



**Central Drug Standard Control Organization
(CDSCO)**

Guidelines

For

**Application processing by Officials in New Medical
Devices**

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Centre for Development of Advanced Computing

(A Scientific Society of the Ministry of Electronics and Information Technology, Govt. of India)

Anusandhan Bhawan, C-56/1, Institutional Area, Sector-62, Noida-201307

Phone: 91-120-3063311-14 Website: <http://www.cdac.in>

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Application Workflow for Officials in New Medical Devices



1. SUMMARY

The process involves the development of the online licensing system for multiple stakeholders like Industry applicants, CDSCO officials from HQ, Zones, Subzones, Port offices, Investigators, medical practitioners. The system will provide an online interface for Applicants to submit applications, upload supporting documents, respond to queries from CDSCO officials and track their application status. It will also enable CDSCO officials to process the applications, generate note sheet, and raise queries and issue approvals / permissions online. The purpose of the document is to specify in detail the Processing of applications of medical devices by the regulatory authority (CDSCO and SFDA).

- The categorization of applications is described in the table as shown below:

Table 1 : Categorization of applications

S. NO	Type of Application	Application processed at	Notified Body Audit required	Inspection report required
1	Manufacturing License(classA & classB)(Form MD-3, 4)	State FDA	YES	NO
2	Manufacturing License(classC & classD)(Form MD-7,8)	Zone, CDSCO HQ	May be	YES
3	Import License(Form MD-14,26,28)	CDSCO HQ	NO	NO
4	Test License(Form MD-16,12)	CDSCO HQ	NO	NO
5	Clinical Investigation(Form MD-22)	CDSCO HQ	NO	NO
6	Clinical Performance Evaluation(Form MD-24)	CDSCO HQ	NO	NO
7	Personal License(Form MD-18)	CDSCO HQ	NO	NO

- The processing of applications by officials and the status during the process are described below:

S.NO	File Status	File With	Actions available to officer
1	Submitted	Nodal Officer	1. View Checklist
			2. Generate Form
			3. Assign to RO
			4. Forward to Notified Body
			5. Upload Inspection Report(Zone)
2	Assign to RO	RO	1. View Checklist
			2. Generate Form

			3. View/Modify Checklist
3	Notesheet pending from RO	RO	1. View Checklist
			2. Generate Form
			3. View Notesheet
			4. Generate Notesheet
4	Notesheet generated by RO	RO	1. View Checklist
			2. Generate Form
			3. View Notesheet
			4. Send file
5	Forward to LA	LA	1. View Checklist
			2. Generate Form
			3. View Notesheet
			4. View/Modify Checklist
6	Notesheet generated by LA	LA	1. View Checklist
			2. Generate Form
			3. View Notesheet
			4. Reject
			5. Approve
			6. Raise Query
			7. Edit device details
			8. Send file
7	Query Raised	LA	1. View Checklist
			2. Generate Form
			3. View Notesheet
8	Approved	Applicant	1. Download Coverletter
			2. Download Permission
9	Forward to DDA	DDA	1. View Checklist
			2. Generate Form
			3. View Notesheet
			4. View/Modify Checklist
10	Notesheet pending from DDA	DDA	1. View Checklist
			2. Generate Form
			3. View Notesheet
			4. Generate Notesheet
11	Notesheet generated by DDA	DDA	1. View Checklist
			2. Generate Form
			3. View Notesheet
			4. Send file
13	Forward to DA	DA	1. View Checklist
			2. Generate Form

			3. View Notesheet
			4. View/Modify Checklist
14	Notesheet pending from DA	DA	1. View Checklist
			2. Generate Form
			3. View Notesheet
			4. Generate Notesheet
15	Notesheet generated by DA	DA	1. View Checklist
			2. Generate Form
			3. View Notesheet
			4. Send file

- The functionality of Notified body is a parallel process and the statuses during processing are described as:

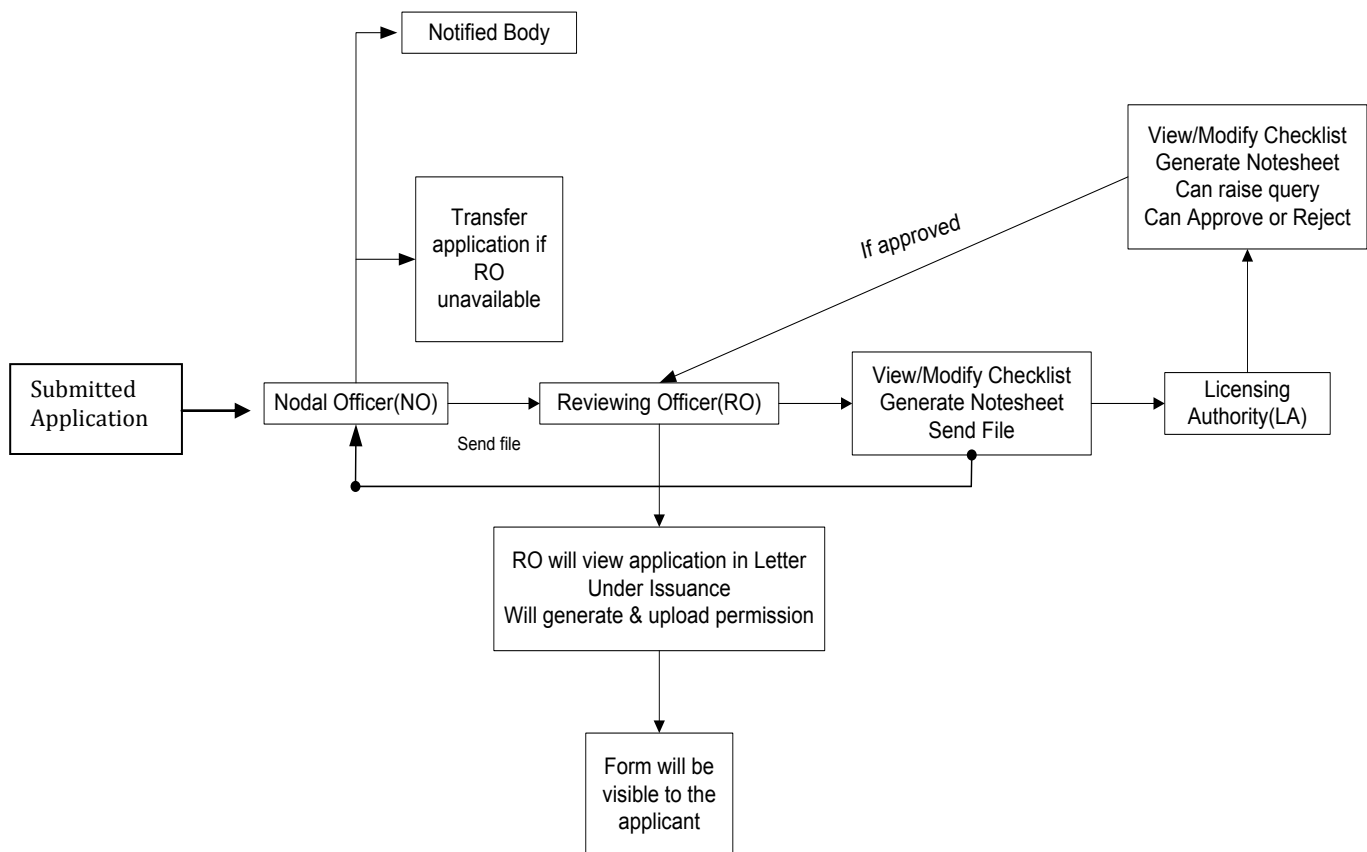
S.NO	File Status	File With	Actions available to officer
1	Request raised for audit	NB	1. View Checklist
			2. Accept
			3. Return to Nodal Officer
2	Accepted for audit	NB	1. View Checklist
			2. Generate Form MD-11
3	Generated Form MD-11	NB	1. Download Form MD-11
			2. Upload Form MD-11
4	Uploaded Form MD-11	NB	1. View Form MD-11
			2. View Observation for audit or inspection

2. INTRODUCTION

The New Medical Devices portal provides flexibility for submission and processing of applications online. The process involves the development of the online licensing system for multiple stakeholders like Industry applicants, CDSCO officials from HQ, Zones, Subzones, Port offices, Investigators, medical practitioners. The official hierarchy is a **three level (state)/five level (zone or headquarters) process**.

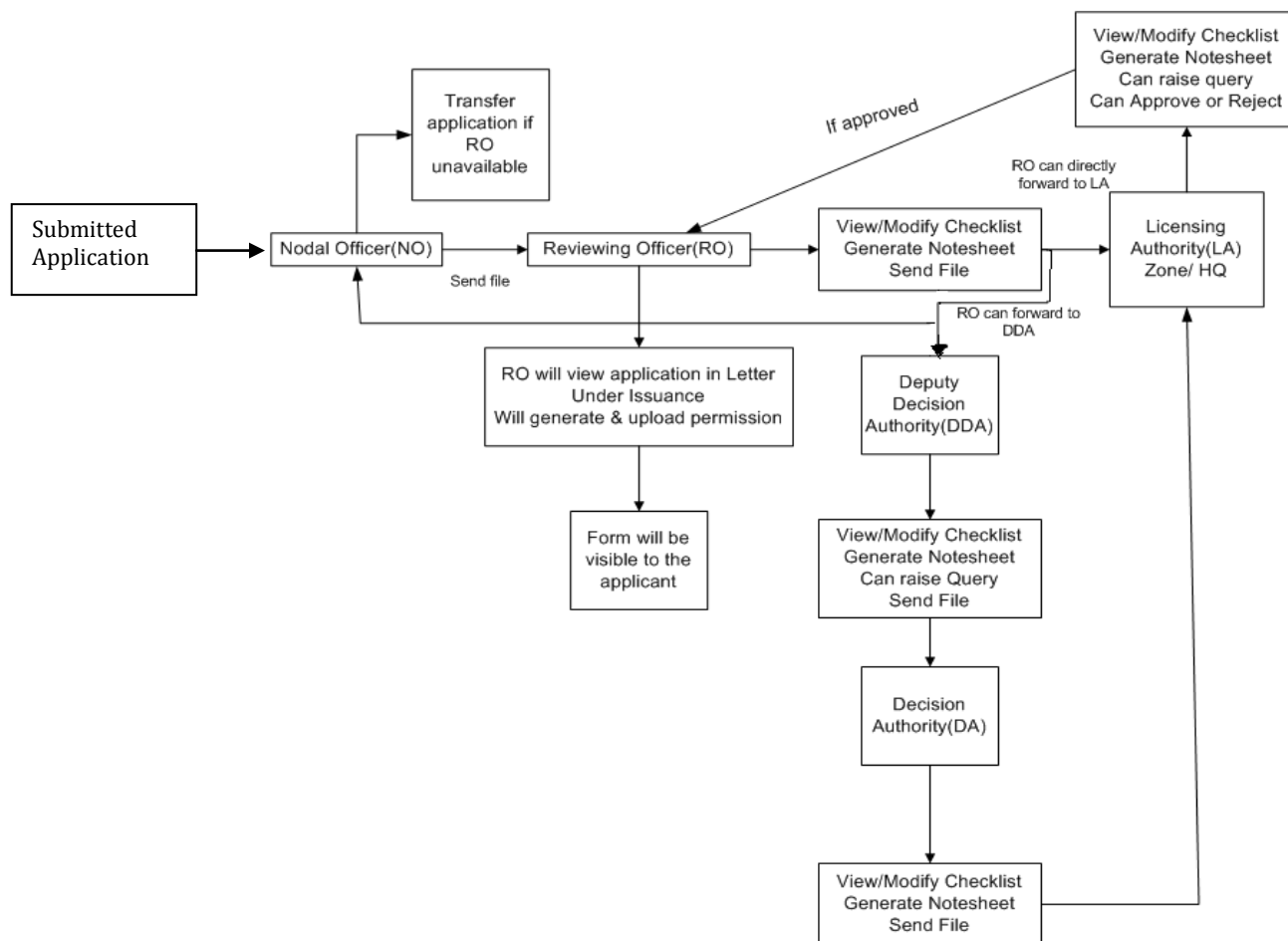
The three level (state) processes is given below:

Nodal Officer → Reviewing Officer → Licensing Authority



➤ The five level (zone or headquarters) process is given as:

[Zonal Process: Nodal Officer → Reviewing Officer → Deputy Decision Authority] → [Head Quarter Process: Decision Authority → Licensing Authority]



2.1 MANUFACTURING LICENSE (Form MD-3, 4)

- Manufacturing license **Form MD-3, Form MD-4** are reviewed and processing by **state FDA**.
- The steps followed are:
 - The submitted applications are seen by the nodal officer under its “**New Application**” tab.
 - The **nodal officer (NO)** will assign applications to **RO (reviewing officer)**.
 - The NO can forward the application to other RO if the previous RO is unavailable.
 - The **NO** can forward the application to **Notified Body**.
 - The application process at Notified Body and state FDA is a parallel process and before application approval Audit report should be uploaded by Notified body.
 - **RO** can view newly assigned files under “**New Applications**” tile.

- **RO** will view/modify checklist and after reviewing, he/she will generate note sheet.
- **RO** will forward the application for further processing to **LA (licensing authority)**. LA can raise query/Approve/Reject the application.
- The LA will review and generate note sheet and then approve application.
- If **LA (state)** finds the application inappropriate **can reject or raise Query**.
- The application will go to RO to generate permission, sign it digitally and upload it and application status will be updated as 'Approved'.

2.2 MANUFACTURING LICENSE (Form MD-7, 8)

- Applications for **Form MD-7 and Form MD-8** are processed at **zones and CDSCO headquarter**.
 - The submitted applications are seen by the nodal officer under its "**New Application**" tab.
 - The **nodal officer (NO)** will assign applications to **RO (reviewing officer)** and will upload inspection report.
 - The NO can forward the application to other RO if the previous RO is unavailable.
 - **RO** can view newly assigned files under "**New Applications**" tile.
 - **RO** will view/modify checklist and after reviewing, he/she will generate note sheet.
 - **RO** will forward application to DDA of zone.
 - **Zonal DDA** will review file, generate note sheet and forward it to **DA of HQ** only if inspection report uploaded by NO of corresponding zone.
 - **DA of HQ** will review file & generate note sheet and then send it to LA/RO/SRO of HQ or NO/DDA of Zone.
 - **LA** will review and generate note sheet and then approve application.
 - If **LA (HQ)** finds the application inappropriate **can reject or raise Query**.
 - The application will go to last assigned RO (either of Zone or HQ) to generate permission, sign it digitally and upload it and application status will be updated as 'Approved'.

2.3 IMPORT LICENSE/TEST LICENSE

- Import license **Form MD-26, Form MD-28, Form MD-14, MD-12, MD-16**, are reviewed and processed at **headquarter level**.
- The steps followed are:
 - The submitted applications are seen by the nodal officer under its **“New Application”** tab.
 - The **nodal officer (NO)** will assign applications to **RO (reviewing officer)**.
 - The NO can forward the application to other RO if the previous RO is unavailable.
 - The application at **RO** level is seen under **“New Applications”**.
 - **RO** has can view/modify checklist and after reviewing will generate note sheet.
 - The **RO** can forward the application for further processing directly to **LA (licensing authority)** or can forward to **DDA (Deputy Decision Authority)/DA (Decision Authority)/NO (nodal officer)** and same can be done by other officers as well.
 - **LA** will review and generate note sheet and then approve application.
 - If **LA** finds the application inappropriate **can reject or raise Query**.
 - The application will go to last assigned RO to generate permission, sign it digitally and upload it and application status will be updated as ‘Approved’.