

# **GUIDANCE NOTE ON INTERNAL AUDIT OF PHARMACEUTICAL INDUSTRY**



**The Institute of Cost Accountants of India**  
(Statutory body under an Act of Parliament)

HQ: CMA Bhawan, 12, Sudder Street, Kolkata-700 016  
Delhi Office: CMA Bhawan, 3, Institutional Area, Lodhi Road, New Delhi-110003

First Edition: July 2014

**Published By:**

The President  
The Institute of Cost Accountants of India  
CMA Bhawan  
12, Sudder Street, Kolkata- 700016

**Delhi Office**

CMA Bhawan  
3, Institutional Area, Lodhi Road, New Delhi- 110003

**Price:**

**The Institute of Cost Accountants of India**

© All Rights Reserved

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form, or by any means, electronic, mechanical, photocopying, recording, or otherwise without prior permission, in writing, from the publisher.

Any mistake, error or discrepancy noted may be brought to notice of PD Directorate which shall be taken care of in the next edition.

**CMA DR. SURESH CHANDRA MOHANTY**  
LLB, FIV, FCMA, Ph.D  
PRESIDENT



**THE INSTITUTE OF COST ACCOUNTANTS OF INDIA**  
(Statutory Body under an Act of Parliament)

CMA Bhawan, 12, Sudder Street, Kolkata-700 016  
Phones : +91-33-2252-2128/ 6459-0085, Fax : +91-33-2252-7993  
Website : www.icmai.in, E-mail : president@icmai.in  
Mobile : +91-99100 30124



*Date: 14th July, 2014*

**FOREWORD**

I am very happy that the Professional Development Committee is bringing out the Internal Audit Guidance Note of Pharmaceutical Industry. The Companies Act 2013 vide Section 138(1) has given cost accountants a mandate to conduct the internal audit of the companies. The Institute is in the process of bringing out many other Sector Specific Internal Audit Guidance Notes to improve the technical knowledge and enhance capacity building of its members to conduct internal audit in the core areas of various sectors of economy.

I am confident that this Guidance Note in lucid language with lot of practical examples will be used as a ready reckoner for members of the profession.

I would like to place on record the tireless efforts of CMA Kirit Mehta and CMA Sukrut Mehta in preparing the very comprehensive Guidance Note of Internal Audit of Pharmaceutical Industry which would be a treasure trove for all cost accountants as well as the professionals working in the pharma industry.

I would acknowledge the valuable contribution made by the CMA Sanjay Bhargave, Chairman, members of the Professional Development Committee and the Directorate in bringing the Guidance Note in the present form.

I would like to convey my sincere thanks to CMA (Dr.) A.S. Durgaprasad, Vice President of the Institute for providing requisite guidance in finalising this document.

I am quite hopeful that the users of the Guidance Note would find it very useful.

**(CMA (Dr.) S.C. Mohanty)**

**SANJAY R. BHARGAVE**  
CHAIRMAN,  
PROFESSIONAL DEVELOPMENT COMMITTEE



**THE INSTITUTE OF COST ACCOUNTANTS OF INDIA**  
(Statutory body under an Act of Parliament)

H.Q.: CMA Bhawan, 12, Sudder Street, Kolkata-700 016  
Phones: 91-33-22521031/1034/1035  
Fax: 91-33-22527993 /1026 /1723  
Website: [www.icmai.in](http://www.icmai.in)

### **PREFACE**

*Companies Act 2013 vide Section 138(1) has given cost accountants a mandate to conduct the internal audit of the companies. For capacity building and to aid members of the Institute to conduct the internal audit in sector-specific industries, the Institute is preparing internal audit guidance notes for various sectors of Indian economy. Each sector of economy has its own peculiarity with respect to technicality, special transactions, manufacturing operations, accounting, special areas where an internal auditor is required to focus more as compared to other areas, maintenance of cost records and cost audit etc. In view this requirement, the Institute is releasing its first Internal Audit Guidance Note for Pharmaceutical Industry.*

*The Internal Audit Guidance Note of Pharmaceutical Industry is divided into two parts namely General and Sector Specific portions. General portion of guidance note covers general principles relating to internal audit including Internal Audit in ERP Environment and Systems Audit. Sector Specific portion covers brief about the sector, government policies and rules relating to sector, legal and regulatory framework, technical peculiarities, special transactions, activities/ services of the sector, audit check list for all these areas etc.*

*I would like to place on record the appreciation and acknowledgement of tireless efforts of CMA Kirit Mehta and CMA Sukrut Mehta in preparing very comprehensive Guidance Note of Internal Audit of Pharmaceutical Industry.*

*I also like to acknowledge the contribution made by CMA J.K.Budhiraja, Director (Professional Development) and his team of Professional Development Directorate for providing technical inputs to experts preparing the Guidance Note.*

*The members of the Professional Development Committee also contributed immensely in shaping the present Guidance Note and provided necessary inputs in concretizing the material.*

*I would like to convey by sincere thanks to CMA (Dr.) S.C.Mohanty, President and CMA (Dr.) A.S.Durgaprasad, Vice President of the Institute for providing guidance and able leadership connected with the Professional Development Committee.*

*I am quite hopeful that the Guidance Note would provide useful guidance to Cost Accountants and industry at large.*



CMA Sanjay Bhargave  
Chairman  
Professional Development Committee

Date: 14th July, 2014

**ACKNOWLEDGMENTS**

**Professional Development Committee of The Institute of Cost Accountants of India  
(2013-14):**

CMA Sanjay R. Bhargave	-	Chairman
CMA M. Gopalakrishnan		Member
CMA H. K. Goel		Member
CMA Sanjay Gupta		Member
CMA (Dr.) Sanjiban Bandyopadhyaya		Member
Shri G. Sreekumar, Government Nominee		Member
CMA. J.K. Budhiraja		Director (PD) and Secretary to PD Committee

## **INDEX OF CONTENTS**

<i>Chapter</i>	<i>Description</i>	<i>Page No</i>
<b>1</b>	Introduction to Internal Audit	1-22
1.1	History and Evolution of Internal Audit	1-2
1.2	Definition	2
1.3	Necessity	2-4
1.4	Objectives	4-5
1.5	Principles	5-8
1.6	Strategy	8-12
1.7	Approaches	12-15
1.8	Terms of Engagement	15-18
1.9	Independence	18-19
1.10	Pronouncements	19
1.11	Legal Requirement for Internal Audit	19-22
<b>2</b>	Documentation and Working Papers	23-27
<b>3</b>	Planning an Internal Audit and Audit Programme	28-31
<b>4</b>	Audit Sampling	32-34
<b>5</b>	Audit Evidence	35-36
<b>6</b>	Analytical Procedures	37-39
<b>7</b>	Accounting System and Internal Control	40-42
<b>8</b>	Control and Risk Assessment	43-49
<b>9</b>	Internal Audit in ERP Environment and Systems Audit	50-53
<b>10</b>	Relying on External Opinion and Reference of Auditor Expert	54-55
<b>11</b>	Audit Conclusion and Corrective Measures	56-58
<b>12</b>	Report Writing and Audit Report	59-61
<b>13</b>	Introduction to Pharmaceutical Industry	62-63
<b>14</b>	Applicable Government Policies and Rules	64-67
<b>15</b>	Legal and Regulatory Framework	68-70
<b>16</b>	Technical Peculiarities	71-72
<b>17</b>	Special transactions peculiar to the industry	73-74
<b>18</b>	Activities/ Services of the industry	75-76
<b>19</b>	Audit of Operational Activities	77-82
<b>20</b>	Audit of Special Areas with reference to peculiar transactions	83-85
<b>21</b>	Audit of Functional Areas	86-90
<b>22</b>	Cost Audit specific to the Industry	91-94
<b>23</b>	Audit follow-up	95-96

24	Checklist	97-98
----	-----------	-------

**Annexure**

	<i>Description</i>	<i>Page No</i>
	<i>Annexure I</i>	100-110
	<i>Annexure II</i>	111-134
	<i>Annexure III</i>	135-145



## **Chapter 1: Introduction to Internal Audit**

### **1.1 HISTORY AND EVOLUTION OF INTERNAL AUDIT**

The establishment of Internal Audit can be linked to the need of independent verification with a view of reducing book keeping errors, general misappropriations and fraud. The systematic verification of records and evidence started being called “Internal Audit”. It was felt that external audit at the end of the year needed to be supplemented by more frequent verification and it was equally important to review and upgrade the process and procedure of carrying out Internal Audit.

With the booming growth of business size and structure, it was felt that many businesses did not have appropriate controls in place to permit full achievement of their strategic objectives. The management of these businesses found it impossible to visually supervise all of the operating areas in their respective field of responsibility or to have sufficient personal contact with individuals, who directly or indirectly reported to them. In seeking ways to deal with these new problems, management appointed special staff people to review and report on what was happening and to probe for the “why”. These people came to be known as "internal auditors."

The internal audit function varied greatly as to the number of people assigned to perform it and in the scope and nature of the work being done. In some organisations, internal auditors were used to check on routine financial and operational activities with a heavy emphasis on compliance, security, and detection of fraud. In others, internal auditors were given higher levels of status and were asked to analyse and appraise more substantive financial and operational activities.

Gradually, internal auditors also began to exhibit “industry specialisation” in terms of their domain knowledge of specific industries such as health-care, oil, gas, and energy, defense, financial services, transportation, wholesale and retail, technology, media and entertainment, telecommunications, government, non-profits and education, etc.

Companies worldwide have witnessed rapid and radical change with organization and industry wide significance. The response of company management to such aggressive global competition has led to an increase in multitudes of the quality (efforts such as six sigma) and risk management initiatives, re-engineered structures and procedures, and enhanced responsibility all based on the ever increasing need for more timely, reliable, and relevant management information. This has also led to a rats’ race between global organizations to implement effective and efficient corporate governance processes. Thus, to no one’s amazement the internal audit function is now being viewed as a qualified group of professionals who help with such experimentation with global corporate governance while supporting key governance processes of monitoring control mechanisms and ascertaining operational performance.

However, to facilitate this escalation in the demand for their services, not only do internal auditors need to obtain and display considerably enhanced set of skills and competencies but they also need to exhibit industry specialisation and exposure to a varied operating specialties within the industry. With

the recent advents of increase in scope and acceptability Cost Audit and Compliance Report, CMAs are in perfect position to demonstrate the requisite skills and competencies necessary for undertaking successful Internal Audit function including risk evaluation and risk management.

## **1.2 DEFINITION OF INTERNAL AUDIT**

The Chartered Institute of Management Accountants, UK (CIMA) defines Internal Audit as:

*'An independent appraisal activity established within an organisation as a service to it. It is a control which functions by examining and evaluating the adequacy and effectiveness of other controls; a management tool which analyses the effectiveness of all parts of an organisation's operations and management.'*

The Institute of Internal Auditors (IIA) also defines Internal Audit on similar lines as:

*'Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organisation's operations. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.'*

These definitions state two clear functions of the Internal Audit activity namely;

**1.2.1 Internal Control:** Internal controls direct, monitor, and measures the company's resources and help to detect and prevent fraud from occurring within an organisation. It can be defined as a process which is performed by the employees of the company as well as the information technology systems that are used to assist the company in achieving its objectives. The management of a company is responsible for establishing the system of internal controls within the organisation, but internal auditors test the controls to make sure they are working effectively.

**1.2.2 Management Tool:** Internal Audit has been used as a management tool which monitors and evaluates the effectiveness of operational processes and risk management of a company. How an organisation sets their objectives and responds to the risks associated with their objective is part of the risk management process. Risk management is a way for companies to manage uncertainty through risk assessment, to develop strategies to manage risk and to mitigate risk by using managerial resources.

Thus, Internal Audit as a function must make recommendations to improve the overall internal control environment including financial and legal compliances, to safeguard assets and to improve the operational performance of the organisation as a whole.

## **1.3 NECESSITY OF INTERNAL AUDIT**

Examples of Scams, Frauds and Misappropriation of power have been reoccurring with at an alarming rate in India and abroad. Many of these frauds are increasing, being caused to lack of adequate internal controls and their appropriate implementation. Thus, it is imperative that companies begin detecting and preventing fraud, testing internal control, and monitoring compliance with company policy and government regulations to safeguard the interest of all its stakeholders, customers and society at large.

Frauds such as Satyam (2009), IPO scam (2004-05), DQS software (2001), Home Trade Portal (2000) and the UTI and CRB scams of late 1990's were all testaments to lack of Internal controls in these companies and the lack of information of the companies' managements. All of these companies could have avoided frauds with the help of a prudent internal audit function and though the role and responsibility of internal audit function may vary in scope and authority in different organisations, there is a clear trend that internal audit is taking on a more strategic and central role increasing the dependence on cost and management accounting data.

In addition to this, business has become more dynamic necessitating regular review of Contribution (Sales Value minus Direct Costs)/ per machine hour or per unit of Key Limiting Factor etc and interpretation of cost data.

It is necessary for every company to continuously ensure authenticity and reliability of data generated and used for decision making and also to avoid duplication of data. It is necessary to verify the source, the quantum and the reliability of all records. The Internal Audit function will primarily concentrate on the system for collection, collation and analysis of data to go into final cost compilation and decision making. The main objective of Internal Audit of Accounts is, to ensure implementation of Control and continuous monitoring of systems being followed.

When Internal Audit is carried out for the first time, the ground rule for Internal Audit needs to be laid down, inter alia, including;

- The Internal Audit will primarily concentrate on flow of data and justification of basis instead of vouching.
- The materiality of cost and product under consideration would always be borne in mind during Internal Audit process.
- Objectivity in approach would be a consistent feature in Internal Audit.
- Main thrust would always be on deviations and significance of deviations with impact of the same on the performance of the organisation.

As the Internal audit cycle stabilizes, it will help companies in the following areas:

**1. Assess Compliance**

The organization needs to adhere to rules, regulations, laws, codes of practice, guidelines and principles as they apply individually and collectively to all parts. The Internal Audit cycle periodically checks such compliances and reviews their adequacy.

**2. Monitoring Controls**

The Internal Audit function must clearly understand the quality and risk management philosophy of the organization before evaluating or reporting on the efficiency and effectiveness of the implementation of management policies.

**3. Analyze Operational Performance**

Internal Audit function works closely with lower and middle level managers to review daily

operations then report their findings. The strategic objectives of the organization play a significant role in understanding how the operations of any given part of the organization fit into the macro level picture.

#### **4. Evaluation on Risk based approach**

Internal Audit function identifies key accomplishments and relevant risk factors while evaluating their significance. Any important change in business, economic, political or social conditions impact the way the internal audit function must assess risk. The role of internal auditing has changed from being a reactive and post mortem form to a more proactive and risk based approach. This enables the internal auditor to anticipate possible future threats and opportunities while simultaneously identifying current concerns and providing their preventives.

The increased interaction between the evolving internal audit function and the management is an important area for organisations to focus on and develop for both short and long term benefits. Once risk factors are identified by the management based on data generated from Internal Audit, it is utmost necessary to assess the quantum and seriousness of risk. For example, various Companies started manufacturing in Hilly States like Himachal Pradesh, Uttarakhand, Jammu & Kashmir and of late in Sikkim and North Indian states. These units will enjoy benefit of exemption from Excise Duty, VAT and Income Tax. Further, past experience had shown that the incentives offered can get diluted half the way causing losses and some times, viability of the new unit. Under such, circumstances, the function of Internal Audit has to be proactive instead of reactive. The Internal Audit should go beyond the records available within the Company.

#### **1.4 OBJECTIVES OF INTERNAL AUDIT**

The Internal Audit is an independent function established by an organization's management to appraise and evaluate the company's activities and monitor of its controls. One of the primary purposes of internal audit is to support the management of the company to effectively discharge their individual and collective responsibilities.

Thus, Internal Audit provides, analyses, appraisals, recommendations, counsel and information concerning the activities reviewed. The internal auditor has a dual role in providing consulting advice, to help the business and also providing objective assurances across the organisation. In brief, help is provided to the management on request, or as spin-off from a previous audit, and there will be clear criteria to approving all requests for help. The internal audit function can help with the following:

- Develop and monitor control frameworks
- Establish reporting structures and formalize communication processes
- Aid the cost reduction and operational performance appraisals
- Develop and continuously monitor risk assessment and management
- Undertake workshops for training and awareness
- Assure compliance with all relevant rules and regulations

- Supporting corporate governance and developing resources for management information

The Internal Audit function must form a part of risk management and formal internal control reporting implementation team for any organization.

The other side of the coin relates to the assurance role of the internal audit function. The internal audit function must guarantee that where control design is wrong, misdirected, misapplied, abused or simply not quite right, employees and company management need to be informed and appropriate action must be engaged. Internal audit is one of the few functions in the organization, which ensures working of all managers and employees work with objectivity, independence and take appropriate action in line with the best interest of the organisation, at all times. This means that what the internal audit function states the effectiveness of internal controls without any vested interests. The internal audit function must review all efforts of employees and management to complete the formal audit assurance work. The internal audit reports are shared with the concerned business managers, and the executive summary to the appropriate director, and summarized report for the audit committee and Board. In effect, the internal audit function touches every aspect of the organization while tackling Internal Control systems but left out of the business's initial audit work, such as a review of managing staff absences and levels of staff morale. The internal audit function must share any process risks or lapses in internal control systems with the audit committee and board.

The Final part of internal audit is relating to compliance with all relevant and stipulated rules and regulations. Most organisations respond to growing compliance requirements by setting up small compliance teams to ensure that the myriad of detailed rules and regulations are properly addressed. This has to be handled very carefully, as there is a need to strike a careful balance between an enforcement and encouragement approach to compliance. All employees need to understand the compliance process and build this into their work and efforts; that is, they should know that compliance is about the need to:

- 1) Established criteria for measurement of compliance
- 2) Setup operational procedures in compliance with the requirements
- 3) Implement all requisite changes and new procedures
- 4) Determine crash gates and hold review meetings
- 5) Communicate changes in operating procedures and train staff, where required
- 6) Ensure compliance is action oriented

Thus, an internal audit function that turns a 'have to' compliance culture into a 'want to' one will reap great benefits in multiple areas of the organisation.

### **1.5 PRINCIPLES OF INTERNAL AUDIT**

The 'Principles of Internal Audit' act as guidelines or standards for undertaking an Internal Audit Function. These principles entail a general list of rules that enable an internal auditor as well as an organisation to not only setup a robust and well-oiled internal audit function but also evaluate gaps in

the existing internal audit framework. A detailed note on each of the principles is provided in the ensuing chapters and forms the basis for undertaking an effective and efficient internal audit. The essentials of an internal audit are mentioned as under:

**a. Independence and Integrity**

Independence of the internal auditor is vastly different from that of the external auditor. Internal auditors should be independent in terms of bias or undue influences, organizational status and personal objectivity, which permit the proper performance of duties and provide decision-able recommendations and findings. The reporting framework of internal auditors should also be reminiscent of the individualistic and consultative nature of the activity.

Along with due independence, the internal auditor needs to depict certain personal and professional attributes which shall enhance the integrity and acceptability of the report. These include but are not limited to: honesty, sincerity, impartiality, business acumen, effective communication skills, and should try to maintain arm's length from all organization's members.

**b. Terms of engagement**

The Terms of Engagement of an internal audit team means to accept an internal audit assignment for an organization post agreement of the activities to be undertaken and formalizing all preconditions of the internal audit. The Terms of Engagement are a common understanding of the terms of reference for the internal audit between the internal audit team and management of the organization. These common understandings have been specified in further detail later on.

**c. Strategy and approach**

The internal audit strategy describes the role of internal audit within the organisation's overall assurance processes and provides an important link between the internal audit charter and the detailed internal audit work plan. It is expected that the strategy will set out:

- the organisation's assurance requirements and the contribution of the internal audit function to that assurance over the period covered by the strategy;
- the broad details of the audit, audit support and non-audit activities that internal audit will undertake; and
- the proportion of resources that will be devoted to the different types of activities that will be undertaken.

The period covered by the strategy can vary, but would normally cover a three to five year period and be reviewed at least annually.

**d. Planning of internal audit**

Internal audit function aligns focus and activities to the organisation's risks. To achieve alignment between the organisation's risks and internal audit coverage, it is imperative that internal audit planning to occur in the context of company-wide assurance mapping, which can be commissioned by the Audit Committee. Within this context, internal audit planning generally involves a detailed work plan, prepared on an annual basis. To provide context, the work plan might be supported by a schedule



of potential audits and an indication of previous audit coverage. This document serves the purpose of setting out in strategic and operational terms the broad roles and responsibilities that are included in the internal audit charter and identifying key issues relating to internal audit capability, such as required skills.

**e. Staffing and Training**

The internal audit should be headed by a person who has substantial exposure to the working of the industry that the company is involved in and also possesses the requisite knowledge of compliances to be adhered to. He or she should be able to plan, direct, control, motivate and organize resources and deliver on timelines to ensure the responsibilities of the internal audit unit are met.

It is important to analyse the budget and time constraints along with the scope and audit plan to determine the appropriate background, skills and competencies that would be required by the internal audit team. An internal audit team requires both technical and soft skills to undertake a smooth internal audit function. The team needs to display a variety of skill levels, qualifications and technical know-how.

It is the responsibility of the organisation to ensure that the internal audit team has accurate knowledge of the organisation's structure and peculiarities related to its functioning. If required, the internal audit team may have to undergo specific trainings to meet the basic objectives of the audit and assess operational risks. Just as the external auditors, the internal auditor should keep abreast of current developments, improvements, new techniques and practices in internal auditing to properly equip him for any unique challenge he may encounter during this rigorous audit process.

**f. Evaluation of Internal Systems and Risk Assessments**

Internal Audit entails a through systems analysis and audit. Internal audit establishes appropriate criteria to determine whether the controls are adequate and assist in achieving the objectives of the system. The stages of a systems audit would normally be:

- 1) Identification of systems and procedures
- 2) Ascertaining control objectives
- 3) Defining control mechanisms to be implemented
- 4) Reviewing the changes to be implemented to adhere to controls
- 5) Implementing new controls and monitoring their performance and adequacy
- 6) Providing a formal opinion on audit objectives and adequacy of control mechanisms

Internal Audit establishes standards and provides guidance on obtaining an understanding of the accounting and internal control systems and on audit risk and its components:

- inherent risk,
- control risk and
- detection risk.

The auditor should assess audit risk and to design audit procedures to ensure that the risk is reduced to an acceptably low level.

**g. Evidence and Analytical Procedures**

The recommendations, findings and comments of the internal audit report should all be based on and supported by appropriate and adequate audit evidence. Evidence should cover all activities checked and controlled by the audit plan with specific notes for possible errors, their materiality and risks of occurrence. An internal auditor should obtain the evidence considered necessary for the achievement of the internal audit assignment objectives. The level of detail required for this evidence depends on the objective and scope of the audit, scale of misstatement or level of risk, cost and time involved in obtaining the evidence and finally reliability of the evidence. Reliance on evidence can be satisfied with its nature, extent, adequacy, consistency and relevance to the internal audit assignment and with the methods governing its collection.

**h. Report Writing, Presentation and Follow-up**

The internal audit report must be written after careful review and analysis of the various audit evidences, notes on internal control systems and risk assessments undertaken during the audit. In case internal auditors come across any fraud or misrepresentations or misappropriations, they have to be reported to the organisation's management or Audit Committee. The internal audit report provides a formal platform to the internal audit team to share its findings, recommendations and comments to the management. The internal audit report should recommend actions for performance improvement and control, and formal records for areas wherein audit was undertaken.

The format and schedule for sharing of the internal audit report presentation should be agreed with the management prior to augment of the assignment. All functional managers should be communicated the audit findings related to their respective areas and final list of actionable decisions must be shared by appropriate management representatives to enable them to take informed decisions. Once, the management has provided for suitable consideration to the internal audit report, the decision points and thereby the recommended actions to be undertaken must be formally recorded along with clear statement of responsibility for completion of assigned tasks.

**1.6 STRATEGIES TO INTERNAL AUDIT**

As mentioned above, the Internal Audit strategy acts as a link between the internal audit charter and the work plan. An internal audit strategy helps in focusing internal audit effort, where it is most useful and effective. The time and resources involved in developing the internal audit strategy should be commensurate with the size and complexity of the organisation and should also align with the organisation's strategic decision. To analyse the internal audit strategy in further detail, it is necessary to understand its purpose, contents of a good strategy and the methodology for development and selection of internal audit strategy.

**a) Purpose of Internal Audit Strategy**

An Internal Audit Strategy is based on the aim and scope of the internal audit. An internal audit strategy helps in:

- a. A bird's eye view of the overall governance, risk management and control system of the organisation,
- b. Focusing the internal audit effort where it is most useful and effective, keeping track of the budgeted time and cost,
- c. Minimising repetition and eliminating duplication of assurance effort,
- d. Ensuring that there are no gaps in the internal audit function and the entire spectrum of control system is analysed,
- e. Identifying the requisite skills, resources and specialisations to deliver an efficient internal audit function,
- f. Providing a reference point and setting up the basic framework for performance appraisal of all functions.
- g. Assessing risk and identifying steps and procedures to mitigate risk.
- h. Introducing a culture of continuous improvement and enhancing feedback by formalizing the communication channel.

**b) Contents of a good of Internal Audit Strategy**

The basic structure of the Internal Audit Strategy will be based on the type of audit being undertaken, expectations of the Audit Committee and management, and finally the size and nature of the Internal Audit function. The precise format and contents would, hence, vary from one organisation to another. However, any internal audit strategy would benefit by incorporating the following:

- a. A brief description of the approach of internal audit selected in developing the strategy and a list of key managers who approved the strategy;
- b. A summary of the organisation's short, medium and long term strategic mission and objectives or KPIs (Key Performance Indicators) to be targeted;
- c. A short summary on the organisation's prima facie risks (both external and internal);
- d. A description of the industry that the organisation operates in and positioning of the organisation in comparison to the industry standards;
- e. A general SWOT analysis of the organisation banks on to deliver commitments and sustain growth;
- f. An estimate of the financial, operational, sales, and human resources budgets and targets over the period of the strategy;
- g. The parameters of time, effort and costs considered to formulate the internal audit work plan;
- h. The allocation of resources to the Internal Audit function along with the time lines for delivery;
- i. The balance of various types of internal audits to be undertaken along with the approved audit scope;

- j. The frequency, distribution and level of detail in the internal audit report;
- k. The details of function-wise and SBU-wise KPI and KRA (Key result areas);
- l. The formal procedure for review and update of internal audit strategy;

**c) Development and selection Internal Audit Strategy**

As mentioned above, the time and resources involved in developing the strategy should be commensurate with the size and complexity of the organisation, and have regard to the organisation's risk profile and the maturity of the organisation's risk management processes. The process would also be expected to be consistent with the organisation's usual business planning processes. In developing the strategy, consideration would normally be given to the following factors:

**d) The organisation's Internal Audit objective and business strategy**

The organisation's Internal Audit objective will determine the strategy to be undertaken. The strategy may have to involve multiple and varied expectations of the audit committee and management and helps communicate the direction internal audit intends to pursue over the life of the plan. These expectations or targets may often include staff training and development, analyzing risks and developing mitigation strategies, reviewing the internal control systems, improving audit and other processes, introducing new technologies or enhancing performance measurement and appraisal.

In order to deliver the an effective internal audit report, the strategy must align with the organisation's strategic direction and demonstrate a good understanding of the goals, objectives and priorities of the organisation as set out in corporate and business plans. Such a statement also provides a focus to develop and prioritize management strategies and tasks designed to achieve those objectives. Business objectives can vary considerably, but often include matters relating to the quality, cost-effectiveness and nature of the audit and other services provided by internal audit designed to meet the organisation's needs. The service delivery model in place will also influence, and be influenced by, the management strategies adopted.

**e) The Internal competencies of the organisation**

The Internal Audit Strategy would be largely influenced by the demography and size of the organisation and its resources. The strategy plans will vary for organisations with different levels of financial, operational, and human resource capabilities. The size and skill level of the internal audit team is also to be considered when developing the strategy. The coverage area should be commensurate with the size and ability of the team else meeting deadlines would be difficult and could severely hamper the quality of the final internal audit report.

**f) The external factors affecting the organisation**

The internal audit strategy is generally developed after considering government policy, economic and social conditions and the expectations of external stakeholders such as vendors, customers, government, public agencies and competitors. External sources for management information and data collection include reports from Parliamentary Committees, central agencies, industry regulators, independent reviewers; rating agencies and external consultants help ascertain threats and opportunities which should be considered as part of developing the internal audit strategy. The expectations of external stakeholders to whom the organisation has a reporting requirement such as

Institutional Investors must also be involved. All of these factors together influence the internal audit strategy and must be continuously monitored to ensure no opportunity is missed and no major risk adversely affects the organization's performance.

**g) The organisation's risk structure and mitigation plan**

The organisation's current and future risk profile will also be an important influence on the internal audit strategy. Provided the company's risk identification process and risk management framework is mature, its risk management plans will be a key source of information in developing the internal audit strategy. In case the organisation does not have a formalised risk assessment and management framework, one of the initial steps incorporated in the strategy would be to formulate and setup the risk management team and plan. The organisation's current and future risk profile would also influence on the types and level of internal audit activity.

In certain situations where the company does not have a mature risk management framework, internal audit will need to develop and modify the existing risk management structure after discussion with the Audit Committee and the senior management of the organisation. The risk management structure will provide a base for mitigation of both internal and external risks.

**h) Assurance and review of internal control systems**

In certain situations where the company does not have a mature risk management framework, internal audit will need to develop and modify the existing risk management structure after discussion with the Audit Committee and the senior management of the organisation. The risk management structure will provide a base for mitigation of both internal and external risks.

**i) Mapping the Internal Audit coverage**

Organisations are increasingly noticing the benefit in conducting an assurance mapping exercise. This consists of an analysis of the significant risks facing the organisation and the extent to which each of the various assurance elements addresses these risks. Such an exercise can be a very useful way of obtaining a broad organisation-wide perspective of the assurance landscape, assist in demonstrating an alignment between the organisation's risks and the proposed assurance coverage, highlight organisation risks that are not being addressed by the assurance program and assist in identifying any gaps or duplication. The internal auditor uses these assurance maps to develop an overall opinion on the organisation's control environment. Thus, it is important that internal audit coverage complements, rather than duplicates other assurance and review activities. An assurance map assists internal audit to identify any gaps or duplication and to develop its work plan, to develop its work plan and to assist the Audit Committee in undertaking the assurance mapping process.

Examples of possible themes include governance, policy and strategic planning, program and project management, client relationships, financial, human resources and information technology systems.

**j) Budget Consideration**

As a matter of principle, the internal audit strategy should first address all the activities that internal audit, the Audit Committee and other stakeholders consider should be included, before reflecting on the possible budget available. However, in case the expectations far exceed the approved budget, the internal audit function can request for an updated budget.

The size of the investment the company wishes to make in internal audit would normally be determined by the Board on the advice of the Audit Committee and multiple factors would be considered before finalization. The internal audit strategy should outline the issues that will be considered in the development of internal audit work plans and should address the achievement of the appropriate level of coverage and the prioritization of reviews.

**k) Management Expectations**

It is important to obtain the views of management about their expectations of the internal audit function. Thus, it can be expected that management could have differing expectations of internal audit and its focus and priorities. In these circumstances, it is important for internal audit function to work through the different perspectives and have follow-up discussions, as required, to ensure that the role of internal audit outlined in the internal audit strategy considers the views similar to that of the management. In its consideration of the strategy, the Audit Committee should be made aware, at least in broad terms, of the views of key stakeholders, particularly if they are not reflected in the document presented.

Generally good Internal Audit function will evolve long term strategy to bring in effective Internal Audit by adding new areas and more detailed analysis year after year as, it may not be possible always to implement everything from very first year.

**1.7 APPROACHES TO INTERNAL AUDIT**

An internal audit will involve a combination of audit approaches and techniques. These include interviews, document reviews, sampling, testing of controls, and analysis of transaction, processes and management information. The audit approaches selected should be the most time and cost-effective given the objectives and scope of the audit. The aim is to collect sufficient, reliable, relevant and useful evidence to enable the internal auditor to come to well-founded conclusions about the program or activity under review and to make appropriate recommendations. Decisions will have to be made at each stage of the internal audit regarding the need for specific testing, data collection and analysis and the extent that reliance can be placed on work of other internal or external reviewers.

There are several types of internal audits. There are financial audit, operational audit, management audit, compliance audit, IS audit, Cost Audit and investigation audit. Each audit has different purpose and characteristic.

**a) Financial Audit**

The purpose of financial audit is to express opinion on financial condition based on analysis, comparisons and test of accuracy. Its scope is on the financial records. The results or comments expected from the audit are to give opinion on the accuracy and reliability of the financial statements.

**b) Operational Audit**

The purpose is to analyse and improve methods of operations and performance of a unit or department. The results or comments expected from the financial audit are to give recommendations to management for the improvement of operations.

**c) Management Audit**

The purpose is to review and evaluate business and management issues to enhance profitability. Its scope is on the business support activities of a unit or the entire organisation. The results or comments expected from the audit are to give opinions on strategic issues and recommendations or solutions.

**d) Compliance Audit**

The purpose is to express opinion as to adherence to internal policies and regulatory rules and requirements and applicable laws relating to the specific aspects of operations and business. The results or comments expected from the audit are to make immediate rectification and compliance thereafter.

**e) IS Audit**

The purpose is to audit on the computer systems and the provision and management of information. Its scope is on the technical reviews on computer systems and their peripherals. The results or comments expected from the audit are to give recommendations on computerization and information systems related.

**f) Investigation**

The purpose is to audit in depth irregularities such as misappropriation of bank's assets or reported fraud or allegations. Its scope is in the area specified to determine modus operandi. The results or comments expected from the audit are to give conclusion to findings with recommendations to prevent recurrence. These types of audits are also undertaken on specific assignment basis by specialized internal audit teams.

In addition to these general approaches, the Institute of Internal Auditor's Research Committee also shortlisted the following five "Value Added Approaches" to internal audit function. These approaches were accepted as basis for identifying emerging focus areas in which internal auditors could add value using non-traditional and innovative approaches. A brief description of each value addition approach follows.

**g) Project Management**

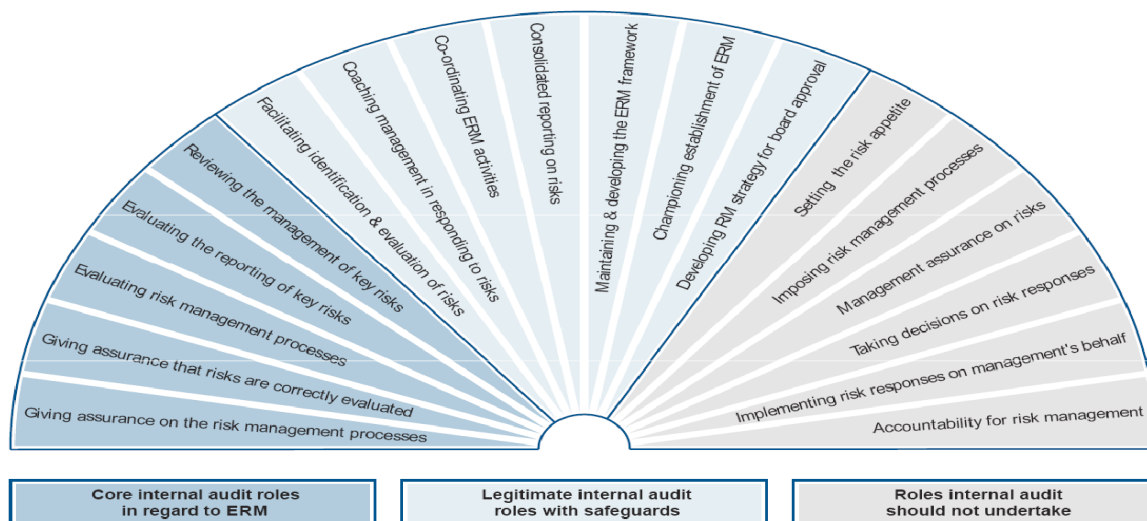
Project Management Audit is the list of activities performed by the internal audit function for the organisation's project management initiatives. Some organizations do not have a dedicated Project Management Office (PMO) or Project Management (PM) framework. Internal audit's engagement may include the following types of activities:

- Plan-Do-Act-Check process determination
- Process information flow
- Monitoring and Controlling project resource allocation process
- Project Risk management

**h) Enterprise Risk management (ERM)**

ERM is generally referred to the methodology implemented by organisations to strategically confront risks and leverage opportunities by implanting risk awareness into the strategy planning and implementation process. ERM is different from internal audit risk assessment as it aims to achieve

broader initiatives of connecting risks to strategic objectives, developing risk response mechanisms, and managing risk to within risk taking ability of the enterprise. The Internal audit function is involved in a number of ways in risk management process in line with general guidelines stating the acceptable roles internal audit team can take on with respect to ERM. The figure below helps determine the extent to which internal audit function can support ERM implementation for an organization.

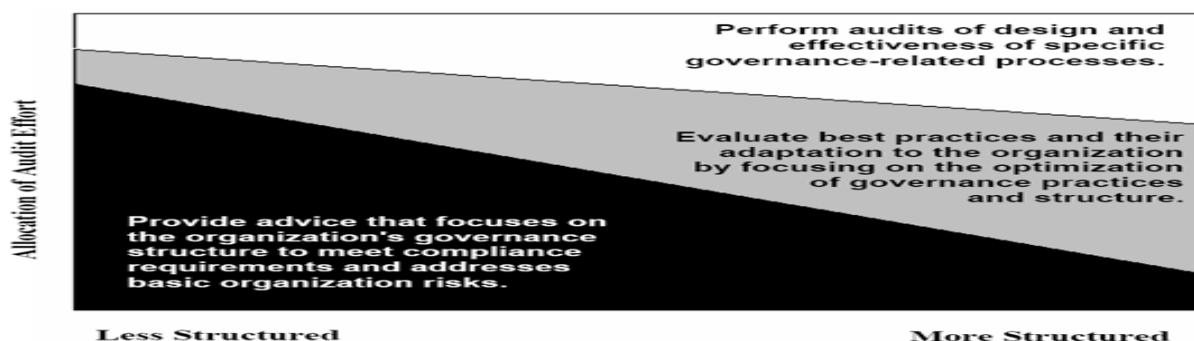


**Internal Audit Roles**

Adopted from: Internal Audit's Value Addition Approach- A Study in the Dallas-Fort Worth Area The Research Committee of the Dallas Chapter of the IIA

**i) Corporate Governance**

Corporate governance was first formally introduced in England by Kraft Foods Inc founder James L. Kraft. It is defined as the system of rules, practices and processes by which a company is directed and controlled. Corporate governance essentially involves balancing the interests of the many stakeholders in a company - these include its shareholders, management, customers, suppliers, financiers, government and the community. The Internal audit function plays a significant role in assisting the company's management with corporate governance. The type of activities performed by internal audit can typically be related to the maturity of the Governance Model in the organisation, as the IIA's "Internal Audit Governance Maturity Model" shows in the figure below:



**Internal Audit Governance Maturity Model**

**Adopted from: Internal Audit's Value Addition Approach- A Study in the Dallas-Fort Worth Area The Research Committee of the Dallas Chapter of the IIA**

**j) Social audits**

Social audits include the processes and practices by which an organization integrates its social responsibilities and sustainable business practices in its daily activities and way of working. Social responsibilities of an organization include various activities such as promotion of public interest, charities, and other philanthropic activities. Sustainability includes practices to promote environmentally friendly activities, prevent environmental disasters, or prevent fraudulent selling while maintaining profitability. Social and sustainable growth goals are gaining increasing importance in business in recent times.

**k) Strategy Audits**

Strategy audit generally comprise of two major activities namely; accurately assessing the strategy setting process with control measure and comparing the direction of the business to the planned direction as outlined in the strategic plan. The definition of business strategy is a long term plan of action designed to achieve a particular vision or set of goals or objectives. The internal audit function can add value through strategy audits and emerge as a key consultant who advises the management and the board on the risks and controls that impact achievement of strategic objectives and value creation.

**1.8 TERMS OF ENGAGEMENT**

The internal audit team must have the confidence and trust of the key stakeholders it works with and be seen as a credible source of assurance and advice. This confidence should not be assumed and can only be established and maintained by having effective working relationship, by delivering high-quality and timely advice and internal audit reports that are seen to be contributing directly to assisting the organisation to meet its responsibilities. The key stakeholders of internal audit are:

- Chief Executive
- Board of Directors
- Audit Committee
- Senior management
- External auditor
- Other reviewers

It is important that details of these relationships are formalised in documents such as the internal audit charter or the Audit Committee charter, good relationships also need to exist at a practical working level to be effective. The importance of these individual relationships is analysed below.

**a) Chief Executive**

While internal audit reports functionally to the Audit Committee, it is important that the Head of Internal Audit has direct access, as and when required, to the Chief Executive.

Organisations today, recognize the advantages in making the Head of Internal Audit directly accountable to the Chief Executive. This not only sends a clear signal about the importance of the internal audit function, it also facilitates regular contact between the Chief Executive and internal audit. This should not be seen as diminishing the role of the Audit Committee, which still advises the Chief Executive on governance issues, but as ensuring unimpeded communication, when required. This contact should be used as an opportunity for internal audit to gain insights into new and emerging risks and issues facing the organisation and to discuss the role the Chief Executive expects internal audit to fulfill in the company.

**b) Board of Directors**

The Head of Internal Audit may formally report to the Board of Directors on the effectiveness of the internal audit function. As the Audit Committee is usually a sub-committee of the Board, this responsibility is often delegated to the Audit Committee. Although the Head of Internal Audit may meet with the Chair and members of the Audit Committee, some Boards periodically meet with the Head of Internal Audit to exchange views and ideas. As a minimum, it is important that the Head of Internal Audit has direct access to the Chair of the Board and the Chief Executive, as and when required.

**c) Audit Committee**

Audit Committees play an integral role in the governance framework of organisations. Audit Committees assist Chief Executives and Boards to understand whether key controls are appropriate and operating effectively. In this respect, the relationship between internal audit and the Audit Committee is crucial and has a number of dimensions which are mentioned below:

- a) Advise the Chief Executive about the internal audit plans of the organisation;
- b) Direct or Coordinate work programs relating to internal and external audits;
- c) Review the content of internal [and external] audits to identify significant matters of concern, and to advise the Chief Executive on good practice or opportunities for improvement;
- d) Review the adequacy of responses to reports of internal and external audits;
- e) Endorse the internal audit charter and be responsible for either reviewing and approving internal audit plans, or recommending their approval by the Chief Executive/Board of Directors;
- f) Act as the internal audit function's primary client and form a sound professional relationship with the internal audit team as a whole and each of its members;
- g) Utilize internal audit reports and its general interaction with the Internal Audit team, to assess the effectiveness of controls and the performance of the organisation and
- h) Utilize the internal audit function to undertake secretariat compliance

Given this relationship, it is important that both formal and informal lines of communication be maintained between internal audit and the Audit Committee and with individual committee members, particularly the Chair. Audit Committee members should be in a position to be able to openly discuss matters of interest with the Head of Internal Audit. In doing this, committee members must be

confident that such discussions will be treated in confidence by internal audit.

It is generally accepted that the Head of Internal Audit, will attend Audit Committee meetings unless there are exceptional circumstances requiring them to be excluded for a particular agenda item. It is also good practice for the Audit Committee to meet privately with the Head of Internal Audit from time to time to ask questions and to seek feedback from internal audit without management being present. This practice also supports the independent role of internal audit.

To assist the Audit Committee in its monitoring responsibilities, internal audit should report to the committee on a regular basis on the status of the internal audit work plan. This report should also provide details of audit activity against planned audits, together with explanations of any significant variations. Internal audit should provide an annual report in an agreed format to the Audit Committee on its achievements and on the use of its resources.

Audit Committees may formally review the performance of internal audit on an annual basis and take an external review of the organisation's internal audit arrangements every five years or so. Internal audit should also report regularly on the status of management's actions to implement agreed internal and external audit report recommendations.

Internal audit functions increasingly are providing Audit Committees and Chief Executives with periodic reports on the patterns, trends and systemic issues identified as a result of internal audit activities.

#### **d) Senior Management**

To effectively fulfill its responsibilities, it is important that internal audit has a professional and constructive relationship with senior management of the organisation.

Internal auditors should interact on a regular basis with members of the senior management team, and through the delivery of practical, business-focused and useful reports and advice, build a relationship that is based on cooperation, collaboration and mutual respect. Meetings with organisation managers should be used as an opportunity to be briefed on key business developments and associated risks facing the organisation. These meetings should also be used to obtain informal feedback about the performance of internal audit and to assist in identifying ways that internal audit can best assist organisation management. One measure of the effectiveness of internal audit is the extent to which managers seek out internal audit to assist them in managing their business. Thus, internal audit team would encourage managers to seek their advice and assistance on either an informal or formal basis as the need arises.

In interacting with management, internal audit must be privy to information that may affect professional and, at times, personal reputations. It is important that internal audit respect the confidentiality of such information and its communication to others be on a strictly need to know basis. In situations where managers consider that such information is being used inappropriately, the reputation and credibility of internal audit is likely to be damaged.

#### **e) External Auditors**

External auditors too must help in developing internal audit strategy and internal audit work plan. Both audit teams need to address the key financial and business systems underpinning the company's

financial statements and to avoid duplication of compliance and assurance. To avoid such duplication, the external auditor must evaluate the work of internal audit function to determine its adequacy for external audit purposes. The Internal audit function can be made responsible for liaising with external auditor on behalf of the organization. Such a role can be a useful way for internal audit team to be aware of planned and actual external audit coverage. Thus, a constructive relationship between both set of auditors assists in the conduct of external audits. The Internal audit function may also be assigned the role of assisting the Audit Committee to assess the service provided by external audit. Such a role can only be fulfilled when there is health communication between internal and external audit teams. This can be achieved by setting up formally establish meetings between internal and external audit to allow for routine exchange of information.

#### **f) Other Reviewers**

Internal audit is one of a number of internal and external review and assurance activities that exist as part of an organisation's governance arrangements. The company shall benefit when all these activities, such as those performed by the Ombudsman and regulators, operate in a coordinated and complementary manner to the greatest extent possible. This requires regular formal and informal contact between review bodies to minimize duplication and overlap. Some organisations see benefit in protocols being formalised for such activities: providing, for example, for the regular exchange of views and information and for the reporting of the results of work undertaken in a coordinated manner.

Protocols can be particularly important in situations where internal audit needs to work closely with other entities as a result of inter-agency or other agreements.

### **1.9 INDEPENDENCE OF INTERNAL AUDIT TEAM**

Independence of an Internal Audit team helps to distinguish it from all other internal controls, systems and procedures. The Internal Audit function is not subject to the authority of the areas of the organization that it audits. Thus, 'operational independence' is ensured and the entire exercise is objective, impartial and free from any conflict of interest, inherent bias or undue external influence. Although the internal audit function is independent in its working, it provides a service to the management, reports to the Audit Committee and is ultimately accountable to the Chief Executive or the Board for the achievement of its set objectives and the utilization of resources.

A conflict of interest can create an appearance of impropriety that can undermine confidence in the internal auditor and the internal audit function. A conflict of interest could impair an individual's ability to perform his or her duties and responsibilities objectively. If independence or objectivity is impaired in fact or appearance, the details of the impairment must be disclosed to appropriate parties. The nature of the disclosure will depend upon the impairment. Impairment of organisational independence and individual objectivity may include, but is not limited to, personal conflict of interest, scope limitations, restrictions on access to records, personnel, and properties, and resource limitations, such as funding. To ensure operational independence of internal audit function, certain measures need to be undertaken by the management. A general list is given below:

- a) The internal audit function must report directly to the Audit Committee

- b) The lead internal auditor must have direct access to the Chairman of the Audit committee and the Board of Directors
- c) Regular meetings must be held between the lead Internal auditor and the management
- d) Any external consultants approached by the internal audit function must be validated by the management
- e) The internal audit charter should not include any activity which may be or lead to a conflict of interest

The above mentioned steps helps the internal audit function maintain objectivity and undertake judgement based purely on tangible evidence devoid of influence.

### **1.10 PRONOUNCEMENTS**

One of the primary functions of the internal audit team is to ensure adherence to internal policies and regulatory rules and requirements and applicable laws relating to the specific aspects of operations and business. Internal audit function has to include business improvement reviews, risk management processes, quality assurance arrangements and management control self-assessment arrangements. However, in addition, there are number of external assurance and review bodies, including external audit, regulators, and the Ombudsman who are submitted various reports and assessments that need to be reviewed.

The Internal Audit function must ascertain whether or not the organisation has conducted its operations in accordance with the provisions of laws and regulations including the external reports and statements submitted through financial and cost records. The internal audit must obtain adequate and appropriate evidence to support the compliance or lack of it by the organisation.

This evidence could be shared with the external auditors to ascertain whether or not accurate disclosures and reported amounts of financial statements are correct. The internal audit function has to identify any non-compliance and recommend modification or change to the internal procedure of compliance. In order to facilitate accurate identification of non-compliance, the internal audit team should develop an understanding of various Legal and Regulatory framework.

Certain organisations operate in regulated industries such as pharmaceuticals, banking, electricity, insurance, telecom and others. The internal audit team needs to understand all relevant policies, orders, rules and regulations to be complied with by the company. The Internal Audit function must take into account all aspects of business and compliance.

There are multiple regulatory requirements which need to be addressed and kept track of when undertaking internal audit. The Internal Audit function must have a checklist of all regulations to be followed and it must guide the management regarding the adequacy of compliance or the lack of it.

### **1.11 Legal Requirement for Internal Audit**

The compliance with the laws of the home country as well as the laws of the foreign country land for existence of businesses in India and abroad is a critical factor. As per the legal obligation / requirement

under different statutes in India and abroad a Company shall have internal audit of its accounts carried out, at such interval and in such manner as may be specified in the relevant Acts/ Regulations.

**Clause 49 of Listing Agreement: Corporate Governance (SCRA)**

In case of the listed companies as per the Clause 49 of Listing Agreement the audit committee should be reviewing the adequacy of internal audit function, if any, including the structure of the internal audit department, staffing and seniority of the official heading the department, reporting structure, coverage and frequency of internal audit.

Under **Section 177 of the Companies Act 2013** the internal auditor, if any, shall attend and participate at meetings of the Audit Committee of the company.

The provisions for constitution of the Audit Committee under Section 292A of the Companies Act 1956 has been replaced by Section 177 of the Companies Act 2013, which are as follows:

177. (1) The Board of Directors of every listed company and such other class or classes of companies, as may be prescribed, shall constitute an Audit Committee.

(2) The Audit Committee shall consist of a minimum of three directors with independent directors forming a majority:

(3) Provided that majority of members of Audit Committee including its Chairperson shall be persons with ability to read and understand, the financial statement.

(4) Every Audit Committee of a company existing immediately before the commencement of this Act shall, within one year of such commencement, be reconstituted in accordance with sub-section (2).

(5) Every Audit Committee shall act in accordance with the terms of reference specified in writing by the Board which shall, inter alia, include,—

- (i) the recommendation for appointment, remuneration and terms of appointment of auditors of the company;*
- (ii) review and monitor the auditor's independence and performance, and effectiveness of audit process;*
- (iii) examination of the financial statement and the auditors' report thereon;*
- (iv) approval or any subsequent modification of transactions of the company with related parties;*
- (v) scrutiny of inter-corporate loans and investments;*
- (vi) valuation of undertakings or assets of the company, wherever it is necessary;*
- (vii) evaluation of internal financial controls and risk management systems;*
- (viii) Monitoring the end use of funds raised through public offers and related matters.*

(6) The Audit Committee may call for the comments of the auditors about internal control

systems, the scope of audit, including the observations of the auditors and review of financial statement before their submission to the Board and may also discuss any related issues with the internal and statutory auditors and the management of the company.

(7) The Audit Committee shall have authority to investigate into any matter in relation to the items specified in sub-section (4) or referred to it by the Board and for this purpose shall have power to obtain professional advice from external sources and have full access to information contained in the records of the company.

(8) The auditors of a company and the key managerial personnel shall have a right to be heard in the meetings of the Audit Committee when it considers the auditor's report but shall not have the right to vote.

(9) The Board's report under sub-section (3) of section 134 shall disclose the composition of an Audit Committee and where the Board had not accepted any recommendation of the Audit Committee, the same shall be disclosed in such report alongwith the reasons therefor.

(10) Every listed company or such class or classes of companies, as may be prescribed, shall establish a vigil mechanism for directors and employees to report genuine concerns in such manner as may be prescribed.

(11) The vigil mechanism under sub-section (9) shall provide for adequate safeguards against victimisation of persons who use such mechanism and make provision for direct access to the chairperson of the Audit Committee in appropriate or exceptional cases:

Provided that the details of establishment of such mechanism shall be disclosed by the company on its website, if any, and in the Board's report

**Section 138(1) of the Companies Act provides** that such class or classes of companies as may be prescribed shall be required to appoint an internal auditor, who shall either be a chartered accountant or a cost accountant, or such other professional as may be decided by the Board to conduct internal audit of the functions and activities of the company.

The **class or classes of companies** have been defined under the **Companies (Accounts) Rules, 2014** issued under Section 138(1) as follows:

**Rule 13. Companies required to appoint internal auditor.-** (1) *The following class of companies shall be required to appoint an internal auditor or a firm of internal auditors, namely:-*

- a. every listed company;
- b. every unlisted public company having-
  - (i) paid up share capital of fifty crore rupees or more during the preceding financial year; or
  - (ii) turnover of two hundred crore rupees or more during the preceding financial year; or
  - (iii) outstanding loans or borrowings from banks or public financial institutions exceeding one hundred crore rupees or more at any point of time during the preceding financial year; or



(iv) *outstanding deposits of twenty five crore rupees or more at any point of time during the preceding financial year; and*

c. *every private company having-*

(i) *turnover of two hundred crore rupees or more during the preceding financial year; or*

(ii) *outstanding loans or borrowings from banks or public financial institutions exceeding one hundred crore rupees or more at any point of time during the preceding financial year:*

**Under SEBI Circular No. MRD/DMS/Cir-29/2008, October 21, 2008** in partial modification of SEBI circular No. MIRSD/ DPSIII/ Cir-26/ 08 dated August 22, 2008 on the above subject, the SEBI has mandated that stock brokers/trading members/clearing members shall carry out complete internal audit on a half yearly basis by chartered accountants, company secretaries or cost and management accountants who are in practice and who do not have any conflict of interest.

**Under Circular of SEBI No. SEBI/MIRSD/CRA/Cir-01/2010** dated January 06, 2010 Internal Audit for Credit Rating Agencies (CRAs) has been prescribed under Regulation 22 of the SEBI (Credit Rating Regulations), 1999, which shall be undertaken on a half yearly basis and shall be conducted by Chartered Accountants, Company Secretaries or Cost and Management Accountants who are in practice and who do not have any conflict of interest with the CRA.

**Under IRDA (Investment) (Fourth Amendment) Regulations, 2008**

- a. An Insurer having Assets under Management (AUM) not more than Rs.1000 crore shall conduct a Quarterly Internal Audit to cover both Transactions and related Systems.
- b. The Audit Report of the company shall clearly state the observation at transaction level and its impact, if any at System level. The Audit Report shall be based on Exception Reporting.



## Chapter 2: Documentation and Working Papers

The Internal Audit Function has to record and share details of all assurances verified, area covered, internal control system checks and process changes recommended. There needs to be hard evidence collected and stored prior to sharing conclusions formed on the evidence. This evidence, observations, status reviews and check points need to be documented to increase reliability and prove effectiveness of the internal audit.

The term 'Documentation' has many meanings but the most relevant is; Documentation is the process of collecting, verifying and storing knowledge, observations, facts and systems in a set of data which may be tangible such as paper, flow charts, SOPs, etc. and intangible such as electronic, audio, video, etc.

The entire internal audit team prepares working papers that record all the information obtained and analyzed that formed the basis for the various observations and recommendations in the internal audit report. These working papers are reviewed by the management and help to:

1. Earmark and support all internal audit communications
2. Facilitate the processes of planning, implementation and review of the internal audit
3. Document all findings and ascertain whether audit objectives were met
4. Aid external assessments of the internal audit process
5. Helps the management ascertain the quality of internal audit and the quantum of work undertaken
6. Ascertain compliance of the internal audit function with the International and domestic rules and regulations.

Thus, when recommending business process improvements, the internal audit team should document both the "As-Is Process" and the "To-Be Process". While many think about it as customary and do it for the same reasons, there are important reasons to the documentation process. Documentation helps the organisation gain long term primary and secondary benefits which have been listed below:

The following are the primary benefits that any organisation seeks to gain by explicitly documenting their processes:

### **a) No Operational Ambiguity**

The first reason for documenting any process is the fact that it reduces operational ambiguity. Any reoccurrence of confusion regarding who is supposed to do what or what are the best practices following which a task needs to be performed, one can look at the detailed documentation and the dispute can be resolved. These documents act as the store of collective organisational knowledge regarding the processes and can be accessed by anyone in times of need.

**b) Training Material**

The documentation also acts as training material to help new resources move up the learning curve faster. Instead of making resources join on the job and learn tacitly, the documentation can be used to give new resources classroom lessons about the tasks that need to be performed. The documentation acts as the training manual and covers the syllabus as well as provides notes to educate the resources. This can be supplemented with on the job hands on floor visits for better and faster creation of efficient resources.

**c) Marketing and Sales**

Documentation can also be used by the marketing and sales department to truly understand what the capabilities of the organisation are. This knowledge helps them to truly determine what they can promise the customer and what can be fulfilled. With the process knowledge, the marketing department will be able to make promises that the organisation can deliver. There will be no need for over and/or under commitment which helps improve customer satisfaction at a later stage.

Apart from the apparent primary benefits which directly aid in the day to day operations of the organisation, there are certain secondary benefits which help the organisation analyse and improve its process continuously. By documenting process changes, the management can understand the knowledge that was used in designing the best practices that are currently followed. This also helps the management decide whether the best practices followed are indeed relevant in the environment they are operating in and saves both additional time and cost of re-justifying the existing model.

Hence, with detailed documentation in place, process improvements can be tracked version to version. This means that the management will have the previous 3 to 4 processes and their performance along with the current process and performance. They can thus see them together and see what changes are producing what results. This will tell them what they are successful at and they can continue doing so.

The Internal Audit Documentation process begins with the Internal Audit Manual, which documents the policies and procedures for conducting audits and managing the internal audit function is important to:

- a) encourage a consistent approach to achieve a quality result
- b) assist new starters to understand the internal audit process
- c) demonstrate an objective and systematic approach to the conduct of internal audits
- d) provide a basis for review and to improve existing practices

The internal audit manual should be tailored to the needs of the internal audit function and would reflect the strategy and approach chosen. It would generally include policies and procedures for:

- a) planning individual audit assignments;
- b) evidencing compliance with professional standards and methodologies;
- c) internal audit fieldwork and supervision;
- d) reporting audit results and categorizing overall audit findings and audit recommendations;

- e) servicing the Audit Committee;
- f) assessing internal audit performance, including conducting client surveys;
- g) records management and security procedures and
- h) reviewing the manual.

The internal audit manual should provide local procedures consistent with applied standards for using diagrams, flowcharts and checklists that can help to generate a better understanding of the processes involved, while including references to templates and any planning and auditing tools assists in promoting the support available to audit teams. The manual may be an electronic document (for example, on an intranet site) that also includes links to electronic copies of other key documents to facilitate updating and access by internal audit staff as it is an important aid in assisting internal audit to produce high-quality audit reports that meet the expectations of management.

The Internal Audit Protocol is a document intended for general reference by both management and internal audit and therefore ought to be made widely available. The format and content of the internal audit protocol is a matter for the Head of Internal Audit in consultation with entity management. The protocol should outline the respective roles and responsibilities of internal audit and management in the course of an audit and the opportunities for consultation during the audit process. The purpose, responsibilities and authority of the internal auditor are set out in the Internal Audit manual which was approved by the management. Internal auditor prepares an internal audit strategy and a work plan in consultation with the management, and the Audit Committee. The internal audit strategy provides the context for internal audit activity. The various stages to be included in Internal Audit Protocol are:

1. Planning;
2. The examination and evaluation of the adequacy and effectiveness of the system of internal control;
3. The audit procedures performed, the information obtained, and the conclusions reached;
4. Review;
5. Communication and
6. Follow-up.

There are several types of internal audit documents. The internal auditor commonly use flowcharts supplemented by narrative descriptions as a starting point to understand the workings of the organization. Once the operational working of the organization is clear and well defined, the internal audit team often uses risk and control matrices for more specific analysis of areas to be covered and targeted. In addition, internal control questionnaires (ICQs), policy and procedure manuals, and other such official papers constitute the commonly used forms of internal audit documentation.

**Flowcharts** help the internal audit team to describe the flow of activity through a process or function along with the relevant documentation. The main output is a process map — a graphical representation of events performed on a routine basis. These process maps can help the internal audit team better understand organizational hierarchies; communication channels; identify risks, controls, paucities, and disorganizations; and develop recommendations for improvements, smooth flow of information and utilization of resources.

**Narrative Descriptions** are generally useful supplements to flowcharts and are made by documentation in detail of the existing practices. Thus, they help to minimize potential misinterpretations. However, narrative descriptions on an independent basis cannot serve as an effective tool for process description as they tend to be lengthy and difficult to review.

**ICQs** or internal control questionnaires generally list answers to questions related to the identification and evaluation of internal controls systems and their effectiveness. An effective ICQ document comprises of a carefully structured and logically sequenced series of questions aimed to document processes and to control gaps, strengths, and weaknesses within the organization's control system. All questionnaire results provide a permanent record of the controls at both an entity and process level and are used for future reviews.

**Risk and Control Matrices** are designed to document risks and controls while facilitating evaluation of the design and success of the control mechanism. These matrices help to obtain initial understanding of the requirements for controls in any process. The internal audit team can locate gaps between the current set of controls and the desirable or targeted level of specific controls of the process.

**Policy and Procedure Manuals** generally establish a systematic framework or guidance note for specific functions, processes and activities of any organisation. These operational level manuals are typically incorporated to manage operation risks while keeping a track of relevant internal controls and risks. These manuals also help to communicate how a particular process is to be managed and ensures alignment with performance improvement objectives of the organization.

**The Organizational Chart** is an important graphic diagram that shows the power relationships inside a company. It states who is the manager and his subordinates in a hierarchical and vertical structure. The use of this chart is very useful for all employees because they can see in a very simple graphic of what is their current position inside the company and their ranks according to their position. An organisational chart is also used for showing the relationships between directors in various departments. For large companies like multinationals, these charts are very complicated and also large, so they are divided into smaller ones for each department within the organisation.

Organizational charts can be divided into three categories: hierarchical charts, matrix charts and flat or horizontal charts. Organisational charts don't show the inter-human relationships that develop inside a company. They only show the formal relationships which help the internal audit team to identify where the responsibility of function lies and who has the appropriate authority to take actionable decisions. This understanding is also very crucial to the efficiency of the internal audit.

**System Reports** are general reports obtained through the existing set of records. These may be maintained manually or electronically through an ERP. System reports are used for and form the basis of all Management Information Systems. These reports are shared with the functional managers and directors from time to time to enable them to be updated with the on goings of the business. There are multiple system reports that the internal auditor has to understand and comment on.

Other Internal Audit Working papers may include, but are not restricted to:

- Planning documents and audit programs;



*The Institute of Cost Accountants of India*

---

- Notes and memoranda resulting from interviews;
- Copies of important contracts and agreements;
- Information about operating and financial policies;
- Results of control evaluations;
- Letters of confirmation and representation;
- Analysis and tests of transactions, processes, and account balances.
- Results of analytical procedures;
- The audit's final communications and management's responses and
- Audit correspondence if it documents audit conclusions reached.



## **Chapter 3: Planning an Internal Audit and Audit Programme**

Planning an internal audit selection of audit coverage, priority of the internal audit and estimating resources of time and costs for the entire internal audit function. The Internal Auditor needs to align its focus and activities to the entity's risks and to achieve this alignment between the entity's risks and internal audit coverage, it is necessary for internal audit planning to occur in the context of entity-wide assurance mapping, which can be commissioned by the management. Thus, internal audit planning generally involves:

- The internal audit strategy that relates the role of internal audit to the requirements of the entity by outlining the broad direction of internal audit over the medium term, in the context of all the entity's assurance activities and
- An Internal Audit work plan, generally prepared on an annual basis, supported by a schedule of potential audits and an indication of previous audit coverage.

Together, these documents serve the purpose of setting out in strategic and operational terms the broad roles and responsibilities that are included in the internal audit charter and identifying key issues relating to internal audit capability, such as required skills.

In addition to the internal audit strategy, a detailed internal audit work plan should be prepared specifying the proposed internal audit coverage over the planning cycle. The length of this planning cycle will depend on the nature of the organisation and its current operating environment. Organisations would be benefited by adopting a rolling work plan rather than a fixed term plan to enable flexibility to the Internal Audit function.

**Internal audit team** should share information and coordinate with other assurance activities to ensure proper coverage and minimize duplication of effort. The internal audit work plan facilitates both tasks and helps internal audit to ensure that it supports the management to the maximum extent possible. Generally, the head of the Internal Audit team must provide advice to the management on the internal audit plan and would review the plans to ensure that they are aligned to the entity's risks before recommending approval of the plan by the Chief Executive.

In **developing the internal audit work plan**, it is appropriate to consider that once the broad strategic direction for audit coverage has been determined, a decision needs to be made about the number and scope of specific audit topics to be included in an internal audit work plan. To assist in prioritizing audit topics it is helpful to develop a set of criteria that can be used to assess and rank potential topics. Criteria can vary from industry to industry but would normally include:

- 1) The importance of the program or activity to the entity's objectives;
- 2) The strategic and operational risks identified in the entity's risk management plan or business unit plans or, in the absence of a mature risk management framework, as identified by internal audit;
- 3) The areas covered to support external reporting obligations of the entity;

- 4) The areas covered by other assurance and review functions;
- 5) The potential or expected benefits of an audit and any specific requests from the management;
- 6) The significance of the findings from any previous internal or external audit or review, particularly relevant reports and recommendations from Parliamentary Committees and
- 7) The length of time since any previous internal or external audit.

Some entities see benefit in allocating numerical scores to each of the criteria and aggregating the scores to arrive at an overall audit ranking. Although audit scores can help to rank audit topics, it should be recognized that such a process still involves judgment of the allocation of individual scores. The principles of prioritization should be documented in the internal audit strategy.

The **Coverage of the internal audit work plan** need be comprehensive and definitive to ensure non value added activities are ignored. Such an internal audit work plan would generally include audits of major information technology systems, audits of major projects and all or a majority of the following activities:

- a) Audits of areas where the risk is judged to be high but the controls are considered to be effective in managing the risk. These audits are to provide assurance that the controls are in fact operating as intended;
- b) Advice on new systems, processes and initiatives-these may be referred to as 'systems under development' audits;
- c) Audits of major information technology systems focusing, in particular, on security and access matters, and audits of major projects;
- d) A number of annual (or more frequent) audits to review key areas of financial, operational, human resource or governance matters across different business units and geographical locations or a series of audits that are conducted each year.;
- e) Audits that review particular topics across the whole entity-such as procurement practices, recordkeeping, ethical conduct and compliance with APS and entity values-or that are aimed at addressing systemic risks;
- f) Follow-up audits of areas audited previously where shortcomings have been identified and
- g) A number of reserve audit topics that could be substituted if planned audits do not proceed.

The program may also include an allowance to undertake ad hoc or special request audits, particularly from the management and the Audit Committee. These reviews may prove to be either advisory or quality assurance reviews and should be budgeted as an addition to the routine assurance program.

Developing the internal audit work plan against a background of prior and projected reviews would enable the management to assess whether the full range of risks, especially compliance risks, are covered over an appropriate period. Selection of audit topics should also be confirmed only after careful consideration of the objectives and scope of individual audits. These factors can have a

significant effect on the cost of the internal audit work plan or the number of audits included in the plan. In particular, consideration should be given to whether it is better to have fewer, more in-depth audits, more audits with a narrower focus, or a combination of both.

**Consultation with the external auditor** to gain an understanding of their perspective on the business risks facing the entity is important. This information is necessary to help ensure that potential duplication and gaps in overall audit coverage are known, and to identify opportunities for the external auditor to rely on the work of internal audit. Any significant areas that are not covered or are duplicated should be highlighted to the management.

The **Size and nature** of the Internal Audit Work plan must factor the following:

**a) The risk tolerance and the risk profile of the entity:**

An entity with a low risk tolerance and a substantial number of risks and, by extension, controls designed to assist in managing the risks, could be expected to have a larger internal audit program than an entity with a higher risk tolerance and a smaller risk profile.

**b) The size and complexity of the entity's business:**

With a larger the number of separate business activities and programs, the internal auditing that could be expected to be required increases.

**c) The physical characteristics of the entity:**

The larger the employees or geographic locations number of, or the greater the level of distributed control, the larger the internal audit program expected to be.

**d) The nature of the information systems:**

The more complex the Internal Control systems environment, the more internal audit activity is likely to be required.

**e) The stability of the entity:**

Internal audit might be required to do more in times of significant change.

**f) The number of internal assurance functions:**

An entity with well-developed quality assurance, compliance or other internal assurance activities is likely to require less internal audit activity.

**g) Level of Resourcing:**

The size of the internal audit work plan will also be influenced by the level of resourcing of the internal audit function as discussed below.

In preparing the plan, sufficient time and resources should also be allocated to:

- a) manage the internal audit function;
- b) monitor and report to the Audit Committee on progress in implementing agreed recommendations in internal and external audit reports and other review bodies;
- c) analyse the risk, control and governance issues arising from internal audit work, and/or the work of other assurance providers, with a view to providing periodic reports to the Audit

- Committee on systemic issues and trends;
- d) support the Audit Committee in discharging its obligations;
- e) provide secretarial support to the management (if specifically defined);
- f) develop and periodically review the internal audit strategy and the internal audit work plan;
- g) provide appropriate professional development to internal audit staff and
- h) Liaise with the external auditor and other relevant external bodies.

Where some or all services are provided by an external provider, sufficient time should also be allocated to enable the contract, or contracts, to be properly managed. In Addition, Internal auditor may be tasked to provide direct assistance to external review functions by performing audit or review procedures under the direction and supervision of the external reviewer. Such activity should be regarded as non-audit activity by the entity.

Organizations should focus on assigning accountability and capturing resource utilization for every audit that is conducted. Such in depth tracking of expenditure related to audits aid in estimating the costs of individual reviews during internal audit planning. It must be noted though that there must be parity between the level of administrative and / or financial costs to undertake the audit and the benefits to the operational system.

Any internal audit work plan should be so detailed as to satisfy the Audit Committee and the management that estimated coverage area of the internal audit is adequate to meet the set objectives of the Internal Audit Charter. The internal audit work plan would generally include:

1. Audit title
2. Functional and Operational Area to be covered
3. Director and manager responsible
4. Type and scope of internal audit
5. The benefit expected by the audit procedure
6. Resources allocation for the purpose of the audit
7. Proposed duration and timelines for completion

The Internal audit work plan is presented to the Audit Committee and the management through mind-maps, executive summary, charts or a mix of such abbreviations of the work plan.

The Internal Audit work plan should be periodically reviewed and any substantive amendments should be approved by the management. Internal audit plans should be prepared and submitted in time to enable them to be considered and approved prior to the commencement of the period to which they apply. Aligning the timing of the internal audit planning process with that of the entity's business planning processes can assist in internal audit planning being aligned with the objectives and priorities of the entity. There is also value in considering the external audit planning cycle so that work being conducted with a view to external audit reliance can be appropriately scoped.

## Chapter 4: Audit Sampling

Internal Audit function does not include verification of all records, entries or transactions. The scope of an internal audit is much broader in comparison to that of statutory audit. The depth of coverage of internal audit, being a management function, would also be much wider. An internal audit function normally is spread beyond checking of financial transactions and is expected to cover comments on internal control systems, risk management, propriety aspect of transactions.

An estimated a team of 2 auditors for Internal Audit can only verify around 300 to 500 documents per working day of 8 hours, depending on, the areas to be concentrated and immediate availability of all documents required. Thus, it is unlikely that assurance of all transactions can be targeted and completed within the budgetary constraints of time and costs. In addition, the internal audit function must not duplicate the assurance activities undertaking by the external auditors. Thus, application of the assurance or verification function to less than 100% of the transactions or population is vital to meeting the deadlines and constraints of duration and costs. This process of selecting and verifying less than the entire population is called as “Sampling”. The extent and methodology of sampling must to be very clearly mentioned in Internal Audit work plan.

Sampling involves some selection of certain sections of the data or population based on its quantitative or qualitative factors. The Internal Auditor must be wary of the risks associated with sampling. In case the sample size selected is not representative of the entire group, the internal audit team’s conclusions based on the sample may be different from the conclusion they would reach if they examined every item in the population. The risk associated with sampling tends to increase when:

- The Estimation of sampling risk is done by using professional judgment rather than statistical techniques.
- There is no means of quantifying sampling risk provided.
- Sample may be larger than necessary or auditors may unknowingly accept a higher than acceptable degree of sampling risk

Thus, the internal audit team must undertake statistically backed sample selection technique to ensure designing efficient samples, measuring sufficient evidence and evaluating results with objectivity.

**Allowable Risk** is calculated as:

$$\boxed{AR = IR \times CR \times DR}$$

**Where,**

**AR** = the allowable audit risk that a material misstatement might remain undetected for the account balance and related assertions.

**IR** = Inherent risk, the risk of a material misstatement in an assertion, assuming there were no related controls.

**CR** = Control risk, the risk that a material misstatement that could occur in an assertion will not be

prevented or detected on a timely basis by internal control.

**DR** = Detection risk, the risk that the auditors' procedures will fail to detect a material misstatement if it exists.

The different methodologies available for statistically based selection of sample size are as follows:

**1) Random Sampling**

In a simple random sample every transaction or data point within the audit population has an equal chance of selection. An easy way of selecting samples would be to use a random number table or random number generator. The Random Number Table is much more effective than manually selecting the random samples as the data in this table portrays the desired properties no matter how chosen from the table: by row, column, diagonal or irregularly. The Random Number Generator undertakes the same function of generating a sequence of numbers or symbols that lack any pattern. Due to random selection there is a reduction in the possibility of any systematic bias that would make the selected group different in character from the overall population.

**2) Consecutive Sampling**

Consecutive sampling is often referred to as convenience sampling. It involves choosing the next, or last however many cases, e.g. the next OR the last 50 transactions, or alternatively, all transactions seen over the course of the previous OR next month. Consecutive sampling is an example of non-probability sampling and is often the most practical way of selecting cases for a 'snapshot' sample of the population. However, it is important to remember that the sample produced may differ in character from the overall population and therefore the internal audit results may not be representative of the overall nature of all transaction in the database.

**3) Quasi Random Sampling**

Quasi random sampling is also referred to as systematic sampling. If the overall audit population is 1000, the representative sample would be 278. Since  $4 \times 278$  is approximately 1000 the internal audit team would select every fourth transaction from the overall database. To ensure that every transaction in your audit population has an equal chance of being selected, the starting point in this method needs to be selected randomly. In this instance the starting number must be between 1 and 4. The start point must be random because if you always started with the first patient, the second patient would never have a chance of being selected. This is an important consideration from a statistical point of view.

**4) Haphazard Sampling**

The Haphazard Sampling method means selecting items on an arbitrary basis, but without any conscious bias. This method, though random in nature, may lead to an increase in the sampling risk as there is no statistical methodology for selecting the starting point or the number of samples.

**5) Block Sampling**

Block sample consists of all items in a selected time period, numerical sequence or alphabetical sequence. The basis for selecting the sequence or group would determine the level of sampling risk of the data. The selection of the sequence or group should be without any conscious bias and the

entire population within the sequence or group must be verified.

## 6) Stratification Sampling

Stratification is the technique of dividing the entire population into relatively homogeneous subgroups. Stratified sampling ensures that the proportion of different groupings present in the population is reflected in the sample. The basis for determining the subgroup should be consulted with the management and specifically mentioned in Internal Audit work plan as well as the final report.

Stratum	Composition of Stratum	Number of Accounts (method used for Selection)
1	Accounts of over INR 1 Lakh	All Accounts
2	Accounts from INR 50,000 to 1 Lakh	50 accounts (Random Generated Number)
3	Accounts Below INR 50,000	20 accounts (Random Generated Number)

The **sample size** selected affects the level of sampling risk of the sample. Every increase in sample size reduces the sampling risk and allowance for sampling risk. The sample size is generally directly proportionate to the characteristics of the population and an increase in the population leads to an increase in the sample size.

In addition, after careful consideration of the methodology of sampling and sample size, the sample selection plan should be based on:

- The relevance of the sample to the audit purpose
- Level of acceptable risk in the sample
- General features of the sample population so as to accurately represent the population
- All un-auditable items or samples must be taken as deviations
- Deviations should be coupled together and their nature or occurrences must be analyzed

In the rare occurrence, when undertaking audit sampling to test control systems or processes, the following steps need to be followed:

- 1) Determine the objective and nature of control system or process
- 2) Determine the risk acceptability
- 3) Define the sample population
- 4) Ascertain the risk of a high tolerable deviation rate
- 5) Estimating the sample population deviation rate
- 6) Determine the sample size based on acceptable deviation
- 7) Selection of the sample
- 8) Validation of the sample selected
- 9) Evaluation and analysis of the samples
- 10) Documentation of the sampling procedure, results and recommendations



## **Chapter 5: Audit Evidence**

The final output expected from the internal audit is to provide conclusions, recommendations, share findings and comment on the various internal control systems in the final report. All of these should be based on documented evidence which has been appropriately sourced and collected during the internal audit. **Audit evidence** is any information used by the auditor to determine whether the information being audited is stated in accordance with established criteria and to arrive at the conclusions on which the audit opinion is based. The determinants of persuasiveness of evidence are:

- 1) Competence – the range of skill, knowledge, or ability
- 2) Effectiveness – adequate internal controls systems and clear communication channels lead to better information
- 3) External Auditor observations – external auditor’s observations are stronger than staff or management comments
- 4) Expert opinions – an expert’s opinions is a practical and authorized basis
- 5) Independence – external evidence is considered as a better form of evidence than internal documents or proofs
- 6) Objectivity – objective evidence is stronger than subjective evidence
- 7) Relevance –pertaining to or in support of the audit objective
- 8) Sufficiency – an adequate amount, quality or quantity

The internal audit evidence collected would be dependent on the following:

- Audit procedures to use – specific procedures should be spelled out for instruction during the audit.
- Sample size – how many items should be tested for each audit procedure.
- Items to select – determine which items in the population should be selected.
- Timing – timing can vary from beginning of the accounting period to closure of it.

Internal Audit Evidence includes any data, information, process flows, vouchers, bills, memos, contracts or transactions. The commonly used procedures for sourcing of internal audit evidence are as follows:

### **a) Physical examination**

Physical examination means inspection or count of tangible assets. It is different from examining documentation that the asset has inherent value.

### **b) Confirmations**

Confirmations mean the receipt of a written or oral response from an independent third party. The Internal Audit team requires a client request for the third party respond directly to the team. Confirmations are usually required when statements or transactions relate to third parties; key examples of third parties include suppliers, banks, attorneys, inventory agents and customers.

**c) Documentation**

Documentation includes both internal and external documents. Internal documents are prepared and used within organisation and do not go outside the company. Whereas external documents have been in hands of a third party to the transaction and are considered more reliable. Documents in general are less reliable than confirmations.

Before recording documents as evidence, proper examination of documents that support a recorded transaction or amount is required; and the direction of testing must be from the item recorded to the supporting document.

**d) Analytical Procedures**

The Internal audit function studies the different relationships among data. Analytical procedures are generally required during the planning and completion phases on all audits. They are necessitated by the existence of unusual fluctuations which occur when significant difference are not expected but do exist or when significant differences are expected but do not exist.

**e) Inquiries of the Client**

The Internal Auditor usually obtains information from the client in response to questions. Although much evidence is obtained through inquiry, it cannot be regarded as conclusive and may be biased in the organisation's favour. To accomplish an unbiased opinion or review, the internal audit team may have to inquire independently with the customers of the organisation.

**f) Re-performance**

Re-performance involves rechecking a sample of the computations and transfers of information. Rechecking of computations consists of testing mathematical accuracy. Rechecking of transfers of information involves ensuring if information is recorded consistently in the accounting records.

**g) Observation**

The Internal audit team should witness the physical activities of the organisation. Observations differ from physical examinations because physical examinations count the assets, while observations focus on organisation's activities and process both.

In the extreme circumstances that the evidence obtained from one source is either in direct conflict or inconsistent with that obtained from another source, the internal audit team must undertake further investigation or additional procedures for resolving the conflict. The Internal Auditor is required to collect appropriate evidence out of the audit process to substantiate their checking and findings.



## 6: Analytical Procedures

**Substantive tests** (also known as substantive procedures) are procedures designed to test for monetary errors or irregularities directly affecting the correctness of financial statements. The Internal audit performs substantive tests to detect material misstatement at the assertion level. Substantive tests of transactions emphasize the verification of transactions recorded in the journals and then posted in the general ledger. **Analytical procedures** emphasize the overall reasonableness of transactions and the general ledger balances. Thus, analytical procedures serve as both audit tests and audit procedure.

Analytical procedures refers to the analysis of significant ratios and trends including the resulting investigation of fluctuations and relationships that are inconsistent with other relevant information or which deviate from predicted amounts. The analysis of these deviations may be achieved through the consideration of comparisons of the entity's financial information with:

- Comparable information for prior periods
- The entity's anticipated results
- Similar industry information.

When performing analytical procedures, the internal audit team must examine both financial data and non-financial data relating to the transaction. Before starting their analytical procedures, the internal auditor estimate the expected value (of the ratio/ trend/ account balance/ transaction, etc.) before calculating the actual value so as to avoid the actual value being biased for the auditor's estimate of the expected value. The expected results are estimated based on preliminary discussions with the management.

After having performed their analytical procedures, the internal audit function then compares the actual results with those expected and looks for reasons for any significant variations. Unexplained variations may indicate a misstatement in the figures in that area, which would lead the auditors to plan their audit work to devote more time and resources to those areas. When the application of analytical procedures does not identify any unusual or unexpected differences, the results provide evidence in support of management's assertions.

Analytical procedures may be performed at any or all three stages in the audit process: the planning phase, the testing phase and the completion phase.

During the **planning phase**, analytical procedures can be used as risk assessment procedures. They help auditors identify significant matters requiring special consideration later in the audit engagement to understand the client's industry and business, to assess going concern, to indicate possible misstatements and to reduce detailed tests.

During the **testing phase**, analytical procedures can be used as substantive procedures in collecting appropriate audit evidence. They can be performed together with other substantive procedures and

they help to indicate possible misstatements and to reduce detailed tests.

During the **completion phase**, analytical procedures can be used as part of an overall review of the financial statements for the auditors to reach conclusions about the fair presentation of the financial statements. The analytical procedures help the auditors to take a final review of the audited financial statements objectively and help to assess going concern and to indicate possible misstatements.

Analytical procedures too have certain inherent limitations. They only provide conclusions on reasonableness of data rather than precision and cannot easily be linked to specific assertions (i.e. the nature or cause of a difference); therefore analytical procedures are less persuasive than tests of details of balances. The substantive evidence gathered using analytical procedures is thus generally used to corroborate other substantive evidence gathered, rather than being used as a sole source of evidence.

On the other hand, Analytical procedures cost the least because of the relative ease of making calculations and comparisons. It is quite often easier for auditors to obtain considerable information about potential misstatements by simply comparing two or three numbers. Tests of controls are low cost because internal audit team simply makes inquiries and observations and examines the evidence of the performance of controls, such as initials on documents. These tests can be done on a large number of items within a short period of time.

To ensure the expected effectiveness and efficiency of an analytical procedure, identification of potential for misstatements need to be assessed. These depend on:

1. The nature of the assertion
2. The plausibility and predictability of relationship
3. The availability and reliability of the data used to develop the expectation
4. The precision of the expectation.

The identification of the relationships and types of data used, as well as conclusions reached when recorded amounts are compared with expectations and require judgment by the auditors, should be documented using the expectation and factors considered in its development, the results of the comparison of the expectation with the recorded amounts or ratios developed from the recorded amounts and finally, any additional auditing procedures performed in response to significant unexpected differences arising from the analytical procedures and the results of such additional procedures.

In practice not all the actual results obtained from analytical procedures will be close to the expected results estimated by internal audit team. As mentioned above, the Internal auditor must then have to investigate and obtain adequate explanations and appropriate corroborative audit evidence. The internal auditor seldom jumps to the conclusion that fraud exists, but has to at least reveal the suitability and reliability of data adopted in the estimation. If they are confident with their data, they normally start by making inquiries of management. This should be followed by a corroboration of management's response. However, if management is unable to provide an explanation or if the explanation is not considered adequate, the internal audit team should consider the need to apply



other audit procedures based on the results of their inquiries.

To conclude, Analytical procedure is a powerful tool that has the potential to increase the efficiency of audits since it is a relatively low-cost procedure that seems to have considerable power in identifying errors or irregularities and in guiding audits. Although the calculation of ratios and comparison of trends are relatively easy tasks, the analysis of ratios and trends requires a good understanding of the organisation's business and industry. Hence analytical procedures are preferably handled by a more experienced internal auditor within the audit team, who has exposure to other companies of the industry. If, in case, a firm of accountants has undertaken the internal audit assignment, either it should have team consisting of experience Cost Accountants to conduct internal audit, cost records and related systems or alternatively, engage a firm of practicing Cost Accountants with a wide exposure to other companies within the industry.



## **Chapter 7: Accounting System and Internal Control**

An Accounting System is often defined as an organized set of manual and computerized accounting methods, procedures, and controls established to gather, record, classify, analyse, summarize, interpret, and present accurate and timely financial data for management decisions. An accounting system performs the crucial task of accumulating data and providing the management with decision making information. Over the years the process of an accounting system has evolved from being a manual and paper based format to an electronic form. In an electronic financial accounting system, the steps in the accounting cycle are independent in nature, self-reconciliatory and adhering to set rules and controls.

For many years now, keeping an accurate track of all the income and expenditure related to the workings of the organization has been considered a crucial function to satisfy the desire of managements and investors to know the profitability and liability of taxes or otherwise. Although earlier organizations relied on pen and paper and time consuming methods to record their accounting activities, over the years through continuous evolution and advancements, computer based software has helped people gain access to robust and easy to implement accounting systems. The evolution of accounting systems from the first DOS-based systems such as 'PcPlus' and 'Lotus123' to today's cloud based or internet based systems are now available.

An Integrated Accounting System is an accounting system which involves joint accounting of cost accounts and financial accounts. This system helps set aside the majority of programs, spreadsheets, and other manual systems and replacing them with one, efficient program that can effectively accomplish nearly all of your accounting needs and goals. An integrated accounting system can perform the wide variety of functions and helps to:

- a) Estimate, report on, and monitor all job costs at summary or detailed levels.
- b) Track employee time, and then convert it into payroll that is posted to job costs.
- c) Easily produce customer statements (or create marketing letters)
- d) Reduce data entry time such as converting the estimates into sales orders and/or invoices, and purchase orders into bills.
- e) Handle inventory purchases, assemblies, and sales

Instead of simultaneously performing all of these different tasks using multiple data collection and analysis points, an integrated accounting system would help incorporate these different activities and correlate their effect on each other. Thus, an integrated accounting system also helps to accurately retain the information needed to access regarding the various activities and components of the business. An integrated accounting system is also cost effective as maintaining several non-integrated systems not only requires duplication of effort, but it's time-consuming and typically yields results that are not useful or accurate. Perhaps the greatest benefit of an integrated system is that it would make reconciliations redundant.

**Internal control**, on the other hand, is the process designed to ensure reliable financial reporting, effective and efficient operations, and compliance with applicable laws and regulations. Safeguarding assets against theft and unauthorized use, acquisition, or disposal is also part of internal control.

The management style and expectations, particularly their control policies, determine the **control environment**. An effective control environment helps ensure that established policies and procedures are followed. The control environment includes independent oversight provided by a board of directors and, in publicly held companies, by an audit committee; management's integrity, ethical values, and philosophy; a defined organisational structure with competent and trustworthy employees; and the assignment of authority and responsibility.

**Control activities** are the specific policies and procedures management uses to achieve its objectives. The most important control activities involve the following:

- a) **Adequacy of documents:** The audit documents must provide adequate and relevant evidence that financial statements are accurate. Controls designed to ensure adequacy of accounting system include the creation of invoices, payment receipts and other documents that are easily available, verifiable by external records and consistently tracked.
- b) **Appropriate authorization** of transactions and activities help ensure compliance of all organizational activities with the established guidelines while keeping a track of deviations through official communications and approvals.
- c) **Independent check** of operational performance of all functions, processes and activities that the organization is involved in helps to ensure the reliability of accounting information along with the efficiency of operations.
- d) **Physical verification of** assets and records helps to protect and ascertain the organization's assets. Physical Verification on a timely basis ensures a complete and accurate Fixed Assets Register.
- e) **Segregation of duties** necessitates that different individuals be assigned responsibility for different elements of related activities of a process to ensure multiple levels of system based checks and controls.

In order to identify and establish effective controls, management must continually assess the risk, monitor control implementation, and modify controls as needed. Top managers of publicly held companies must sign a statement of responsibility for internal controls and include this statement in their annual report to stockholders.

**Internal control of accounting systems** involves a series of procedures designed to promote and protect sound management practices, both general and financial. Following internal accounting control procedures will significantly increase the likelihood that:

- 1) financial information is reliable, so that managers and the board can depend on accurate information to make programmatic and other decisions
- 2) assets and records of the organisation are not stolen, misused, or accidentally destroyed

- 3) the organisation's policies are followed
- 4) Government regulations are met.

The preliminary step in developing an effective internal accounting control system is to identify those areas where abuses or errors are likely to occur. The management can also provide the internal audit function with a checklist of the areas and the questions to consider when planning this system. The following areas and objectives are generally targeted in developing an effective internal accounting control system:

- 1) Cash and cash equivalents
- 2) Cash disbursements
- 3) Cheque issuance
- 4) Grants, gifts, and bequests
- 5) Current Assets and Current Liabilities
- 6) Inventories
- 7) Trade Receivable and Trade payable
- 8) Non Current Assets and Non Current Liabilities
- 9) Secured and Non Secured Loan
- 10) Deposits
- 11) Transfers
- 12) The annual budget and periodic comparisons of financial statements
- 13) Personnel policies, Payroll

The management is commonly responsible for overseeing the day-to-day implementation of these policies and procedures. However, due to the number of detailed requirements involved, there should be specific responsibilities delegated in the organisation with the responsibility of understanding and monitoring any specific regulations and compliance factors. A general list of regulators and policies to be complied with are given in chapter 14.

The internal auditor's management letter is an important indicator of the adequacy of internal accounting control structure, and the degree to which it is maintained. The management letter, which accompanies the audit, cites significant weaknesses in the system or its execution. By reviewing the management letter with the management, asking for responses to each internal control lapse or recommendation, and comparing management letters from year to year, a useful mechanism for monitoring is created for financial safeguards and adherence to financial policies. The need to periodically review the internal accounting control system which has been established and modify it to include new circumstances and regulations is a continuous and important activity of every Internal Audit.



## Chapter 8: Control and Risk Assessment

Risk management is the management function used for developing, maintaining and implementing the Risk Management Framework, strategy and policy. Risk management systems help in enhancing the organisation's ability to manage uncertainty by protecting assets whilst ensuring compliance. Many organisations in India and around the world continue to be ignorant of the need and importance of a robust risk management system. The internal auditor should identify the need for a change in behavior and mindset in relation to risk management as and when:

- Every function or process does not have one or more well defined risk factors that act as indicators to risk assessments
- Risk awareness among staff and management is low
- The organization begins to focus on financial control of expenses rather than a broad level internal control through guidelines
- The top level management start believing that risk management is not their concern and agenda in meetings
- Internal control system review is viewed as a compliance report rather than a daily activity
- There is a lack of clearly defined business objectives in the short term

The process of risk management generally involves:

- 1) A clear understanding of the organization's long and short term objectives
- 2) Identification of the risks associated with non-performance or deviation from set objectives
- 3) Assessment of the probability and potential impact of particular risks factors that are crucial to achieving operational performance
- 4) Development of action plans and delivery programs to address the identified risks
- 5) Monitoring and evaluating the risks on a continuous basis

Every area of an organization whether it is strategy, operations, accounts, human resources and environment. Examples of such risks are loss of key staff, reductions in financial and other resources, disruptions to the flow of information and communications, fires or other physical disasters, leading to interruptions of business and / or loss of records. Generally, risk should also include issues related to fraud, waste, abuse and mismanagement.

Some of the **types of risks\*\*** that may need to be considered are given below, however, this list should not be regarded as exhaustive and it is not industry specific. Actual risks faced by a company are likely to include more industry-specific types of risks and to relate to the particular circumstances of the company.

### **A) Business Risks**

- Wrong business strategy
- Competitive pressure on price / market share
- General / regional economic problems
- Industry sector in decline
- Political risks
- Adverse government policy
- No attention to information technology (IT) aspects of strategy and implementation
- Obsolescence of technology
- Substitute products
- Takeover target
- Inability to obtain further capital
- Bad acquisition
- Too slow to innovate and reengineering
- Too slow to respond to demands from market and customers

### **B) Financial Risks**

- Market risk
- Credit risk
- Interest risk
- Currency risk
- Treasury risk
- Liquidity risk
- Overtrading
- High cost of capital
- Misuse of financial resources
- Going concern problems
- Occurrence of types of fraud to which the business is susceptible
- Misstatement risk related to published financial information
- Breakdown of accounting system

- Unreliable accounting records
- Unrecorded liabilities
- Penetration and attack of IT systems by hackers
- Decisions based on incomplete or faulty information
- Too much data and not enough analysis
- Unfulfilled promises/pledges to investors

### **C) Compliance Risks**

- Breach of Listing Rules
- Breach of financial regulations
- Breach of Companies Ordinance requirements
- Breach of competition regulations
- Breach of other regulations and laws
- Litigation risk
- Tax problems
- Health and safety risks
- Environmental problems

### **D) Operations and Other Risks**

- Inefficient / ineffective management process
- Business processes not aligned to customer / market demand and strategic goals
- Loss of entrepreneurial spirit
- Missed or ignored business opportunities
- Other business probity issues
- Other issues giving rise to reputational problems
- Poor brand management
- Failure of major change initiative
- Inability to implement change
- Stock-out of raw materials
- Skills shortage
- Physical disasters (e.g., fire and explosion)

- Computer viruses or other system malfunctions
- Failure to create and exploit intangible assets
- Loss of intangible assets
- Loss of physical assets
- Loss of key people
- Loss of key contracts
- Lack of orders
- Lack of business continuity
- Succession problems
- Inability to reduce cost base
- Over-reliance on key suppliers or customers
- Onerous contract obligations imposed by major customers
- Failure of new products or services
- Failure to satisfy customers
- Poor service levels
- Quality problems
- Product liability
- Failure of major projects
- Failure of big technology related projects
- Failure of outsource providers to deliver
- Lack of employee motivation or efficiency
- Industrial action
- Problems arising from exploiting employees in developing countries
- Inefficient / ineffective processing of documents
- Breach of confidentiality

**\*\*Adapted from *Implementing Turnbull – A Boardroom Briefing*, ICAEW**

Risk management is essential for reducing the probability that corporate objectives will be jeopardized by unforeseen events. The board must determine the type and extent of risks that are acceptable to the company, and strive to maintain risk within these levels. Internal control is one of the principal means by which risk is managed.

In the business world, a company's objectives and the environment in which it operates are continually evolving and, as a result, the risks that it faces also change. A sound system of internal control depends on a thorough and regular evaluation of the nature and extent of the risks to which the company is exposed. The systems and processes of control need to be sufficiently flexible to be able to change and adapt as the environment and the company's organisation, objectives and activities develop over time. The purpose of internal control is to help manage and control risk appropriately, rather than to eliminate it.

**The basic fundamentals** of a Good Risk management and Internal Control system including but are not limited to:

- 1) Risk Awareness
- 2) Integrated consultation and business decision making process
- 3) Continuous emphasis on internal control and strategy
- 4) Focus on Business Objectives
- 5) Crash Gates and Early Warning mechanisms to enable quick responses
- 6) Reliable and Timely business information

Thus, an effective, efficient and progressive risk management system and policy would help the organisation reduce the time management spends "fire-fighting", increase in change initiatives, lower the cost of capital, provide useful feedback and information for strategy setting, achieve and maintain competitive advantages and reduce uncertainty of results and events.

In order to embed the risk management process firmly into the organisation, all employees must be trained and should have the necessary knowledge, skills, information and authority to establish, operate and monitor the system of internal control. This will require an understanding of the company, its objectives, the industries and markets in which it operates and the risks that it faces. In addition, the business process should be so modified that they incorporate risk management as a part of the everyday working. As an elaborate risk management process can be a distraction from the key point, which is that incorporating control within existing processes enables each person in the organisation to become more focused on meeting the business objectives and in managing significant risks that relate to the tasks performed. Reduction of duplicate or repetitive controls within the work environment help increase the empowerment for people within the company to work to satisfy the needs of customers.

**Risk assessment** involves the identification and analysis of risks underlying the achievement of objectives, including risks relating to the changing regulatory and operating environment and business strategy, as a basis for determining how such risks should be mitigated and managed. Risk affects an organisation's ability to survive and successfully compete. However, avoiding risk completely is never possible and thus, the management must decide how much risk can be prudently accepted and strive to maintain risk within this level. Setting objectives is a pre-condition to risk assessment and management. It is a prerequisite for and enabler of internal controls, although not a component as such. These should be expressed around the future rather than the past or present and should be

focused on achievable goals. The management should consider whether any existing objectives are able to meet the challenges that it is likely to face over, at least, the next two to three years. By setting high level objectives at the entity level and more specific objectives at the activity level, an entity can identify factors that are critical to the achievement of goals.

The biggest concern whenever setting objectives should be “SALY”. This stands for “Same as Last Year” and can hamper even the most prudent risk management systems. The management should be cautious of the “SALY” approach to risk assessment and care diligence is required to avoid the same.

There are various techniques used to identify risks including the periodic reviews of economic and industry factors affecting the business, senior management conferences and meetings with industry analysts. Whatever method be adopted, the management needs to consider carefully the factors that contribute to or increase risk, including issues such as past experience of failure to meet objectives; quality of personnel; significant changes, such as increased competition; legislative, regulatory and personnel changes; market developments, and the significance of particular activities to the entity and their complexity.

Risk should also be identified at the activity level, which can help to focus risk assessment on major business units or functions and also contribute to maintaining acceptable levels at the entity-wide level. Following the initial identification of the significant risks to the company achieving its objectives, it may be useful to consult throughout the company on issues such as:

- a) awareness of the company’s business objectives, business strategy and related significant risks;
- b) the company’s risk management policy;
- c) whether the control strategies adopted are effective and what needs to be done to put them into effect;
- d) the fundamentals of good risk management and internal control and
- e) ways in which improvements can be made in order to mitigate the significant risks affecting the ability of the company to achieve its business objectives;

This consultation can help to identify whether the management has identified all the significant risks relevant to the objectives. It can also provide the management with a solid foundation for its review of the effectiveness of internal control and for its reporting on control. Following the identification of entity-wide and activity risks, a risk analysis should be performed. Once the significance and likelihood of risk have been assessed, the management needs to consider how the risk should be managed. Fundamental to risk assessment is a process to identify changed conditions and take action as necessary. Mechanisms to identify relevant and important changes should, as far as possible, be forward looking and early warning systems should be in place to identify data signals of new risks.

The final step in the process is that of prioritizing risk. Risks may be prioritized according to their impact and likelihood.



- A. Require immediate action;
- B. Consider action and have a contingency plan;
- C. Consider action and
- D. Keep under periodic review.

The impact should be considered not merely in financial terms, but more importantly, in terms of potential effect on the achievement of the company's objectives. Not all risks will be identified as significant. Non-significant risks should be reviewed regularly, particularly in the light of changing external events, to check that they remain non-significant.

Having identified and then prioritized the significant risks in gross terms, it is then helpful to determine for each of these,

- a) do the directors wish to accept this risk?
- b) what is the control strategy to avoid or mitigate the gross risk?
- c) who is accountable for managing the risk and maintaining and monitoring the controls?
- d) what is the residual risk, that is the risk remaining after the application of the control processes? and
- e) What is the early warning mechanism?

It should be noted that, while risk assessment is a part of the internal audit function, the plans, programs and other actions deemed necessary to address the risks are an essential part of the overall management process but are not regarded as an element of the internal audit.



## **Chapter 9: Internal Audit in ERP Environment and Systems Audit**

Enterprise resources planning (ERP) systems were first seen utilized in for accounting in early 1990s. These systems, which are essentially vendor defined enterprise wide accounting systems, promised fully integrated applications built upon common, centrally defined databases. The benefits of these systems were supposed to be manifold. An ERP system would eliminate the need to manage information flows manually by allowing the effect of every business transaction to be disseminated throughout the enterprise via update to a common database. It would provide real-time information to support operational and managerial decision activities as every application would be working with the current version of the operational database rather than working with slightly stale data as was the case in old fragmented systems. An adopting organisation would be able to reduce the time to close accounts and create financial reports in real time, as the data in databases is current all the time.

Yet the adoption and acceptance of ERP systems has been less than ideal. These systems are complex and touch upon many business processes that cut across functional boundaries. Before redefining the organisational structure, the set of accounts, and business processes; specifying new master and transaction data items; and choosing among accounting methods, it becomes necessary to meticulously re-examine organisation structure and business processes. As part of implementation, many steps embedded in the old environment become unnecessary, particularly those associated with managing the flow of data and information across organisation boundaries or managing workflow documents. This in turn leads the adopting firm to re-engineer itself both at the entity and process levels. The ERP implementation projects thus face very significant technical and organisational challenges.

Despite following a structured project management methodology, these projects often fail or never realize their full promise. Many organizations faced cost overruns, missed completion deadlines, abandoned implementations, and, in a very few cases, bankruptcies associated with attempted ERP implementations. Many organisations found that even after implementing ERP systems, managers were depending on manual procedures and reports created by the legacy systems. From an internal audit perspective, ERP systems created new opportunities as well as new challenges. On one hand, the use of an integrated system increases transparency in business processes and, at the same time, eliminates the need for controls assuring data consistency and accuracy as data move from one system to the next. With a single data entry point, need for entering the data associated with a transaction separately into different applications is eliminated; and therefore the controls to enforce data validity, data accuracy, and data privacy constraints need to implemented only once. As the system resides in one centrally controlled database, the risk of privacy violation can be identified more easily and the steps necessary to satisfy privacy constraints can be implemented more readily.

Integrated systems provide for improved audit planning and execution. If a new government regulation requires the organisation to institute a new internal control, it has to be incorporated only once into an integrated system. On the other hand, the complexity of an ERP system creates additional risks during both the implementation and the operational stages. During the implementation, the organisation

faces risks due to possible poor project planning and control, dependence on external consultants and integrators, resistance to organisational change, and lack of specialized skills needed to customize the system and populate it with organisational data. Even when implementation is relatively smooth, risks remain during the operational phase. An integrated environment often precludes the possibility of switching to a new system for an individual function, even if the new system has better functionality and easier maintenance routines. An integrated system presents the possibility that a small glitch introduced in one part of the system, perhaps as part of a routine maintenance activity, brings down the entire system potentially disrupting the firm's business operations.

In essence, the benefits of a unified integrated system are traded off against the risk diversification achieved with multiple, independent systems. Integrated systems also complicate audit planning as the auditor must gather evidence encompassing the entire system in an integrated manner. While there have been many studies of the risks in ERP implementations, there is not much research on the role that internal auditors play in ERP adoption and the impact ERP systems have on internal auditors' abilities to manage risks. However, the Internal Audit function must be able to ascertain various risks related to any new ERP system as well as warn the management with regards to any possible risks in modifying or implementing a new process of information flow.

In the operations risks category includes factors relating to physical processes (e.g., disruption in production cycles, procurement, human resources, quality assurance), external business environment (e.g., change in competitive landscape), and customer relationship management. An ERP system may help reduce the level for risk for most factors. The only exception is risk associated with the user training. ERP systems lead to improvement in internal audit team capabilities for risk assessment in all categories including user training, with the biggest improvement in assessing HR and procurement related risks. In the financial risk category, we include liquidity and credit risk, and price risk (arising because of exposures from such sources as interest rates, currency, stock prices, and commodity prices.). ERP systems seem to reduce financial risks while improving an internal auditor's ability to assess and manage these risks. Specifically, liquidity and credit risks decreased, or at the worst, stayed the same for all firms, with the largest improvement for the price risk.

In the technical risk category, we included factors associated with adoption of information technology, network, and data center operations, quality in data and application, availability of technical skills. Despite their ability to provide an integrated application platform, thereby eliminating many unnecessary data entry steps and awkward interfaces, surprisingly, ERP systems were perceived to increase technology risk.

However, the ERP system also perceived to provide better tools to assess and manage technology related risks. For all risk factors, more respondents felt that ERP systems improved their risk management ability than those that did not. In the miscellaneous risk category, we include factors associated with fraud and reporting errors, compliance with regulatory requirements, political and legal, privacy violations. ERP systems seem to make a significant reduction in risk associated with fraud, regulatory noncompliance, and financial reporting errors. In addition to risk reduction, there seems to be an indication of a significant improvement in the organisation's ability to assess and manage the risk

associated. ERP adoption may lead to reduced risks of privacy violation and provides a better mechanism for assessing and managing this risk. ERP systems seem to have minimal effects on risks associated with legal, political, environmental, and international issues.

While there is no consistent pattern over all it does seem that the cost associated with managing operations and financial risks goes down while the cost associated with managing technology risks goes up. It would be interesting to see if the pattern holds as the ERP systems become more mature and skill sets available for maintaining and managing skill become commonplace.

### **INTERNAL AUDIT STAFFING AND PERSONNEL ISSUES**

ERP systems have led a significant shift in the overall focus in the internal audit . An integrated environment leads to elimination of many points of failure by eliminating manual work and document flows. In an ERP environment, internal auditors should then spend less time in crisis management and resolving problems once they have arisen and more on making sure that the internal controls are functioning properly. Even though internal audit teams are rarely involved in the implementation stages, ERP systems seem to allow them to spend less time on managing problems and much more time on process review and quality assurance. Adoption of ERP system also creates a need for additional skills in the internal audit groups. In the new environment, internal auditors have to have enough knowledge and skills to understand of the internal workings of the ERP system adopted by the organisation. Although some firms were willing to engage outside consultants or hire new employees, most organizations choose to acquire the requisite skills for successful ERP implementation through training and re-skilling current employees. The cost for managing operational and financial risk has not changed significantly but the costs of managing the technology risk has gone up.

### **CONCLUSIONS, LIMITATIONS, AND FUTURE RESEARCH**

ERP systems adoption leads to a significant change in the information processing environment at the organisation. The transition from fragmented ad hoc systems to integrated systems allows for automated and document flows, eliminates replications and the resulting inconsistencies in the data. They allow for built in controls to data verification and data integrity. Yet these systems are complex and require significant effort in implementing and specialized skills in customizing in maintaining the systems. ERP adoption thus leads to new risks during both during implementation and operational stages.

ERP systems generally lead to significant improvements in internal audit function's ability to assess and manage risk in most risk categories. On the other hand, there is an increase in the levels of technology risk factors and operational risk factors, a decrease in financial risks, and wider variation in miscellaneous risk factors. Post implementation of ERP systems, internal auditors are spending more time in quality assurance in processes rather and less time in managing crises. However, as is the case with most organizations, loss of time and effort tend to increase when internal auditors do not play a more important role in implementation, particularly in defining internal control or being part of the reengineering effort necessitated by ERP adoption.



*The Institute of Cost Accountants of India*

---

Thus, to conclude, the internal audit can help to identify, review, and provide recommendations for key controls associated with the project and can provide assurance that the ERP system will support business processes and enforce business controls on an ongoing basis. The use of collaborative internal auditors on all critical phases of an ERP project is the best approach to increasing the likelihood of a successful ERP adoption.

## **Chapter 10: Relying on External Opinion and Reference of Auditor Expert**

The growth of internal auditing over the years has led to much consideration for relying on internal audit work by external auditors. Recent developments in businesses around the globe require specialisations in addition to the internal audit competences which are offered by experts and these experts are increasingly being involved throughout the entire internal audit function. The organisation or the head of the internal audit function may opt for an auditor's expert or an external opinion is as follows:

1. Risk may increase when other expertise is needed to assess the processes, activities or risks
2. Utilize competence and capabilities which are specialized in nature
3. Keep the situation under review as the audit progresses – circumstances may change
4. Nature, significance and complexity of the subject is highly sensitive to the organisation's performance

Although, it must be noted that an auditor's expert may not always needed in every case. In some cases, the internal audit function has collectively enough understanding of a field to perform the internal audit without an auditor's expert or an external opinion.

The key to success areas in managing external providers or auditors' experts, involve but are not limited to:

- Defining the objectives of the assignment
- Resources of time, effort and money available for the assignment
- Considering the experts' experience and knowledge in providing internal audit support service
- Selection of the expert with appropriate experience, knowledge and value addition basis
- Monitoring expert's technique of working and evaluating the results
- Nature, importance and complexity of the assignment

At times there is a well-defined and extensive audit plan wherein a broad range of skills are required to meet the audit objectives. In such a case, it would be appropriate to establish a panel of service providers to facilitate the internal audit team. Such a panel allows additional skills and flexibility at the disposal of the internal audit team. Where the expert is assigned to perform a small parcel of work, there is limited opportunity for the expert to develop the required understanding of the entity and its business needs. This lays further importance on establishing clear deliverables and as an added safeguard, service delivery requirements should be outlined in a contract with the expert.

Another key safeguard in ensuring that the expert delivers a quality internal audit service is that the expert allocates sufficient time and effort to audit assignments and has in place effective supervision arrangements, including sufficient review by the internal audit team. It is preferable to include a clause in the contract nominating the expert who will provide the audit services and to may require the

organization to be consulted before such assignment is shared.

Generally, internal auditors are not part a of large service firms, which may also be seeking to provide other services to the company as this can generate a conflict of interest and limit the ability of the internal audit function to review parts of the organisation. Organization also engage more than one internal audit service provider, so as to ensure work undertaken by a firm is not reviewed by the same firm. It should also be noted that a firm engaged as an internal auditor must retain the key responsibility of objectivity and independence even if a different part of the same firm is engaged in consultancy work within the organization.

Even though the internal audit function may be completely outsourced, responsibility for the overall efficiency and effectiveness of the internal audit function remains with the organization. It is therefore important for the management retains control of the internal audit strategic direction and to actively monitor the performance against the internal audit work plan and manual.

The internal audit function must always be assigned a senior employee of the organization to manage the delivery timelines corresponding to the internal audit work plan. The organization's representative has specific responsibility for activities such as monitoring the internal audit function's performance, managing the contract and the relationship with the internal audit function and setting up formal communication channels. Such a resource is of assistance to the internal audit team as it can act as another level of confirmation / vetting on internal audit findings and recommendations. In larger organizations with complex structures and hierarchies, the internal audit team to understand particular organizational working culture and provide advice on sensitive matters.

The internal audit function must include the internal audit manual and strategy in the assignment contract. The contract should establish robust performance and quality measures and the performance of the internal audit function should be formally assessed from time to time.



## **Chapter 11: Audit Conclusion and Corrective Measures**

The ability to identify audit findings, communicate them and determine the internal audit conclusions adds the most value to the internal audit function. Internal Audit Findings are the combination of observations, recommendations and results that the internal audit team collects in the course of audit and by the conclusion of the investigation and audit.

The preliminary step is to evaluate all the evidence and observations that the internal audit team has collected against the internal audit objective and criteria. Internal audit evidence includes any factual information or data collected while pursuing the internal audit. The internal audit objectives and criteria as mentioned in the internal audit charter must include the standards, procedures, rules and regulations of the organization that must be considered during the internal audit. Such criteria state the requirements that the organization must confirm to and the limits that the internal auditor must work within. The internal audit findings help to identify conformance or otherwise with the internal audit criteria. The Internal audit function must provide data and evidence of both conformance and non-conformance.

Where the internal auditor has to identify areas or opportunities for cost reductions and/or improvements in productivity, the audit findings must also include observations or any “MUDA” or inefficiencies and ineffectiveness. The Internal audit findings of all stages must be summarized along with the conformity requirements and should also include details of areas, functions or processes that were covered under audit.

The management of organizations usually focuses on nonconformities or inadequacies of control. They are more interested in knowing what needs to be corrected or fixed than what is being done correctly and need no change. Thus, all evidence supporting nonconformities should be well documented and recorded. All irregularities may also be grouped based on the level of impact to the organization such as minor, major or potentially risky. However, at times the management takes the onus of defining the severity of the nonconformity as well as the corrective action plan.

Even though the management may be in a better position than the internal audit team to determine the appropriate action plan, the internal audit team can accurately gauge the significance of the irregularity with their multi company and industry exposure. Thus, the management and internal audit team must work closely to assure all nonconformities are well documented, assessed and corrective action plans are implemented.

Although nonconformities form an important part of the internal audit findings, they may not be the intended final objective of the internal audit. Certain other internal audit objectives include determination of project status, gaps in control systems and creating action plans for business challenges.

Internal audit findings are recognized at every stage during the course of the audit. But, conclusions are only determined at the end of the entire audit exercise. All observations and information meeting the

qualitative and quantitative criteria as determined in the internal audit charter form the basis for these audit conclusions. An in-depth review of all audit findings leads to a comparison between the inputs to achieve a progressive output.

After considering the inherent uncertainties of the internal audit process such as test checks, the internal audit team should first internally agree on the audit conclusions and forward the same to the management via the head internal auditor. Usually, the head internal auditor chairs this meeting and decides on any conflicting views to finalize the audit conclusions all the while seeking consensus of the entire internal audit team. The audit conclusions must be finalized only after considering and evaluating all options and recommendations

Audit conclusions can address several issues and given below are common issues that conclusions address:

- 1) Audit conclusions aid to ascertain the effectiveness of control exercised by the management system when compared to the audit criteria
- 2) Audit conclusions must have a detailed assessment of the effectiveness of implementation, maintenance and improvement of the control system. The internal audit function must note the procedure for deployment of the organization's control system along with whether the system maintenance based on adhering to requirements, correcting irregularities and taking corrective action. Any prospects for improvement must be incorporated as the audit conclusion through preventive and innovative actions.
- 3) Audit conclusions may also assess the capability of the management data collection and review process. The management must be able to assure continuing suitability, adequacy, effectiveness and improvement of the control system and operational effectiveness.

The Corrective Action Process is the final step of the Internal Audit Process and is used wherever corrective action is warranted. As findings are identified through the internal audit process, the Internal Audit Team will discuss the findings with the management and confirm with an understanding of both the data and the process, and validate that the facts of the finding are correct.

Throughout this process, the managers responsible for change or corrective measure implementations are identified, and provide a recommendation on how to resolve the finding appropriately. Once the internal audit report is shared, the finding may be loaded into a Corrective Action Database and followed-up on. Quarterly meetings may be held with the management to communicate the status and provide updates for each open finding. A general checklist of corrective action would include:

- 1) The first step to undertake corrective actions is to ensure the internal audit function accurately understands the finding that has been identified. The Management must work with the internal auditor to understand the source of the data, the significance of the risks identified. The main goal of this step is to identify risk and proceed to fixing it appropriately.
- 2) The employee or manager in charge of the area of concern or at risk must be shared the authority to lead the action plan to revise the present practice. Ideally, the assigned manager

must be able to understand how the process works, and provide informed ideas, make empowered decisions and be involved with the internal audit function during identification of the finding.

- 3) Control systems can be defined as a set of processes intended to ensure an expected outcome with minimal variances. The extent to which these control systems should be implemented would be based on the relative risk of failure and the significance of the risk. There are different types of control systems and depending on the desired action, the appropriate control system is selected. Any **preventative control** is designed in such a way that a predefined corrective action is undertaken prior to the commencement of the process. A **detective control** is designed to identify and highlight any deviations or variances from the set tolerance levels. A **directive control** is designed to guide the staff to follow the established rules and regulations which supports the ultimate objective.
- 4) Wherever deemed necessary, new control systems are setup and post evaluation of the steps for new controls, the next step is to develop timelines and crash gates for submission of the process audit and evaluation report. This report which is to be compiled by the internal audit function provides the first review to management of the estimated period required to resolve the nonconformity.
- 5) Post completion of these steps, a summary of the corrective actions is provided for the final report in the corrective action worksheet. This summary must include the “Action Planned v/s Taken” for each finding reported. The Corrective Action Worksheet is a document which not only helps document the corrective action process for each finding but also helps in tracking the follow up of actions implemented.

Thus, the Corrective Action process is the key to an effective control environment within an organization, and the Internal Audit Team will help to identify the right changes to be made in order to improve the organization’s operational success and maintain sustainability.



## Chapter 12: Report Writing and Audit Report

Internal Audit reports should be accurate, objective, constructive, clear, concise, and timely. The Audit Report is the principal means by which audit findings are communicated to management and the Audit Committee for the purpose of reporting on the scope of the audit performed and the audit results. Each audit finding should be classified as a major control weakness, minor control weakness, exception, observation, or a violation of law, rule or regulation.

The Internal Audit Report's findings summary should be of sufficient detail to identify the control weaknesses, exceptions, observations or violations of law, rule, or regulation, and should include supporting facts to the extent considered necessary. The risk exposure presented by a control weakness should be identified. A recommendation for corrective action should be included for each control weakness, exception, observation and violation of law, rule, or regulation. The various types of findings are as follows:

- 1. Major Control Weakness:** Identifies a control weakness that presents a high risk exposure or risk of loss, or that has a significant adverse effect on the achievement of an important operating objective related to a core business process, key business activity, or critical business function. Major control weaknesses generally require prompt corrective action to reduce the risk exposure.
- 2. Minor Control Weakness:** Identifies a control weakness that presents a low to moderate risk exposure or risk of loss, or that has a minor adverse effect on the achievement of an operating objective related to a business process, business activity, or business function. Minor control weaknesses generally require timely corrective action to reduce the risk exposure.
- 3. Exception:** Identifies an error or occurrence (event) which did not conform to established policy or an established control procedure, or a condition which does not conform to generally accepted control principles or business practices, however, it does not constitute a control weakness. A related control weakness may exist, depending on the nature and pervasiveness of the exceptions. Exceptions generally require corrective action to remedy the exception.
- 4. Observation:** Identifies a condition such as an operating policy, operating procedure, or operating practice that is not efficient or effective, however, the condition does not constitute a control weakness. Observations merit management consideration to realize improved efficiency or effectiveness.
- 5. Violations of Laws, Rules and Regulations:** Identifies violations of laws, rules, or regulations.

Each Audit Report should include an overall internal control rating based on the audit findings.

Commonly accepted ratings are as follows:

- (i) Satisfactory:** The internal control system is effective. Established control procedures reasonably assure the achievement of operating and control objectives. If control weaknesses exist, they are

only minor control weaknesses. Risk exposure or risk of loss is low.

- (ii) **Needs Improvement:** The internal control system is generally effective. Only minor control weaknesses exist, however, their effect on the internal control system is more pervasive and the achievement of important operating or control objectives is not reasonably assured. Risk exposure or risk of loss is moderate.
- (iii) **Unsatisfactory:** The internal control system is ineffective. One or more major control weaknesses exist that have a significant adverse effect on the achievement of important operating or control objectives. Risk exposure or risk of loss is high.

A Draft Internal Audit Report should be issued to the process owners and any other individuals (i.e. executive management) included on the Distribution List. Draft Internal Audit Reports should be issued on a timely basis following the completion of each audit.

A written management response should be provided for each major control weakness, minor control weakness, exception, observation or violation of a law, rule, or regulation included in a Draft Internal Audit Report. As applicable, the management response to any finding should identify corrective action taken or planned and include a completion date for corrective action taken, or a target completion date for planned corrective action. Each management response should designate one comment owner. Management has responsibility for establishing comment ownership.

All written management responses to audit findings noted in Draft Internal Audit Reports should be submitted to the Internal Auditor within a reasonable period of time (i.e. 10 calendar days) of the issuance date of the Draft Internal Audit Report. Reasonable deviations from this time requirement may be allowed for valid reasons such as illness, vacation, or unexpected demands on time to meet the operating needs of the department or organisation.

In the event that the management does not concur with audit findings, conclusions, recommendations, or the internal control rating, identified in the Draft Internal Audit Report, management should, at its discretion, indicate the reason(s) in its written management response. Following receipt of management's written response to a Draft Internal Audit Report and prior to the issuance of a Preliminary Audit Report, the Internal Audit team should discuss with management and attempt to resolve any differences of opinion with regard to the Draft Audit Report audit findings, conclusions, recommendations, internal control rating or adequacy of a management response in terms of proposed corrective action.

Following receipt of a written management response to each audit finding noted in a Draft Internal Audit Report, the Internal Auditor should issue a Preliminary Audit Report that incorporates the written management responses. The Preliminary Audit Report should be issued to the individuals identified on the Distribution List. Management should have additional time (i.e. 5 calendar days) from the issuance date of the Preliminary Audit Report to review the Report and provide any additional or revised management response.

After expiration of the allowable time for management's written response, a Final Audit Report, incorporating management's written responses or non-responses to audit findings and any corrective

action taken or planned, should be issued to the Audit Committee.

Any unresolved difference of opinion with regard to audit findings, conclusions, recommendations, internal control rating, or adequacy of a management response in terms of proposed corrective action should be arbitrated and resolved by the Audit Committee at their discretion. The Audit Committee's determination should function to resolve the difference of opinion and bind all parties to the resulting determination. In the event the Audit Committee is unable to arrive at a determination, for whatever reason, the matter should be resolved by the Board of Directors at their discretion.

An Internal Audit Report should ideally include the following:

- 1) Audit Name and Report Issuance Date;
- 2) Audit Report Addressee(s): Identifies the process owners to whom the Audit Report is directed;
- 3) Report Distribution List: Identifies all parties to whom the Audit Report is distributed;
- 4) Scope and Objective of the Audit: Identifies the major activities, processes and functions reviewed and identifies the time period the audit is meant to review (dates of sample tested documents and procedures);
- 5) Auditor's Conclusions and Internal Control Rating: Identifies the auditor's opinion regarding the adequacy and effectiveness of internal controls to include an internal control rating;
- 6) Narrative overview of the business activity and its associated internal controls;
- 7) List and detailed explanation of the Major Control Weaknesses, Minor Control Weaknesses, Exceptions, Observations and Violations of Law, Rules and Regulations noted during the audit;
- 8) Internal Auditor's Recommendation: recommendation for corrective action as it applies to each audit finding;
- 9) Management Response: A section for management to include its written response to the audit finding and state any corrective action taken or planned;
- 10) Target Completion Date: Identifies the date corrective action will be completed by management and
- 11) Comment Owner: Identifies the manager responsible for ensuring corrective action is taken as it applies to the audit finding.



## **Chapter 13: Introduction to Pharmaceutical Industry**

The Indian pharmaceutical industry currently tops the chart amongst India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. It ranges from simple headache pills to sophisticated antibiotics and complex cardiac compounds; almost every type of medicine is now made in the Indian pharmaceutical industry. This Industry is driven by knowledge, skills low production costs and international quality products has witnessed a robust growth from production turnover of about INR 5,000 crores in the year 1990, to over INR 1 lac crores in 2009-10, comprising of domestic market of INR 62,000 crores and export of INR 42,000 crores. Globally, it is the 3<sup>rd</sup> Largest producer of medicines by volume and yet, 14<sup>th</sup> in terms of sales value. The lower value is due to the fact that Indian formulations are among the lowest priced in the world. The cost of medicines continues to be an important component in overall Medicare costs in the country. It constitutes less than 20% of the aggregate Medicare expenditure in the country.

The Indian pharmaceutical sector is highly fragmented with more than 20,000 registered units. It has expanded drastically in the last two decades leading to severe price competition and government price control. The Pharmaceutical industry in India caters to the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals, and Injectable. There are approximately 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India.

Pharmaceutical industry is a typical sector and medium to large scale units market anything between 200 to 800 products. If the company is very active in the export market, then the number of products may sky rocket to couple of thousands, because, the product required to be sold in those foreign countries have to comply with the requirement of FDA/MHRA authority of those respective countries. Further, there are different norms for Packing Materials in different countries and the Packing Materials have to be printed in different languages for different countries. This will multiply the number of products. If one considers 15 to 17 input materials for each formulation, the Companies may be handling phenomenal number of inputs.

These features necessitate much detailed exercise on material management front. It also calls for standardization of Packing Materials to reduce the variety and thereby reduce the necessity of holding very wide range of Packing Materials. Internal Audit needs to look at this rationalization of specification where ever it is feasible. For example - in case of Foil and Blister, the back of foil or strip is plain and if its size is rationalized, then the inventory of such foil can be controlled.

In case of Bulk Drug/Active Pharmaceutical Ingredient (API), it is necessary to consider purity and consistency and on detailed analysis it may appear that a particular supplier may turn out to be cheapest considering all the cost, especially for the input which requires cold chain (controlled temperature all throughout the transit from the manufacturer to the consumer).

Over the past decade, pharmaceutical companies have entered a difficult period where shareholders,

the market, and regulators have created significant pressures for change within the industry. The core issues for most of drug companies are declining productivity of in-house R & D, patent expiration of number of block buster drugs, increasing legal and regulatory concern, and pricing issue. As a result larger pharmaceutical companies are shifting to new business model with greater outsourcing of discovery services, clinical research and manufacturing.

Current global financial conditions and the threat of a broad recession accelerated the timetable for implementing transformational changes in global organisations, as the industry confronts lower corporate stock prices and an increasingly cost-averse customer. Leaders of the largest global pharmaceutical companies recognize the need for transformational change in their organisations, but will need to move swiftly to ensure sustained growth.

Though the industrial growth in India had below expectation of people, Indian Pharmaceutical Companies are not affected by negative outlook. Primarily, because the market scenario both at home and in international market has witnessed good performance and expectation continues to be positive. On the contrary, the other countries have started looking at Indian pharmaceutical products because they are cost effective. With more and more molecules are slated to come off patents, Pharmaceutical Industry in India sees expanding market horizon. Several Pharmaceutical Companies have upgraded their manufacturing and testing facilities to meet strict standards set up by advanced countries. Yet Pharmaceutical Industry will have to brave issues like:

- Drug Price Control,
- Regulatory amendments and improvement,
- Consistent quality management and
- Compliance with global standards, if it wants to effectively penetrate into export market.

Many studies by leading industry experts and macro-economists have predicted that India will see the largest number of merger and acquisitions (M & As) in the pharmaceutical and healthcare sector as this seems to be the only logical option for market consolidation and stability.

According to reports of IDMA (Indian Drug Manufacturers Association), the Indian pharmaceutical market is expected to grow at a CAGR of 15.3 per cent during 2011-12 to 2013-14. The growth of Indian pharmaceutical companies will also be driven by the fastest growing molecules in the diabetes, skincare, and eye care segment. Additionally, the certain pharmaceutical companies such as Cipla, Ranbaxy, Dr Reddy's Labs and Lupin might soon be part of the government's ambitious 'Jan Aushadhi' project. In an attempt to commercialize the project, the Government is likely to rope in the private sector to bulk-procure generic drugs from them. There are currently 117 Jan Aushadhi stores across the country and the plan is to expand to at least 600 in the next two years and 3,000 by 2016.



## **Chapter 14: Applicable Government Policies and Rules**

There are various Government Policies and Rules applicable to the pharmaceutical sector. It is amongst one of the regulated industries. There are many problems faced by the organisations within this industry in accessing requisite information in order to comply with the regulatory requirements domestically and in the regulated foreign markets. The important Indian and International guidelines and regulations to be followed are as under:

- 1) **CDSCO**: The Central Drugs Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare, Government of India provides general information about drug regulatory requirements in India.
- 2) **National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012)**: The Department of Pharmaceuticals has notified the National Pharmaceutical Pricing Policy-2012 (NPPP-2012). The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – “essential medicines” – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all.
- 3) **Drugs (Price Control) Order (DPCO), 2013** : Drugs (Prices Control) Order 2013 has been issued with the objective to improvise and endow with the basic health care and availability of basic medicines at an affordable price across the country, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, notified the Drugs (Prices Control) Order 2013 ("DPCO 2013") in May 2013. The DPCO 2013 empowers the National Pharmaceutical Pricing Authority ("NPPA") to regulate prices of 348 essential drugs. As per the new DPCO 2013, all strengths and dosages specified in the National List of Essential Medicines (NLEM) will be under price control.  
  
Prior to the 2013 regime, the DPCO 1995 included 74 bulk medicines within its ambit and the pricing of the drugs were fixed on the basis of manufacturing costs declared by the drug manufacturers.
- 4) **D&C Act, 1940**: The Drugs & Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs in India. It helps protect against manufacture and sale of misbranded, adulterated and spurious drugs.
- 5) **GCP Guidelines**: The Ministry of Health, along with Drugs Controller General of India (DCGI) and Indian Council for Medical Research (ICMR) has come out with draft guidelines for research in human subjects. These GCP guidelines are essentially based on Declaration of Helsinki, WHO guidelines and ICH requirements for good clinical practice.
- 6) **The Pharmacy Act, 1948**: Baring sale of drugs through institutional sales, the sale of all drugs are directed through retail pharmacy outlets. The Pharmacy Act, 1948 is meant to regulate the profession of Pharmacy in India.

- 7) **DMROAA, 1954:** The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 provides to control the advertisements regarding drugs; it prohibits the advertising of remedies alleged to possess magic qualities.
- 8) **NDPSA, 1985:** The Narcotic Drugs and Psychotropic Substances Act, 1985 is an act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.
- 9) **WHO:** WHO guidelines on medicines policy, intellectual property rights, financing & supply management, quality & safety, selection & rational use of medicines, technical co-operation and traditional medicines.
- 10) **ICH:** International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) guidelines defining quality, safety, efficacy & related aspects for developing and registering new medicinal products in Europe, Japan and the United States.
- 11) **OECD:** Organisation for Economic Collaboration and Development including 30 member countries covers economic and social issues in areas of health care.
- 12) **EMA:** European Medicines Agency (EMA), a decentralized body of the European Union headquartered in London, prescribes guidelines for inspections and general reporting and all aspects of human & veterinary medicines in the European Union.
- 13) **US FDA:** All Regulations, guidelines, notifications, news and communications from United States of America Food and Drug Administration. Any export sale to USA must comply with US FDA requirements.
- 14) **TGA:** Specifications regulating medicines, medical devices, blood, tissues & chemicals, issued by Therapeutic Goods Administration, the Australian regulatory body.
- 15) **MHRA:** News, warnings, information and publications of Medicines and Healthcare products Regulatory Agency (MHRA), responsible for ensuring efficacy and safety of medicines and medical devices in the UK.

In addition to these industry/product specific regulations, the common rules pertaining to the excise duty, service tax, sales tax and other business related rules and policies must also be complied with.

- 16) **Excise Duty:** As discussed herein above, there are variations in applicability of excise duty on the following count:
  - a. Company manufacturing its own bulk drugs and formulations
  - b. Company manufacturing its own bulk drugs and formulations but part of the process and/or recovery of chemicals is outsourced.
  - c. Company purchasing input from a related party or selling it to related party.
  - d. Company manufacturing at site of support manufacturer but, the clearance and

payment excise duty is undertaken in name of principal company.

- e. Manufacturing of life saving drugs exempted from excise.
- f. The product is subject to state excise duty and not central excise duty.

**17) Service Tax:** In case a company supplies raw and packing material, and pays the conversion charges on basis of output, the transaction is subject to service tax. The internal auditor must ensure that due and reliable process is in place to record the exact quantum of work, the value paid and service tax attracted and paid thereon in registered form, as the Cost Auditor may request the same at the time of cost audit.

At times companies carry out research or part thereof on behalf of other companies. It is necessary for the internal audit function to ensure that cost of material, manpower, and utilization of machinery is properly recorded such activities and the amount billed shall also attract service tax. This service tax on input service can be set off against liability for both service tax and excise duty.

**18) VAT / Sales Tax:** Different states in India notify different rates of VAT/Sales Tax. The assessable value and VAT/Sales tax payable on that needs to be compiled in a registered form as the same will be asked for by the Cost Auditor and reported in Cost Audit Report.

**19) Income Tax:** If a company has its manufacturing facilities located in hilly states, and another facility located in other states, it is necessary to take utmost care in determining the profits of unit in hilly state which is exempted from income tax hence, the unit in hilly state should be treated as independent unit and its profit or loss should be worked out.

**20) Transfer Pricing International:** There are several multinational foreign companies which have pharmaceutical manufacturing activities in India and abroad. The cost of pharmaceuticals is the lowest in India, by an estimate it is 5% of prevailing retail prices in USA and 7% of prevailing retail prices of Europe. On the other hand, several Indian pharmaceutical companies also have their setup in various countries across the globe and they frequently deal with their Indian arms. The tax authorities in both the countries are concerned about the tax on profit made by such related parties and therefore, it is necessary to work out distribution of profits between the Indian arms and foreign on one of the following basis:

- a. Comparable uncontrolled price method
- b. Transactional net margin method
- c. Profit split method
- d. Cost plus method
- e. Resale price method
- f. Such other method as may be prescribed by the Board

These methods are also prescribed under the newly implemented domestic transfer pricing.



**21) Transfer Pricing Domestic:** With effect from 1<sup>st</sup> April, 2012, the transfer pricing rules have been notified for related party transactions even within India. The compliance of the same also needs to be addressed by the internal audit function.

The Internal Audit function should audit the procedures and compliances and ensure smooth working of the company.



## Chapter 15: Legal and Regulatory Framework

Indian Pharmaceutical Companies fall within the purview of the Companies Act, the Drug and Cosmetic Act, Drug (Price Control) Order, 1995, replaced by Drugs (Price Control) Order (DPCO), 2013. The regulatory framework includes the authorities like Drug Controller General of India (DCGI); National Pharmaceutical Pricing Authority (NPPA), Ministry of Chemical and Fertilizer and Department of Pharmaceuticals, Government of India. All these authorities extensively use cost data for protecting interest of patients and genuine growth of the industry. Among the various rules and regulations mentioned earlier, the Drugs and Commodities Act, 1940, the Drugs (Price Control) Order, 1995 and Drugs (Price Control) Order 2013 are the most relevant and unique in nature.

As mentioned earlier, the Drugs & Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs in India. In addition to defining and protecting against misbranded, adulterated and spurious drugs, the other important schedules are:

- 1) **Schedule M** of the D&C Act specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs.
- 2) **Schedule T** of the D&C Act prescribes GMP specifications for manufacture of Ayurvedic, Siddha and Unani medicines.
- 3) The clinical trials legislative requirements are guided by specifications of **Schedule Y** of The D&C Act.

The price control on medicine was first introduced in 1963 in the aftermath of the Chinese aggression with the promulgation of the Drugs (Display of Prices) Order, 1962 and amended in the years 1966, 1970 (under the Essential Commodities Act, 1955), 1979, 1987 and 1995. For the purpose of Drugs (Price Control) Order, 1995 (DPCO), there were 74 Bulk drugs identified and brought price control regime with certain exceptions such as drugs produced by small scale units or through indigenous R&D were exempted. These policies were based on the principles of industry's growth, cost effective production, innovation and strengthening of capacity.

The present Drug Policy of 1994 as implemented by Drugs (Price Control) Order, 1995 (DPCO), was introduced in the context of liberalization of the economy and abolishment of Industrial Licensing as well as allowing foreign investment in the country, Including in pharmaceutical industry. The principle of price control, broadly adopted in this policy represented a radical departure from the earlier policies. This envisaged control over price of drugs on the basis of company's turnover and market share. The control over prices was to be based on the cost of production with an allowance for post-production expenses and Maximum Allowable Post-manufacturing Expenses.

The salient features of DPCO, 1995 are:

- 1) Only Para 3 to 11 and Para 13 to 21 were delegated to NPPA by SO number 637(E) dated 4th September, 1997.

- 2) The prices of 74 bulk drugs and formulations containing anyone of them were brought under price control by Drugs (Price Control) Order, 1995.
- 3) The small scale sector complying with two conditions namely: it is manufacturing the formulation in its own unit or unit of other SSI unit and the formulation is sold under the brand name of SSI unit and a declaration to this effect is priced with the Ministry of Chemicals and Fertilizers.
- 4) Every manufacturer of Bulk drugs and formulations (other than SSI) is required to file price application for bulk drug under Para 3 of DPCO, 1995 or for formulation under Para 8 of DPCO, 1995.
- 5) The method of calculating price is specified under Para 7 of DPCO.
- 6) The government may notify the price of formulations under Para 8 or under Para 9. Under Para 8, a specific price is allowed to specified manufacturers whereas under Para 9, a ceiling price would be announced after considering the cost and efficiency of the major manufacturer and such price will be applied to all the units including SSIs.
- 7) There are provisions for recovery of overcharge under Para 12 and 13.
- 8) If a company is not satisfied with the price notification by National Pharmaceutical Pricing Authority (NPPA), then an appeal can be made within 15 days under Para 22.
- 9) There is specific power to exempt under Para 25.
- 10) As per the provisions of Para 26, Para 22: 'Power to Review', Para 23: 'Power to issue guidelines' and Para 25: 'Power to Exempt' cannot be delegated to NPPA.

Thus, it would be appreciated that Pharmaceutical Industry manufacturing both Bulk Drug and Formulation need to compile their cost very effectively to justify reasonable price for its Bulk Drug on one hand and Formulation on the other hand. The Cost Price study in case of Bulk Drug/Active pharmaceutical Ingredient is very detailed inter alia including the gross consumption of Raw Material and Process Material less Recoveries; net consumption of input materials, the cost of recoveries and purification of Raw Material and Process Material and detailed consideration of cost of utilities and overheads.

With the recent National Pharmaceutical Pricing Policy, 2012 (Given at Annexure I) being approved, the Drugs (Price Control) Order, 2013 (Given at Annexure II) came into effect. There are several important changes which have been adopted in comparison to the DPCO, 1995. Certain salient features of these changes are as under:

- 1) While DPCO, 1995 was primary applicable on the use of 74 Bulk Drugs or API, the new DPCO, 2013 is applicable to the formulations mentioned in Schedule I based on the NLEM (National List of Essential Medicines) as published by the Ministry of Health and Family Welfare.
- 2) While under DPCO, 1995, the "Ceiling Price" and the "Maximum Retail Price" were interchangeable, however under the new DPCO, 2013, Ceiling Price is defined as Average Cost

- to Retailer plus Margin to Retailers which has been fixed by the act at 16% and various methods of calculating ceiling price have been discussed from paras 4 to 16.
- 3) The standard for notification of prices has been revised from the “cost of major manufacturer” to the “average of all manufacturers” with market share greater than 1%.
  - 4) The government has frozen the price of scheduled formulations as prevailing on 31<sup>st</sup> May, 2012 (or as revised thereafter). There will not be any increase for a period of 12 months and thereafter the price can be increased corresponding to the increase in the “Wholesale Price Index (WPI)” for the preceding calendar year. However, a reduction in WPI would attract a compulsory reduction in price to the same extent.
  - 5) The price of non-scheduled formulations can be increased up to 10% per annum under new DPCO.
  - 6) For determining the price of “New Drugs” the new DPCO will rely on the concept of “Pharmacoeconomics”.
  - 7) The New DPCO 2013 has revised various forms under Schedule II. They are:
    - a. **Form I** for Price Fixation of New Drug (Scheduled Drugs only);
    - b. **Form II** for submission of New Prices (Any revisions whether scheduled or nonscheduled);
    - c. **Form III** for quarterly returns of all production and sale of drugs;
    - d. **Form IV** for Discontinuation of Drugs;
    - e. **Form V** for Price list to be shared with dealers, State Drugs Controllers and Government.
  - 8) Another change in DPCO, 2013 is with regards to discontinuation of a scheduled formulation. If in case, a company wishes to discontinue a scheduled formulation, it must notify the government 6 months before such discontinuation via form V, and even thereafter, the government may order the company to continue production for a period not exceeding one year within 60 days of receiving form V.
  - 9) In case a company does not have a notified price for a new drug, which is deemed as a scheduled formulation, the entire price of the drug will be considered as overcharge.
  - 10) Finally, the new DPCO also covers retailers of pharmaceuticals and not only manufacturers. Under **Para 25**, every retailer shall display the price list (form V), as shared by the manufacturer, on a conspicuous part of the premises so as to be easily accessible to any person wishing to consult the same. Also, under **Para 28**, no dealer can withhold sale of any drug (whether scheduled or nonscheduled) to a customer intending to purchase such a drug.



## **Chapter 16: Technical Peculiarities**

The pharmaceutical industry is technology oriented and its business inter alia includes manufacturing and marketing lifesaving drugs and Vaccines against life threatening diseases and epidemics. In this industry all efforts are required to be put in to ensure for manufacturing under absolute hygienic condition and reaching the medicines to the length and breadth of this vast country. At the same time, ensure the cheapest and reliable source of medicine. There are several instances where Indian Pharmaceutical companies have made critical medicine available to various countries at 1/10 or 1/15 of prices prevailing. In some countries this is possible only on account of dedicated technical staff and continuous use of techniques of Cost and Management Accountancy in ensuring availability at right quantity and right price. Internal Audit has substantial role in plugging leakages in cost and losses to enable industry to continue the availability as stated herein above.

In year 2005 Government announced an incentive scheme for promoting manufacturing activities in Hilly States. The intensive included excise duty and VAT exemption for 10 yrs and exemption from Income Tax for 5 years (when excise was 16%, VAT was 4% and Income Tax was 33%). Consequently, states like Himachal Pradesh, Uttaranchal and Jammu Kashmir received lot of response. Nearly 200 Pharmaceutical projects came up in state of Himachal Pradesh only. Most of the companies, which had huge manufacturing activities in other states put up plants in Hilly States increasing the capacity in Pharmaceutical Industry by almost 50%-60%.

However, the demand did not go up in the same proportion and consequently, it led to idle capacity at original plant. The benefit expected to be derived from the Hilly States stood diluted by cost of idle time at original plant and due to the cost of transport of input to Hilly States and transport of Finished Goods to market. Hence, it was very essential to ascertain the saving on land and additional cost on the other hand to assist the net benefit of going to Hilly States. Secondly, the benefit of excise and VAT could not be realized in respect of Formulation subject to price control as the company could not charge excise and VAT unless it paid the same.

A couple of company which produce price control Formulation in Hilly States incurred losses as the Cenvat credit on material was not allowed as final product was not subject to excise duty and VAT. Had the product been manufactured at original plant such lose would not have taken place. This was one more issue from angle of risk management under Internal Audit.

Pharmaceutical industry like FMCG evolves details strategy to arrive at their products mix. They venture into small segment of all Indian market. The company always put thrust on following items:

- 1) The Formulation with high contribution (Net Sales Value – Direct Cost);
- 2) The Formulation with potential to grow fast at 25% - 35% per year namely, medicine for Cardiac, Neurological and Diabetic, which are new in market and have tremendous potential to grow;
- 3) The products which are compatible with your present group of Formulation doing well in the

market e.g. a company having strong presence for cardiac product may be able to grab larger market share for new sunrise Formulation in Cardiac Domain.

It is essential to ascertain, whether the company uses cost data to prepare the marketing strategy and compare the actual performance based on expected profitability. In distribution there are two options available:

- 1) To have own warehouses at all major cities and distribution by the company.
- 2) To appoint Clearing and Forwarding agents, who would hold goods for the company and dispatch as per instructions.

The cost and benefit of both the action need to be examined and decision for the distribution of material has to be taken. Secondly, all such storage places either of company or of Clearing and Forwarding agents needs to be outside the octroi limit of the city so that company can save octroi duty on Formulations sold to other cities and town.

Some large companies have central warehouse facilities in central part of India and they forward goods to the location where demand is there to ensure that the company should monitor movements of each Formulation at each location and if it finds demand in one place is less and movement is slower then move those Formulation to area where they are fast moving.

Certain products like insulin, vaccine are atmosphere sensitive and they need to be stored and transported under air conditioning and controlled temperature both for domestic market and export. These products require "COLD CHAIN" transportation which will keep track of temperature at interval of every 15 minutes and if the temperature rises beyond permissible limit the Formulation is likely to be rejected.



## **Chapter 17: Special transactions peculiar to the industry**

Pharmaceutical Industry has unique features of manufacturing and indirect marketing. The Formulation is marketed to a doctor or hospital and it is purchased by patient or their families through retail pharmacists.

### **OUTSOURCING**

This is an industry where outsourcing from other manufacturer is usual thing and significant portion of industry is involved into it in one way or the other. The industry had more substantial manufacturing facilities to Hilly States of Himachal Pradesh, Jammu & Kashmir, Uttaranchal and Sikkim. It has its own issues which are dealt with in details separately in other place in this guidance note.

This process are so streamlined that procuring Formulations from other manufacturer is very common. However, it has its own issues from Internal Audit angle as substantial Raw Material and Packing Material are lying at support manufacturer's place and the yield is variable factor within limits. At times material are supplied directly to support manufacturer.

### **PRINCIPAL TO PRINCIPAL (P2P)**

In case of Principal to Principal transaction the support manufacturer himself buys Raw Material and Packing Material from the approved sources. Under the circumstances, the scope of risk management increases manifold raising special issues dealt with at a subsequent chapter.

### **Loan Licensing**

Many companies directly or indirectly supervise the operations of support manufacturer in terms of input, sellable output, recovery from process, balance of raw and packing material at support manufactures location and dispatches from where generally there would be an agreement from support manufacturers that he will not procure any packing material directly nor will he produce anything with formula and process of the principal.

However, there is eventuality that, an unscrupulous manufacturer may produce some quantity without the knowledge of the principal and sell in the market. This can happen in 2 ways:

- 1) Additional batches are produced by support manufactures and cleared under duplicate batch number. Such batches are cleared without payment of excise duty and VAT resulting in very high profit for the support manufacturer.
- 2) In second case, presuming that there is an agreement to give production of 95% of batch size and the manufacture delivers say, 93% and dispose-off remaining 2% straight in market. In such case, the cost of procurement would work out to be quite high. Hence, it is most essential that proper tracking of all the input materials and more precisely the packing material needs to be verified on continues basis to eradicate any chance of such shortages.

A similar situation would take place in P2P. The organisation would be further damaged if the support manufacturer were to procure all the material from approved sources including packing material and produce extra quantities and sell directly in open market.

The difference between the value addition for P2P transaction and net realization for sale to third party would be phenomenally different causing financial loss and dent in market share of the company. Thus, the issue needs serious consideration from risk management under Internal Audit. While presenting these risks or opportunities to the management, the various reports to be submitted and discussed must relate to:

- **LL dependence analysis:** Dependence on a loan licensed manufacturing must be grouped on and estimated against the following:
  - Turnover from LL products.
  - Contribution to fixed expenses of companies.
  - Profit from LL products in value and as a percentage of total company profits.
- **Key Cost Analysis:** The key costs of the company relating to materials, supply chain, marketing, administration, and branding must be ascertained and considered while pricing products. When undertaking procurement through P2P or LL, the company must always be wary of recovering both material and LL costs at the minimum.
- **Market and Key Customer Analysis:** When analyzing the performance of the sales and marketing functions, the internal audit must provide the management with detailed analysis of:
  - Business Group wise profit contribution;
  - Business Group wise profit margins;
  - Key customer profit contribution;
  - Region wise turnover and margin and
  - Regional and SBU profitability and turnover movements over time.

Based on the above mentioned reports; products and customers may be grouped in to various categories based on contribution to fixed costs and margin both.

- **Working Capital and Inventory Management Analysis:** When undertaking procurements through P2P or LL, the most critical area of management becomes the cost of working capital and its related inventory management. Since materials are to be provided by the company, in LL manufacture, there is a need for utmost care in calculating and monitoring the expected, actual and variances in yields. Also, any non-moving or slow moving inventory severely damages the working capital requirements and may lead to a cash crunch.

The availability and regular use of these reports must be ensured and reported by the internal audit function.

## **Chapter 18: Activities/ Services of the industry**

The activities covered under this sector, are broadly defined as Pharmaceutical activities. Practically, the activities covered in this sector can be broadly classified into following segments:

### **1. Manufacturing of Bulk Drug/ API:**

Over a period of time, China has emerged to be the cheapest source of Bulk drug/ API and many of the Chinese APIs are available at a price far below the cost of Indian manufacturers. This has given a rise to a trend, unlike all other industries, the cost of input materials are either stagnant or reducing year after year. Thus, a sizable number of APIs are no longer being manufactured in Indian resulting in huge idle time costs. Yet, many companies continue to manufacture some of the APIs to meet their in-house requirements. However, the concept of 1980s that every pharmaceutical company must manufacture API is gradually diluting.

### **2. Manufacturing of Formulations for sale:**

As it is evident from previous paragraph, the manufacturing of API is gradually becoming a part of history primarily due to a cheaper source of API from China. Thus, Indian pharmaceuticals have started concentrating their activities on formulations. With the creation of good manufacturing facilities, MNCs and Large Indian pharmaceutical houses alike have started outsourcing from support manufacturers. Today in market, there are many MNC pharmaceuticals outsourcing upto and in excess of 90% of their requirements; domestic as well as international.

### **3. Manufacturing for others:**

On loan License basis, that is, the principal will supply all the raw and packing materials and the company will convert them into Bulk Drug/ API or pharmaceutical formulations. This can be construed as labor jobs. In Pharmaceutical industry it is known as loan license activity meaning the principal has allowed his license to manufacture to this company to produce the same product under the same brand name. Loan license is duty bound to handover 100% of production to such principal.

There is one more way of producing for others. In such case, the support manufacturer will buy the requisite raw and packing material and manufacture and pack as per requirement of the principal. In such deal, the support manufacturer and principal deal with each other as independent principal to principal (P2P). In such cases, the Bulk Drugs / Formulations, as the case may be, are sold at a consolidated price to the principal.

- 4.** Manufacturing of Bulk Drug/ API and/ or Formulations in 100% Export Oriented Unit (100% EOU) or in Special Economic Zone (SEZ) with an intent to export.
- 5.** There are certain companies which outsource production activity either through Loan License or through P2P transaction. These companies are primarily marketing companies holding very good brand names and fully concentrate on marketing and distribution.



### *The Institute of Cost Accountants of India*

---

Over a period of time, India has emerged as a major manufacturing hub for pharmaceutical formulation to various countries world over. Several factories have come up in India, complying very stringent standards laid down in compliance of US FDA, UK MHRA (Medical and Healthcare Products Regulatory Agencies), Australian FDA, South African MHRA, European MHRA, WHO GMP etc. Hence, these companies can supply product to Indian Exporters exporting to those countries or to importer or distributors in those countries.

The cost structure of each such approval is different as manufacturing standards than the same set by Drug Controller General of India (DCGI) for setting up pharmaceutical factory in India. At present, by and large India is one of the cheapest sources of pharmaceutical products world over.

The manufacturing standards have continuously being revised upwards by DCGI making cost of companies substantially dynamic. For exports the packing standards also keep on getting revised providing further dynamism to cost structures.



## **Chapter 19: Audit of Operational Activities**

### **Input Material**

The following records needs to be checked for input materials:

- 1) Checking of Production plan showing production proposed month wise, scheduling of batches, machine allocation and utilisation, programme to increase capacity utilisation and productivity.
- 2) Checking of the time for preparatory, machine setting, change parts and testing etc, before production can be launched.
- 3) Checking of Procurement procedure including number of quotations/ tender desired.
- 4) Checking of procedure and controls for finalization and acceptance of quotation/tender after comparative analysis of quantity, quality, delivery period, credit period, excise duty, VAT, octroi and service tax implication as also supplier suitability/desirability.
- 5) Internal checks for receipt of material at factory gate.
- 6) Checking Record of receipts at gate.
- 7) Checking procedure for physical receipt and counting and weighing of material.
- 8) Checking procedure for testing, acceptance, rejection of material.
- 9) Checking procedure for returning of rejected materials.
- 10) Checking of procedure for Forwarding Material Receipt Note (MRN) and Test Report to Stores Dept. along with party's Challan, packing slip, Railway/Road Receipt and documents for octroi/ local body tax etc. Thereafter forward these documents to Accounts Dept. for payments,
- 11) Checking of Landed cost register showing:
  - a. Date of Receipt.
  - b. Material Receipt Note.
  - c. Supplier Code
  - d. Specification of material received.
  - e. Material code.
  - f. Purchased within country/ imported.
  - g. Quantity billed.
  - h. Quantity received.
  - i. Basic rate of material.

- j. Excise Duty rate and amount,
- k. VAT rate and amount,
- l. Transport cost.
- m. Transit insurance if paid by purchaser.
- n. Loading and unloading charges.
- o. Octroi duty/ local body tax (rate and amount);
- p. Total cost for domestic purchase.
- q. For import custom duty payable/ paid (rate and amount).
- r. Clearing and forwarding charges.
- s. Loading/ unloading charges.
- t. Local transport cost to factory.
- u. Loss in transit/ evaporation in quantity.
- v. Value of quantity rejected and returned.
- w. Net quantity received.
- x. Total cost (total and per Kg)
- y. Less credit for returnable containers
- z. Less Cenvat and VAT credit.
- aa. Net cost to company.
- bb. Cost per Kg/ unit item 'aa' divided by item 'w'.

**FORMAT FOR QUOTATION COMPARISON:**

To check whether the Company is using the previous format for landed cost register for comparing quotation and finding out the eligible lowest bidder (L1) or any other format.

**FORMAT FOR MATERIAL CONTROL SYSTEM:**

In Pharma industry, consumption of input have to be in line with standards, as the quantities of active pharma ingredient is predetermined and there cannot be even slightest variation. The variation in quantity can be only on account of:

- a. Purity of input materials, if material is 92 % pure compared to standard 95 % pure, it will require more input compared to predetermined. Internal Auditor must verify such excess consumption and report,
- b. Alternatively, another supplier supplies 97 % pure materials against standard specification of 95 %, the consumption may be less. This difference should be reported by Internal Auditors,

- c. Left over quantities of input materials specifically bought for an export order or a tender and there does not appear to be alternate use, in such cases.
- d. Yield of the batch is lower pushing up material and other costs.
- e. Evaporation/deterioration/wastage in stores due to extended storage,
- f. Recovery of solvent after manufacture of Bulk Drugs,
- g. To check procedure for checking the purity of inputs and methods for augmenting /fortifying API.

Efficiency of production can be adversely affected, if the batch size is reduced below effective size of batch as the startup time/cost and other costs will remain same, though the batch size has gone down.

### **Inventory Valuation:**

To check the method of inventory valuation and its impact on profitability of a particular accounting period.

It is evident that in Pharmaceutical industry, there are a large number of Formulations and few of them are produced every month. Depending on demand, the formulation may be manufactured every month or as and when required, once in 3 months, once in 5 months etc. This leads to 2 features namely; that though there will be repetition of production but it may or may not be next month or at a regular interval.

Hence, the conventional method of minimum quantity of stock cannot be applied without modification.

The effective control over quantity of materials would envisage checking of the following:

- The requirement of Bulk Drug/API for budgeted production during the next month.
- Minus Quantity held in stock.
- Minus quantity of API on order and expected during the month.
- Equal to quantity required to be purchased during the month.
- Excess quantity in stock (if any)
- Time frame within which, excess material in stock will be utilized for company's production.
- How many percent of total stock expected to be held at the end of current month is not likely to be utilized during next month.
- How much of stock not expected to be utilized in next 3 months.
- Any plan for disposal of such stock.
- Any packing materials lying in stock for formulation/s production of which is discontinued. Are these materials saleable?

- Is there any residual quantity of API lying unutilized for several months?
- Is there any item of WIP, which has not been converted into FG for over 1 month for which reasons may be not be listed
- Other issues:

The quantum for maximum stock, minimum stock, reordering level and economic ordering quantity are determined and followed on regular basis. The significant cash discount (3% to 5%) is available for cash payment for purchase of inputs, if yes check whether benefit for the same been taken by the company.

The material cost can be influenced by wastage and yield. In case of manufacturing Active Pharma Ingredient (API), if one wants to manufacture 200 to 300 kgs. of API, at times it is required to put in 10,000 to 12,000 liters of Solvents. These solvents just facilitate chemical reaction but do not get into the final API. After the batch is manufactured the Solvents are recovered from the mother liquor (residue of the batch). The recovery of such solvent could be in range of 80 to 90 % of input.

#### **CAPACITY UTILISATION:**

Manufacturing capacity in Pharmaceutical Industry has special features. This is one of the few industries, wherein investment in building and utilities is very high compared to investment in productive machines. Hence, one can expand capacity without significant capital investment in this industry, there are Companies which are willing to undertake production for payment of Conversion Charges both for domestic market as well as exports to regulated market. On the other hand, if a Company has spare capacity, it can accept manufacturing on behalf of other Company. The following points need to be taken by Internal Auditors for the purpose of assessing a pharmaceutical company's performance:

- Does the company have capacity constraint for any of its product line and if yes, does company outsource on Loan License (LL) basis.
- Are there instances that company has production capacity available within plant and yet the production of formulations is outsourced? If yes, justification for the same is made available or permission is obtained from higher ups.
- Are there set of machines like coating, the process of which is abandoned by company some time back and machines are lying idle and there are stores and spares lying in the Company.
- Is generation of utilities like power, steam, DM water, RO water, air conditioning, air compressor are efficient, and how many percentage of the capacity is utilised.
- Power factor.

The Cost Records will give information an exact number of machine hours required for manufacturing actual production of a period/ year. Installed capacity for such machine per shift is available in the

company as under:

**No. of machines x 250 days x 8 hours per shift/day**

And compare this with machine hours required for given production. If there is sizable difference between the two, the concept of idle time cost needs to be brought in, clearly specifying the machine hours available and machine hours utilized. In the Pharmaceutical industry, the cost of manufacturing machines like compression machine for tablets, capsule filling machine, liquid/ injection filling machine, powder filling machine constitute a small fraction of amount invested in creating manufacturing infrastructure. Hence, in many cases there are stand by machines, capacity of such machines needs to be excluded from total capacity. If there are different capacities machines like 16 station, 27 station, 45 station compression machine, 1 representative capacity needs to be ascertained say, 27 station compression and 45 station compression machine should be considered 1.67 station machine and 16 station machine should be considered 0.6 machine

It is necessary to ascertain whether effectiveness of each size of machine for different product is being ascertained and used for management decision making.

#### **MANPOWER:**

Even though certain activities such as packing and quality control continue to be manpower intensive, the industry average of manpower costs for medium and large scale units is about 3% to 4% of total turnover. When undertaking internal audit of manpower requirement and utilization during the year, the following need to be audited:

- What is the total requirement of manpower- skilled, semi-skilled, unskilled and helper/ own and contract labor for achieving given level of production
- Is employment of manpower close to budgeted manpower comparable to the production levels achieved
- What percent of manpower is met through contract labor
- What is the ratio between skilled and other labor.
- What is the output achieved against labor deployed. This analysis is based on annual and month wise data during current year. (For example, in Satyam, the manpower was added only in category of non-billable engineers leading to abuse of manpower resource)

#### **STOCK POLICY:**

In Pharmaceutical Industry, generally a Company markets hundreds of formulations and as it requires to be close to market, it may held at C & F Agents' place of Company's godown virtually in every state. Thus several products at many places multiply the cost of holding it. Hence, the following issues form part of Internal Audit programme:

- What is the estimated sale of each formulation/month and what is the stock level of finished goods;

- What is the expected time frame to liquidate the finished stock on hand at the end of the last month;
- What is the stock level in terms of month's sale with various C & F agents/ Depots;
- Does company have policy of shifting stock from location, where it moves slowly to a location, where movement is high to avoid expiry of formulations;
- What is the percentage of expiry, breakage, leakage of each formulation;
- Does company use any anti- counterfeit items to avoid duplication of product;

### **HOW IS PERFORMANCE OF MARKETING STAFF ASSESSED?**

The growth of Pharmaceutical Companies is based on growth in sales of the Company. But at the same time, it is important to analyse the product mix sold by the Company. Pharmaceutical Industry is growing at approximately 14 % per annum with rate of growth for different product groups. There are two Companies tracking movement in sale of each product group of all major Companies, whose analysis is taken as trend finder in Pharmaceutical industry.

Initially, Pharmaceutical Companies use to assess the performance of its Marketing Staff based on sales value only.

With Cost Accounting being effectively followed by the industry, the importance of contribution was realised and reporting moved from absolute sale value to Contribution generated by a field staff.

Today, the performance of a sales person is assessed on the following basis:

- Sales value generated only.
- Contribution (Sales Value – Variable Cost) generated.
- Effort on improving sales of high contributing formulations like medicine for cardiac, neurological and diabetics.
- Percentage of market share captured, compared to industry's growth.

The Internal Auditor should assess the performance of managers based on these and other relevant criteria.



## **Chapter 20: Audit of Special Areas with reference to peculiar transactions**

The following are the peculiar transactions and special features of Pharmaceutical Industry:

### **1. LOAN LICENCING:**

In case of Loan Licensing, the Raw Materials and Packing Materials are supplied by the principal and the same is converted by the support manufacturer into Formulations. A percent of Yield is agreed upon by both the parties and it is necessary to ensure that 100% of Quantity (of the agreed output) sent is either received back in form of finished product or debit note is raised on support manufacturer for the short fall. Detailed methods of working out requirement of Bulk Drug/API are required to produce the targeted quantum of output. Further Bulk Drug/Active Pharma Ingredient (API), the expensive input is generally available in pack of 25 kg. The batch size of the Formulation may require 20/22 kg then accounting of balance of quantity (25 - 22 kg) and recovery from support manufacturer will influence the overall profitability of the product.

On the other hand, generally there is an agreed percentage of yield. However, the underline condition is the actual production (even if it exceeds normative yield) will be required to be handed over to the principal, even if it is more than agreed yield. This point should be borne in mind when company is finalizing appointment of support manufacturer.

Other things being equal and product is not under Price Control, if it is outsourced from a Hilly State namely Himachal Pradesh, Uttarakhand, Jammu & Kashmir and Sikkim. The principal company can save in terms of Excise Duty minus Cenvat plus VAT.

However, procurement of Formulation subject to Price Control from Hilly State will not benefit the company as if the Excise Duty and VAT are not paid on Finished Goods, hence, the excise duty and VAT cannot be included in MRP of the final product. Hence, there will not be any Cenvat Credit for Excise Duty and VAT paid on input. The Cenvat Credit on the input material will be the net loss to the company.

In case of Loan License, it is always desirable that, there is substantial control over quantity of packing material required to be consumed and actually consumed because the checking will discourage the unauthorized use of Packing Material by unscrupulous support manufacturer.

A live example of what can happen is narrated hereunder:

A company placed an order of 100,000 plastic bottles of cough syrup from the support manufacturer and the agreed percentage of yield was 95%. Thus, the support manufacturer is required to deliver minimum 95,000 units, presuming manufacturing loss of 5 %, the support manufacturer will be able to manufacture 95000 units and it would require only 95000 empty plastic bottles. The crux here is, there can be wastage of Raw Material in process to the extent of 5%. The Packing Material required would be between 95000 and 96000 bottles and not 100,000 bottles. In most of the cases, damaged bottle could

be returned to the supplier of bottle, who will replace the bottles free of cost. When bottles are consumed more than output it may happen that remaining bottles not returned might have been filled in by the support manufacturer and sold in open market at full value.

## **2. QUANTITY SOLD ON BONUS/ DEAL/ FREE SCHEME:**

In pharmaceutical and FMGC industry bonus/ deal/ free scheme is very regular feature and companies keep on declaring bonus/ deal/ free scheme for different formulations month after month to promote sale of such formulations. On the other hand it is also mandatory for manufacturer to take back the product when it nears the expiry date. In such cases, it is utmost essential that the product supplied under bonus/ deal/ free scheme has an identification mark, so that at the time of giving credit on the returned product, the credit is not given to the trader only at the rate of the material given under deal scheme. Further, it is equally important to check the quantum of deal scheme to ensure that the scheme does not result in loss to the company.

### **Justification of bonus/ deal scheme/ discount:**

Deal scheme are offered to achieve genuine increase in quantity of sale of subject formulation. Generally, a justification note is submitting to higher ups highlighting benefit expected from the scheme. A typical scheme will work as under:

A company is selling 30000 strips of a formulation per month with anticipated 20% increase in sales on giving the scheme that for price of 10, company gives 11 packs. Thus the normal sale per year is 360,000 strips and the scheme will help sale to 36000 strips per month and 432,000 strips per year.

However, generally quantum goes up because traders pull forward purchases of future months till the cost of stock holding is less than the rate of scheme (10%) i.e.; value of money at expected rate. If one presumes that the trader values his funds @ 2.5% per month. It is very essential for Internal Auditor to find out what is the genuine increase due to this deal/bonus scheme.

The word Bonus/Deal/Free Scheme means that for a price of say 10 stripes the company will deliver 11 stripes. In other words the trader will benefit by 10%. The traders have very good sense of calculating their benefits, if he values his money at 2.5% per month he will buy his requirement for 4 months (i.e. 2.5% for 4 months = 10%).

In that case, if scheme is offered for Jan and Feb 2013 the trader will place order for four months at the end of Feb' 13. Hence, there will be no or negligible sale in March and April and lower than normal sale (30000 strips) in May and June. Audit question will be "has the company really gained market share and maximize profit for company by giving Deal Scheme.

As the trader is holding large quantity of medicines, he will try to sell more of this company's medicine and thereby the company may gain in terms of market share. The benefits need to be assessed by the company and only if it is beneficial, then the kind of scheme be allowed. These schemes have more implication that if trader is left with unsold quantity near expiry then the company will have to take it back. If it did not have the identification mark for the quantity sold under scheme than it may land up paying full price (instead of discounted price to such trader).



### *The Institute of Cost Accountants of India*

---

Deal Scheme, Bonus Scheme and free Scheme has virtually same meaning to people in Pharmaceutical Industry. However, the tax authorities interpret it differently. For example, a company announces a scheme that for every purchase of ten strips, eleven strips would be dispatched. In case of “Deal Scheme” and “Bonus Scheme”, there is no problem because the authorities interpret that for the price of ten, eleven strips are delivered, i.e. if the price per strip is INR10, then, eleven strips are dispatched for the aggregate value of INR100(INR9.11 per strip). However, in case of “Free Scheme” the authorities interpret that when ten strips are purchased, the eleventh strip is given “Free”, thus there is no sales realization for unit given free and therefore, there is no excise duty paid on it. If no excise duty is paid on sale, CENVAT credit on inputs cannot be claimed. Hence, the internal audit function must understand the risks related to using the words “Free Scheme” while conducting the internal audit of deal schemes.



## **Chapter 21: Audit of Functional Areas**

### **1. ADMINISTRATION DEPARTMENT:**

As it is evident from earlier Para, there are lots of activities both in production and technical department on one hand and marketing and distribution department on the other hand. The Administration function is very crucial because it is utmost necessary to coordinate efforts of both the set of functions namely, production and technical as well as marketing and distribution. Administration department is service center with primary objective of coordinating efforts among production, technical, marketing and distribution. In nutshell, administration has to coordinate the direction of effort between these departments. In layman's language one can say that it is job of administration department to ensure that the production department has to produce what can be sold effectively at a remunerative price and marketing department will sell what can be manufactured efficiently and at effective cost.

For example: the finance function is part of Administration and it has to judiciously make funds available for procuring raw material, funding production activity, holding WIP and Finished Goods and extending credit to customers and recover the money from them. Thus, it is a tight rope walking to ensure that every lac of rupee has to be deployed in such a way that all the functions take place without much adverse effect.

Further, an Integrated Business Plan (IBP) for long term is prepared and then it is broken down into smaller periods like year, quarter or month to achieve short term and long term goals and the same has to be monitored consistently. The overall performance of the company and setting up and achieving long term goal is the activities of Administration Department. As companies carry out operational audit of various functions it is equally important to carry out management audit of corporate level activities. The concept has not been readily accepted in the Indian scenario primarily because of control of business by their family or group of individuals. However, with professional management of the company it has become rule of the game, especially in fast growing Pharmaceutical Company. This kind of management audit is gaining importance primarily because the ownership and responsibility are separated.

### **2. MATERIAL MANAGEMENT:**

As discussed earlier the number of items to be purchased or procured and variety of combinations of procurement available in the market influence the function of material management. The company generally divides its input material into ABC Category. Generally, Bulk Drug/API are considered in A category which has small volume but substantially higher value and on the other hand the exceptions (the other material having very low cost) are required in larger quantity, it may be going to more than one product and has low value. To keep the procurement department efficient many pharmaceuticals companies invite tenders for C class and some of the B class items and sign rate contract for the whole year and the supplier will supply quantities as required from month to month.

**PROCUREMENT FROM HILLY STATES:**

The product from Hilly States plant may result in saving of excise duty and VAT and has substantial impact on cost structure of the product.

When company has invited quotation/tender from different parties, it is utmost essential to analyse comparative price considering all ingredients of landed cost. As per format given at the beginning of Chapter 16 (Landed Cost Register), further are 2 more points pertaining to material ordering and holding which should be practiced consistently.

**Format to clear a proposal for Purchase:**

Serial Number	Material Name	Material Code	Expected Requirement	Less: Free Stock	Less: Material on Order	Quantity to be purchased	EOQ (Economic Order Qty)
1	2	3	4	5	6	7	8

It is a must that all the columns are filled and no short cut is taken.

**Format for control over unnecessary Purchase:**

Serial Number	Material Name	Material Code	Quantity in stock	Expected Consumption in April	Expected Consumption in May	Expected Consumption in June	Others (Contingency)	Plan to clear current stock by:
1	2	3	4	5	6	7	8	9

When a company’s purchase department has to purchase several thousand types of Materials, it is advisable that the company gets into rate contract for C class items and one contract will ensure supply for several months. The same thing applies for some of the B class items also.

Sometimes, the company receives the export order or local tender for a formulation. Some quantity of inputs and Packing Material are left over after completion of the order. In pharmaceutical Industry for every input and finished Formulation, there is an expiry date, therefore utmost care should be taken in ensuring that the left over stock is NIL or negligible and such left over materials are disposed off at the earliest.

For comparison of Tender/Quotation/Bid the following format of quotation needs to be followed and the lowest eligible supplier needs to be identified. The term lowest eligible supplier pre-supposes following conditions:

- a) His goods are of acceptable quality.
- b) His technical and financial capacity is satisfactory to supply the size of order.
- c) He has financial capability to procure requisite Working Capital and execute the order within the time frame.

- d) The origin of such supplier may be given due weight-age, if his factory is located in Hilly Areas and enjoys excise and VAT exemptions or
- e) If the input material is volatile and transport appears to be dangerous as in case of sulphuric acids etc, then a supply from nearby manufacturer is more advisable.

When procurement is for a unit in SEZ, the supply may be preferred from 100% EOU or SEZ Unit to get the benefit of exemption available to EOU/SEZ.

### **3. STORES ACCOUNTING:**

It is necessary to check the method of valuation of issue of materials as only two methods are allowed under Income Tax namely First in First Out (FIFO) and Weighted Average Method. This rate should be factual rate and not predetermined rate for ERP/SAP System. In ERP/SAP language, it is called Moving Weighted Average. The Companies Act, and tax Authorities like Income Tax, Central Excise Duty, VAT, Sales Tax, Octroi/ Local Body Tax etc. always insist on actual value of the materials and will not accept standard or Pre-determined rates are not acceptable. Thus, if a company does not maintain accounts on actual basis, it has far reaching effects.

There should be detailed system to account for left over material, slow and non-moving material and unless these materials are likely to be utilized within forcible time, they should not be carried forward as the closing stock.

Due provision should be made for evaporation and deterioration in storage and only net quantities should be considered for carry forward.

When a pharma Company planning to enter a highly regulated market like USA, UK etc., it is necessary to manufacture full size batch for validation by concerned authority. Such validation batches are not allowed to be sold. Hence, it has no commercial value at the end of the year. Following the principle of “Cost or Market Value, whichever is less”, the value of such stock cannot be included in value of closing stock.

### **4. FINANCE AND ACCOUNTS DEPARTMENT:**

Finance is a crucial function and efficient management of the same can ensure efficient functioning of the unit. Clear cut plan for mobilization of funds or collection of trade debtors and deployment of resources for various functions of business is the function of Finance Dept. It is most important function as flow of liquidity from raw materials >> Work-in-process >> Finished Goods >> Receivables >> Cash.

Further, Finance Dept. in consultation with Marketing Dept. should fix credit limit for each stockiest and wholesaler. It may also exercise control over level of inventory. Fund Requirement for CAPEX and to ascertain the viability of CAPEX whether the projects under consideration meet the expected payback, fund flows and Internal Rate of Return (IRR).

### **5. MARKETING AND DISTRIBUTION:**

For Internal Audit of Marketing Function, it is utmost essential to start with the marketing budget for

the year because depending on the marketing budget the production procurement and distribution plan will be finalized and more importantly the effect of deviation from budget would be very crucial to control the operations.

The production plan for the company will always be based on marketing budget read with stock policy and deviations are monitored and production plan may be altered by adhering to following table:

Serial Number	Name of Product	Product Specification	Product Code	Expected sales in Next month	Add: Stock at end of month	Less: Stock at beginning of month	Quantity to be produced
1	2	3	4	5	6	7	8

Any excess production in a month should be monitored with a view to keep slow moving and non-moving stock at the lowest.

Same way the stock at Carrying and Forwarding Agent needs to be managed with following statement:

Serial Number	Name of Product	Product Specification	Product Code	Expected sales in Next month	Add: Stock at end of month	Less: Stock at beginning of month	Quantity to be supplied	Quantity to be Transferred
1	2	3	4	5	6	7	8	9

## 6. HRD AND PERSONNEL DEPARTMENT:

Pharmaceutical company is considered to be more dynamic than other industries because the option available on procurement and putting up facilities are wider than other industries. A large number of companies in Pharmaceutical Sector have gone to Hilly States and are marketing their products to several countries world over in addition to marketing its product in every state in India. In addition to this, new product ranges including specialty products are continuously introduced making it necessary to continuously assess the requirement of manpower in next quarter, in next year, for new plant or new marketing area in India and abroad and for R & D Activities. The manpower is a must to convert the projections and budgets into reality with the help of right kind of people, in right number, at right place. Thus, all plants and projections will materialize if right kind of manpower is mobilized more so for marketing efforts and timely replacement of people who leave the company. The company should avert loss of production, loss of market share or loss of opportunity for want of requisite right kind of people at right place.

## 7. IT DEPARTMENT:

Pharmaceutical companies on an average grow at the rate of 13%-14% per year and the requirement of data is increasing year after year to effectively manage the business and to grow faster than competitors. In such scenario, all good companies try to grow in each segment at a rate higher than industry's average and under such circumstances very effective and proactive IT Department is a must and the efforts of IT Department will go long way in converting the potential into business at an early



date and at a rate higher than industry average. The IT Department should either be capable of developing additional programs or augmenting data from additional systems or help assisting, generating additional data in requisite format and at requisite frequency.

**8. TRANSPORTATION:**

Generally large Pharmaceutical Companies like FMGC Companies sell their products to the length and breadth of the country and it is utmost necessary to ensure that almost all the products are available where company has promoted the product or is penetrating into the market. Under such circumstances, logistic and transport of medicine to the length and breadth of the country is a must and is key to success of marketing efforts.

**9. OTHERS:**

In Pharmaceutical Industry it is unwritten law like FMGC to keep a track not only of your company but effective planning and effort of the other company. Like when company creates additional production facility in Hilly States there has to be detailed planning of how manufacturing facility and manpower will be deployed at original location. What is the long term integrated business plan for next 5 years and 10 years and where do they expect company to be after 10 years, both in terms of volume and international presence.



## **Chapter 22: Cost Audit specific to the Industry**

Pharmaceutical sector, being a regulated industry, had always been under surveillance of Government from both the angle of quality of Bulk Drugs and Formulation supplied and price at which, the same is made available to public at large. Government wants to keep continuous watch over the cost and price of Bulk Drugs and Formulations to ensure accuracy of data and cost, Government of India for the first time promulgated “Cost Accounting Records (Bulk Drugs) Rules, 1976” and “Cost Accounting Records (Formulations) Rules, 1989” under Section 209 (1)d of the Companies Act, 1956. In year 2011, both these cost accounting records rules were superseded and consolidated into “Cost Accounting Records (Pharmaceutical Industry) Rules, 2011”. The Ministry of Corporate Affairs has notified new rules relating to cost records and cost audit on 30<sup>th</sup> June 2014. Vide Rule 3(B)(a)(vii), the companies engaged in “*Drugs and Pharmaceuticals*” are required to maintain the cost records and conduct the audit of these cost records as per the provisions of these rules.

Till year 2010, the Companies were covered under Cost Audit by specific order issued by Central Government to a Company. Later Ministry of Corporate Affairs, notified the Companies (Cost Audit Report) Rules, 2011 on 3<sup>rd</sup> June 2011 which were applicable to **all the companies including foreign company as defined under section 591 of the Companies Act, 1956 and engaged** in manufacturing Bulk Drugs and/or Formulations. The Ministry of Corporate Affairs, Government of India has again revised the above rules pursuant to provisions in the Companies Act 2013 relating to maintenance of cost records and cost audit vide Section 148(1) and (2). The revised Rules “**Companies (Cost Records and Audit) Rules 2014**” have been notified by Ministry of Corporate of Affairs on 30<sup>th</sup> June 2014. The provisions of these rules are as follows:

- i. **Application of cost records:** The Companies engaged in “*Drugs and Pharmaceuticals*” shall be required to maintain the cost records if the following thresholds limit are fulfilled:
  - (i) in the case of a multi-product or a multi services company (i.e. a company producing more than one product or service), any product or a service for which the individual turnover (from such specific product or such specific service) is rupees fifty crore or more;
  - (ii) in the case of a company, producing any one specific product or service, if the net worth of the company is rupees one hundred and fifty crore or more or the turnover is rupees twenty five crore or more.

The cost records are to be maintained in the **Form-CRA-1** of the said Rules by the companies on which these rules are applicable. **Extract** of Form-CRA-1 is given at **Annexure III**.

- (1) The gist of the details required to be maintained under Form CRA-1 by the companies are as follows:
  - (i) Input Material(s)/ Service(s)
  - (ii) Salaries and Wages

- (iii) Utilities
  - (iv) Service Department Expenses
  - (v) Repairs and Maintenance
  - (vi) Fixed Assets, Depreciation and Lease Charges
  - (vii) Overheads
  - (viii) Royalty and Technical Knowhow
  - (ix) Research & Development Expenses
  - (x) Quality Control Expenses
  - (xi) Work-in-Progress and Finished Stock
  - (xii) Captive Consumption
  - (xiii) By-Products
  - (xiv) Joints Products/ Services
  - (xv) Packing Expenses
  - (xvi) Interest and Other Borrowing Costs
  - (xvii) Expenses or Incentives on Exports
  - (xviii) Pollution Control
  - (xix) Production Records
  - (xx) Sales Records
  - (xxi) Any other Items of cost
  - (xxii) Adjustment of cost variances
  - (xxiii) Cost Statements
  - (xxiv) Reconciliation of Cost and Financial Accounts
  - (xxv) Statistical Reports
  - (xxvi) Records of Physical Verifications
  - (xxvii) Related Party Transactions
- (2) The cost records referred to in sub-rule (1) shall be maintained on regular basis in such manner as to facilitate calculation of per unit cost of production or cost of operations, cost of sales and margin for each of its products and activities for every financial year on monthly or quarterly or half-yearly or annual basis.
- (3) The cost records shall be maintained in such manner so as to enable the company to exercise, as far as possible, control over the various operations and costs to achieve optimum



economies in utilisation of resources and these records shall also provide necessary data which is required to be furnished under these rules.

- ii. **Cost Audit :** The Companies engaged in “*Drugs and Pharmaceuticals*” shall be required to conduct the cost audit of the records so maintained if the following thresholds limit are fulfilled:
- (1) In the case of a multi-product or a multi services company, the requirement for cost audit shall apply to a product or a service for which the individual turnover (from such specific product or such specific service) is rupees one hundred crore or more;
  - (2) the case of a company producing any one specific product or service, the requirement for cost audit shall apply if the net worth of the company is rupees five hundred crore or more or the turnover from such product or such service is rupees one hundred crore or more.
- iii. **Cost Audit Report:** Every cost auditor, who conducts an audit of the cost records of a company, shall submit the cost audit report along with his or its reservations or qualifications or observations or suggestions, if any, in **form CRA-3** along with Annexure to the Cost Audit Report as prescribed ***under Companies (Cost Records and Audit) Rules 2014***.

Twenty Four Annexures have been prescribed under the rules. The following are the Annexures:

1. General Information
2. Cost Accounting Policy
3. Process of Manufacture of Good(s)/Delivery of Service(s)
4. Good(s)/Service(s) Details (For the company as a whole)
5. Quantitative Information for Each Good(S)/Service(S) separately
6. Details of the major input materials/service used for good(s) manufactured/service(s) rendered under reference
- 6(A). Standard/ Actual Consumption of Input Material(S)/Service(S) Per Unit
- 6(B). Break-Up of Cost of Input Material(S)/Service(S) imported during the Year
7. Utilities
8. Salaries and wages – for the good(s)/service(s) covered (For company as a whole)
9. Repairs and Maintenance (For company as a whole)
10. Net fixed assets and depreciation (For company as a whole)
11. Net block, depreciation and lease rent (For good(s)/ service(s) covered)
12. Overheads (For company as a whole)



13. Research and development expenses
  14. Royalty and Technical Know-how Charges
  15. Abnormal/Non-Recurring Cost
  16. Non-Moving Stock (good-wise/ service-wise details of non-moving stock may be provided)
  17. Written Off Stock /Forfeited Services (good-wise/ service-wise details may be provided)
  18. Inventory Valuation (at the end of the year)
  19. Sales/Revenue of the good(s)/service(s) covered
  20. Margin per Unit of Output/service rendered
  21. Related Party Transaction
  22. Central Excise/Service Tax Reconciliation for the Good(s)/service(s) under reference
  23. Profit Reconciliation
  24. Cost Statement (for each good(s)/service(s) separately
- iv. **Submission of Cost Audit Report to Central Government:** Every company covered under these rules shall, within a period of thirty days from the date of receipt of a copy of the cost audit report, furnish the Central Government with such report alongwith full information and explanation on every reservation or qualification contained therein, in **form CRA-4** alongwith fees specified in the Companies (Registration Offices and Fees) Rules, 2014.
- v. **Exemption of certain companies from applicability of Rules:** The requirement for cost audit under these rules shall not be applicable to the following companies:
- (i) whose revenue from exports, in foreign exchange, exceeds seventy five per cent of its total revenue or
  - (ii) which is operating from a special economic zone.



## **Chapter 23: Audit follow-up**

Once the Internal audit has been completed and the internal audit report has been discussed and submitted to the Audit Committee and/or management, a list of findings, recommendations and prescribed actions are compiled with specific timelines for completion clearly indicating the manager responsible and for longer projects, the various crash-gates to be followed and periodicity of the interim report. It is the duty of the internal audit function to establish a follow-up process that helps the management to ensure whether or not the recommended actions have been effectively implemented or has the management accepted the risk of not taking the requisite action. An annual review and Report of Outstanding Audit Comments has to be adopted by the Internal Audit function to meet the needs of the management and to be complied with the follow-up requirement noted above.

To facilitate the follow-up process, Internal Audit function maintains a database of outstanding audit comments. This database tracks identifying information about each Internal Audit report or close-out letter along with a summary of each finding in the report or letter, the manager responsible for taking corrective action, and the estimated completion date for corrective action. Audit comments issued by external audit groups should be loaded into the database when they are received. The database will also track, whether or not a deficiency/ short coming has been corrected, what was done to correct the issue, whether corrective actions should be tested, and the date corrective action was complete.

In most cases, follow-up reviews will be done jointly by the head of internal audit team and the management. However, if requested by management, follow-up on the status of selected findings in a separate review may be presented on a more frequent basis. Also as time is available during the year, inquiries about and status of previously issued findings may also be reviewed. Approximately 3 to 4 weeks before the annual follow-up is scheduled to begin, the completeness of the Findings database is compared to list of pending issues. If any reports have not been entered into the database, have the internal audit function must complete the report and findings forms and have this information added to the database. Once the database is confirmed as being current, the queries and report programs that are used to create reports shall also be updated.

The head of Internal Audit team should prepare a memorandum for the management that notifies them that the internal audit activities are underway and describes the follow-up process. This memo should include:

- timeframes for the project,
- a copy of the outstanding findings relating to areas reporting to the manager responsible,
- a request that they distribute the findings to these areas and ask the managers to provide Internal Audit team with the information requested,
- a statement that these comments were previously distributed as part of an audit report or close-out letter, and
- notification that the results will be reported to the management.

The notification memo should be sent to each functional head along with the status of internal audit findings for each finding related to the function's areas of responsibility.

As the findings status are updated and returned to Internal Audit team, the information should be reviewed for reasonableness, completeness and adequacy. The internal audit team, with the approval of the functional heads, shall determine which of the responses need to be tested and what level of testing is appropriate. Working papers and work programs should be generated and reviewed as with any other audit project.

At the conclusion of the test work and after updating the Findings database, reports of outstanding or closed findings and a cover letter of explanation should be generated and distributed to the following groups allowing approximately 2 weeks for each group to review and respond:

- Functional Heads – also receives list of report of Corrected Findings
- Functional Directors
- Audit Committee
- Executive Management
- Board of Directors

After each of these groups has reviewed the reports and any necessary corrections to the database have been made, the final versions of the Outstanding Findings report, the Repeat Findings report, and, if necessary, the Closed Findings report should be produced for the management and issued.

Generally, the agenda for monthly meetings is finalized by considering issues arising out of Internal Audit Report. The Internal Audit Report needs to be discussed at monthly meeting and areas requiring attention are zeroed down. The functional Managers are assigned task arising out of this report, line of action is worked out and a senior manager is directed to supervise the task entrusted. When the task is complete and situation is brought under control or project is accomplished, final action taken report is submitted to monthly meeting and higher ups. The comment owner or designee should give written communication to the Internal Auditor, upon completion of corrective action in response to an internal audit finding. In the event corrective action has not been completed by the established target completion date, the comment owner should provide a written communication to the Internal Auditor on the status of corrective action, circumstances or reasons that have prevented the completion of corrective action, and specify a revised target date by which corrective action will be completed.

Management should complete corrective action measures in response to reported external audit findings in a timely and reasonable manner. The Internal Auditor is typically requested to act as the co-coordinator of remedial efforts between management and external auditors. In such a case, the comment owner or designee should give written communication to the Internal Auditor upon completion of corrective action in response to an external audit finding. In the event corrective action has not been completed by the established target completion date, the comment owner should provide a written communication to the Internal Auditor a progress report on the status of corrective action, circumstances or reasons that have prevented the completion of corrective action, and specify a revised target date by which corrective action will be completed.

## **Chapter 24: Checklist**

A general list of records required to be checked to validate process of undertaking Internal Audit of a pharmaceutical organisation is as under:

- Quantity, Rate and Value of the receipts, issues and stocks of each item of Raw Materials, Process, Packing and other materials;
- Quantity, Rate and Value of the receipts, issues and stocks of each item of Raw and Process Materials recovered;
- Quantity, Rate and Value of the receipts, issues and stocks of each item of Stores & Spares;
- Details of Man Power Cost including number of persons employed, Man-days available, Man-days worked, loss of man days due to absenteeism and other stoppages as also payment to employees;
- Details of item wise production, dispatches and stock of each variety of bulk drugs and formulations manufactured by the Company;
- Calculation of installed capacity and utilized capacity on the basis of expected/actual product mix for the year;
- Details of standard input (Inputs with Overages + expected manufacturing losses) for one batch of each product;
- Break up of cost of imported materials;
- Details of quantity, rate and value of Power, Gas and Diesel for Gen Set and Furnace Oil purchased, generated and consumed;
- Details of Repairs and Maintenance for Land & Building, Plant & Machinery and others showing capitalization, if any;
- The Company maintains records with respect to fixed assets and the same is in the process of being compiled cost-center wise;
- Details of Depreciation charged in Profit & Loss Account of the Company and allocation and apportionment to various cost centers on pre-determined basis;
- Details of collection, allocation, apportionment and of overheads to each cost center including details of overheads excluded on idle capacity; absorption;
- Method of working out idle time of machines and other productive assets and cost thereof with method of treating the same.
- Details of Research and Development and Quality Control cost incurred;
- Details of Physical verification of stock, method of valuation, details of non-moving stock and right of stock;

- Details of quantity, rate and value of product wise sales;
- Details of cost of sales, sales value and margin on each major product;
- Financial position and Ratio Analysis;
- Capitalization of Revenue Expenses and its charging in subsequent years;
- Related Party Transactions with Holding Company, Fellow Subsidiary, Associate Companies, Subsidiary Company, Joint Venture, Individuals or its relatives having controlled or significant influences from voting power and method of arriving at Transfer Price;
- Key Management Personnel and his/her relatives;
- Enterprise controlled / influenced by Key Management Personnel;
- Reconciliation of production and clearance for Excise, Cenvat Credit, Reconciliation of Excise duty paid and recovered and reconciliation of Sales Turnover as per finance and assessable value;
- Reconciliation of sales both from Factory and C & F agents and VAT or Sales Tax payable thereon. VAT Credit, Reconciliation of VAT / Sales Tax payable/paid; Reconciliation of Sales Turnover as per finance and assessable value;
- Reconciliation of Profit between Financial Accounts and Cost Accounts;
- Cost sheets for production and sales of each product;
- Details of Advanced Licenses procured, Obligation for export there under, last date for fulfillment of obligation and obligation outstanding as at the end of the year. Extension, if any, obtained for fulfillment and last date for fulfillment as per extension order. Details of payment made to Customs Authority for such extension.
- Vouchers and details of travels by marketing staff, distant chart and tariff by rail / road / other transport.
- Bills for hotel Stay, time to check in and check out, location confirmation for each town/ village /area etc. This is facilitated by mobile phone billing.
- The projects assigned to Info Tech Departments and right prices, progress on each one of the project, log book for each IT engineer for jobs attended to as it is maintained in IT Companies.
- To ascertain whether is it possible that finished goods are dispatched by the same truck, in which raw and packing materials and stores are received, especially in case of factories in hilly states.
- The details of deal scheme / bonus scheme / free scheme needs to be verified to ensure that the benefit derived from such scheme is not diluted or nullified because of high variable cost of inputs.



# **ANNEXURE**

संख्या सं० सी० अ०-33004/99

REGD. NO. D. L.-33004/99

  
**भारत का राजपत्र**  
**The Gazette of India**

असाधारण  
EXTRAORDINARY  
भाग I—खण्ड 1  
PART I—Section 1  
प्रधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं० 275] नई दिल्ली, शुक्रवार, दिसम्बर 7, 2012/अग्रहायणा 16, 1934  
No. 275] NEW DELHI, FRIDAY, DECEMBER 7, 2012/AGRAHAYANA 16, 1934

रसायन एवं उर्वरक मंत्रालय  
( औषधि विभाग )  
अधिसूचना  
नई दिल्ली, 7 दिसम्बर, 2012

विषय: राष्ट्रीय औषधि मूल्य निर्धारण नीति, 2012 ( एनपीपी-2012 )

1. प्रस्तावना और पृष्ठभूमि

फा. सं. 31011/16/2012-पीआई-II.— 1.1 भारतीय औषधि उद्योग ज्ञान, कौशल, न्यून लागत उत्पादन तथा अंतर्राष्ट्रीय गुणवत्ता उत्पादों के लिए जाना जाता है और वर्ष 1990 में इसका कुल उत्पादन लगभग 5,000/- करोड़ रूपए मूल्य का था जो वर्ष 2008-10 में बढ़कर एक लाख करोड़ रूपए मूल्य से भी अधिक का हो गया है जिसमें घरेलू बाजार का लगभग 62.055 करोड़ रूपए का उत्पादन और 42.154 करोड़ रूपए के निर्यात शामिल हैं। मात्रा की दृष्टि से यह उद्योग विश्व में दहाइवों का तीसरा सबसे बड़ा उत्पादक उद्योग है तथा मूल्य की दृष्टि से विश्व में इसका 14वां स्थान है। निम्नतर मूल्य इस तथ्य के कारण है कि भारतीय उत्पादों विरुद्ध सबसे कम मूल्य वाली बाइयो हैं। तथापि, इसके बावजूद देश में चिकित्सा बरिधियों पर लागू व्यय में बाइयो की कीमत महत्वपूर्ण घटक बना हुआ है।

1.2 चीनी आक्रमण के बाद औषधि (मूल्य प्रदर्शन) आदेश, 1982 तथा औषधि (कीमत नियंत्रण) आदेश 1963 के प्रस्तावना के परिणामतः देश में औषधियों पर पहली बार मूल्य नियंत्रण प्रणाली लागू की गई। ये आदेश भारत सुप्रीम अदालत के अतीत प्रख्यापित किए गए थे। इन आदेशों के परिणामतः औषधियों के मूल्य 1 अप्रैल, 1983 से स्थिर हो गए। इसके बाद देश में विभिन्न सिद्धांतों के आधार पर समग्र-समग्र एवं कई मूल्य नियंत्रण प्रणालियां विभिन्न आदेशों के जरिए अधिसूचित की गईं जिनमें मूल्य के निर्धारण की अदमि और मूल्य के निर्धारण का संसद संशोधित औषधि नीतियों के अनुसार आदेश-दर-आदेश अलग-अलग था। ये क्रमशः औषधि कीमत (नियंत्रण) आदेश 1988, औषधि कीमत (नियंत्रण) आदेश, 1970 के दिन्हें आपश्चक वस्तु अधिनियम, 1955 के अतीत औषधियों को आपश्चक वस्तु घोषित करके आपश्चक वस्तु अधिनियम, 1955 के अतीत जारी किया गया था।

4530 GI/2012

(1)

## **NATIONAL PHARMACEUTICALS PRICING POLICY, 2012 (NPPP-2012)**

### **1. PREAMBLE AND BACKGROUND**

- 1.1 The Indian pharmaceutical Industry, driven by knowledge, skills, low production costs and international quality products has witnessed a robust growth from the production turnover of about Rs. 5000 crores in 1990 to over Rs1 lakh crore in 2009-10 comprising about Rs, 62,055 crores of domestic market and Rs. 42,154 crores of exports. It is, globally, the 3rd largest producer of medicines by volume yet 14th in terms of value. The lower value is due to the fact that Indian medicines are amongst the lowest priced in the world. However, despite this medicine costs continue to be an important component in the overall medicare expenditure in the country.
- 1.2 Price control over drugs was first introduced in the country in the aftermath of the Chinese aggression with the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. These were promulgated under the Defence of India Act. With these orders, the prices of drugs were frozen w.e.f. the 1st April, 1963. Thereafter, a series of price control regimes were notified through various Orders in the country from time to time based on different principles, in which the span of control of prices as well as the nature of control of prices varied from Order to Order as per the disposition of the respective Drug Policies. These were the Drugs (Prices Control) Order of 1966, the Drugs (Prices Control) Order of 1970 - issued under the "Essential Commodities Act 1955 by declaring drugs to be essential commodities under the EC Act, 1955. Thereafter the Drugs (Prices Control) Order of 1979 and Drugs (Prices Control) Order, 1987 were issued following the declaration of Drug Policy, 1978 and Drug Policy 1986. All these Policies were broadly based on the principle of effecting control over prices of essential drugs and later bulk drugs, as well as availability of drugs while at the same time attending to the requirements of the indigenous industry for growth cost effective production, innovation and strengthening of capacity.
- 1.3 The present Drug Policy of 1994, as implemented through the Drugs (Prices Control) Order, 1995 was introduced in the context of the liberalization of economy and the abolishment of industrial licensing, as well as allowing of foreign investment in the country, including in the drug industry. The principle for price control broadly adopted in this policy represented a radical departure from the earlier policies. This envisaged control over prices of drugs on the basis of economic criteria as represented in the market share of different companies in the context of total market sales turnover of various drugs. Thus, those drugs were brought under the ambit of price control, where the company turnover was of a particular level and where the market share of leading producers was beyond a particular level. The control over prices was to be on the basis of the cost of production with allowance being given for post production expenses. As per the criteria of 1994 Policy, a list of 74 bulk drugs was identified and these drugs as well as the formulations based on these drugs (currently about 1577 in number) were brought under the price control regime. Certain exceptions such as for small scale units, drugs produced through indigenous research and development, etc were envisaged for exemption under the Policy.

1.3.1 In the year 2000, further liberalization in the economy was effected, in light of which, Foreign Direct Investment (FDI) in the pharmaceutical sector was brought in the automatic route and the limit raised upto 100%. Following this, a new pharmaceutical pricing policy was introduced in the year 2002 which further liberalized the span of control over pricing. The turnover limit for purposes of price control was raised from Rs. 4.00 crores to Rs. 25.00 crores and the parameters of market share were also relaxed further. All drugs where unit price did not exceed Rs. 2.00 were also excluded from the ambit of price control. There were also exemptions given for drugs developed through indigenous R&D, New Delivery Systems etc. The 2002 Drug Policy was, however, challenged in the Karnataka High Court, which by order dated 12.11.2002 issued stay on the implementation of this Policy. This order was challenged by the Government in the Supreme Court which vacated the stay vide its order dated 10.03.2003 but observed as under:

*“we suspend the operation of the order to the extent it directs that the Policy dated 15.2.2002 shall not be implemented. However we direct that the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of the price control and further directed to review drugs, which are essential and life saving in nature till 2nd May, 2003”.*

1.3.2 In the light of the order of the Supreme Court, it was decided that a fresh Pharmaceutical Pricing Policy be formulated and accordingly, the 2002 Drug Policy was never implemented and the 1994 Drug Policy continued to be applicable and continues till date.

1.4 Meanwhile, in accordance with the guidelines of the Supreme Court above, the Ministry of Health & Family Welfare revised the List of medicines in the National List of Essential Medicines (NLEM) earlier notified in 1996. The revised list was notified as NLEM, 2003. In November 2004, the Government also set up a Task Force under the Chairmanship of Principal Advisor, Planning Commission, Dr. Pronab Sen to look into the issue of price control options other than price control and other issues and to make recommendations for making available life saving drugs at reasonable prices. The basis of drugs to be considered was the NLEM, 2003, being the latest list at that time. The Pronab Sen Committee submitted its recommendations in September, 2005. The revision in the existing policy of pricing of pharmaceutical products has been under consideration at different levels. In the meanwhile, in 2011 the Ministry of Health & Family Welfare revised the NLEM and notified the new NLEM, 2011. It may be noted that various drug policies adopted from time to time have tried to cope up with the challenge of striking a balance between the at times varying requirements of enabling industry to grow and at the same time ensuring affordable and reasonably priced medicines to the consumers, particularly the poorer masses. This balancing of diverse and conflicting interests is indeed a difficult task, as is the reconciling of short term interests with long term goals and concerns.

1.5 The Government is therefore seized with the goal of enabling industry growth with attendant socio-economic benefits along with balancing the declared objective of providing better health care including making available essential medicines at reasonable prices to all. The Drug Policy, 1994 needs to be revised to meet the challenges brought about by the competitive international

pharmaceutical industry in a globalised economic environment, as much as meeting the country's requirements for safe and quality medicines at reasonable prices. Therefore, the Government hereby enunciates the National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) which seeks to replace the Drug Policy enunciated in September, 1994 as "Modifications in Drug Policy, 1986" (Drug Policy 1994). The NPPP-2012 is in continuation of the Policy announced earlier in 1994.

1.6 The National Pharmaceuticals Pricing Policy 2012 presently seeks to limit itself to the central objective of promulgating the principles for pricing of Essential Drugs as laid down in the "National List of Essential Medicines – 2011 which was declared by the Ministry of Health and Family Welfare, Government of India vide communication No.12-01/essential medicines/08-DC/DFQC, dated 8th June, 2011.

1.7 Other related and required steps for promoting growth of the Pharmaceutical Industry as well as development of new drugs including patented drugs, along with institutional mechanisms for better access to healthcare in the context of availability of medicines in general, would be formulated separately through a wholistic policy and thereafter adopted by the Government after due consultative process.

## **2. OBJECTIVES OF THE PRESENT POLICY**

As stated above in its present form, the Drug Policy of 1994 needs to be modified in the context of changed global environment for industry as well required changes in the mechanism to make available essential medicines to the masses. The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all. The reasons are further elaborated later in the Policy Document.

## **3. KEY PRINCIPLES OF NATIONAL PHARMACEUTICALS PRICING POLICY 2012**

The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012 are:

- (1) Essentiality of Drugs
- (2) Control of Formulations prices only
- (3) Market Based Pricing

3.1 The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of **essentiality of drugs**. This is different from the **economic criteria/market share principle** adopted in the Drug Policy of 1994. The reasons for the adoption of the principle of "**Essentiality**" as a key criteria are:

- (i) The "Essentiality" criteria for drugs under the NPPP-2012 is to be met by considering the List of medicines specified in the National List of Essential Medicines as revised from time to time and most recently declared by the Ministry of Health and Family Welfare, Government of India.

- (ii) The NLEM has been prepared by an Expert Core Committee constituted by the Director General of Health Services (DGHS) out of the WHO model list of essential medicines, Essential Drugs Lists of various States, medicines used in various National Health Programmes and Emergency Care Drugs.
- (iii) The NLEM contains such medicines that satisfy the priority health needs of the country's population.
- (iv) The NLEM medicines are required to be made available within the context of a functioning health system at all times in adequate quantities in the appropriate dosage forms to serve large public masses.
- (v) The Hon'ble Supreme Court in its Order dated 10.03.2003 in SLP No. 3668/2003 (Union of India Vs. K.S. Gopinath and others) has also emphasized the need to "..... consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control....."
- (vi) The current principle of economic/market share criteria needs to be changed now, given the fact that out of the 348 medicines listed in the NLEM-2011, only 34 drugs are included amongst the 74 drugs listed in the First Schedule of "The Drugs (Prices Control) Order, 1995 (DPCO 1995).

3.2 The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be **on the basis of regulating the prices of formulations only**. This is different from the earlier principle of regulating the prices of specified Bulk Drugs and their formulations adopted in the Drug Policy 1994. The reasons for adoption of this principle of price control of "**Formulations Only**" are:

- (i) That the Bulk Drug - API (Active Pharmaceutical Ingredient) - may not fully reflect the 'Essentiality' of the actual drug formulation – now the subject of focus - due to the possible applicability of the API in manufacture of various formulations which may or may not be considered "Essential" for the larger healthcare needs of the masses.
- (ii) The emphasis on price control starting at the bulk drug stage itself has in recent times, resulted in amongst other reasons shifting of manufacture of drugs away from the notified bulk drugs under price control. In fact only 47 bulk drugs out of the 74 notified in the First Schedule of the DPCO, 1995 are now under production. This has had a cascading effect on the formulations manufactured from the concerned bulk drugs which in turn has affected the availability of such formulations. The consumer-patient has been adversely affected in the process.
- (iii) The task of pricing both the bulk drug and the formulation makes it complicated and time consuming without commensurate direct benefits to the consumer who is actually affected only by the price of the final end product, i.e., the formulation - made from the bulk drug rather than its bulk constituents.
- (iv) The price control in the form of formulations only ensures more specific pricing control of the required medicine which is in the interest of the consumer from the point of view of the actual

prescription by the Doctor. This aspect is more important for a country like India where there is large asymmetry in the information between the doctor and the patient.

- (v) Since the bulk drug manufacturer is constrained to sell at a fixed price, the manufacturer is always likely to give preference to an existing buyer rather than to a potential new entrant. This constrains the emergence of new companies and formulations in the price-controlled segment and is inherently anti-competitive and also does not benefit the consumer-patient for the same reason.

3.3 The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of regulating the prices of formulations through **Market Based Pricing (MBP)**. This is different from the earlier principle of regulating the prices through Cost Based Pricing (CBP) under the Drug Policy 1994. The reasons for adoption of this principle are:

- (i) Under Cost Based Pricing, the prices of drugs have to be calculated in detail every year which requires a complex variety of data. For this, the manufacturers are required to provide their pricing data in an extremely detailed manner which is intrusive and so highly resisted by the individual manufacturers resulting in possible manipulation and time delay of provision of the base costing data. This also makes it difficult to properly check the data provided by individual manufacturers in a timely and adequate manner. Additionally the data can vary in terms of production cost depending on technologies used for production.
- (ii) Under Market Based Pricing, the pricing would be based on widely available information in the public domain as against individual manufacturer level production costing data which would result in more transparent and fair pricing.
- (iii) Under Cost Based Pricing as the controlled prices of formulations of a particular API are determined on a “lowest common denominator” basis, they tend to be clustered within a narrow band. This allows virtually no space for a new entrant to come in at an uncovered price point. As a result, production activity and competition in the product segment tend to stagnate. This is neither good to the consumer-patient nor for industry growth.
- (iv) The Indian economy is today largely market-driven and, particularly in the area of pricing of manufactured products, prices are determined by market conditions and market forces. Administered prices exist in a few areas, such as pricing of petroleum products and procurement prices of food-grains but these are closely connected with a regime of subsidies paid by the Government. To determine the price on the basis of costing, particularly where the inputs prices themselves are not subject to any form of price control and are determined in the open market by market forces, would indeed be anomalous and would, in the medium and long term, lead to severe distortions, particularly in the product-mix and investment patterns in the industry and there could be a serious possibility of production moving out of controlled drugs into non-controlled drugs. As indicated in para 3.2(ii) above, this has, amongst others, been a factor in the shifting of manufacture away from bulk drugs notified under the DPCO, 1995. This would have serious implications for the availability of NLEM medicines in the future and for the growth and structure of the pharmaceutical industry as a whole. Further the

resultant implications of this on the growth and innovation may also impact the industry's ability to invest in enhancing its capabilities to capture the export potential likely to open up on account of the almost US\$ 300 billion worth of drugs (including biological drugs) falling off patent in the US and other western countries upto 2015. In the new policy, where Ceiling Prices will be fixed, there would be ample space for manufacturers to position themselves in an appropriate price band below the Ceiling Price thereby also retain competition in the market.

- (v) Since the prices fixed of all drugs (bulk & formulations) under the existing DPCO are envisaged to be frozen for one year in the policy with increases allowed up to WPI, the impact of the policy will be an additional impact.

#### **4. PRINCIPLES FOR DRUGS PRICE CONTROL AND DETERMINATION IN NPPP-2012**

- (i) Price regulation would be on the basis of 'Essentiality' of the drug as laid down in the "National List of Essential Medicines - 2011" declared by the Ministry of Health and Family Welfare, and modified time to time, in public interest under Drug Price Control Order.
- (ii) Price regulation would be applied only to formulations, i.e. the medicine actually used by the consumers, and not to any upstream products such as bulk drugs and intermediates.
- (iii) The Span of Price Control shall be as per the dosages and strengths as listed in NLEM- 2011.
- (iv) The methodology of fixing a ceiling price of NLEM medicines, by adopting the Simple Average Price of all the brands having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine, will be as per the formula below:

**(Sum of prices of all the brands of the medicine having market share more than and equal to 1% of the total market turnover of that medicine) / (Total number of manufacturers producing such brands of the medicine)**

- (v) The formulations will be priced only by fixing a Ceiling Price (CP). Manufacturers would be free to fix any price for their products equal to or below the CP. The CP's would be fixed on the dosage basis, such as per tablet / capsule / standard injection volume as listed in NLEM-2011.
- (vi) The Ceiling Price will be fixed on the basis of readily monitorable Market Based Data (MBD). To begin with, the basis for this readily monitorable market data would be the data available with the pharmaceuticals market data specializing company – IMS Health (IMS). Wherever required this data would be checked by appropriate survey/ evaluation by the National Pharmaceutical Pricing Authority (NPPA). As the IMS data gives price figures for stockist level prices hence in order to arrive at ceiling Price (which will be the maximum retail price), the IMS price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers.
- (vii) For drugs not in the IMS data, NPPA would collect data by commissioning the same.

- (viii) For the medicines where there is no reduction of price due to absence of competition, the overall percentage reduction in the price of same molecule with other dosage and strength will be applied; otherwise the overall percentage reduction in the price of medicines in the same therapeutic category will be applied.
- (ix) The CP for a drug listed in the NLEM would be the Simple Average of Prices as calculated on the basis of IMS data six months prior to the date of announcement of the new National Pharmaceutical Pricing Policy i.e. the “Appointed Date” for bringing the new Policy into effect. For a drug whose data is not available in IMS, the NPPA will commission the data within a reasonable time for determining the Simple Average Prices also on the basis of prices prevailing six months prior to the Appointed Date. Thus the Simple Average Prices data date for the drugs available in IMS data and collected by NPPA would be same. Once the Simple Average Price is fixed, NPPA would monitor its implementation on a continuous basis through a proper methodology and system.
- (x) The prices of these NLEM-2011 medicines will be allowed an annual increase as per the Wholesale Price Index as notified by the Department of Industrial Policy & Promotion. It is proposed to fix the 1st April of every year as the reference date for this. Accordingly, on 1st April of every year, companies will be automatically authorized to revise their prices upto the limit of the increase in the Wholesale Price Index for the previous year. In case of decline in Wholesale Price Index, a corresponding reduction in the ceiling price will be obligatory. The NPPA itself will also separately notify the revised ceiling prices as applicable as on the 1st of April each year, and in case any company has fixed the prices not consistent with the revised ceiling prices, the NPPA will take appropriate action to have these revised.
- (xi) The Simple Average Price of all the brands of the medicine having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine - the Reference Prices for calculation of Simple Average Price - may also change on an annual basis due to changes in the MAT value. However, there would be no annual revision of Ceiling Prices on the basis of MAT. Revision of Ceiling Prices on the basis of MAT value would be carried out only once in five years or as and when NLEM is updated/revised. However, the Government will revise the ceiling price of a medicine under NLEM, if there is a significant change in the market structure of the particular medicine even in between 5 years.
- (xii) Non-price Control Drugs: Under the existing price control regime, the prices of Non-Scheduled drugs are monitored, and in case the prices of such drugs increase by more than 10% in a year, subject to certain criteria, government fixes the prices of such medicines from time to time. In the proposed policy, all essential drugs are under price control. It would follow that non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces. However, in order to keep a check on overall drug prices, it is proposed that prices of such drugs be monitored on regular basis, and where such price increase at a rate of above 10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit, for next 12 months.

- (xiii) Imported Drugs: The Ceiling Prices determined for drugs falling under the span of control as in 4(iv) above shall also be applicable to such drugs that are imported. There will be no separate determination of Ceiling Prices for imported drugs falling under the span of control.
- (xiv) Overlap drugs between DPCO 1995 and NLEM-2011: The prices of medicines which are a part of DPCO 1995 but not in NLEM-2011 would be frozen for one year and thereafter a maximum increase of 10% per annum, as in case of other non-NLEM medicines will be allowed.
- (xv) Patented Drugs: There is a separate Committee constituted by the Government order dated 1st February, 2007 for finalizing the pricing of Patented Drugs, and decisions on pricing of patented drugs would be taken based on the recommendations of the Committee.
- (xvi) Exemptions: To promote innovation and R&D following drugs will be kept out of any type of price control:
  - (a) A manufacturer producing a new drug patented under the Indian Patent Act, 1970 (product patent) and not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period of 5 years from the date of commencement of its commercial production in the country.
  - (b) A manufacturer producing a drug in the country by a new process developed through indigenous R&D and patented under the Indian patent Act, 1970, (process patent) would be eligible for exemption from price control in respect of that drug for a period of 5 years from the date of the commencement of its commercial production in the country.
  - (c) A formulation involving a new delivery system developed through indigenous R&D would be eligible for exemption from price control for a period of 5 years from the date of its market approval in India. The certification of innovation and R&D may be provided by the office of Drug Controller General of India (DCGI).
- (xvii) The revision of NLEM for the purpose of price control is a dynamic process and any drug can be added in NLEM in public interest under Drug Price Control Order on the recommendation of Ministry of Health and Family Welfare.
- (xviii) The production levels, availability and accessibility to the NLEM drugs and formulations should not fall after price control is introduced and the Department of Pharmaceuticals will ensure that production levels are maintained by an appropriate mechanism. If a manufacturer of a NLEM drug with dosages and strengths as specific in NLEM, launches a new drug by combining the NLEM drug with another NLEM drug or a non-NLEM drug or by changing the strength and dosages of the same NLEM drug, such manufacturers shall be required to seek price approval from the Government before launching the new drug.
- (xix) Ministry of Health and Family Welfare will consider making prescription of drugs by generics names mandatory.
- (xx) The distribution of quality affordable generics drugs through Jan Aushadhi Stores will be strengthened.

## **5. ESSENTIAL ISSUES FOR THE IMPLEMENTATION OF THE POLICY:**

Control over drug prices can be only one element of an overall strategy for provision of affordable healthcare. The existence of a vibrant, competitive, innovative drug industry would be an equally important part of such a strategy. In addition to this, such a strategy would have to incorporate programs of affordable healthcare to a majority of the population, either through direct Government healthcare programs or insurance linked programs, and an overarching Pharma Control Policy, as part of the system of provision of affordable healthcare to the public at large, would also have to address several related issues. Some of these are:

- (i) Provision of direct healthcare to citizens by expanding healthcare cover through the State healthcare system, in combination with an insurance cover based healthcare system.
- (ii) Improvement of access to drugs for specialized treatment (anti-cancer, anti-HIV etc) through special assistance scheme for subsidizing the prices of such drugs, especially for BPL and APL families.
- (iii) Streamlining of the system of procurement of drugs by the Government for ensuring procurement of quality drugs at reasonable prices. This would apply in all Government procurement, both by the Central Government, States, PSUs. In fact, a strong and transparent drug purchase policy for bulk procurement of drugs by the government would also help in determining reasonable Ceiling Prices for NLEM drugs under the Pharmaceutical Pricing Policy, in future.
- (iv) Promotion of non-branded generic drugs and low cost drugs by creating a well spread out low-cost pharmacy chain through the Jan Aushadhi Program, so that the last mile reach of essential drugs are accessible and affordable to every village/town in the country.
- (v) As per the recommendations of the High Level Expert Group Report on Universal Health Coverage for India submitted to the Planning Commission in October, 2011, strengthening of Pharmaceutical Central Public Sector Enterprises is essential to play a major role in benchmarking the prices and play a role in stabilizing the market forces and enable access to medicines. Further, the CPSUs may be mandated for producing such essential medicines as determined by the Government as per the requirement from time to time. The CPSUs need to be further strengthened by bringing them under the Drug Procurement System through preferential allocation of such requirement under the Public Healthcare System.
- (vi) Education of the public in general as well as Medical fraternity, and making it obligatory for Doctors to also prescribe non-branded generics along with branded generics.
- (vii) Implementation of special schemes for providing accessibility of drugs to low income families, especially BPL families.
- (viii) Setting up of drug banks.
- (ix) Taking up measures for strengthening of the pharmaceutical industry in the following areas:
  - (a) Strengthening and rationalizing the drug regulatory system.

- (b) Bringing on a common platform all the regulatory authorities related to drug standards, bio-pharmaceuticals, clinical trials and Pharmacopeia.
- (c) Promotion of research and development in the pharmaceutical sector, directly through research institutions and universities, as well as through provision of seed capital, venture capital funding and subsidies to innovative drug companies.
- (d) Enablement of domestic pharmaceutical companies to achieve international GMP/GLP and GCP standards.
- (e) Development of Human Resource, particularly in critical areas to meet the requirements of pharmaceutical industries.
- (f) Rationalization of excise duties on pharmaceuticals.
- (g) Setting up of common infrastructure through pharma development parks, pharma cluster schemes in order to strengthen and facilitate the smaller units in the pharmaceutical industries.
- (h) Rationalization of pharma retail trade and strengthening of pharma supply chains.

5.1 All these issues require detailed consultation and cooperation of all other Departments of the Government, and the Department of Pharmaceuticals will take steps to initiate a wholistic policy on Pharmaceutical Sector in due course. To the present context, the National Pharmaceuticals Policy will be limited to the aspect of the Pricing within the domain of National Pharmaceuticals Pricing Policy- 2012.

## **6. IMPLEMENTATION:**

A new Drugs (Price Control) Order would be notified as soon as possible after the Notification of the New Policy. The National Pharmaceuticals Pricing Authority will be the implementation authority for the new Policy and the new Drugs (Prices Control) Order. The NPPA would be provided required organizational and financial support so as to enable it to implement the new Policy in an effective, speedy and transparent manner. In due course, however, the DPCO, which is presently mandated under the Essential Commodities Act, would be replaced by specific legislation covering the issue of price control and monitoring of drugs, which would be fine tuned to the requirements of the drugs regulatory regime.

-----

**MINISTRY OF CHEMICALS AND FERTILIZERS****(Department of Pharmaceuticals)****ORDER**

New Delhi, the 15th May, 2013

**S.O. 1221(E).**—In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955, (10 of 1955), and supersession of the Drug (Prices Control) Order, 1995, except as respect to things done or omitted to be done before such supersession, the Central Government hereby makes the following Order, namely:-

**1. Short title and commencement.**— (1) This Order may be called the Drugs (Prices Control) Order, 2013.

(2) It shall come into force on the date of its publication in the Official Gazette.

**2. Definitions.**— (1) In this Order, unless the context otherwise requires,—

- (a) "**Act**" means the Essential Commodity Act, 1955 (10 of 1955);
- (b) "**active pharmaceutical ingredients or bulk drug**" means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is used as such or as an ingredient in any formulation;
- (c) "**brand**" means a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers;
- (d) "**ceiling price**" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order;
- (e) "**dealer**" means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and includes his agent;
- (f) "**distributor**" means a person engaged in the work of distribution of drugs and includes an agent or a stockist for stocking drugs for sale to a dealer;
- (g) "**existing manufacturer**" means manufacturer existing on the date of publication of this order in the Official Gazette.
- (h) "**Form**" means a form specified in the Second Schedule;
- (i) "**formulation**" means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include —
- (i) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;
- (ii) any medicine included in the Homeopathic system of medicine; and
- (iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;
- (j) "**generic version of a medicine**" means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name;
- (k) "**Government**" means the Central Government;
- (l) "**import**" with its grammatical variations and cognate expressions means bringing a drug into India from a place outside India for its sale;
- (m) "**local taxes**" means any tax or levy (except excise or import duty included in retail price) paid or payable to the Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer;
- (n) "**manufacturer**" for the purpose of this Order means any person who manufactures, imports and markets drugs for distribution or sale in the country;
- (o) "**market share**" means the ratio of domestic sales value (on the basis of moving annual turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of the all brands and generic versions of that medicine sold in the domestic market having same strength and dosage form;
- (p) "**margin to retailer**" for the purposes of this Order shall mean a percentage of price to retailer;
- (q) "**market based data**" means the data of sales related to a drug collected or obtained by the Government as deemed fit, from time to time;



**Drugs (Prices Control) Order, 2013**  
Extraordinary, Part II, Section 3, Sub-section(ii) dated 15<sup>th</sup> May 2013  
Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

Dated 15<sup>th</sup> May, 2013  
New Delhi  
**25 Vaisakha Saka 1935**

**ORDER**

**S.O. 1221(E).**— In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955, (10 of 1955), and supersession of the Drug (Prices Control) Order, 1995, except as respect to things done or omitted to be done before such supersession, the Central Government hereby makes the following Order, namely:—

**1. Short title and commencement.**— (1) This Order may be called the Drugs (Prices Control) Order, 2013.

(2) It shall come into force on the date of its publication in the Official Gazette.

**2. Definitions.**— (1) In this Order, unless the context otherwise requires,—

(a) **“Act”** means the Essential Commodity Act, 1955 (10 of 1955);

(b) **“active pharmaceutical ingredients or bulk drug”** means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is used as such or as an ingredient in any formulation;

(c) **“brand”** means a name, term, design, symbol, trademark or any other feature that identifies one seller’s drug as distinct from those of other sellers;

(d) **“ceiling price”** means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order;

(e) **“dealer”** means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and includes his agent;

(f) **“distributor”** means a person engaged in the work of distribution of drugs and includes an agent or a stockist for stocking drugs for sale to a dealer;

(g) **“existing manufacturer”** means manufacturer existing on the date of publication of this order in the Official Gazette.

(h) **“Form”** means a form specified in the Second Schedule;

(i) **“formulation”** means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include —

(i) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb)

- systems of medicines;
- (ii) any medicine included in the Homeopathic system of medicine; and
- (iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;
- (j) **“generic version of a medicine”** means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name;
- (k) **“Government”** means the Central Government;
- (l) **“import”** with its grammatical variations and cognate expressions means bringing a drug into India from a place outside India for its sale;
- (m) **“local taxes”** means any tax or levy (except excise or import duty included in retail price) paid or payable to the Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer;
- (n) **“manufacturer”** for the purpose of this Order means any person who manufactures, imports and markets drugs for distribution or sale in the country;
- (o) **“market share”** means the ratio of domestic sales value (on the basis of moving annual turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of the all brands and generic versions of that medicine sold in the domestic market having same strength and dosage form;
- (p) **“margin to retailer”** for the purposes of this Order shall mean a percentage of price to retailer;
- (q) **“market based data”** means the data of sales related to a drug collected or obtained by the Government as deemed fit, from time to time;
- (r) **“maximum retail price”** means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack;
- (s) **“moving annual turnover”** in a particular month means cumulative sales value for twelve months in domestic market, where the sales value of that month is added and the corresponding sales of the same month in the previous year are subtracted;
- (t) **“National List of Essential Medicines”** means National List of Essential Medicines, 2011 published by the Ministry of Health and Family Welfare as updated or revised from time to time and included in the first schedule of this order by the Government through a notification in the Official Gazette;
- (u) **“new drug”** for the purposes of this Order shall mean a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines.

- (v) "**non-scheduled formulation**" means a formulation, the dosage and strengths of which are not specified in the First Schedule;
- (w) "**pharmacoeconomics**" means a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another;
- (x) "**price list**" means a price list referred to in paragraphs 24 and 25 and includes a supplementary price list;
- (y) "**price to retailer**" means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes;
- (z) "**retail price**" means the price fixed by the Government for a new drug under paragraph 5 ;
- (za) "**retailer**" means a dealer carrying on the retail business of sale of drugs to customers;
- (zb) "**scheduled formulation**" means any formulation, included in the First Schedule whether referred to by generic versions or brand name;
- (zc) "**schedule**" means a Schedule appended to this Order;
- (zd) "**wholesaler**" means a dealer or his agent or a stockist engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency;
- (ze) "**wholesale price index**" means annual wholesale price index of all commodities as announced by the Department of Industrial Policy and Promotion, Government of India, from time to time.

All other words and expressions used herein and not defined but defined in the Act or the Drugs and Cosmetics Act, 1940 (23 of 1940) shall have the meanings respectively assigned to them in the said Acts.

**3. Directions to manufacturers of active pharmaceutical ingredients or bulk drugs or formulations.– The Government may, -**

- (i) with a view to achieve adequate availability and to regulate the distribution of drugs, in case of emergency or in circumstances of urgency or in case of non-commercial use in public interest, direct any manufacturer of any active pharmaceutical ingredient or bulk drug or formulation to increase the production and to sell such active pharmaceutical ingredient or bulk drug to such other manufacturer(s) of formulations and to direct formulators to sell the formulations to institutions, hospitals or any agency as the case may be;
- (ii) for the purpose of giving any direction under sub-paragraph (i), call for such information from manufacturers of active pharmaceutical ingredients or bulk drugs or formulations, as it may consider necessary and such manufacturer shall furnish the required information within such time the Government may fix.

**4. Calculation of ceiling price of a scheduled formulation.– (1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:**

**Step1.** First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:

**Average Price to Retailer, P(s)** = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

**Step2.** Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:

$$P(c) = P(s).(1+M/100), \text{ where}$$

P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.

M = % Margin to retailer and its value =16

(2) The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also.

**5. Calculation of retail price of a new drug for existing manufacturers of scheduled formulations.**– (1) The retail price of the new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4.

(2) (i) the price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of “Pharmacoeconomics” of the new drug, on the recommendation of a Standing Committee of Experts formed under paragraph 15.

(ii) the retail price of such new drug shall be fixed by adding sixteen percent margin to retailer on the price to retailer as fixed in item (i):

**6. Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition.**– (1) where the average price to retailer of a scheduled formulation, arrived at as per the formula specified in sub-paragraph (1) of paragraph 4, has the effect of,-

(a) no reduction in average price to retailer with respect to the prices to retailer of the schedule formulation; and

(b) there are less than five manufacturers for that formulation having one percent or more market share, the ceiling price shall be calculated as under:-

(i) in the event of other strengths or dosage forms of the same scheduled formulation is available in the list of scheduled formulation, the average price to retailer shall be calculated as under:

**Step1:** First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

$$P(s) = P_m \{1 - (P_{i1} + P_{i2} + \dots) / (N * 100)\} \text{ Where,}$$

**P<sub>m</sub>** = Price to Retailer of highest priced scheduled formulation under consideration.

**P<sub>i</sub>** = % reduction in Average Price to Retailer of other strengths and dosage forms (calculated as in step1 of sub-paragraph (1) of paragraph 4) in the list of schedule formulations w.r.t the highest priced formulation taken for calculating the average price to retailer of such strengths and dosage forms.

**N** = Number of such other strengths or dosage forms or both in the list of schedule formulations

**Step2.** Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

$$P(c) = P(s) \cdot (1 + M/100), \text{ where}$$

**P(s)** = Average Price to Retailer of the scheduled formulation as calculated in step1 hereinabove and

**M** = % Margin to retailer and its value=16

(ii) in the event of other strengths or dosage forms of the scheduled formulation is not available in the schedule but there are other scheduled formulations in same sub- therapeutic category as that of the scheduled formulation, then the Ceiling Price shall be calculated as under:

**Step1:** First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

$$P(s) = P_m \{1 - (P_{i1} + P_{i2} + \dots) / (N * 100)\}, \text{ Where,}$$

**P<sub>m</sub>** = Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration.

**P<sub>i</sub>** = % reduction in Average Price to Retailer of other schedule formulations (calculated as in step1 of sub-paragraph (1) of paragraph 4) in same sub-therapeutic category as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer.

**N** = Number of such other schedule formulations in same sub-therapeutic category as that of the scheduled formulation under consideration.

**Step2.** Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

$$P(c) = P(s) \cdot (1 + M/100), \text{ where}$$

**P(s)** = Average Price to Retailer of the scheduled formulation as calculated in step1 above and

**M** = % Margin to retailer and its value=16

*Explanation.*- where the scheduled formulation under consideration is coming under more than one sub-therapeutic category, the Average Price to Retailer of the scheduled formulation shall be calculated after taking into consideration the percentage reduction in Average Price to Retailer of other schedule formulations under all such sub-therapeutic categories and the lowest average price to retailer shall be taken for calculating the ceiling price of the scheduled formulation under consideration;

(iii) in case the other strengths or dosage forms of the scheduled formulation are not available in the schedule and there is no sub therapeutic category of the scheduled under consideration, the ceiling price shall be calculated as under:

**Step1:** First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

$$P(s) = P_m \{1 - (P_i1 + P_i2 + \dots) / (N * 100)\} \text{ Where,}$$

**P<sub>m</sub>** = Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration.

**P<sub>i</sub>** = % reduction in Average Price to Retailer of other schedule formulations (calculated as in step1 sub-paragraph (1) of paragraph 4) in same therapeutic category as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer.

**N** = Number of such other schedule formulations in same therapeutic category as that of the scheduled formulation under consideration.

**Step2.** Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

$$P(c) = P(s) \cdot (1 + M/100), \text{ where}$$

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step1 above and

M = % Margin to retailer and its value=16

*Explanation.*- where the scheduled formulation under consideration is coming under more than one therapeutic category, the Average Price to Retailer of the scheduled formulation shall be calculated after taking into consideration the percentage reduction in Average Price to Retailer of other schedule formulations under all such therapeutic categories and the lowest average price to retailer shall be taken for calculating the ceiling price of the scheduled formulation under consideration.

(2) Notwithstanding anything contained in this paragraph, where the price has been fixed and notified by the Government under the Drugs (Prices Control) Order, 1995 the provisions of sub-paragraph (1) shall not apply.

**7. Margin to retailer.**– While fixing a ceiling price of scheduled formulations and retail prices of

new drugs, sixteen percent of price to retailer as a margin to retailer shall be allowed.

**8. Maximum retail price.**– (1) The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under:

**Maximum Retail Price = Ceiling price + Local Taxes as applicable**

(2) The maximum retail price of a new drug shall be fixed by the manufacturers on the basis of retail price determined by the Government plus local taxes wherever applicable, as under:

**Maximum Retail Price = Retail Price + Local Taxes as applicable**

**9. Reference data and source of market based data.**– (1) Initially, the source of market based data shall be the data available with the pharmaceuticals market data specializing company – IMS Health (IMS) and if the Government deems necessary, it may validate such data by appropriate survey or evaluation.

(2) The Government may in the due course of time come out with other appropriate mechanism of collecting or obtaining the market based data related to drugs and the decision of Government with respect to collection or obtaining of data shall be final.

(3) The market based data, for fixing the ceiling price of scheduled formulations for the first time after the notification of this order, shall be the data of May, 2012.

(4) The market based data for fixing the retail price of new drugs available in the market, shall be the data available for the month ending immediately before six months of receipt of application for fixing the price of the new drug.

(5) The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six month of notification of revision in the first schedule.

(6) Notwithstanding anything contained in this order, the reference date for the formulations which are part of the Drugs (Prices Control) Order, 1995 shall be as per the provisions of paragraph 10 of this Order.

**10. Pricing of the formulations covered under Drugs (Prices Control) Order, 1995.**– (1) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of the said order, up to 31<sup>st</sup> May, 2012, shall remain effective for further one year i.e. up to 30<sup>th</sup> May' 2013 and the manufacturers may revise the prices of such scheduled formulations as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and thereafter the formula as in sub- paragraph (1) of paragraph 4 of this

Order shall be applied for fixing the ceiling prices of such formulations.

(2) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of Drugs (Prices

Control) Order, 1995 after 31<sup>st</sup> May, 2012, shall remain effective for one year from the date of notification of such prices under Drugs (Prices Control) Order, 1995 and immediately thereafter the manufacturers may revise the prices as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and on the 1<sup>st</sup> April of succeeding financial year, the formula as in sub-paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such schedule formulations.

(3) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, up to 31<sup>st</sup> May 2012, shall remain effective for further one year i.e. up to the 30<sup>th</sup> May'2013 and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order.

(4) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, after 31<sup>st</sup> May 2012, shall remain effective for one year from the date of notification of such prices and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order.

**11. Ceiling price or retail price of a pack.**– (1) The average price to retailer calculated as per the provisions in paragraphs 4, 5 and 6 shall be on the dosage basis, (per tablet, per capsule or injection in volume as listed in first schedule) and the ceiling price or retail price of a pack shall be reached by multiplying the same with the number or quantity in the pack as the case may be.

(2) In the event of the unit of the dosage for a scheduled formulation not available in the first schedule, the lowest pack size for that category of medicine, as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder, shall be taken as unit dosage for calculating the ceiling price or retail price as the case may be, for that scheduled formulation and this shall be applicable while calculating the per unit price of even non-scheduled medicines for arriving at the retail price in case of paragraph 5.

**12. Price of formulations (branded or generic version) listed in the National List of Essential Medicines, launched by a manufacturer**– (1) A manufacturer, launching a scheduled formulation, shall be free to fix the price of the scheduled formulation equal to or below the ceiling price fixed for that schedule formulation by the Government.

(2) Where an existing brand is re-launched by another manufacturer the provisions of paragraph 13 shall be applicable.

**13. Price of scheduled formulations for the existing manufacturers.**– (1) All the existing manufactures of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price (plus local taxes as applicable):

Provided, that in case of scheduled formulations produced or available in the market before the date

of notification of ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price of such scheduled formulation does not exceed the ceiling price (plus local taxes as applicable).

(2) All the existing manufactures of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price lower than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government shall maintain their existing maximum retail price.

(3) Annual increase in maximum retail price may be carried out as per the increase in the wholesale price index with respect to previous year as per the provision of sub-paragraphs (2) and (3) of paragraph 16.

Provided that in case of decline in wholesale price index, a corresponding reduction in the prices shall be made as per the provision of sub-paragraph (4) of paragraph 16.

**14. Fixation of ceiling price of scheduled formulations.**– (1) The Government shall fix and notify the ceiling prices of the scheduled formulations in accordance with the provisions of the paragraphs 4 and 6, as the case may be, and no manufacturer shall sell the scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government.

(2) Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the Government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging.

**15. Fixation of retail price of a new drug for existing manufacturers of scheduled formulations.**– (1) The Government shall form a Standing Committee of such Experts, as it may deem fit, within sixty days of notification of this order with a view to recommend the retail prices of new drugs on the principles of “Pharmacoeconomics”.

(2) Where an existing manufacturer of a drug with dosages and strengths as specified in National List of Essential Medicines launches a new drug, such existing manufacturers shall apply for prior price approval of such new drug from the Government in Form-I specified under Schedule-II of this Order.

(3) On receipt of the application under sub-paragraph (2), in the event of the new drug available in domestic market, the Government shall fix the retail price of the new drug in accordance with the provision of sub-paragraph(1) of paragraph 5 and in the event of the new drug not available in domestic market, the Government shall forward the same to the Standing Committee of Experts who shall examine the application on the principles of “Pharmacoeconomics” and make recommendations of retail price of the new drug to the Government within thirty days of the receipt of application.

(4) The Government shall, on receipt of recommendation under sub-paragraph (3), within thirty

days, fix the retail price of such new drug and such price shall be applicable to such applicant of such new drug.

(5) Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the Government, if any, along with interest thereon from the date of launch of the new drug, in addition to the penalty.

(6) No existing manufacturer of a scheduled formulation shall sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government for such new drug and in case such a manufacturer is found to sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government, such manufacturer of the new drug shall be liable to deposit the overcharged amount along with interest from the date of overcharge, in addition to the penalty.

**16. Revision of ceiling price of scheduled formulations.**— (1) The Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar year on or before 1<sup>st</sup> April of every year and notify the same on the 1<sup>st</sup> day of April every year.

(2) The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required.

(3) Information about the revision, if carried out, shall be forwarded to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision and non-submission of information under this sub-paragraph shall be construed as non revision of maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised maximum retail price (MRP), alongwith interest thereon from the date of overcharging.

(4) In case of decline in wholesale price index, there shall be a corresponding reduction in the maximum retail price and in case of scheduled formulations produced or available in the market before the date of notification of revised ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price (MRP) of such scheduled formulation does not exceed the revised ceiling price (plus local taxes as applicable) and information about the revision shall be sent to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision.

(5) Non-submission of information under the sub-paragraph (4) shall be construed as non-reduction in maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the maximum retail price revised based on decline in wholesale price index, alongwith interest thereon as overcharged amount from the date of overcharging.

**17. Amendment of the list of scheduled formulation.**— (1) A decision to amend the first schedule, clearly stating the reasons thereof, shall be taken by the Government within sixty days

of receipt of communication from the Ministry of Health and Family Welfare and the amendment(s) or revision, if required, in the first schedule shall be notified and thereafter, the ceiling price(s) for the medicine(s) added in the first schedule shall be fixed as per the provisions of this order within a period of sixty days from the date of the notification.

(2) The medicines omitted from the first schedule shall fall under the category of non-scheduled formulations.

**18. Revision of ceiling price on the basis of moving annual turnover (MAT).-** The revision of ceiling prices on the basis of moving annual turnover value shall be carried out,-

(i) as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier;

(ii) when the number of manufacturers of a scheduled formulation, having price of a scheduled formulation more than or equal to seventy five percent of the ceiling price fixed and notified by the Government, has decreased by twenty five percent or more than the number of manufacturers as existing on the reference date;

(iii) when the number of manufacturers of a scheduled formulation, having prices of their scheduled formulation equal to or lower than twenty five percent of the ceiling price fixed by the Government, has increased by twenty five percent or more than the number of manufacturers as existing on the reference date.

*Explanation.-* For the purpose of items (ii) and (iii) the “reference date” shall be for first revision of ceiling price May, 2012 and for second or subsequent revision the date of previous revision of the ceiling price.

**19. Fixation of ceiling price of a drug under certain circumstances.-** Notwithstanding anything contained in this order, the Government may, in case of extra-ordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any Drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year.

**20. Monitoring the prices of non-scheduled formulations.-** (1) The Government shall monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months.

(2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty.

**21. Monitoring the availability of scheduled formulations.-** (1) The Government shall monitor the

production and availability of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation and the manufacturer of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation shall furnish the information as stated in Form-III of schedule-II of this Order quarterly.

(2) Any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market shall issue a public notice and also intimate the Government in Form-IV of schedule-II of this order in this regard at least six month prior to the intended date of discontinuation and the Government may, in public interest, direct the manufacturer of the scheduled formulation to continue with required level of production or import for a period not exceeding one year, from the intended date of such discontinuation within a period of sixty days of receipt of such intimation.

**22. Recovery of dues accrued under the Drugs (Prices Control) Order, 1979 and to deposit the same into the Drugs Prices Equalisation Account.**– (1) Notwithstanding anything contained in this order, the Government may by notice, require a manufacturer, importer or distributor as the case may be, to deposit the amount which has accrued under the provisions of the Drugs (Prices Control) Order, 1979 on or before the commencement of this order, into the Drugs Prices Equalisation Account and the manufacturer, importer or distributor, as the case may be, shall deposit the said amount into the said account within such time as the Government may specify in the said notice.

(2) The existing amount, if any, in the Drugs Prices Equalisation Account on or before the date of commencement of this Order, and the amount deposited under sub-paragraph (1) shall be utilised for;-

(a) paying to the manufacturer, importer or distributor, as the case may be, the shortfall between his retention price and the common selling price or, as the case may be, the pooled price for the purpose of increasing the production, or securing the equitable distribution and availability at fair prices, of drugs;

(b) meeting the expenses incurred by the Government in discharging the functions under this paragraph; and

(c) promoting higher education and research in Pharmaceutical Sciences and Technology and for the purposes incidental thereto.

**23. Recovery of overcharged amount under Drugs Prices Control Orders 1987 and 1995.**– Notwithstanding anything contained in this order, the Government shall by notice, require the manufacturers, importer or distributor or as the case may be, to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under the provisions of Drugs (Prices Control) Order, 1987 and Drugs (Prices Control) Order, 1995 under the provisions of this Order.

**24. Carrying into effect the price fixed or revised by the Government, its display and proof thereof.**– (1) For all the scheduled formulations having maximum retail price (MRP) higher than ceiling price (plus local taxes as applicable), the manufactures shall revise the maximum retail price

(MRP) not exceeding the ceiling price (plus local taxes as applicable):

Provided that in case of scheduled formulations produced or available in the market before the date of notification of ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of the notification that the maximum retail price of such scheduled formulation does not exceed the ceiling price (plus local taxes as applicable).

(2) Every manufacturer of a schedule formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the maximum retail price of that formulation based on the ceiling price notified in the Official Gazette or ordered by the Government in this behalf with the words "Maximum Retail Price" preceding it and the words 'inclusive of all taxes' succeeding it.

Every manufacturer shall issue a price list and supplementary price list, if required, in Form V to the dealers, State Drugs Controllers and the Government indicating reference to such price fixation or revision as covered by the order or Gazette notification issued by the Government, from time to time.

(3) Every retailer and dealer shall display the price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

**25. Display of prices of non-scheduled formulations and price list thereof.**– (1) Every manufacturer of a non-Scheduled formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the maximum retail price of that formulation with the words "Maximum Retail Price" preceding it and the words 'inclusive of all taxes' succeeding it.

(2) Every manufacturer shall issue a price list and supplementary price list, if required, of the non-Scheduled formulations in Form-V to the dealers, State Drugs Controllers and the Government indicating changes, from time to time.

(3) Every retailer and dealer shall display the price list and the supplementary price list, if any, as furnished by the manufacturer or importer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

**26. Control of sale prices of formulations.**– No person shall sell any formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less.

**27. Sale of split quantities of formulations.**– No dealer shall sell loose quantity of any formulation at a price which exceeds the pro-rata price of the formulation.

**28. Manufacturer, distributor or dealer not to refuse sale of drug.**– Subject to the provisions of the Drug and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder, -

(a) no manufacturer or distributor shall withhold from sale or refuse to sell to a dealer any

drug without good and sufficient reasons;

(b) no dealer shall withhold from sale or refuse to sell any drug available with him to a customer intending to purchase such drug.

**29. Maintenance of records and production thereof for inspection.**— Every manufacturer shall maintain records relating to the sales of individual active pharmaceutical ingredients or bulk drugs manufactured or imported and marketed by him, as the case may be, and the sales of formulations units and packs and also such other records as may be directed from time to time by the Government and the Government shall have the power to call for any record and to inspect such records at the premises of the manufacturer.

**30. Power of entry, search and seizure.**— (1) Any Gazetted Officer of the Central Government or of a State Government, as the case may be, authorised by a general or special order by the Central Government or by the State Government, as the case may be, in this behalf may, with a view to securing compliance with this Order or to satisfy himself that the provision of this Order have been complied with—

- (a) enter and search any place;
- (b) seize any drug, alongwith the containers, packages or coverings in which the drug is found, in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened, and thereafter take all measures necessary for securing production of the drug, containers, packages or coverings, so seized, in a court of law and for their safe custody pending such production;
- (c) seize any document, such as, cash memo or credit memo books, books of account and records of purchase and sale of the drugs in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened.

(2) The provisions of Code of Criminal Procedure, 1973 (2 of 1974), relating to search and seizure shall, so far as may be, apply to searches and seizures under this Order.

**31. Power to review.**— Any person aggrieved by any notification issued or order made under paragraphs 4, 5 and 6 of this Order, may apply to the Government for a review of the notification or order within a period of thirty days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as the case may be, and the Government may make such order on the application as it may deem proper:

Provided that pending a decision by the Government on the application submitted under the above paragraph, no manufacturer shall sell a scheduled formulation or a new drug, as the case may be, at a price exceeding the ceiling price or retail price, as the case may be, fixed by the Government of which a review has been applied for.

**32. Non-application of the provisions of this order in certain cases.**— The provisions of this order shall not apply to, -



(i) a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970) (product patent) and not produced elsewhere, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial production in the country.

(ii) a manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development and patented under the Indian Patent Act, 1970 (39 of 1970) (process patent) for a period of five years from the date of the commencement of its commercial production in the country.

(iii) a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India:

Provided that the provision of this paragraph shall apply only when a document showing approval of such new drugs from Drugs Controller General (India) is produced before the Government.

*Explanation.-* Notwithstanding anything contained in this Order, for the purpose of this paragraph “new drug” shall have the same meaning as is assigned to under rule 122E of the Drugs and Cosmetics Rules, 1945;

**File No.31011/17/2012-PI-II**

**(Shambhu Kallolikar)**

**Joint Secretary to the Government of India**



**SCHEDULE-II FORM - I**

**PROFORMA FOR APPLICATION FOR PRICE FIXATION / REVISION OF A NEW DRUG FORMULATION RELATED TO NLEM FORMULATION**

**(See paragraphs 2(u),5,7,8,9,15)**

1. Name of the formulation:
2. Name and address of the manufacturer/importer :
3. Name of the Marketing Company, if any:
4. Composition as per label claimed and approved by Drug Control Authorities:
5. Drugs Control Authority Permission Number and Date (copy to be enclosed):
6. Date of commencement of production / import:
7. Type of formulation (Tablets/ Capsules/ Syrup/ Injection/ Ointment/ Powder etc.):
8. Size of packs (10's/ 100's/ 1 ml/ 2 ml/ 10 ml/ 5 gms/ 10 gms etc.)
9. Therapeutic category/ use of the formulation.
10. The Retail Price claimed for approval
11. Reason for submission of application for price fixation / revision.
12. Any other information relevant to product and its process of manufacturing/ packaging/ distribution.

---

**The information furnished above is correct and true to the best of my knowledge and belief. Place:**

**Authorized Signatory:**

**Name:**

**Date:**

**Designation:**



## SCHEDULE-II

### FORM - II

#### PROFORMA FOR SUBMISSION OF REVISED-PRICES FOR SCHEDULED FORMULATIONS

(See paragraph 16)

1. Name and address of the manufacturer / importer / distributor.
2. Name and address of the marketing company, if any.

Sl. No.	Name of the Product (Formulation and its dosage forms)	Composition of scheduled formulation/ new drug	Pack Size	WPI change w.r.t preceeding Year	Price to retailer (incl. of E.D.) (Rs.)		Maximum Retail Price (incl. of E.D.& Taxes) (Rs.)		Ceiling Price (Notified) (Rs.)	Effective Batch No. and date
					Pre-Revised	Revised	Pre-Revised	Revised		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
	<b>Scheduled Formulations</b>									
	Own Manufactured Formulations									
	Purchased/Imported Formulations									



**Notes:-** In case of purchased formulation, name of the manufacturer shall be indicated.

**The information furnished above is correct and true to the best of my knowledge and belief.**

**Place:**

**Authorised Signatory:**

**Name:**

**Date:**

**Designation:**



**FORM – III**

**PROFORMA FOR QUARTERLY RETURN IN RESPECT OF PRODUCTION/IMPORT AND SALE OF NLEM DRUGS  
(See paragraphs 21(1))**

1. Name and address of the manufacturer/importer:
2. Name and address of marketing company, if any:
3. Details of production/import and sale for the Quarter of a Year: .....

**TABLE-A**

Name of the Scheduled Formulation	Composition /Strength	Dosage Form	Unit(No/ kg/Ltr)	Production/Import Level				Domestic Sale					
				Previous Year	Current Year				Previous Year	Current Year			
					1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter		1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	1 <sup>st</sup> Quarter
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)

**TABLE-B**

Name of the Bulk Drug/API used in Scheduled Formulation	Unit (Kg/ Ltr)	Installed Capacity	Production/Import Level				Domestic Sale					
			Previous Year	Current Year				Previous Year	Current Year			
				1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter		1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)



*The Institute of Cost Accountants of India*

---

**Constraints, if any:**

**Note:** (1) Production outsourced / carried out on job work basis should also be included

**The information furnished above is correct and true to the best of my knowledge and belief.**

**Place:**

**Date:**

**Authorised Signatory:**

**Name:**

**Designation:**



**SCHEDULE-II FORM - IV**

**PROFORMA FOR SUBMISSION OF THE DETAILS IN RESPECT OF DISCONTINUATION OF THE PRODUCTION AND/ OR IMPORT OF SCHEDULED FORMULATION**

**(See paragraphs 21(2))**

1. Name of the formulation:
2. Name and address of the manufacturer/importer :
3. Name of the Marketing Company, if any:
4. Composition as per label claimed and approved by Drug Control Authorities:
5. Drugs Control Authority Permission Number and Date (copy to be enclosed):
6. Ceiling Price and date of notification:
7. Existing maximum retail price (MRP) and its effective date:
8. Therapeutic category as per NLEM:
9. Date of commencement of production / import
10. Proposed date of discontinuation:
11. Reasons for discontinuation of production / import:
12. Year-wise Production/Import during the last 5 years including current year
13. Year-wise sale during the last 5 years including current year
14. Whether any new drug as defined under Proviso of Definition of “New Drug” under DPCO, 2013 has been launched or intended to be launched. If so, the details thereof:
15. Any other information relevant to discontinuation of scheduled formulation:

**Place:**

**Date:**

**Authorized Signatory: Name:**

**Designation:**



SCHEDULE-II FORM - V

**PROFORMA FOR PRICE LIST**

(See paragraphs 2(x),24,25,26)

1. Name and address of the manufacturer / importer / distributor.
2. Name and address of the marketing company, if any.

**TABLE-A**

Sl. No.	Name of the Product (Formulation and its dosage forms)	Composition approved by Drug Control Authorities	Pack Size	Price to retailer (incl. of E.D.) (Rs.)	Maximum Retail Price (incl. of E.D.& Taxes) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	<b>Scheduled Formulations</b>				
	Own Manufactured Formulations				
	Purchased/Imported Formulations				

**TABLE-B**

I. No.	Name of the Product (Formulation and its dosage forms)	Composition approved by Drug Control Authorities	Pack Size	Price to retailer (incl. of E.D.) (Rs.)	Maximum Retail Price (incl. of E.D.& Taxes) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	<b>Non-Scheduled Formulations</b>				
	Own Manufactured Formulations				
	Purchased/Imported Formulations				



**Notes:-** In case of purchased formulation, name of the manufacturer shall be indicated.

**The information furnished above is correct and true to the best of my knowledge and belief.**

**Authorised Signatory:**

**Place:**

**Name:**

**Date:**

**Designation:**

## **Annexure III**

### **Form – CRA-1**

*[Pursuant to Rule 5(1) of the companies (cost records and audit) rules, 2014]*

#### **Form in which Cost Records shall be maintained**

#### **PARTICULARS RELATING TO THE ITEMS OF COSTS TO BE INCLUDED IN THE BOOKS OF ACCOUNTS:**

##### **1. INPUT MATERIAL(S)/SERVICE(S):**

(1) Proper records shall be maintained showing separately all receipts, issues and balances both in quantities and cost of each item of raw material/input services (including all direct charges upto the works) required for the production of goods or rendering of services under reference. The basis, on which quantities, cost of issue and consumption are calculated, shall be indicated in the cost records and followed consistently. In the case of imported raw materials/input services, proper records shall be maintained showing quantity of imported material/service, Free On Board value, overseas freight, insurance, customs duty and inland freight charges along with license-wise quantities allowed, actual quantities imported, actual quantities consumed, quantities in stock and quantities yet to be imported out of total licensed quantities. If both indigenous and imported materials/services are consumed, the records showing details of percentage mix of the same have to be maintained for each item.

(2) Proper records shall be maintained separately showing the receipts, issues and balances both in quantities and cost of each item of intermediate material/service, process material, additives, bought out components, sub-assemblies, accessories, semi-finished goods, consumable stores, spares, other indirect materials/services etc. used in the production of the goods/rendering of services under reference. The cost shall include all direct charges upto works/services delivered. In case of additives, bought out components/bought out services, sub-assemblies, accessories, semi-finished goods, consumable stores, spares and other indirect materials/services, proper records shall be maintained for the value and quantity issued/rendered in a financial year suitably adjusted for consumption. If the life of any input material/service is more than one financial year, necessary adjustment should be made. If the life of any input material/service is not known, consumption may be assessed on technical basis.

(3) Where the company produces these raw materials/input services, intermediates or process materials, separate records showing the cost of production/cost of service of such items, shall be maintained. The basis on which quantities and cost of issues and consumption of such materials/services produced or processed by the company are calculated, shall be indicated in the cost records and followed consistently.

(4) The issues, consumption of all raw materials/input services, intermediates, process materials, additives, manufactured, bought out components/ bought out services, sub-assemblies, accessories,

semi-finished goods, consumable stores, spares and other indirect materials/services shall be identified with the process wise production of goods/rendering of services.

(5) Proper records shall be maintained indicating the quantity as well as value of recoveries at different stages/processes having significant value in relation to cost of material/service. In case the recoveries are not reused in the process and are sold/rendered or disposed of without further processing/rendering, the realisation from such sales shall be recorded and adjusted against the process concerned. In case further processing/augmentation is necessary to make the recoveries usable or saleable, as the case may be, proper records of the cost involved for such further processing/augmentation shall be maintained. If such processing/augmentation is done by any outside agency, proper records to show the quantity sent for processing/augmentation, quantity received back after processing/augmentation and cost incurred thereon shall be maintained. The net realization, if any, shall be adjusted against the major process relating to such recoveries. The cost of recoveries shall be determined on equitable and reasonable basis and applied consistently. The records indicating the actual sales realization of recoveries shall also be maintained.

(6) Proper records shall be maintained to show the receipts, issues and balances, both in quantities and cost of each item of consumable stores, other process materials/services not covered above, small tools and machinery spares, indirect materials/services etc. The cost shall include all direct charges upto works/services delivered.

(7) The cost of consumable stores, small tools and machinery spares shall be charged to the relevant cost center/service centre or department or production process of goods or rendering of services on the basis of actual issues. In the case of consumable stores and small tools, indirect services, the cost of which are insignificant (less than 5% of the cost of material consumed), the company may, if it so desires, maintain such records for the group of such consumable stores, tools and indirect services.

(8) Proper records shall be maintained showing the quantity and value of wastage, spoilage, rejections and losses of raw materials/input services, intermediates, process materials/services, consumable stores, small tools and machinery spares, whether in transit, storage, manufacture or at any other stage. The method followed for adjusting the above losses as well as the income derived from the disposal of rejected and waste materials/services including spoilage, if any, in determining the cost of good(s)/service(s), shall be indicated in the cost records. Any abnormal wastage or spoilage or rejection or losses shall be indicated distinctly and separately along with reasons thereof.

(9) Proper records shall also be maintained to indicate the value of raw materials/input services, intermediates and process materials/services, finished and semi-finished goods/services, consumable stores, small tools and machinery spares, additives, manufactured, bought out components/bought out services, sub-assemblies, accessories, semi-finished goods/services, consumable stores, spares and other indirect materials/services which have not moved/ utilized for more than twelve months.

(10) Where any credit under Central Value Added Tax (CENVAT) under the Central Excise Act, 1944 (1 of 1944) or Finance Act in case of service tax, any other benefits of the nature of CENVAT/Service Tax credit,

are available on any item of material/service, the cost of such material/service shall be shown after adjusting such credit or benefits.

(11) If any of the input materials/services is processed through an outside party, proper records shall be maintained for the quantity sent for processing, quantity received after processing, balance quantity of material/service, losses and wastage of material/service during processing, by-products recovered, if any, and the cost involved in processing/rendering of service.

## **2. SALARIES AND WAGES:**

(1) Proper records shall be maintained to show the attendance and earnings of all employees assigned to the cost centres or departments and the work on which they are employed. The records shall also indicate the following separately for each cost centre or department:

- (a) piece rate wages (wherever applicable);
- (b) incentive wages, either individually or collectively as production bonus or under any other scheme based on output;
- (c) overtime wages;
- (d) earnings of casual or contractual labour;
- (e) bonus or gratuity, statutory as well as other;
- (f) contribution to superannuating scheme;
- (g) cost of employees stock option;
- (h) leave travel concession; paid holidays;
- (i) leave with pay;
- (j) Training, workshop, seminar expenses;
- (k) Medical/health, safety, education expenses;
- (l) any other statutory provision for labour welfare;
- (m) any other free or subsidized facility.

(2) The records shall be maintained in such a manner as to enable the company to book these expenses cost centre wise or department wise with reference to goods/services under reference and to furnish necessary particulars. Where the employees work in such a manner that it is not possible to identify them with any specific cost centre/service centre or department, the employees cost shall be apportioned to the cost centre/service centres or departments on equitable and reasonable basis and applied consistently.

(3) The idle labour cost shall be separately recorded under classified headings indicating the reasons therefor. The method followed for accounting of idle time payments shall be disclosed in the cost records.

(4) Any wages and salaries allocable to capital works, such as, additions to plant and machinery, buildings or other fixed assets shall be accounted for under the relevant capital heads. The method followed for accounting of such payments in determining the cost of the goods/services under reference shall be on equitable and reasonable basis and applied consistently. The said method shall be disclosed in the cost records also.

(5) The cost of normal retirement benefits payable to employees shall be recorded separately and charged to cost. The method followed for accounting of such costs in determining the cost of the goods/services under reference shall be on equitable and reasonable basis and applied consistently and disclosed separately. Termination benefits which are payable in addition to the normal retirement benefits, such as benefits under voluntary retirement scheme, expenses treated as abnormal and not forming part of salaries and wages and cost of production of goods/rendering of services.

### **3. UTILITIES:**

(1) Proper records shall be maintained showing the quantity and cost of each major utility such as power, water, steam, effluent treatment, etc. produced and consumed by the different cost centres in such detail as to have particulars for each utility separately.

(2) If a utility is purchased, proper records showing the delivered cost including all direct charges shall be maintained for the quantity and value of each utility purchased.

(3) Where a utility is produced and supplied by any other unit of the company or any related party, proper records shall be maintained to assess cost and the quantity of the utility so procured.

(4) The cost of utility, if any, supplied to any other unit(s) of the company or any related party, shall be calculated on equitable and reasonable basis and applied consistently.

(5) The cost of utility allocated/apportioned to the cost centers and further to the individual goods/services shall be on equitable and reasonable basis and applied consistently.

(6) Where any utility is one of the major inputs to the raw material used in production or manufacture of any of the goods/services under reference, such direct utility shall be included in the cost of such raw material/input service and shown accordingly.

(7) Proper records indicating any subsidy, grant/incentive, credits, recoveries, abnormal costs, penalties or damages paid etc. in respect of utilities shall be maintained.

(8) The records shall also indicate the measures taken on conservation of energy and its corresponding impact on per unit cost of goods/services.

### **4. SERVICE DEPARTMENT EXPENSES:**

(1) Proper records shall be maintained to indicate expenses incurred in respect of each service cost centre like engineering, work shop, designing, laboratory, safety, transport, computer cell, welfare etc. These expenses shall be apportioned to other services and production departments on equitable and reasonable

basis and applied consistently. Where these services are utilized for other goods/services of the company also, the basis of apportionment of such expenses to goods/services under reference and to the other goods/services shall be on equitable and reasonable basis and applied consistently. The said basis shall be disclosed in the cost records also. Proper records shall be maintained to indicate cost of purchase, production, distribution, marketing and price of services with reference to sales to outside parties. Proper records shall also be maintained regarding cost of services received from/rendered to related parties and cost of service cost centre incurred in foreign exchange besides proper maintenance of records in respect of any subsidy, grants, incentives, credits/recoveries, any abnormal cost, penalty and damages.

#### **5. REPAIRS AND MAINTENANCE:**

(1) Proper records showing the expenditure incurred by the workshop, tool room and on repairs and maintenance in the various cost centres or departments shall be maintained under different heads. The records shall also indicate the basis of charging such expenses to different cost centres or departments. Records in respect of repairs and maintenance cost of jobs done in-house and outsourced, cost of major overhauls, repair and maintenance paid/payable to the related party, incurred in foreign exchange and any subsidy, grant, incentive, credits/recoveries, penalty and damages and any abnormal portion of this item of cost shall be maintained. The manner of charging a share of the cost of workshop, tool room and repairs and maintenance expenses shall be on equitable and reasonable basis and applied consistently.

(2) In addition to the above, records shall indicate the amount and also the proportion of closing inventory of stores and spare parts representing items which have not moved for over twenty four months.

(3) The expenditure on major repair works from which benefit is likely to accrue for more than one financial year shall be shown separately and absorbed in the cost over the period for which such benefits are expected to accrue on equitable and reasonable basis and applied consistently. Method of accounting along with the basis of allocation of such costs shall also be clearly indicated in cost records.

#### **6. FIXED ASSETS, DEPRECIATION AND LEASE CHARGES:**

(1) Proper and adequate records shall be maintained for assets used for production of goods/rendering of services under reference in respect of which depreciation has to be provided for. These records shall, inter-alia, indicate grouping of assets under each good/service, the cost of acquisition of each item of asset including installation charges, date of acquisition and rate of depreciation.

(2) Those records which enable to identify and/or allocate gross fixed assets, accumulated depreciation up to the year and net fixed assets under the heads; land and building, plant and machinery, furniture and fixtures etc. employed for goods/services under reference shall be maintained. The basis of apportionment of common assets to the goods/services under reference shall be on equitable and reasonable basis and applied consistently. In case of revaluation of assets, the same shall be indicated separately and depreciation on revaluation shall also be indicated separately.

(3) The basis on which depreciation is calculated and allocated or apportioned to various cost centre/service centres or departments and absorbed on all goods/services shall be clearly indicated in the cost records. If depreciation charged or chargeable to the cost centres or departments is in excess or lower than the depreciation calculated by applying the rates of depreciation prescribed under the Companies Act, 2013, such amount of excess or lower depreciation shall be indicated clearly in the cost records. The cost records shall also show the effect of such excess or lower depreciation, as the case may be, on per unit cost of each good/service. The cumulative depreciation charged in the cost records, against any individual item of asset shall not, however, exceed the original cost of the respective asset.

(4) Proper records shall be maintained giving details of assets taken or given on lease. The break-up of lease rental in terms of financial charges, depreciation etc. paid or received shall be maintained separately. The details shall be maintained separately for assets taken from or given to related party.

## **7. OVERHEADS:**

(1) Proper records shall be maintained for various items of indirect expenses comprising overheads pertaining to goods/services under reference. These expenses shall be analyzed, classified and grouped according to functions, namely, works, administration, selling and distribution, Head Office expenses.

(2) Proper records shall be maintained in respect of overheads incurred in foreign exchange, any subsidy, grant, incentive, credits/recoveries, unabsorbed overheads and any abnormal portion and also relating to resources received from or supplied to any related party,

(3) Where the company is also manufacturing goods/rendering services other than the goods/services under reference, the records shall clearly indicate the basis followed for apportionment of the common overheads including head office expenses of the company to such other goods/services and the goods/services under reference, including capital works. Where certain expenses forming part of overheads can be identified with particular goods/services, such expenses shall be first segregated and charged to the relevant goods/services in the first instance and thereafter the residual expenses under the above categories of overheads shall be apportioned on equitable and reasonable basis and applied consistently. The overheads chargeable to capital works shall be indicated separately in the cost records. The basis of apportionment or absorption of overheads to the cost centres or departments and the goods/services shall be indicated in the cost records. The records shall be maintained in such a manner as to indicate the details of works, administration, selling and distribution overheads, H.O. expenses etc.

## **8. ROYALTY AND TECHNICAL KNOW-HOW FEE:**

Adequate records shall be maintained showing royalty and/or technical know-how fee including other recurring or non-recurring payments of similar nature, if any, made for the goods/services under reference to collaborators or technology suppliers in terms of agreements entered into with them. Such records shall be kept separately in respect of each such agreement or arrangement. The basis of charging such amount, including lump sum payment and its treatment shall be indicated in the cost records.

## **9. RESEARCH AND DEVELOPMENT EXPENSES:**

(1) Proper records showing the details of expenses, if any, incurred by the company for research and development work on the goods/services covered under these rules, according to the nature of development of goods/services - existing and new, design and development of new facilities and market research for the existing and new goods/services, shall be maintained separately. The records shall also indicate the payments made to outside parties for the research and development work. The basis of charging such amount, including lump sum payment and its treatment shall be indicated in the cost records.

(2) The basis of charging these expenses to the cost of production of goods/services under reference and to other goods/services shall be indicated in the cost records. Where the utility of research and development work extends to over more than one financial year, such expenses shall be charged to the cost of goods/services under reference and to all other goods/services on equitable and reasonable basis and applied consistently indicating the criteria on the basis of which it has been decided to extend the utility period of these expenses to more than one financial year.

(3) Proper records shall be maintained in respect of such expenses incurred in foreign exchange and any subsidy, grant, incentive, credits/recoveries, penalty or damages paid and any abnormal portion and also for resources received from or supplied to any related party.

(4) The expenses incurred by the research and development department for providing technical know-how to outsiders shall be recorded separately and excluded from the cost of goods/services under reference. The amount recovered for providing technical know-how to outsiders shall also be indicated separately and excluded from the income arising from the sale of goods/services under reference.

## **10. QUALITY CONTROL:**

Adequate records shall be maintained to indicate the expenses incurred in respect of quality control department or cost centre/service centre for goods/services under reference. Where these services are also utilized for other goods/services of the company, the basis of apportionment to goods/services under reference and to other goods/services shall be on equitable and reasonable basis and applied consistently. Proper records shall be maintained in respect of such expenses relating to resources received from or supplied to the related party, incurred in foreign exchange and any subsidy, grant, incentive, credits/recoveries, unabsorbed overheads and any abnormal portion etc.

## **11. WORK-IN-PROGRESS AND FINISHED STOCK:**

The method followed for determining the cost of work-in-progress and finished stock of the goods and for services under delivery or in-process shall be appropriate and shall be indicated in the cost records so as to reveal the cost element that have been taken into account in such computation. All conversion costs incurred in bringing the inventories to their present location and condition shall be taken into account while computing the cost of work-in-progress and finished stock. The method adopted for determining the cost of work-in-progress and finished goods shall be followed consistently.

**12. CAPTIVE CONSUMPTION:**

If the goods/services under reference are used for captive consumption, proper records shall be maintained showing the quantity and cost of each such goods/services transferred to other departments or cost centres or units of the company for self-consumption and sold to outside parties separately.

**13. BY-PRODUCTS:**

Proper Records shall be maintained for each item of by-product, if any, produced showing the receipt, issues and balances, both in quantity and value. The basis adopted for valuation of by-product for giving credit to the respective process shall be equitable and consistent and should be indicated in cost records. Records showing the expenses incurred on further processing, if any, as well as actual sales realization of by-product shall be maintained. The proper records shall be maintained in respect of credits/recoveries from the disposal of by-products.

**14. JOINT PRODUCTS/SERVICES:**

Where more than one product/service which is of equal economic importance arises from a process, the cost up to the point of separation of products/services shall be apportioned to joint products/services on reasonable and equitable basis and shall be applied consistently. The basis on which such joint costs are apportioned to different products/services arising from the process shall be indicated in the cost records.

Proper records shall be maintained in respect credits/recoveries from the disposal of joint products/services.

**15. PACKING EXPENSES:**

Proper records shall be maintained separately for domestic and export packing showing the quantity and cost of various packing materials and other expenses incurred on primary and/or secondary packing indicating the basis of valuation. Where such expenses are incurred in common for other goods also, the basis of apportioning the expenses between the relevant goods shall be on equitable and reasonable basis and applied consistently. Proper records shall be maintained in respect of packing materials received from or supplied to the related party, costs incurred in foreign exchange and any subsidy, grant, incentive, credits/recoveries, unabsorbed overheads, penalty and damages, any abnormal portion etc.

**16. INTEREST AND OTHER BORROWING COSTS:**

(1) Proper records shall be maintained for money borrowed for each project and/or working capital and interest charged thereon. The amount of net interest and other borrowing costs shall be allocated or apportioned to the goods/services under reference and other goods/services on equitable and reasonable basis and applied consistently. The basis of further charging of the share of interest to the various types of such goods/services shall also be equitable and reasonable and applied consistently. The basis of such allocation or apportionment shall be spelt out clearly in the cost records.

(2) Net interest and other borrowing costs incurred for project under execution shall be capitalized for

the period up to the date the project is commissioned.

- (3) Proper records shall be maintained in respect of such expenses paid/payable to the related party, incurred in foreign exchange and any subsidy, grant, incentive and any amount of similar nature received/receivable, payment of penal interest or fine/damages paid.
- (4) Proper records shall be maintained in respect of such expenses incurred relating to prior periods and taken to reconciliation directly.

**17. EXPENSES OR INCENTIVES ON EXPORTS:**

- (1) Proper records showing the expenses incurred on the export sales, if any, of the goods/services under reference shall be separately maintained so that the cost of export sales can be determined correctly. Separate cost statements shall be prepared for goods/services exported giving details of export expenses incurred or incentive earned.
- (2) Proper records shall be maintained giving the details of export commitments license wise and the fulfillment of these commitments giving the reasons for non-compliance, if any. In case, duty free imports are made, the cost statements should reflect this fact. If the duty free imports have been made after actual production, the statement should reflect this fact also.

**18. POLLUTION CONTROL:**

- (1) Expenditure incurred by the company on various measures to protect the environment like effluent treatment, control of pollution of air, water, etc., should be properly recorded. Records relating to basis of distribution of pollution control expenses, such costs of jobs done in-house and outsourced separately, pollution control costs paid/payable to related parties, incurred in foreign exchange and any subsidy, grant, incentive, credits/recoveries, any abnormal portion of such costs, penalty and damages paid and any amount received/receivable from pollution control agency.

**19. PRODUCTION RECORDS:**

- (1) Quantitative records of all finished goods (packed or unpacked)/services rendered showing production, issues for sales and balances of different type of the goods/services under reference, shall be maintained. The quantitative details of production of goods/services rendered shall be maintained separately for self-produced, third party on job work, loan license basis etc.

**20. SALES RECORDS:**

Separate details of sales shall be maintained for domestic sales at control price, domestic sales at market price, export sales under advance license, export sales under other obligations, export sales at market price, and sales to related party/inter unit transfer. In case of services details of domestic delivery/sales at control price, domestic delivery/sales at market price, export delivery/sales under advance license, export delivery/sales under other obligations, export delivery/sales at market price, and delivery/sales to related party/inter unit transfer. Such details shall be maintained separately for each plant/unit wise or service centre wise for total as well as per unit sales realization.

**21. ANY OTHER ITEM OF COST:**

Proper records shall be maintained for any other item of cost being indispensable and considered necessary for inclusion in cost records for calculating cost of production of goods/rendering of services, cost of sales, margin in total and per unit of the goods/services under reference.

**22. ADJUSTMENT OF COST VARIANCES:**

Where the company maintains cost records on any basis other than actual such as standard costing, the records shall indicate the procedure followed by the company in working out the cost of the goods/services under such system. The cost variances shall be shown against separate heads and analyzed into material, labour, overheads and further segregated into quantity, price and efficiency variances. The method followed for adjusting the cost variances in determining the actual cost of the goods/services shall be indicated clearly in the cost records. The reasons for the variances shall be duly explained in the cost records and statements.

**23. COST STATEMENTS:**

- (1) Cost statements (quarterly and annually) showing quantitative information in respect of each good/service under reference shall be prepared showing details of available capacity, actual production, production as per excise records, capacity utilization (in-house), stock purchased for trading, stock and other adjustments, quantity available for sale, wastage and actual sale etc. during current financial year and previous year.
- (2) Such statements shall also include details in respect of all major items of costs constituting cost of production of goods/services, cost of sales of goods/services and margin in total as well as per unit of the goods/services. The goods/services emerging from a process, which forms raw material or an input material/service for a subsequent process, shall be valued at the cost of production/cost of service up to the previous stage.
- (3) Cost Statements (quarterly and annually) in respect of reconciliation of indirect taxes showing details of total clearances of goods/services, assessable value, duties/taxes paid, CENVAT/VAT/Service Tax credit utilized, duties/taxes recovered and interest/penalty paid.
- (4) If the company is operating more than one plant, factory or service centre, separate cost statements as specified above shall be prepared in respect of each plant, factory or service centre.
- (5) Any other statement/information considered necessary for suitable presentation of Costs and Profitability of goods/services produced by the Company shall also be prepared.

**24. RECONCILIATION OF COST AND FINANCIAL ACCOUNTS:**

- (1) The cost statements shall be reconciled with the financial statements for the financial year specifically indicating the expenses or incomes not considered in the cost records or statements so as to ensure accuracy and to adjust the profit of the goods/services under reference with the overall profit of the company. The variations, if any, shall be clearly indicated and explained.
- (2) A statement showing the total expenses incurred and income received by the company under

different heads of accounts and the share applicable to other goods/services and the goods/services under reference shall be prepared and reconciled with the financial statement.

**25. STATISTICAL RECORDS:**

- (1) The records regarding available machine hours or direct labour hours in different production departments and actually utilized shall be maintained for production of goods/rendering of services under reference and shortfall suitably analyzed. Suitable records for computation of idle time of machines and/or labour shall also be maintained and analyzed.
- (2) Proper records shall be maintained to enable the company to identify the capital employed, net fixed assets and working capital separately for the production of goods/rendering of services under reference and other goods/services to the extent such elements are separately identifiable. Non-identifiable items shall be allocated on a suitable and reasonable basis to different goods/services. Fresh investments on fixed assets for production of goods/rendering of services under reference that have not contributed to the production of goods/rendering of services during the relevant period/year shall be indicated in the cost records. The records shall, in addition, show assets added as replacement and those added for increasing existing capacity.

**26. RECORDS OF PHYSICAL VERIFICATION:**

Records of physical verification may be maintained in respect of all items held in the stock such as raw-materials, process materials, packing materials, consumables stores, machinery spares, chemicals, fuels, finished goods and fixed assets etc. Reasons for shortages/surplus arising out of such verifications and the method followed for adjusting the same in the cost of the goods/services shall be indicated in the records.

**27. RELATED PARTY TRANSACTIONS:**

(1) In respect of related party transactions or supplies made or services rendered by a company to a company termed “related party relationship” and vice-a-versa, records shall be maintained showing contracts entered into, agreements or understanding reached in respect of -

- (a) purchase and sale of raw materials, finished good(s), rendering of service(s), process materials and rejected goods including scraps, etc;
- (b) utilisation of plant facilities and technical know-how;
- (c) supply of utilities and any other services;
- (d) administrative, technical, managerial or any other consultancy services;
- (e) purchase and sale of capital goods including plant and machinery; and
- (f) any other payment related to the production of goods/rendering of services under reference.

(2) These records shall also indicate the basis followed for arriving at the rates charged or paid for such goods or services so as to enable determination of the reasonableness of such rates in so far as they are in any way related to goods/services under reference.