and finalized.
3. The General Guidelines and the Specific Guidelines for Initial and Renewal of DOH-LTO/DOH-COA (Section V. A and B of this A.O.) shall be applicable during the transition period. Submission of documentary requirements including the copy of the proofs of payment to HFSRB/RO-RLEDs shall be in hard copies, while those for FDA shall be in hard copies and soft copies saved in universal serial bus (USB) flash drive. The processing of the complete application forms and documentary requirements shall be done manually.
4. The HFSRB/RO-RLED and FDA shall designate OSS Evaluators who shall assess the completeness and technical correctness of the submitted documents.

5. The same timelines shall be observed for all processes (initial/renewal) as stated in Section V. A and B.

XI. REPEALING CLAUSE

This repeals/revokes A.O. No. 2007-0024 known as Guidelines for the Licensure of Department of Health Hospitals and A.O. No. 2008-0027 titled One-Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital-Based Dialysis Clinics and Non-Hospital-Based Ambulatory Surgical Clinics with Ancillary Services.

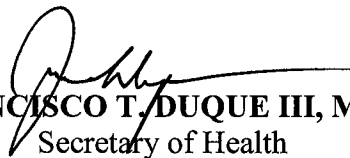
Provisions from previous issuances that are inconsistent or contrary to the provisions of this Order are hereby rescinded and modified accordingly.

XII. SEPARABILITY CLAUSE

In the event that any provision or part of this Order is declared unconstitutional or null and void or rendered invalid by any court of law of competent authority, those provisions not affected by such declaration shall remain valid and effective.

XIII. EFFECTIVITY

This Order shall take effect fifteen (15) days after its approval and publication in the official gazette or two (2) newspapers of general circulation.


FRANCISCO T. DUQUE III, M.D., MSc.
Secretary of Health



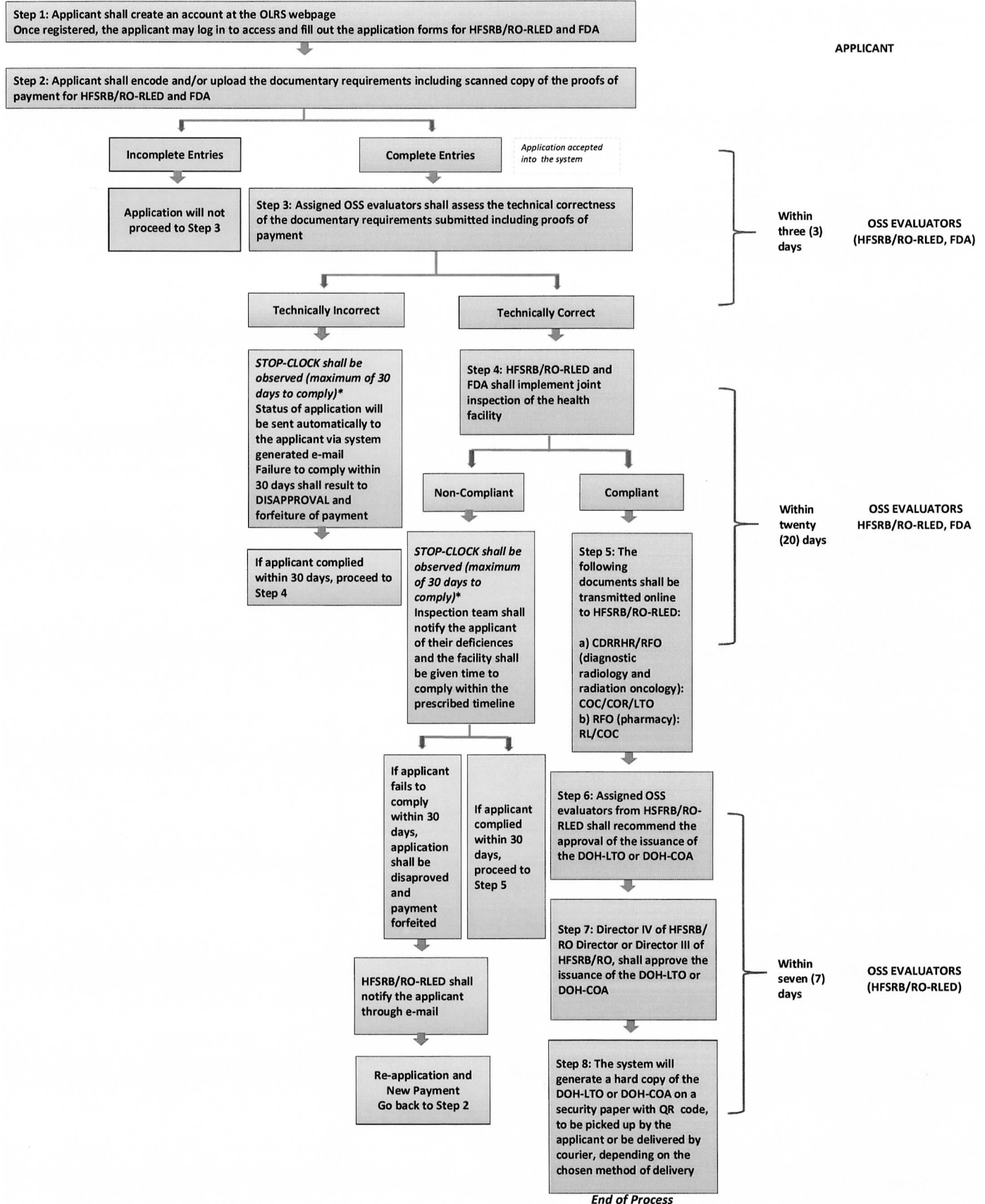
Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Annex A
A.O. No. 2018- 0016

ONE-STOP SHOP LICENSING SYSTEM PROCESS FLOW
INITIAL

TIME TABLE

PERSON/S RESPONSIBLE



Note: Once licensed, applicant shall be assigned a National Health Facility Registry Code as its new username and a system generated password for DOH-LTO/DOH-COA renewal and shall be transmitted via email.

***The counting of days shall be stopped ("STOP-CLOCK") until all deficiencies have been complied with.**



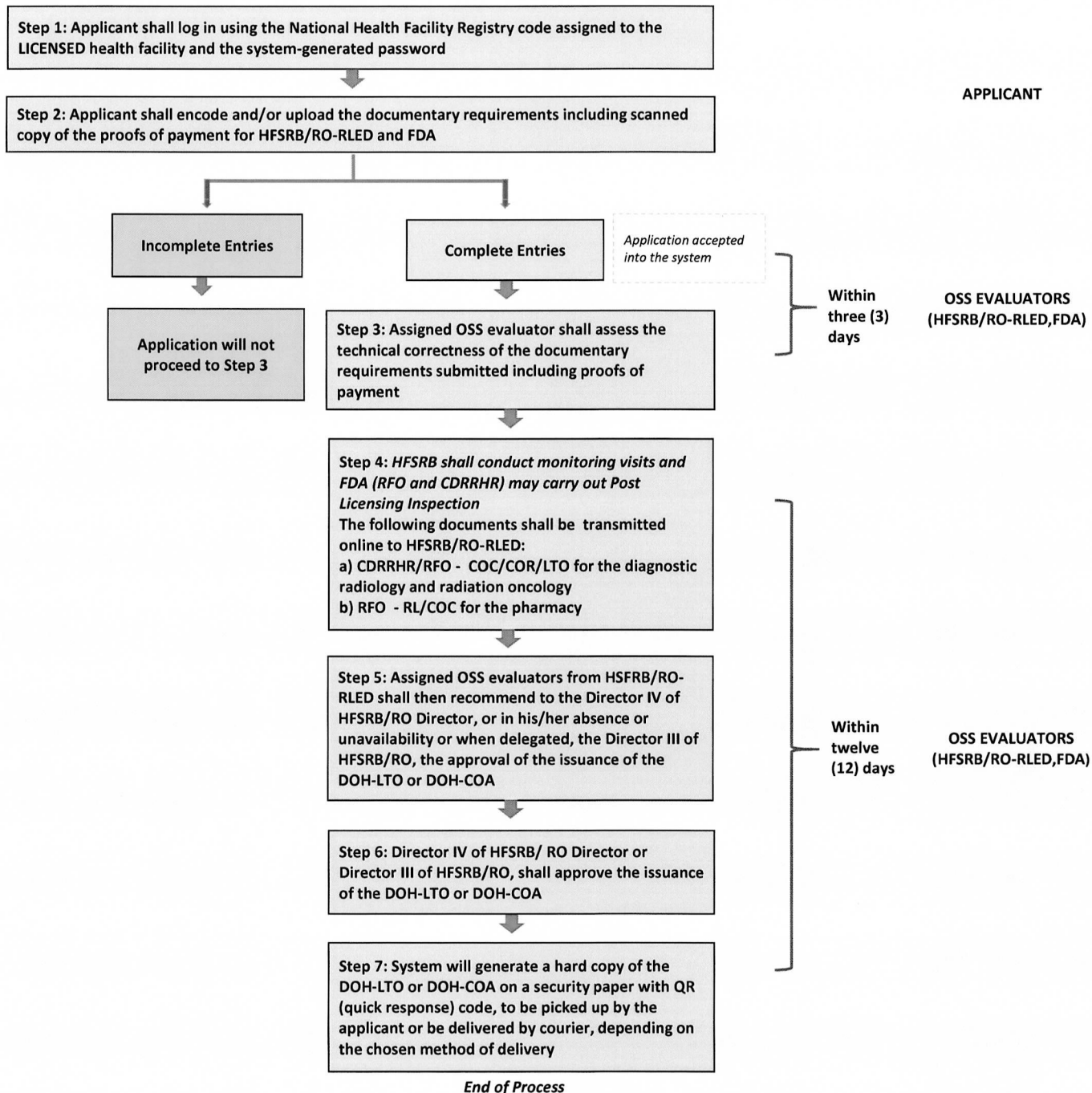
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Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Annex B
A.O. No. 2018-0016

**ONE-STOP SHOP LICENSING SYSTEM PROCESS FLOW
AUTOMATIC RENEWAL**

TIME TABLE

PERSON/S RESPONSIBLE



Note: For those applicants that are not eligible for automatic renewal, the timeline for issuance of DOH-LTO/DOH-COA shall follow the initial application process.

DOH-OSSOLS-PFR-Annex B
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