**Regulatory Requirements for Medical Devices and IVDs in India**

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**Lecture – 10**
**How to Obtain a Licence to Manufacture a Medical Device?**

Welcome to Regulatory Requirement for Medical Devices and In Vitro Diagnostics in India lecture 8 that is How to Obtain a Licence to Manufacture a Medical Devices and In Vitro Diagnostics?

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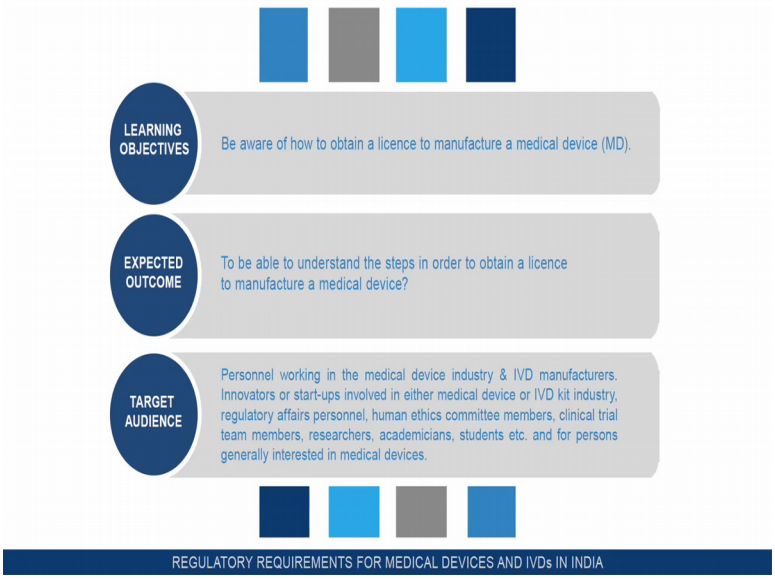


Now, learning objective of this lecture be aware of how to obtain a licence to manufacture medical devices and in vitro diagnostics. Expected outcome able to understand the steps need to obtain a licence to manufacture a devices or in vitro diagnostics. Target audience personnel working in the medical device industry in vitro diagnostic manufacturers, innovator, startups involved in either medical devices or in vitro diagnostic kit industry. Regulatory affairs personal, human ethics committee member, clinical trial team member, researcher, academician, students and the person generally interested in medical devices.

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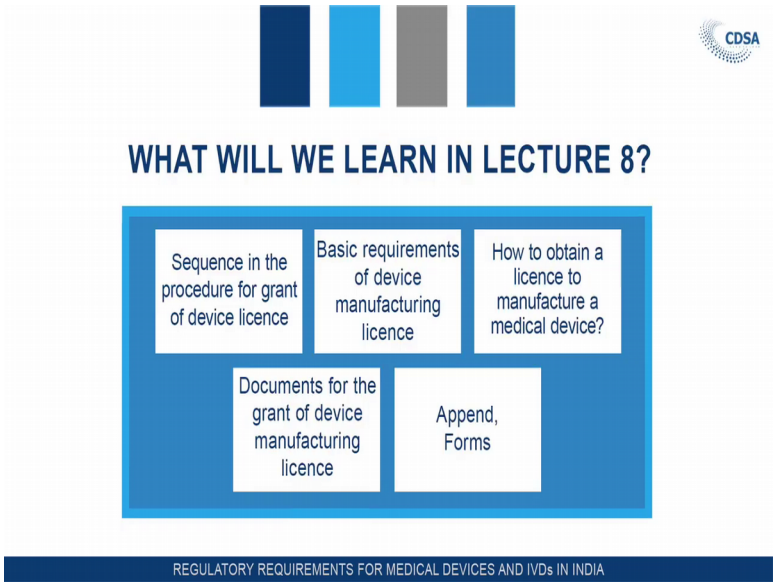


What will we learn in the lecture 8? We will learn how to obtain a licence to manufacture in medical devices and in vitro diagnostics. The sequence in the procedure for grant of device licence. Basic requirement of manufacturing licence forms. What are the forms applicable for grant of manufacturing licence? Technical documents; technical documents required for grant of manufacturing licence. So, how to obtain a licence to manufacture in medical devices?

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Any product that is controlled by Drugs and Cosmetic Act and Rules, as a drug, need a licence to manufacture. Why licence is required? Because to keep a control on the product to maintain the product efficacy safety and the quality.

To avoid duplicate and therefore, harmful product away. Keep track of the products moving in the market. Keep consistence in the manufacturing of the product. To have all those criteria the licence is required and through the licence we can control this.

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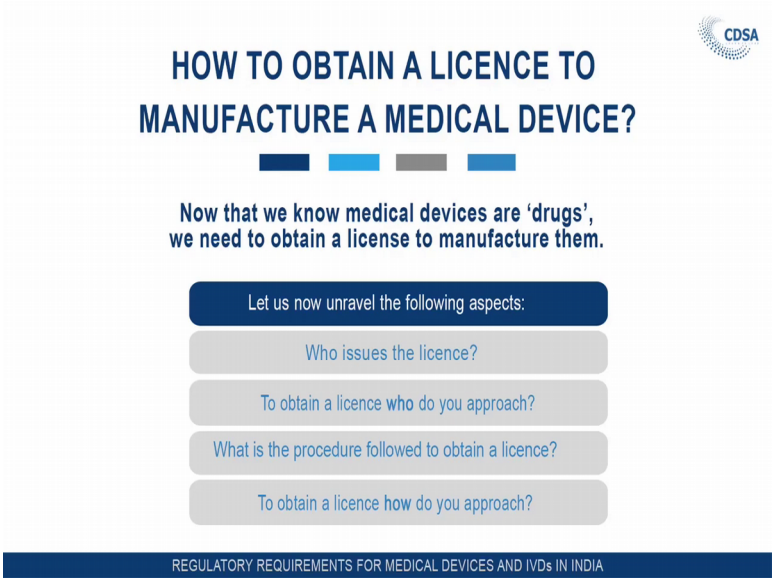


How to obtain a licence to manufacture medical devices? Now that we know medical devices are drug and the drugs which are regulated under the Drugs and Cosmetic Act and Rules, there under licence is required. Let us now unravel the following aspects; who issues the licence? To obtain a licence who do you approach? How is the procedure to obtain a licence or to obtain a licence how do you approach?

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No in the Medical Device Rules we have discuss the authorities, authority is responsible for grant of manufacturing licence. The State Licensing Authority and the Central Licensing Authority two authorities they are responsible for grant of manufacturing licence of the medical devices and in vitro diagnostics. The controlling power of each authority has been prescribed in the medical device rule 2017.

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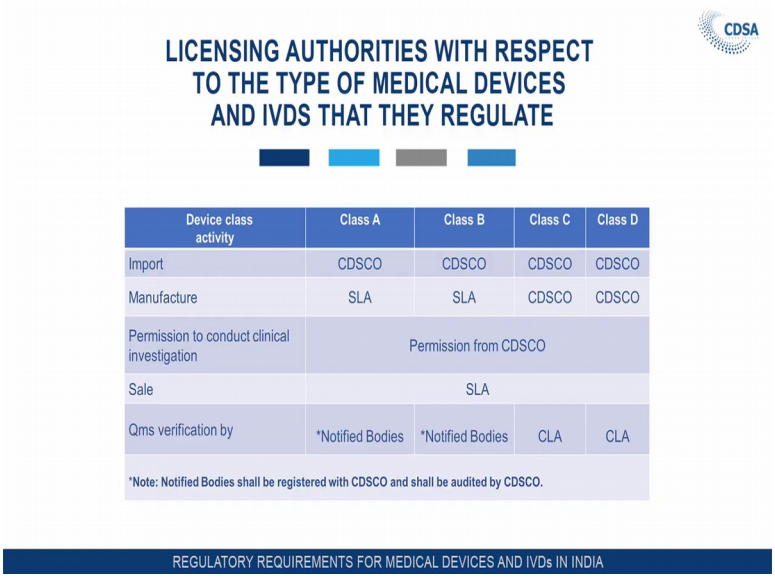


Also we have discuss that for which class of the medical devices, who are the authorities? For manufacturing State Licensing Authority is responsible for grant of

manufacturing licence for class A and class B devices. And the Central Licensing Authority that is CDSCO is responsible for grant of manufacturing licence of class C and class E devices.

In case of Qms verification, Qms audit for class A and class B we discussed many time that notified body is responsible for Qms verification of the class A and class B medical device manufacturing unit. And the Central Licensing Authority they are responsible for Qms inspection of class C and class D devices. Notified body who are the notified body is responsible for Qms verification of the class A and class B devices. The notified body which is registered with the Central Licensing Authority, they are only the responsible for Qms verification of the class A and class B devices.

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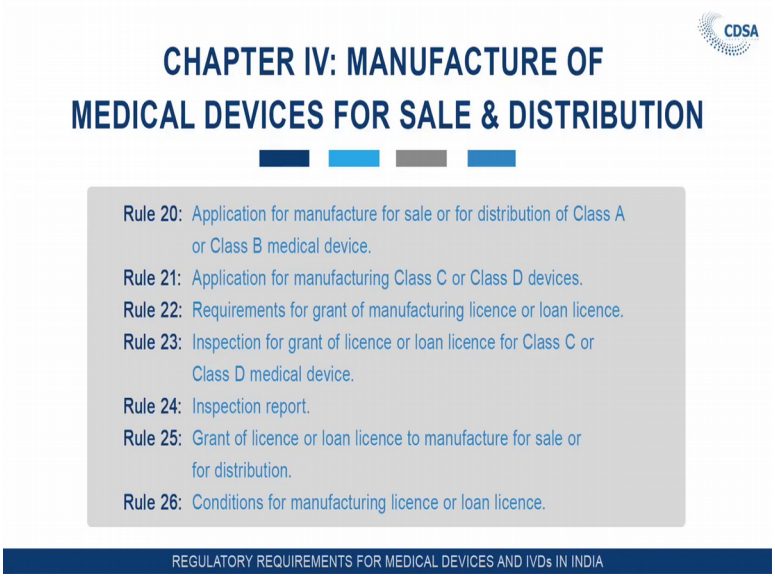


Now, the rules which rules deals with the grant of manufacturing licence of the medical devices and in vitro diagnostics. Which chapters have the provision for manufacturing of the medical devices? We have discussed in the Medical Device Rule 2017 where the total 12 chapters have been incorporated and 96 rules are there.

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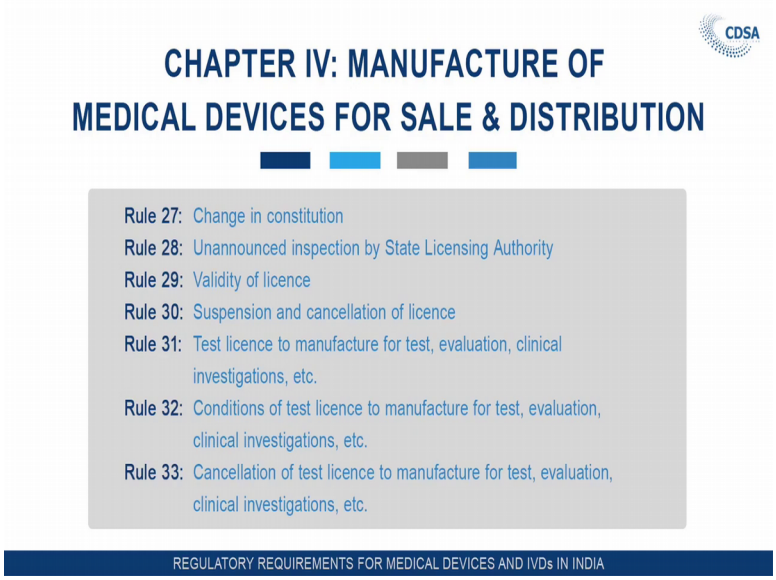


So, chapter 4 of the medical device rules gives the provisions for grant of manufacturing licence for medical devices and in vitro diagnostics under this chapters different rules are there for different purpose rule 20 to rule 33 have given for each of the different types of manufacturing licence we will discuss one by one this rules.

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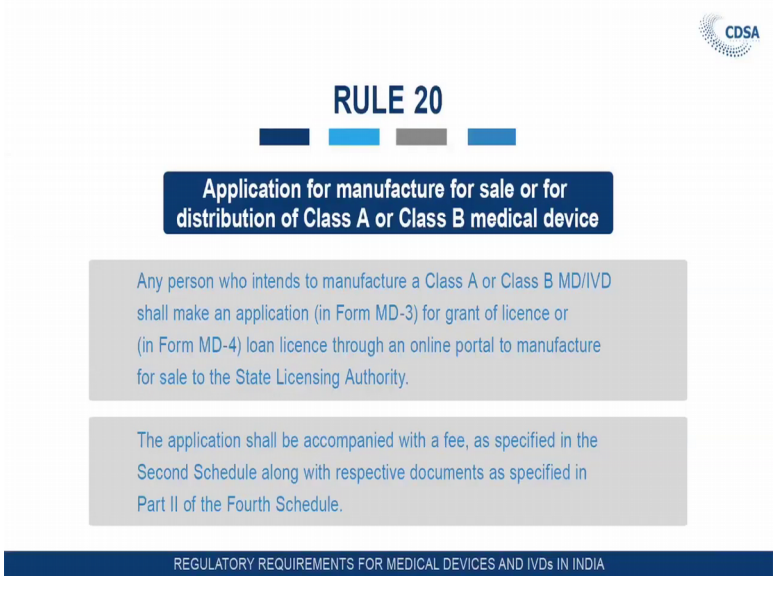


Come to rule 20, the rule 20 that is application for manufacture of sale or for distribution of class A and class B medical devices. Under this rule any person who intends to manufacture a class A or class B medical devices or in vitro diagnostic, shall make

application in MD 3 for grant of licence or in MD 4 that is loan licence through an online portal to the Central Licensing Authority.

And when apply for grant of manufacturing licence or loan licence through this portal this licence will be diverted to the concerned State Licensing Authority who is responsible for grant of licence. The application shall be accompanied with a fees, as specified in the second schedule we have also discuss that what is second schedule?

Second schedules is the fees details of the fees required to be submitted for different activity. So, for manufacturing what rules required to be submitted for different types of classes it is prescribe in the second schedule. As per the second schedule the applicant has to submit the requisite fees and also the requisite document the technical document which is required to be submitted for grant of manufacturing licence that details has been given in the part II of the fourth schedule.

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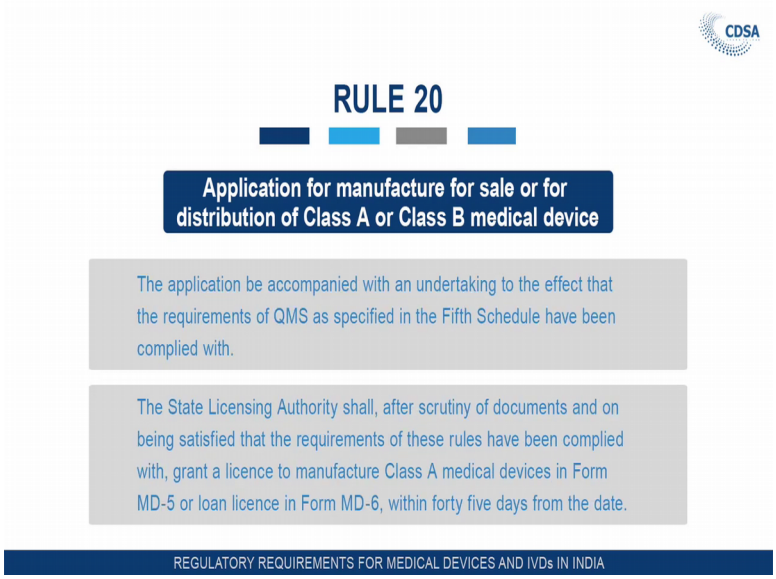


The application shall be accompanied with an undertaking to effect that the requirement of quality management system as specified in the fifth schedule have been complied with. The applicant has to given the has to submit this undertaking (Refer Time: 06:40) they are fulfilling the requirement of quality management system as specified in the fifth schedule. The State Licensing Authority who is responsible for grant of manufacturing licence. Review the applications and after being satisfied the requirement under this rules

they will grant the licence to manufacture class A medical devices in MD 5 or loan licence in MD 6, within forty days from the date of receipt of the application.

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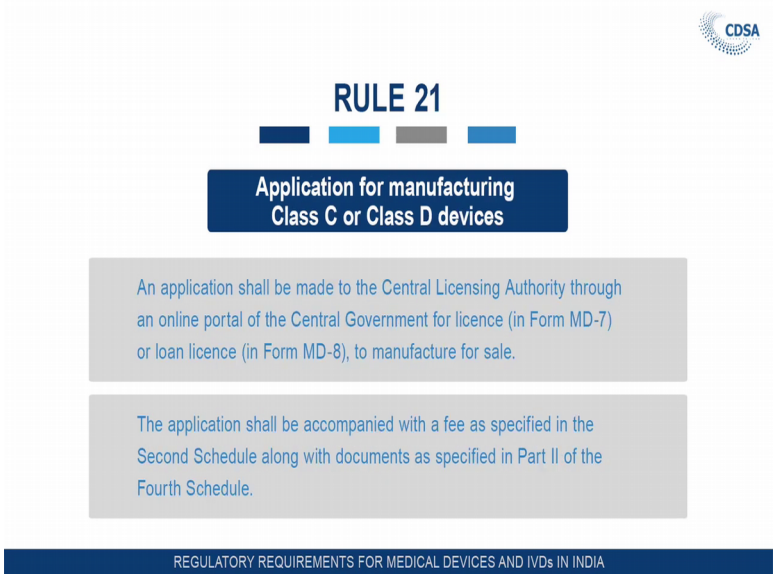


Rule 21 that is application for manufacturing of class C and class D devices. Here an application shall be made to the Central Licensing Authority through an online portal for grant of licence to manufacture or grant of loan licence, to manufacture the medical devices and in vitro diagnostics.

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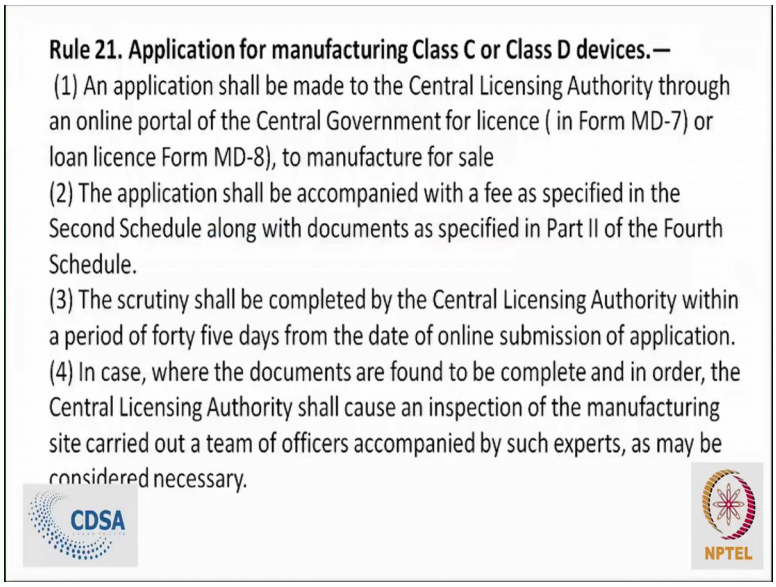

The application shall be accompanied with the fees, fees as a specified in the second schedule and also the technical documents as a specified in the part II of the fourth schedule.

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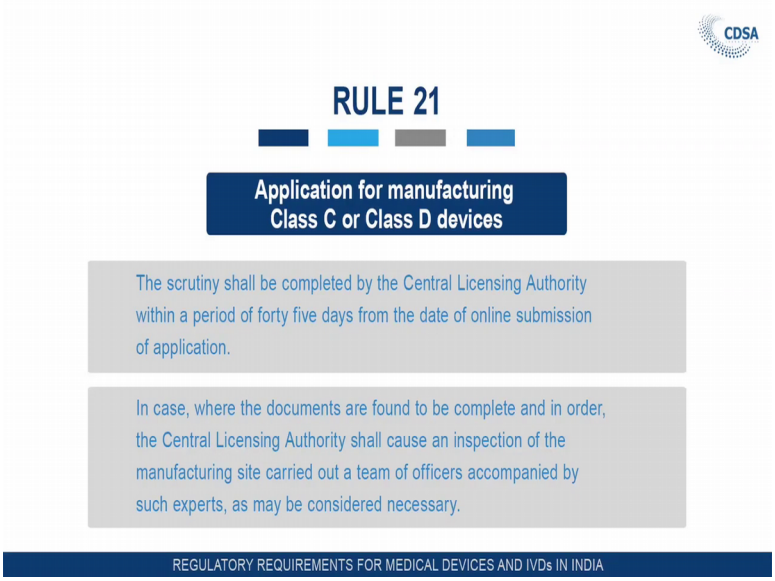


The scrutiny shall be completed by the Central Licensing Authority within a period of forty five days through online only. And where the documents are found to be complete and in order the Central Licensing Authority shall cause an infection inspection of the manufacturing site. The inspection will be carried out by a team of the officer accompanied by an expert if necessary the experts maybe co opted for integration of for inspection of the manufacturing site of the class C or class D devices.

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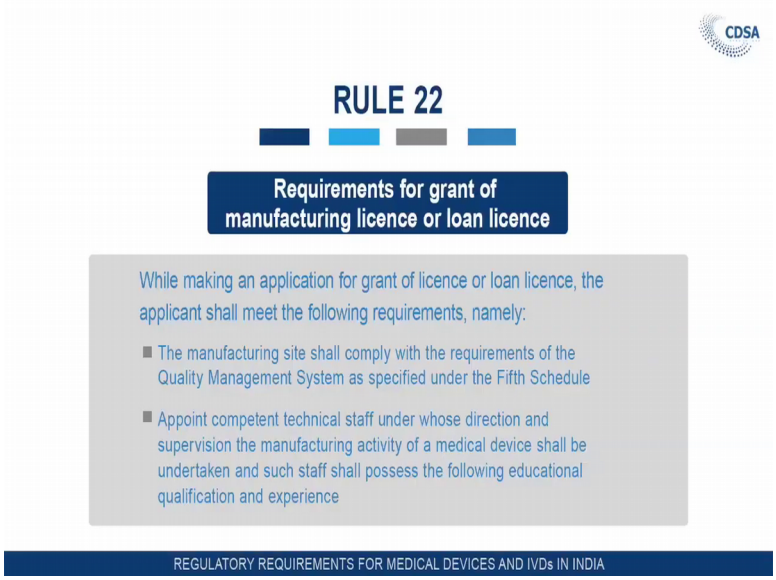


Rule 22, that is the requirement for grant of manufacturing licence or loan licence. While making the application for grant of licence or loan licence, applicant shall meet the following requirements, what are those requirement? The site shall comply with the requirement of the quality management system and undertaking in this regard as to be submitted by the applicant.

The manufacturer has to appoint competent technical staff under whose direction and supervision. The manufacturing activity of the medical devices shall be undertaken and such staff shall possess the requisite qualification as a specified with the medical device rule 2017.

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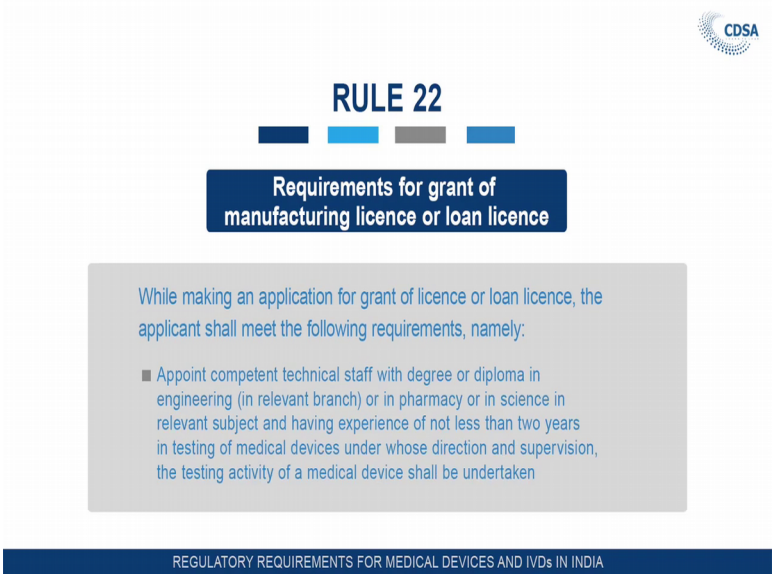


The person should have bachelor degree in engineering or the pharmacy of the relevant field with minimum 2 years of experience that is given in the medical device rule 2017. Also the manufacturer has to appoint competent technical staff with degree in diploma or engineering or in the pharmacy or science or in relevant areas with the experience of two years in the testing of the medical devices. And in vitro diagnostic was direction and supervision the testing activity of the premises is carried out.

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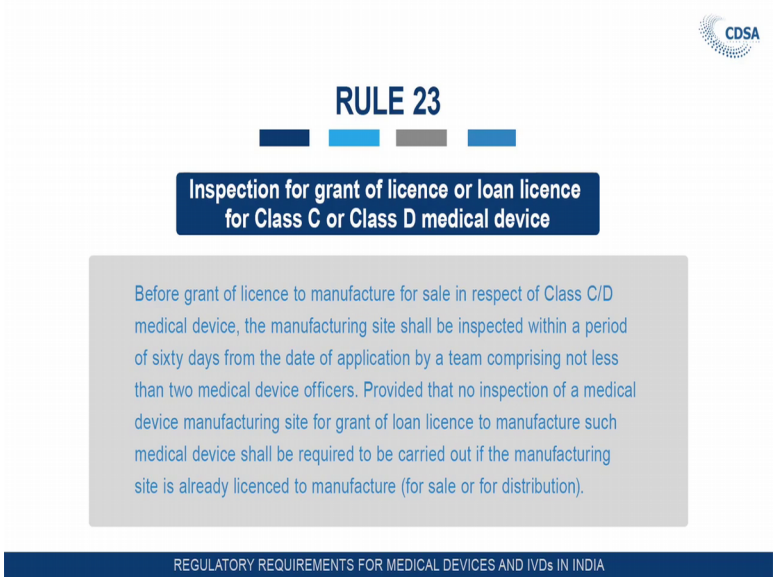

Rule 23; that is inspection of grant of licence or loan licence for class C and class D devices. Before grant of licence to manufacture for sale in distribution of the medical devices, in respect of class C and class D. The manufacturing site shall be inspected within a period of sixteen days the time line has been given in the medical device rule and this inspection will be carried out by a team comprising of not less than two medical device officer.

However, no inspection for the medical device manufacturing site for grant of loan licence is required. If the manufacturing site is already licence to manufacture such medical devices for sale and distribution. This provision we have paid to avoid unnecessary repetition of the inspection. If the facilities already inspected earlier and they have complied with the Qms as specified in the fifth schedule at the time of grant of no licence by the uniform, no further inspection generally required to be carried out.

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The inspection report after completion of the inspection, the inspection team shall forward the descriptive report containing the findings of the inspection and their recommendation they have to submit to the Central Licensing Authority through online portal and also forward a copy of the same to the applicant.

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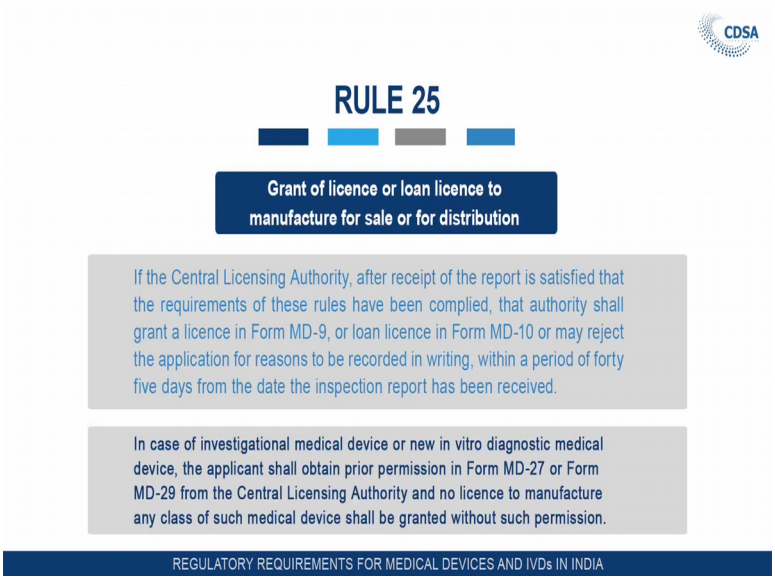


Rule 25, that is the grant of licence or loan licence to manufacture for sale or distribution of medical devices. If the Central Licensing Authority, after receipt of the satisfied report and the document as required under forth schedule of the medical device rule 2017. If the documents and inspection reports for satisfactory by the Central Licensing Authority. The licence shall be granted inform MD 9 or the loan licence in form MD 10.

The Central Licensing Authority may also reject the application for the reason to be recorded in writing within a of forty five days, from the date of inspection of the report. If certain measure non compliances were observed by the Central Licensing Authority. In case of the investigational medical devices or new in vitro medical devices, the applicant shall obtain prior permission in form 27 or form 29 from the Central Licensing Authority and no licence to manufacture any class of such devices shall be granted without such permission.

The applicant as to establish the safety and performance of the devices which falls under the investigational medical devices or if it is a new in vitro diagnostic. After obtaining the permission they will applied to the Central Licensing Authority for grant of manufacturing licence or loan licence in form MD 9 or MD 10.

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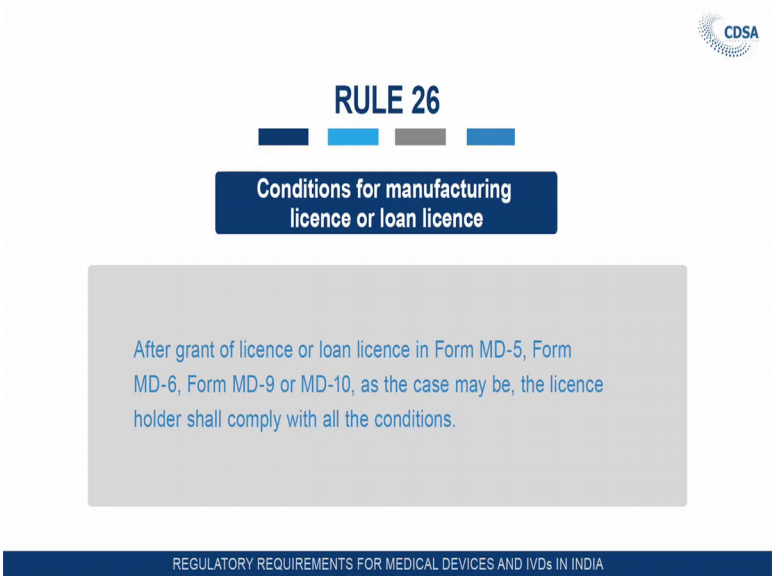


Now rule 26, rule 26 gives the conditions of the licence, manufacturing licence or loan licence. After grant of the licence or the loan licence in form 5 or form MD 6 or form MD 9 or form MD 10, as may be case the licence holder shall comply with the conditions.

The conditions of the licences is mention in the rule 26 certain condition like the licence holder as to produce the licence before the medical device officer or the Central Licensing Authority. In case they wish to examine their licence for any reason they approve inform to the licensing authority, in case of any changes in the premises, in the facility, in the quality control of the manufacturing of the medical devices they have to inform to the licensing authority within a stipulated timeline for any change in the constitution of the firm.

They have to inform the licensing authority about any adverse event observed by them on their product manufactured by the manufacturer for marketing into the country they have to also inform any major changes in the manufacturing of the medical devices. If there is change in the intended use of the devices or if there is a change in the sterilization process of the devices or there is if there is a change in the material of construction of the devices.

All those changes which falls under the major category of the major changes as specified in the schedules they have to intimate to the Central Licensing Authority or the State

Licensing Authority. And for the major changes they need to obtain the prior approval, for minor changes only they have to inform by way of the notification.

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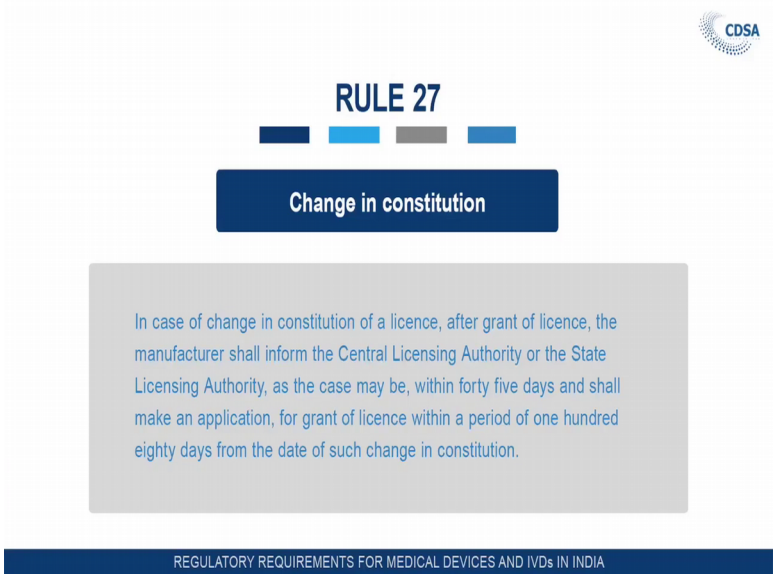


Rule 27, that is change in the constitution. In case of change in the constitution of the licensing, after grant of the licence the manufacturer inform the Central Licensing or the State Licensing Authority, as the case may be within forty five days and shall make a application, for grant of licence within period of one eighty days from the date of such changes and in such cases a fresh licence is required to be obtained.

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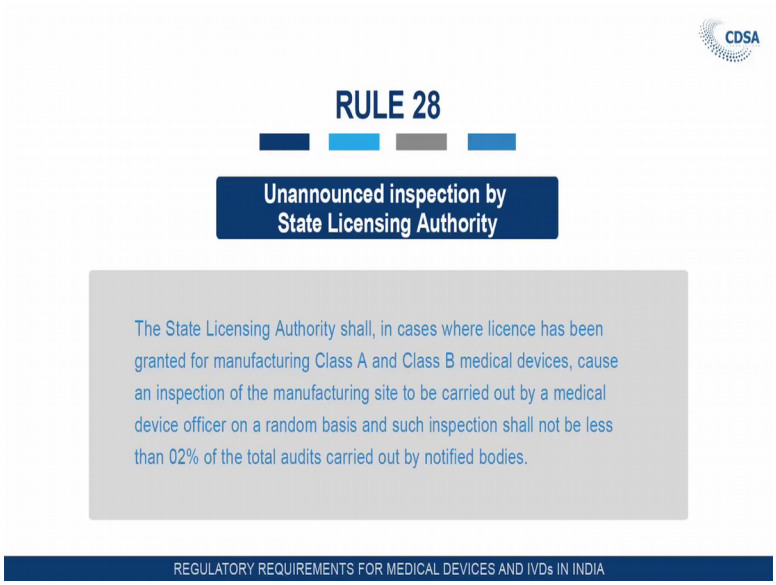

Rule 28, that is unannounced inspection by the State Licensing Authority. As we have discuss earlier for the Qms verification of the class A and class B devices the State Licensing Authority shall be responsible for grant of manufacturing licence or grant of loan licence based on the Qms audit carried out by the notified body. So, under this rule that provision has been made the State Licensing Authority shall carried out the inspection of 2 percent of the site which have been frequented by the notified body for granted manufacturing licence.

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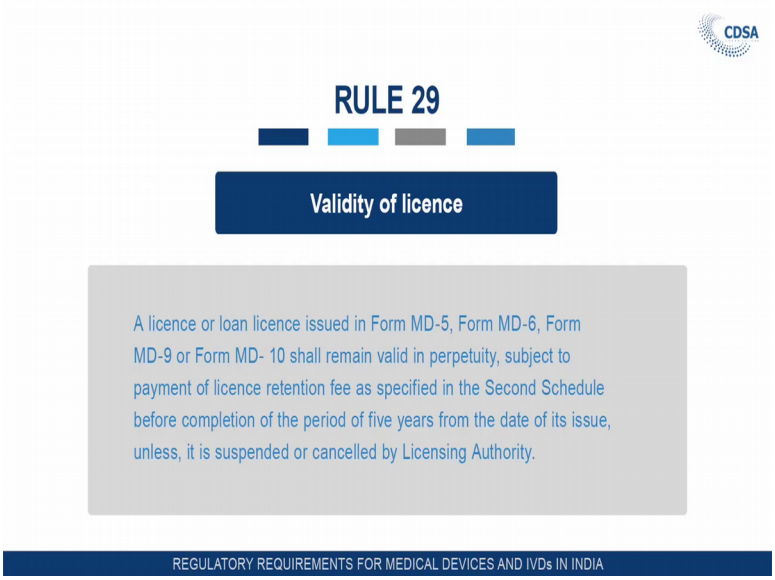


Rule 29, that is the validity of the licence. A licence or loan licence issued in form MD 5, form MD 6, form MD 9 or form MD 10 shall remain valid in perpetuity, we have discusses earlier also many times. Subject to the payment of the retention fees as specified in the second schedule. At the interval of every five years from the date of it issue, then their licence will be considered in perpetuity. Till the suspension or cancellation of the licence by the licensing authority or till the withdrawn by the licensee.

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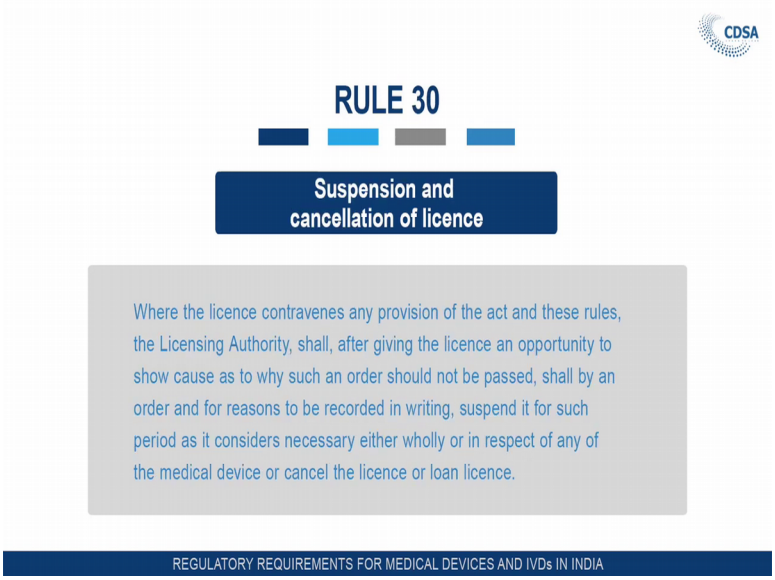


The suspension and cancellation of the licence under rule 30, that provision has been made. Where the licensee contravene any provisions of the act and these rules, the licensing authority shall after giving so cause as to why such an order should not be passed, shall by an order or for the reason to be recorded in writing, suspend it for such a period as it consider necessary either wholly or in respect of the medical devices or cancel the licence or the loan licence.

The suspension and cancellation of the licence provision have been made under this rules. Before cancellation of suspension the licensing authority shall so cause the licensee and if the proper justification is not there licensing authority may cancel or suspend the licence for the particular reason.

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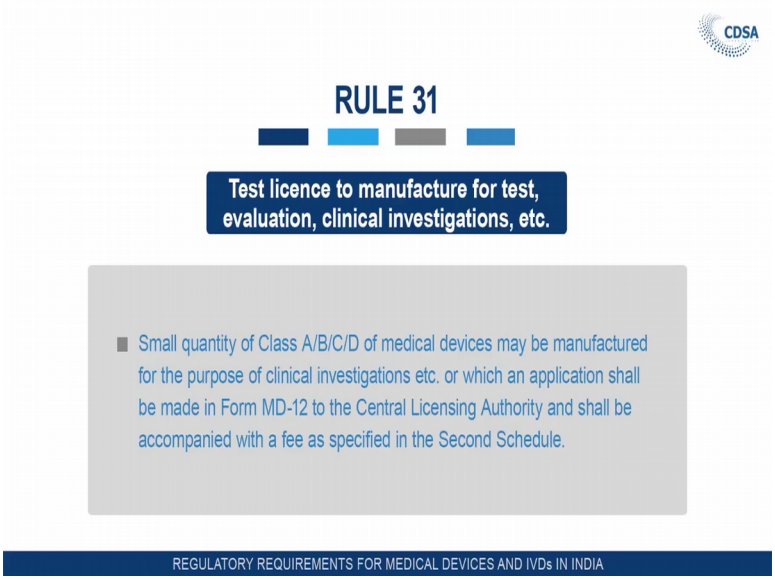


Rule 31, the provision for grant of test licence to manufacture, medical devices or in vitro diagnostics for test and evolution or clinical investigation. For a small quantity of class A class B class C and class D devices the manufacture shall obtain test licence to manufacture the test batches for the purpose of test analysis for the purpose of evaluation, for the purpose of clinical investigation or for the purpose of demonstration.

Under this test licence they will manufacture the test batches they will generate the certain data, they will generate the qc data, they will generate the safety data, they will generate the efficacy data and the data they will submit for grant of manufacturing of the particular medical devices. That provision has been made earlier this licence was issued by the State Licensing Authority. Now the Central Licensing Authority is responsible for grant of test licence for all classes of the medical devices.

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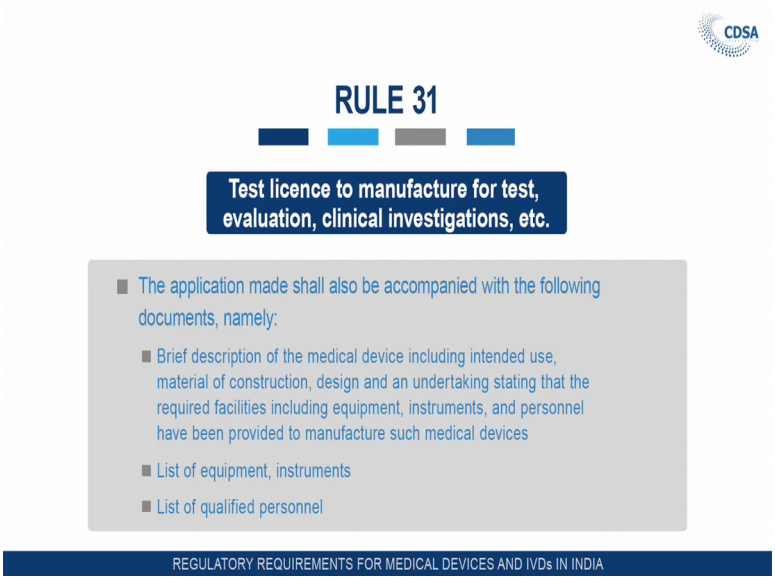


While submitting the application the applicant has to submit the certain formation. They have to submit the brief description of the medical devices it is intended use, material of construction, device, undertaking stating that the required facility including the equipment, instrument and the personnel have been provided to the manufacture of such medical devices. Whatever the list of the equipment or instrument is there they have to give that, they have to submit the details of the list of the qualified person, they have to submit the details of the qc parameter of that medical devices or then vitro diagnostic to be manufactured for text and analysis.

They have to submit the test method; they have to submit the specification of the product, they have to submit the layout plan of the facility all those information the applicant has to submit it along with the requisite fees to the Central Licensing Authority. And the Central Licensing Authority will grant the test licence for the purpose of test and analysis of the product.

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Now basic requirement for applying the manufacturing licence. While applying the licence to the concerned State Licensing Authority or the Central Licensing Authority the manufacturer they have to fulfill the requirement as mentioned in the Medical Device Rule 2017. The facility should be in the line of quality management system as prescribe in the fifth schedule of the Medical Device Rule 2017. The equipments required for manufacturing of the particular devices to be manufactured.

The technical manpower, the documentation of the activities all the SOPs, work in sections, procedures they have to set up the laboratory and instruments for testing of the devices and materials. All these facility are to be inspected and a scrutinized during the inspection of the firm by the licensing authority or by the notified body. Then what technical document required to be submitted at the time of submission of the application? The details of the technical documents has been given in the forth schedule of the Medical Device Rule 2017.

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And many times also we have discussed the same the documents that required to be submitted with respect to the manufacturing of the in vitro diagnostics or medical devices. The device description, intended use of the devices, specification including the variant and accessory. Material of construction, what is the material of construction of the devices? Working principles and use of the novel technology if any. The labels of the devices, package inserts, IFU, user manual, wherever applicable that information they required to be submitted. The summary of any reported serious adverse event in India and action taken by the manufacturer.

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Analytical performance summary including the sensitivity and specificity that is required for the in vitro diagnostics. The site master file or plant master file that is given in the part III of the forth schedule. Device master file as specified in appendix II of the medical devices or appendix III for the in vitro diagnostics constitution details of the firm.

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The essential principle checklist for demonstrating and demonstrating confirmatory to the essential principles for safety and performance of the medical devices. Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provision of quality management system as specified in the Medical Device Rule 2017 fifth schedule.

And for in vitro diagnostic performance evaluation report is also required to be submitted. Now fees and forms for the medical devices relevant form. We have all already discusses that here the forms.

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For grant of manufacturing of class A class B class C and class D devices. MD 3 that is the application for manufacturing licence for class A and class B devices. MD 4 that is the loan licence application for class A and class B devices. MD 7 that is the application for grant of manufacturing licence for class C and class D devices.

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MD 8 application for loan licence class C and class D devices. MD 5 that is the manufacturing licence issued by the State Licensing Authority for class A and class B devices. MD 6 that is the loan licence issued by the State Licensing Authority for class A

and class B devices. MD 9 is the manufacturing licence issued by the Central licensing Authority for class C and class D devices. MD 10 that is the loan licence issued by the Central Licensing Authority for class C and class D devices.

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Fees for medical devices and in vitro diagnostic kits for class A and class B medical devices, site fees is 5000 and rupees 500 is distinct medical devices. For class C and class D medical devices and in vitro diagnostics, the site fees is 50000.

And the product fees, device fees for each distinct medical devices 1000 Indian rupees. This is a fees structure and the forms, application forms related to manufacture and loan licence for different class of the medical devices and the licence or loan licence for different class of the medical devices. Now the standards of the medical devices, what is standard is applied for the medical devices being manufactured by the manufacturers?

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Rule 7, of the Medical Device Rule 2017 gives the provisions for product standard of the medical devices, as per rule 7 Bureau of Indian Standard or the standard set up by the Central Licensing Authority is applicable for the devices which is being manufactured in the country. If there is a no BIS standard or no standard approved by the Central Licensing Authority for the particular medical devices.

The other international standards ISO International Organization for Standardization or International Electro Technical Committee IEC standards is applicable for those devices. If there is no ISO or international standard is available, in such cases the manufacturers validated standards approved by the Central Licensing Authority is applicable.

So, the standard supply it for the devices that provision has been given in the rule 7 of the Medical Device Rule 2017. Now the labelling provision of the medical devices what labelling requirement has to be follow by the manufacturers also that is follow for the imported products.

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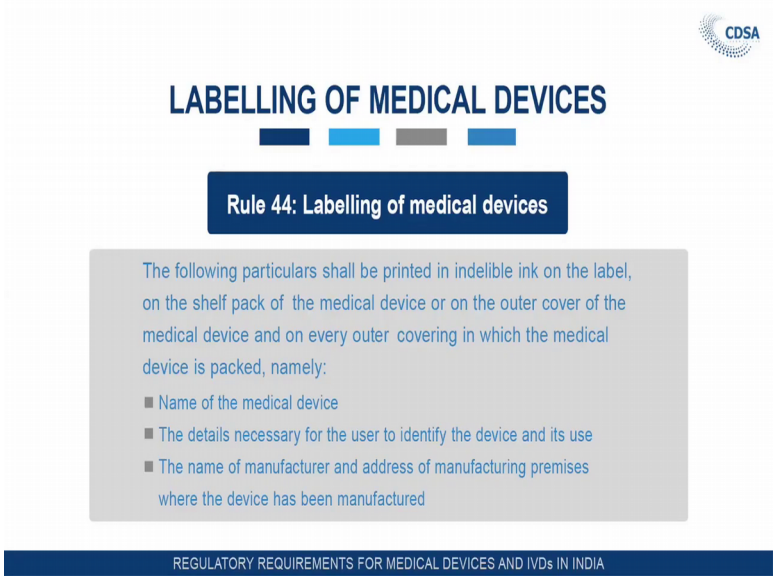


So, the labelling provision for the medical devices that is given in the chapter 6 and the rule 44 gives the details what labelling requirement is there for the medical devices and in vitro diagnostics.

Then formation shall be printed indelible ink on the label, on the shelf back of the medical devices or on the outer cover of the medical devices and on every outer covering in which the medical devices is packed. Then formation which are to be submitted are as under. The name of the medical devices that has to be mentioned on the label of the devices. The details necessary for the user to identify the devices and its use if it is there it has to be mention. The name of the manufacturer and address of the manufacturing premises where the device has been manufactured detail address has to be mentioned on the label.

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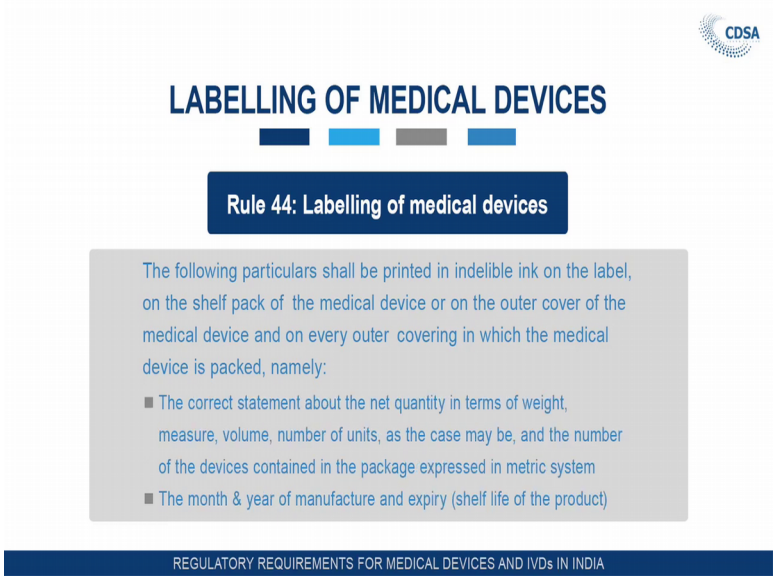


The correct statement about the quantity in terms of weight, measures, volume, number of units wherever is applicable they have to mention in metric system. The month and year of the manufacture or expiry that is the shelf life of the product has to be mentioned on the label.

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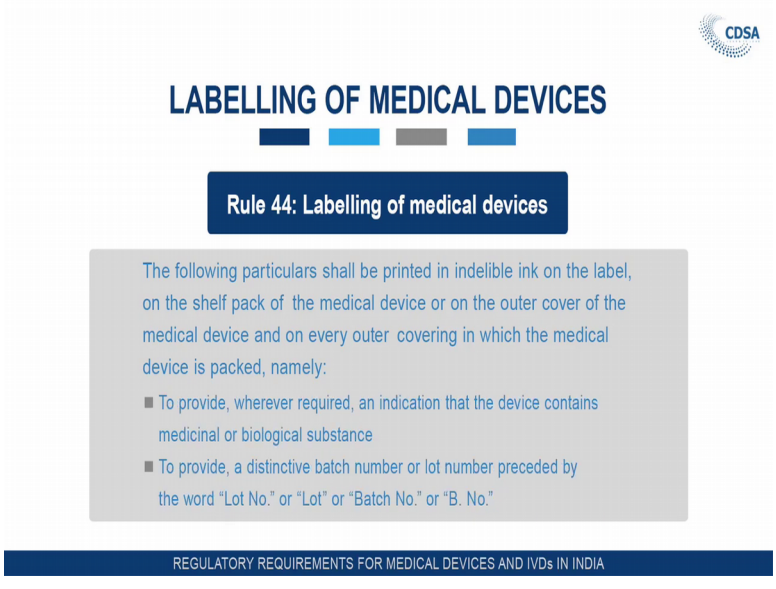


To provide wherever required the indication that the device contain medicinal or biological substances if. So, then formation has to be mentioned on the label of the product. To provide, a distinct batch number or lot number preceded by lot number or lot

or batch number or B dot and no dot. This information they have to mention on the label of the product.

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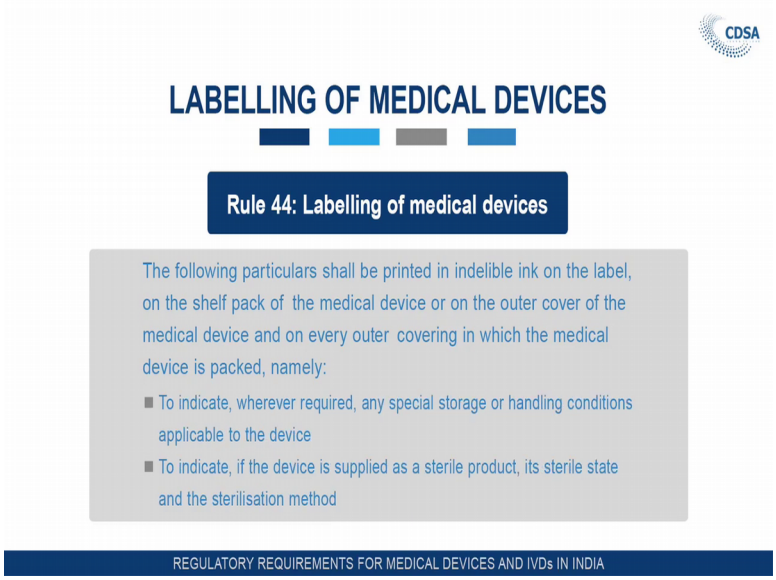


If there any special storage or handling condition applicable for the devices that information also has to be mentioned on the label. If the device is supplied as a sterile if it is a sterile it is state and the sterilisation method has to be mentioned. Like if it is sterilised by EtO in the label the symbol or EtO that startup information has to be mention on the label of the product.

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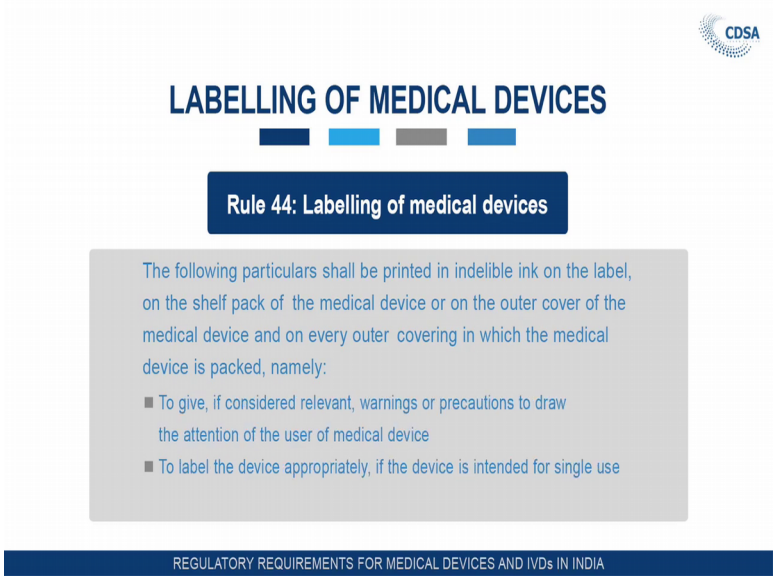

Warning or precaution to draw the attention of the users of the medical devices, if the device required so that information also need to be mentioned on the label. If it is a single use devices that it has to be mentioned on the label of the product.

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If the medical devices is intended for distribution to the medical professionals as a free samples; physician sample not to be sold that caption has to be capture on the label of the product. And other such information that required to be mentioned on the label of the medical devices.

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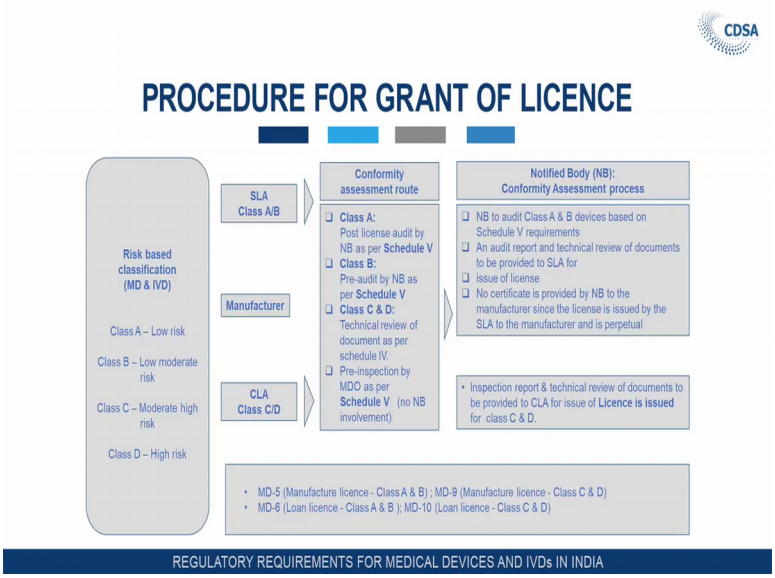


Now the what procedure followed for grant of manufacturing licence. This is the one slide where the short of flowchart is there. The risk based classification we have discussed that. Based on the risk of the classes medical devices and in vitro diagnostics have been classified as class A class B class C and class D devices.

And also we have discussed for class A devices State Licensing Authority is responsible for grant of manufacturing licence and the center licence is responsible class C and class D devices. The application for all the classes has to be submitted through the centre online portal and for A and B medical devices the application directly diverted to the concerned State Licensing Authority. And for C and D it is with the Central Licensing Authority. The documents, the requisite fees and the application form that we have discuss once it is submitted to the Central Licensing Authority or the State Licensing Authority as per the requirement of the Medical Device Rule 2017.

And if the document found satisfactory, the conformity assessment is to be carried out for class A and class B. The notified body will audit the site manufacturing site of class A and class B devices with respect to verifying the conformance of the quality management system. For class C and class D the Central Licensing Authority the offices of the Central Licensing Authority will be responsible for audit of inspection of the class C or class D devices with respect to conformance of the Qms.

After submitting the report if the report found satisfactory and the document technical document submitted by the firm is in order. The licensing authorities shall grant the licence to the manufacturer of the class C and class D devices. And the State Licensing Authority based on the audit report of the notified body and the technical documents submitted by the manufacturers by class A and class B.

They will consider their application for grant of manufacturing licence or grant of the loan licence. We have also discussed that MD 5 that is the manufacturing licence for class A and class B devices. MD 9 that is the manufacturing licence for class C and class D devices. MD 6 loan licence for class A and class B, MD 10 is the loan licence for class C and class D devices.

So, the licence issued by the Central Licensing Authority we have also discussed that that is in perpetual. There is a no validity provided the licensee so I will submit the requisite tradition fees of at the interval of at every 5 years. So, this is the procedure for grant of licence. Now forms we have discussed this is the one slides we are all the relevant form related to manufacturing of licence or by loan licence that is related to medical devices and in vitro diagnostic have been given. The licence to manufacture class A and class B devices application in MD 3 and the licence will issue.

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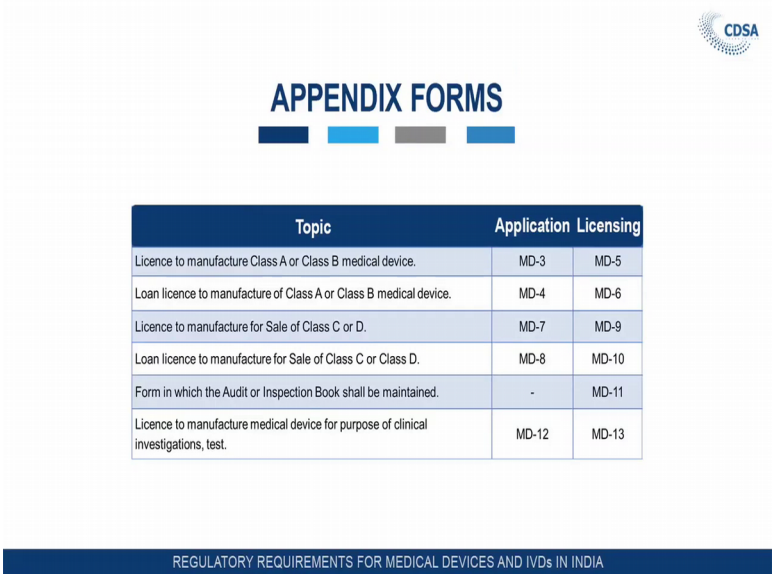


| Topic | Application | Licensing |
|---|---|---|
| Licence to manufacture Class A or Class B medical device. | MD-3 | MD-5 |
| Loan licence to manufacture of Class A or Class B medical device. | MD-4 | MD-6 |
| Licence to manufacture for Sale of Class C or D. | MD-7 | MD-9 |
| Loan licence to manufacture for Sale of Class C or Class D. | MD-8 | MD-10 |
| Form in which the Audit or Inspection Book shall be maintained. | - | MD-11 |
| Licence to manufacture medical device for purpose of clinical investigations, test. | MD-12 | MD-13 |

In MD 5 loan licence for A and B, MD 4 is the application, MD 6 is licence for C and D application is MD 7. Licence in MD 9, loan licence for manufacture of the class C and

class D devices, application is MD 8, licence is MD 10. Forms in which the audit or inspection book shall be maintained by the licensee MD 11, licence to manufacture the medical devices for the purpose of test, evaluation or clinical investigation, application in MD 12, licence in MD 13.

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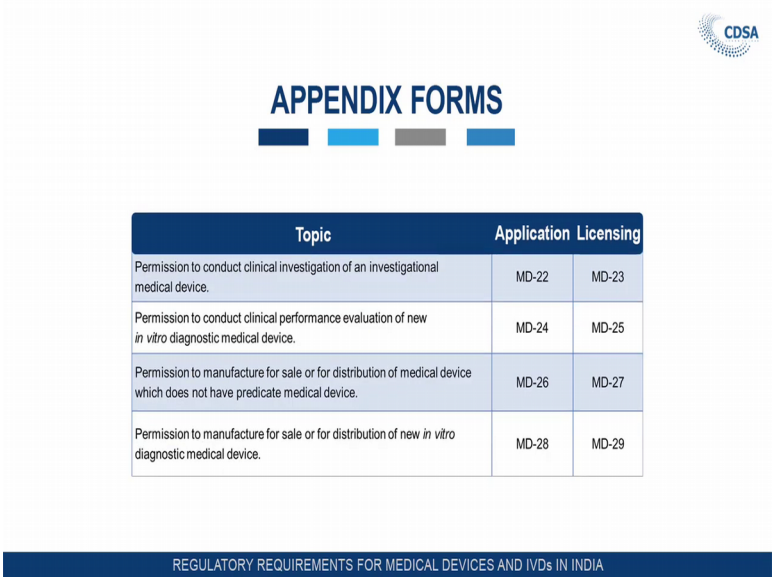


Permission to conduct the clinical investigation of the investigational devices, application in MD 22 and the permission is granted by the Central Licensing Authority in MD 23. Permission to conduct the clinical performance evaluation of new in vitro diagnostics MD 24, application and the permission is an MD 25. Permission to manufactured for sale or for distribution of the medical devices which does not have the predicate devices MD 26 is the application and the permission is MD 27. Permission to manufacture for sale or distribution of the new in vitro diagnostics application MD 28 and the permission is issued in MD 29.

These different forms have been described in the Medical Device Rule 2017. So, in this lecture we have covered what are the rules applicable for the grant of manufacturing licence? Who are the authorities responsible for grant of manufacturing licence for class A class B devices and over the authority responsible for manufacturing of class licence for class C or class D devices? We have also covered which rules, which chapters applicable for the medical devices. What is standard is required? What is the living

provision applicable for the medical devices and in vitro diagnostics? All that topics we have covered in this chapter.

So, if you have some more you required some more detail about the provisions of the medical device rule you go through the website of the CDSCO, were the medical device rule is there. And if you have any further doubts you want to see clarification you approach to us for further clarification. Now, just have some sort of question answer session. So, will take one two questions whether you understand or not have you aware of that or not.

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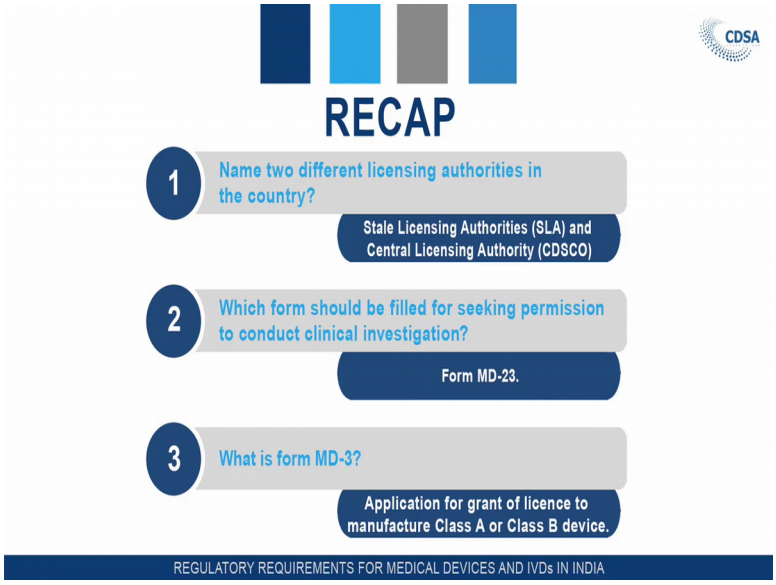


Now, name the two different licensing authority in the country which is responsible for grant of manufacturing licence we have discussed so many times that is State Licensing Authority and the Central Licensing Authority. Now, which forms is to be filled for permission to conduct the clinical investigation, the forms required to obtain the permission to conduct the clinical investigation it is MD 23. Now, what is MD 3? MD 3 is the licence to manufacture class A or class B medical devices it is not licence it is a application for grant of licence to manufacture class A and class B devices.

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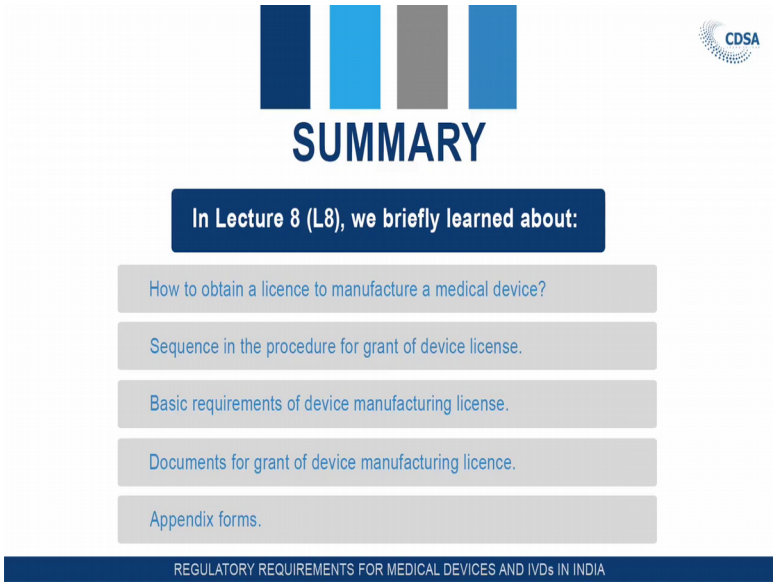


So, thank you very much and hope next chapter we will cover the remaining part of the Medical Device Rule 2017. So, in summary the lecture we briefly learnt about the how to obtain the manufacturing licence. The sequence of the procedure of the grant of the manufacturing licence. Basic requirement for the manufacturing licence. Documents for grant of medical device manufacturing licence and the forms. So, I hope you understand the requirement for the grant of manufacturing licence.

Thank you very much.