1st National Conference on Medical Waste Management, February 6 & 7, 1999

ORGANISER: Baroda Management Association, Vadodra
CO-SPONSOR: US Asia Environmental Partnership, Mumbai

SUBJECT: Post-conference Comments on **'Bio-Medical Waste (Management and Handling) Rules, 1998, MoEF notification dated 20th July 1998, The Gazette of India No. 460**

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Background to this note

This is a delegate's response contribution to the proceedings of the Medical Waste Management conference.

During summarisation of session chaired by **Lt. Col. L. K. Nagendra**, thought provoking questions were put forward by him towards as to what extent the Bio-Medical (Management and Handling) Rules, 1998 of MoEF were appropriate in its totality for proper and stringent implementation.

Speakers **Mr. Ravi Agarwal** of Srishti (NGO), New Delhi and **Dr.(Mrs.) Geeta Mehta** of Lady Hardinge Medical College (HOD Dept. Of Microbiology), New Delhi emphasised the need to fine tune the 1998 Rules for its Colour Coding in Schedule II table on page 14 and to remove some of the ambiguities of its correlation with the waste category and its Treatment & Disposal methods tabled in Schedule I on page 13. Both of them have a representation opportunity on such issues when discussed at MoEF and CPCB meetings.

The suggestions presented in this note are based on information compiled from Waste Management Handbooks, Published articles, Guidelines from bodies like US EPA, WHO, and Pollution Control Boards in US and UK. These suggestions which is a result of experiences gained over the years in evolution of Medical Waste Management and its implementations could prove to be useful in Indian context in successfully meeting the challenges and tasks ahead.

To begin with the comments are given on Schedule II (Colour Codes / Type of container) & Schedule I (Categories / Treatment & Disposal) to address the colour coding issues. Later the comments are related to Schedule V (Standards for Treatment and Disposal of Bio-Medical Wastes) and Schedule VI on implementation time-schedules..

Section A: Waste Category, Treatment Options and Colour coding

Colour Coding and Type of Container for Disposal of Bio-Medical Wastes in Schedule- II

The primary purpose of colour coding and symbolising is that its understanding and importance is widely known to the public at large and to workers in a particular industry. Striking household examples would be that of POISON, FIRE, HIGH VOLTAGE, and FLAMABILITY. You will note that under the Indian Motor Vehicle Act, 1988 the symbol of Biohazard is incorporated with other symbols depicting 'No-parking', 'No-horn', 'No-entry' etc., and every driving licence holder is deemed to be aware of it. It is mandatory for Vehicles carrying Biohazard material to display this Biohazard symbol as is the case with vehicles transporting Flammable, Corrosive, Poisonous materials and the likes. What is important here to note is that the colour and symbols depicting hazards should be different and distinguishable from that of the normal day to day activities. With this understanding the Black colour coding in the Bio-medical rules is being questioned, and along with it the Waste categories 5, 9 and 10 grouped in it are being dealt with.

Colour Coding: BLACK

'In the UK for example, black bags (which have widespread use in the collection of Domestic Wastes from ordinary households) are recommended for general non-hazardous wastes category- Ref. **WHO, Geneva 1992**, Managing Medical Wastes in Developing Countries'. Even in the Metro cities of India, Black bags are widely used for collection of domestic and office waste, and Municipal Corporation's Solid Waste handling worker identifies it as domestic wastes. Since there is no category for general non-hazardous wastes in the Indian MoEF Rules, the Black colour coding should be removed. Now, the 'Type of container' and 'Treatment & Disposal' options for the cat.5, Cat.9 and cat.10 grouped under the 'Black colour' coding is also questionable and the matter is now being discussed below.

Waste Category No.9- Incineration Ash

This waste category is colour coded as Black.

- Incineration Ash is a potentially hazardous material when the waste material constitutes metals, plastics, waste oils etc., and could contain hazardous materials like oxides of metal, dioxin and furans in the ash residual. Incineration of metal 'sharps' would very well deposit the oxides of metals in the residual ash. Incineration Ash with these hazardous constituents would be categorised under Hazardous waste and its relevant symbol should be used. Incineration Ash is not a Biohazard waste.
- Incineration ash when casually dumped in open space is a source of environment pollution causing fine fly ash Suspended Particulate Matter (SPM) to spread and pollute the air. Matter of fact 'Her Majesty's Inspectorate of Pollution' UK under the Process Guidance Note IPR5/2 on 'Waste Disposal & Recycling Clinical Waste Incineration' recommends "Adequate cleaning equipment should be provided and maintained, such as a vacuum cleaner, to clean up promptly any spilled ash. Any such vacuum cleaner should be fitted with an absolute filter. The dry sweeping of spillage is not acceptable. - Ref. Paragraph 3.2"
- The 'Type of container' for Incineration Ash should not be a 'plastic bag'. It should have a Solid, Sealed, Impervious and High temperature resistant container. This incineration ash container should be safely buried such that there is no leach out of metal oxides and any other pollutants to contaminate the ground water.
- When the waste feed to the incinerator is only pathological material, the residual ash will be sterile, non-toxic and non-hazardous which can be put to useful purpose.

The above explanation gives reasons to **reconsider** the 'Black colour coding', 'Type of container' and 'Method of disposal' for **waste category No.10 for Incineration ash**, as stated under Bio-Medical (Management and Handling) Rules, 1998 of MoEF

Category No.10 – Chemical Waste (solid)
This waste category is colour coded as Black.

- The likely chemical wastes in this category should be listed. For each of the listed chemicals its effects to: a) Health, b) Flammability, c) Reactivity, d) Contact and e) Special properties should be tabulated. Against each of these effects the rating should be given in the order of Minimal, Slight, Moderate, Serious and Severe. Example is sited below.

CHEMICAL	HEALTH	FLAMMABILITY	REACTIVITY	CONTACT	SPECIAL PROPERTIES
Formaldehyde	serious	moderate	moderate	serious	Carcinogen, Corrosive
Mercury	severe	minimal	slight	serious	Poison

- Based on the Effects and Ratings for a specific chemical, a suitable compatible container should be provided. These containers should be solid, sealed, impervious and corrosion resistant. They should be labelled as per their hazardous rating.
- 'Chemical waste should be incinerated at high temperature, alternatively they may be buried in a containment landfill i.e. one in which the base and capping are lined with a layer of clay or a plastic membrane, but this special waste landfill must be kept strictly inaccessible to scavengers. **Ref. - WHO, Geneva 1992**, Managing Medical Wastes in Developing Countries, Annexure 1, paragraph 5 on page 30'
- A Master Chemical Inventory list should be maintained at each facility tabulating all the chemicals they use along with its Effects and Ratings, as explained above.

The above explanation gives reasons to reconsider the 'Black colour coding', 'Type of container' and 'Method of disposal' for **waste category No.9** for **chemical waste (solid)**, as stated under Bio-Medical (Management and Handling) Rules, 1998 of MoEF

Category No.5 – Discarded Medicines & Cytotoxic Drugs

This waste category is colour coded as Black.

- '**Cytotoxic** drugs must never be discharged to the environment. **Ref. – *WHO, Geneva 1992**, Managing Medical Wastes in Developing Countries, section 4 on page 13'.
- '**Cytotoxic** drugs may be burnt or chemically degraded by well-qualified specialists, but should never be diluted and discharged to sewer. **Ref. - WHO, Geneva 1992**, Managing Medical Wastes in Developing Countries, section 6.5 on page 21'
- **Cytotoxic** wastes: which in addition to being toxic are mutagenic and/or teratogenic when discarded or spilled. Ref WHO*.
- **Cytotoxic** drugs, because of their high potential to kill Varity of organisms, are an acute danger for the environment Ref. WHO*.
- Discarded cytotoxic drugs **should never be buried**. They act as mutagens to all biological beings. Ref WHO*.
- 'A solution may be to establish at national level an agency to collect, store and process discarded chemicals including pharmaceuticals. At hospital level it is only when a high temperature incineration is available that disposal of pharmaceuticals other chemicals and even cytotoxic drugs becomes easy. Ref. - WHO, Geneva 1992, Managing Medical Wastes in Developing Countries, section 6.2 on page 19'

The above explanation gives reasons to **reconsider** the 'Black colour coding', 'Type of container' and 'Method of disposal' for **waste category No.5** for discarded medecines and cytotoxic drugs, as stated under Bio-Medical (Management and Handling) Rules, 1998 of MoEF

Colour coding YELLOW & RED for Waste Category No.6

- Waste **category No.6** in for items contaminated with blood, and body fluids such as cotton dressings, soiled plaster cast, bedding etc., has been classified for colour coding **Yellow** as well as for **Red** in Schedule II..
- There should be only one Colour coding and that should be based on the waste category.
- Colour coding should not be as per Treatment options.
- Workers and public at large should be aware of the nature of hazard of to the waste by its colour coding.
- **Single choice of colour for infective waste for category No.6 should be considered**, probably as Yellow.

Colour coding YELLOW & RED for Waste Category No.3

- Waste **category No.3** for Microbiology and Biotechnology waste has been classified for colour coding **Yellow** as well as for **Red** in Schedule II..
- **There should be only one Colour coding and that should be based on the waste category.**
- **Colour coding should not be as per Treatment options.**
- Workers and public at large should be aware of the nature of hazard of to the waste by its colour coding.
- Single choice of colour for infective waste for category No.3 should be considered as Yellow.

Colour coding RED & BLUE/WHITE TRANSLUCENT for Waste Category No.7

- Waste **category No.7** in for disposable items such as tubing, catheters, intravenous sets etc has been classified for colour coding **Red** as well as **for Blue/White Translucent** in Schedule II.
- There should be only one Colour coding and that should be based on the waste category.
- **Colour coding should not be as per Treatment options.**
- Workers and public at large should be aware of the nature of hazard of to the waste by its colour coding.

Categories for Bio-Medical waste - Schedule I

Isolation wards Waste

- 'All wastes from Isolation wards should be regarded as infected waste not containing sharps. **Ref. - WHO, Geneva 1992**, Managing Medical Wastes in Developing Countries.'
- **All wastes from Isolation wards be included in categories of Bio-medical wastes in Schedule I.**

Preserved Pathology / Biological Specimens

- Specimens are preserved in Formaldehyde solution for prolonged periods of One year and beyond. Current practice is to periodically discard these specimens.
- Incineration is the established practice in disposal of specimens preserved in Formaldehyde solution.
- Footnote [**@**] in the **Schedule I** indicates that there will be no chemical pre-treatment before incineration. This clause will be a deterrent to the currently followed practice of incineration of pathology specimens preserved in formaldehyde.
- **A provision should be made in the Bio-Medical (Management & Handling) Rules, 1998 to permit disposal of these specimens under controlled incineration and along with add-on pollution control devices for emission /gas cleaning procedures.**

Section B: Standards for Treatment and Disposal of Bio-Medical Wastes

This section deals with suggestive recommendations and comments related to standards for Treatment and Disposal of Bio-Medical wastes specified in the Bio-Medical (Management and Handling) Rules, 1998.

Operating Standards for Incinerators

- Recently in the US on August 15 1997 Final Rule on US Environment Protection Agency document 40 CFR Part 60,6560-50-P related to Hospital/Medical/Infectious/Waste Incinerators (HMIWI) was promulgated. One of Highlights in the Final Rule states that "Since, Emission Standards for HMIWI are feasible, the **EPA is barred from promulgating design standards for HMIWI**." This really means that the emphasis is in achieving the end emission results and promulgating design standards for incinerators in the Indian Bio-Medical (Management and Handling) Rules, 1998 should be avoided.
- Another highlight in the final rule states that "Emission standards allow greater flexibility in the methods used to reduce emission. **Owners of HMIWI are free to meet emission limit in the manner that is least costly to them**". To an extent the Indian Bio-Medical Rules are in line with this when they have added in a note that 'Suitably designed pollution control devices should be installed/retrofitted with the incinerator to achieve the emission standards emission limits, **if necessary**.'

Combustion efficiency (CE)

- The combustion efficiency incorporated in the incinerator guidelines in the UK, US and in the Handbooks is 99.99%. It will be appropriate to give a guideline of 99.99% CE in the Indian Bio-Medical (management and handling) Rules, 1998.
- Combustion Efficiency of >99.99% is one of the criteria for minimising formation of Dioxin, Furan and other Chlorinated Organic Micropollutants.

Emission Standards

- The unit of emission value for Particulate matter, Nitrogen oxides and HCl should be clearly indicated in words as **microgram/Cu. Meter**. Many users interpret 'mg' as milligram instead of microgram. In the CPCB Notification on National Ambient Air Quality Standards the unit has been indicated as **$\mu g/m^3$.**
- **Minimum stack height of 30 meters** above ground has been specified in the Indian Bio-Medical waste rules. This is not technically appropriate for small incinerators. Reference to small incinerators in Industrial Air Pollution handbook edited by Albert Parker, the Chapter 20 'Incineration of Refuse' by H. B. Johnson and J. M. Burnett. , Under paragraph on **Small Incinerators** it states that "It is not really practicable to fit such small incinerators with dust collectors of the standard installed in large plants, and in small unattended incinerators it is difficult to ensure the furnace temperature is high enough at all times to prevent odour. Moreover the chimneys of such small plants cannot be made high enough or the velocity high enough to avoid downdraught and downwash of the gases if the chimneys are on the roof of the flats."
- A mere number of 30-meter height chimneys are technically inappropriate. The height of the chimney should consider Factors influencing Aerodynamic Shadow. The height of the chimney shall not be less than the height of the zone of turbulent air layers formed due to uneven heights of buildings near the chimney. Tall stacks are necessary to disperse pollutants into the atmosphere in order to maintain an acceptable air quality standard at the ground level.
- Height of stack (chimney) is a function of various factors, for example, mass rate of emission, efflux velocity, temperature of effluent, topographical conditions, meteorological conditions of the area where stack is located and lastly, the air quality standards that must be maintained.

- For determining chimney height reference **to IS 6533 (Part 1) : 1989** on '**Design and Construction of steel Chimney – Code of Practice (Part 1 Mechanical Aspect)** should be made along with other prevailing standards and local state laws.
- Structural Aspect of Chimney should be referred to in **IS 6533 (Part 2)** Basic dimensions, Minimum thickness of steel, Allowable deflection, Allowance for corrosion, Maximum permissible stress, and Allowance for temperature.

Standards for: Chemical Treatment, Waste Autoclaving and Microwave Treatment.

- Careful bacteriological testing to show that disinfection is complete should be carried out at regular intervals for all treatment methods.. Indeed disinfection may pose serious risks because management and manual workers may tend to regard wastes that have been **"treated"** for disinfection as safe, when in fact they are not (unless tested), and so take less care when they are handling them, thereby exposing themselves to serious hazards. (Ref. - WHO, Geneva 1992, Managing Medical Wastes in Developing Countries,).
- 'No standard test methods currently exist for evaluating the level of microbial inactivation that is achieved when steam autoclaving is used to treat medical waste. While medical waste may contain many of the same pathogens as are associated with contaminated medical instruments it is assumed that medical waste contains a much higher concentration of such organisms in a much more complex matrix. Because of these differences it was necessary to develop a unique test method specifically for the assessment of steam autoclaving as an effective medical waste treatment technique. **Ref. Evaluation of Medical Waste Treatment Technologies**, Final Report, January 1993, **EPA contract Number 68-WO-0032**, Washington, pages 7-1 and 7-2."
- Levels of Microbial Inactivation, as Levels (I, II, III and IV) as defined in '**Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies. April 1994, USA.** A Report of the State and Territorial Association on Alternate Treatment Technologies. – Final document prepared by Nelson S. Slavik, Ph.D., President, Environment Health Management Systems, Inc.,' should be studied and adopted for India MoEF Rules or guidelines.
- **For Level IV of Microbial Inactivation (i.e., inactivation of Vegetative bacteria, fungi, lipophilic / hydrophilic viruses, parasites, and mycobacteria, and B. Stearothermophilus spores a 6 Log_{10} (10^6) reduction or greater should be considered for adoption in MoEF rules and guidelines**. Ref. Evaluation of Medical Waste Treatment Technologies, Final Report, January 1993, EPA contract Number 68-WO-0032, Washington, and Ref., Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies. April 1994, USA. A Report of the State and Territorial Association on Alternate Treatment Technologies. – Final document.
- Routine Test has been defined in MoEF Rules under section 'Standards for Waste Autoclaving' paragraph VI, page 17, to verify specific temperature achievement at several points distributed within the waste. **This should not be construed, as a treatment Validation Test. Routine Validation Test requirement needs to be incorporated in the MoEF Rules and Guidelines**.

- 'In addition to Formaldehyde, the EPA, as part of the Resource Conservation and Recovery Act (RCRA), has specified a number of laboratory solvents as hazardous compounds. These solvents are so intimately mixed with the medical wastes that separation is impractical. Microwave and autoclave technologies can vaporize these compounds, creating air toxics that require thermal oxidation for their destruction. These are shown in table below. – Ref. **Standard Handbook of Hazardous Waste Treatment and Disposal, Second Edition, Editor Harry M. Freeman**, Section 8.16 authored by Gordon F. Blizard, Jr., page 8.235'

Hazardous Solvents Typically Found in Medical Waste. **

Acetone	Ethyl alcohol	Petroleum ether
2-Butanol	Heptane	2-Propanol
Butyl alcohol	Hexane	Sec-butyl alcohol
Cyclohexane	Methyl alcohol	Tert-butyl alcohol
Diethyl ether	Methyl cellosolve	Tetrahydrofuran
Ethyl acetate	Pentane	Xylene

(**Ref. – R. G. Barton, G. R. Hassel, W. S. Lanier, and W. R. Seeker, EER Corporation, Irvine, California under EPA Contract 68-03-3365 and CA Air Resources Board Contract A 832-155. December, 1989)

- **MoEF Rules should study and incorporate air emission levels from vapour discharges from Microwave and Autoclave waste treatment plants**.

Schedules for Implementation of MoEF Rules for Biohazard waste.

- 'It will not be possible for all medical establishments everywhere in the world to achieve the highest possible standards in a short time. In many ways it is better to adopt incremental approach, which states that any improvement is better than none, even if the standards are not yet what would be desired.- Ref. **WHO, Geneva 1992**, Managing Medical Wastes in Developing Countries, Annexure 1, page 2, clause 1'.
- **MoEF Rules on Bio-Medical wastes should enforce at the earliest to all users small and big across the country**, sub-clause (1) '***Bio-medical waste shall not be mixed with other wastes'*** under clause 6 'Segregation, Packing, Transport and Storage', page 11. **This single clause would serve to be the first incremental step in immediate implementation of the rules**.
- SCHEDULE VI in MoEF Rules on Bio-medical wastes refers to implementation time-schedule for to several category of Cities, Hospitals and institutes, for set-up of treatment facilities like Incinerator / Autoclave / Microwave system. Therefore, **the time-schedule for wastes Segregation, Storage, Packaging, colour-code, and chemical disinfection should be no sooner the prescribed authority is appointed.**
- **Wastes treatment implementation for "Animal Houses" should be advanced from the given time-schedule of December 31, 2002**.

Conclusion Summary

- MoEF's Bio-hazard (Management and Handling) Rules, July 27, 1998 are very comprehensive and covers all aspects of Medical Waste Management. This sound framework of Rules needs to be expanded periodically as needed.
- Forums such as the 1st National Conference on Medical Waste Management (MWM), and bodies like BMA , USAEP, and NGO's would pursue, as fallout of this conference, towards the cause to promote Safe MWM practices.
- It is a wishful thinking that the delegate's comments presented in this note will be found useful to some. The interested parties exposed to this note would view and discuss it within their regional circles for betterment towards improved MWM.
- MWM is a very vast subject dealing with expertise in Management, Science, Medicine, Engineering, Economics and Law. Therefore, further dialogue and periodical feed back on matters related betterment and implementation of MWM is welcomed, always.