Environmental Remediation of Contaminated Sites
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Lecture 05
Major Aspects of Risk Assessment

Hello everyone, again, welcome back to the latest lecture session. I believe, in the last set of sessions we have been looking at a couple of examples that would provide the context with respect to the applications of this course. And I believe then we moved on to looking at the course outline and started looking at or looked at in brief, the relevant rules, the hazardous and other wastes, transboundary movement and such, the 2016 rules. We looked at them briefly and we do plan to come back to that later.

And then we started discussing the relevant aspects with respect to risk assessment. So again, why do we need to consider risk assessment now. So again this will help the relevant decision maker or policy maker or the relevant management, to be able to identify those pathways, which are relatively more potentially troublesome, and also to cut out any subjectiveness. We did talk about this, if we have a quantitative figure, that helps in many myriads of waste. Why is that, typically out there we have lot of rumor mongering and such, but if I can put a number in that regard, it will convey the information, in well to the better manner.

Again, in that context we looked at a few examples that would I believe help us compare the different risks, I think we looked at a few light-hearted examples in that context. And in that regard, when we talk about allocating resources, at least in the long term, for particular aspects, how are the decisions typically made? For example, India today is not the India it was 20 years ago or 40 years ago, the priorities then were different, the priorities now were different. Same case with different countries or humans, or different sets of populations and such or different nations now.

So again, what I am trying to say is, let us say, my priorities earlier are different from my priorities now. Again, the standards of life or quality have improved and so on. So in that context obviously the decision makers can put a value on human life. I believe it is not greatly well practiced in the Indian context, but to my knowledge it is practiced out there though.

Obviously there are going to be politically pressures depending upon situation or scenario, but in general when we are looking at long-term planning with respect to taking up different measures or such, we come up with these aspects, how much is human life worth.

So in this context we are going to look at particular set of examples that would illustrate this particular aspect better. And again why are we looking at that because later on when we are trying to allocate resources we are obviously going to look at which particular pathway to pay greater attention to. Again, coming back to our particular aspect, how much is saved life worth. So I believe I have a few examples here.

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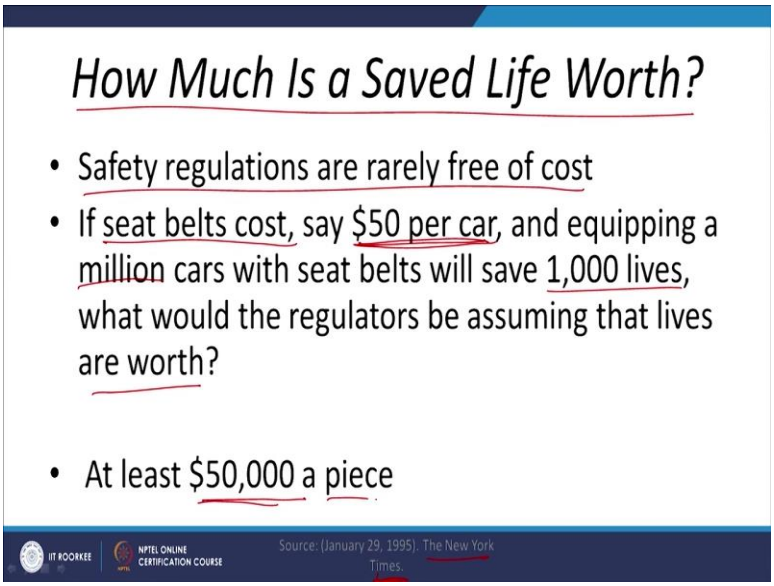

So again, any changes or such or any improvement in infrastructure or changes in policy, they are going to have knock-on effects and obviously costs involved. So again, that is why we have the saying here safety regulations are rarely free of cost. So here we have an example, if seatbelts cost I think $50 per car, I mean this is the data that I had from New York Times, and the data in dollars I guess, per car, and equipping million cars with seatbelts will save thousand lives.

What would the regulators be assuming that the lives are worth. Again, you know simple math and such, so at least $50,000 is the worth that we are putting on a human life. So for example, if I am able to save 1000 lives, if I equip million cars or 10 power 6 cars with seatbelts and it costs 50 pounds or dollars per car to be able to save this. So you know what is the worth I am putting

on human head, it is $50,000. But obviously looking at that in the context looks like currently at least in the western world the worth of human life is around 3 to 5 million dollars.

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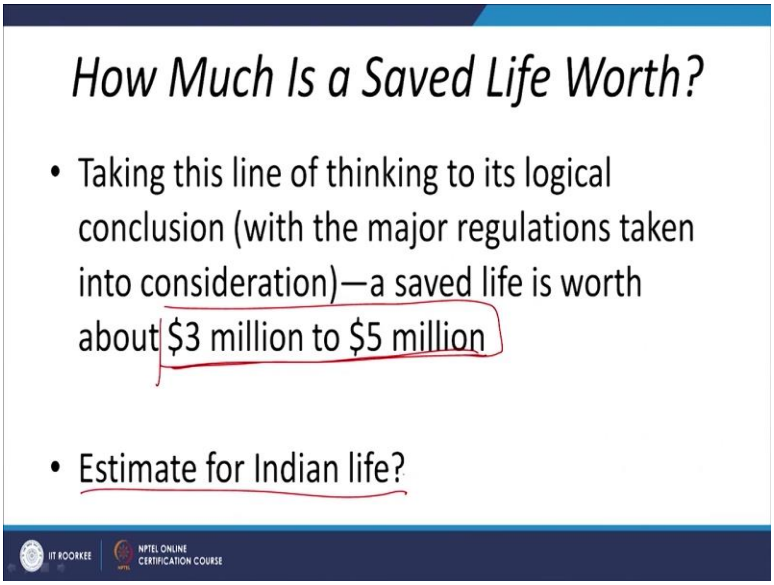

Again, I tried to look up the relevant data in the Indian context, I have not found that out. For example, when you hear of some accidents or such, you hear people doling out compensation, but usually they are politically influenced or emotionally influenced decisions. But when you look at long-term planning or such and so on, and look at relevant policy measures, usually it is always better idea to obviously have some worth associated with the human life.

And again in that context I tried to look at the estimate for Indian life, but I could not, but the nearest I came to, was that it is around 20,000 rupees, that is what I came to see. Again, I guess the light-hearted illustration any way 3 to 5 million dollars in the western world typically. Again, these are generic figures that I am throwing out, but they are based on some research that I looked at. And again, in the Indian context, it seems it is around 20,000 rupees or so.

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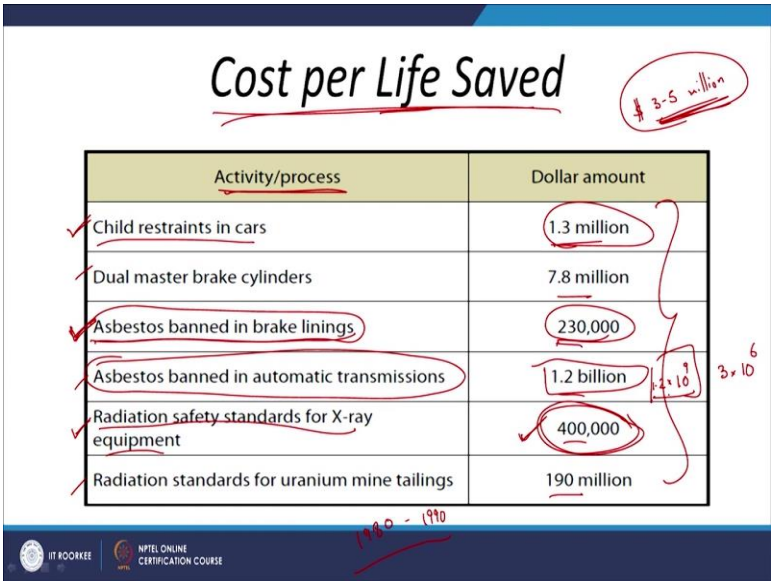

Again, moving on to our relevant aspect, so how are decisions made, if I look at different aspects or activities, and calculate the cost per life saved in dollar amount, I have various aspects here, various activities and various cost associated per life. So looking at this I believe again this data is from 1980s or 1990s. Again, so if we look at these aspects, which particular aspect do you think the decision maker would try to look at first.

Obviously radiation safety standards for x-ray equipment: relatively lower cost, and we saw that the average was around 3 to 5 million dollars. So obviously you know the relevant person will see that the cost per life saved here is less than the average that they usually consider, so they can or would like to implement this particular aspect. Certainly again, child restraints in car because again as you will see that particular value is lower than the average value per life and so on and so forth.

Again, asbestos was banned in brake linings, this I am sure about. I think it had issues with relevant air pollution, even in the work place where the relevant brake linings were fabricated and put in place. So this was, as I mentioned put in place, as in asbestos was banned in brake linings. But this particular aspect as in asbestos being banned in automatic transmission, as you see it is 1.2 billion, billion as in 1.2 * 10 power 9, but the average is 3 * 10 power 6. Thus, being much higher than the cost of this particular average value that we place on a human life.

This particular aspect as in asbestos in automatic transmissions has not yet been banned to my current knowledge, but as you see it costs lesser to implement, asbestos being banned in brake linings, and obviously you see the reasoning here. So similar analogy here is if you have limited resources and you look at different pathways, exposure pathway from the air, from groundwater ingestion or dermal contact and so on.

Then I am going to look at the relevant resources, look at the relatively more riskier pathway or pathway that would lead to greater adverse effects, and then I would try to obviously remediate those particular aspects.

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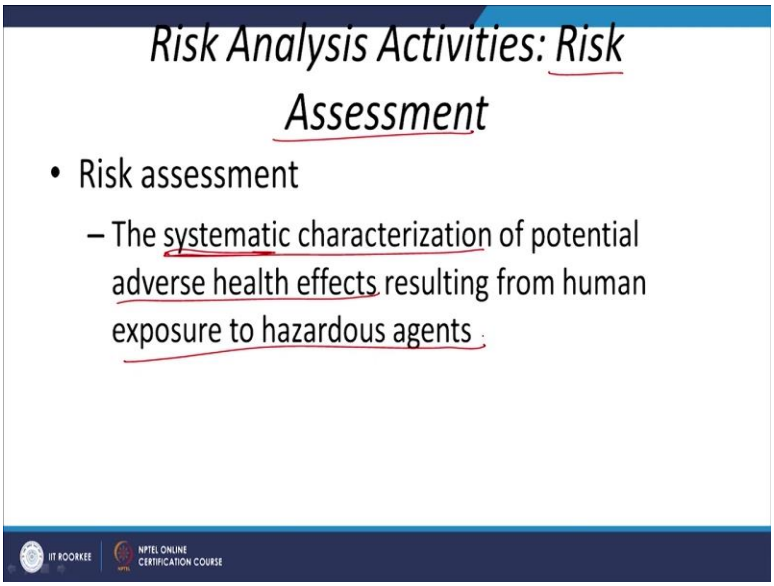

So here we are going to move on to risk assessment. So it is worth looking at particular set of terms that we associate with risk assessment, let us look at what they are. So it is systematic, that is one particular aspect, so systematic characterization of the adverse health effects from human exposure to hazardous agents.

So I am trying to characterize the adverse health effects from sustained or systematic exposure to hazardous substances. So how do I characterize that obviously; you know the process obviously I am looking at is risk assessment.

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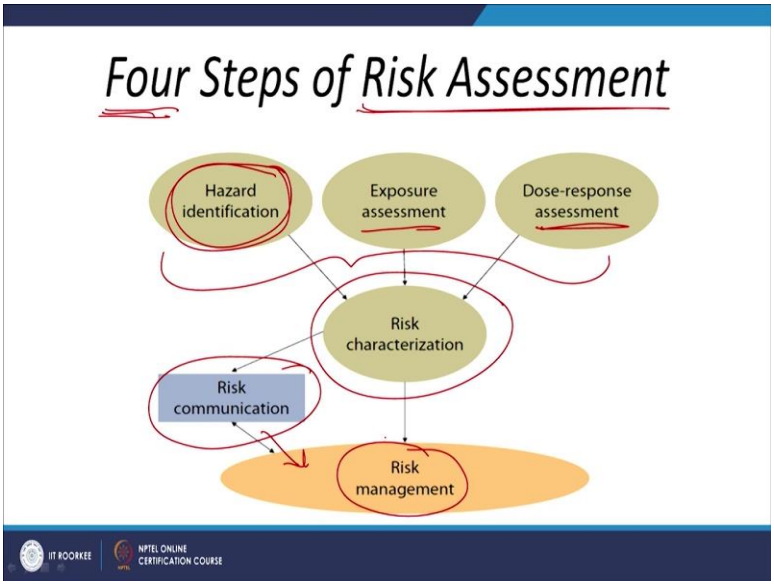

So there are four obviously major aspects in the context of risk assessment. One is the hazard identification, again that is self-explanatory. So what are the chemicals of concern.

I am looking at a particular landfill site or we have an industrial zone or set of industrial clusters out there near Haridwar or Bahadrabad, where there are issues with some contamination of groundwater and such, and the relevant local population is concerned with it. So if I am conducting the risk assessment there obviously after relevant analysis, if it is a heavy metal then by AAS, for other kinds of organic compounds by GCMS or LCMS and so on, I can get the list of chemicals of concern.

Just because they are chemicals of concern does not mean they are toxic, so I need to obviously get the information about what adverse effects if any do you think these chemicals of concern are going to have. Also I need to know what are the possible pathways, what are the concentrations at the source, concentrations at the receptor and so on. So that would come in the context of data collection and hazard identification.

And then exposure assessment itself relatively self-explanatory, we are going to look at that in greater detail again. And then dose response or toxicity assessments, again that is one particular aspect. So considering these three aspects obviously I can come up with characterizing the risk. After the relevant calculations, I am going to characterize the risk and put a number on the different kinds of risk from different pathways and so on.

So in that context obviously the risk has to be communicated either to the public or to the management and then it is up to the management to look at how they are going to manage this risk or how they are going to decrease this risk if required. If the risk is deemed to be too less, as in I think for carcinogens we do know it is either 10 power -4 or 10 power -6, typically 10 power -6 is what is looked at. So if the risk due to the carcinogens in that particular area is less than 10 power -6, the manager can say or the relevant person or decision maker would probably take a call and say it is not worth putting in more money or resources in remediation of this particular site.

So in that context again if the risk is higher obviously the manager would like to look at which pathways to consider and to what extent does the risk need to be decreased to. Again we are going to look at these aspects in greater detail, but again as I mentioned, hazard identification or data collection, exposure assessment, dose response; from all these aspects we are going to look at the relevant calculations. We are going to look at a few examples in due course and then we are going to look at risk characterization and so on and so forth.

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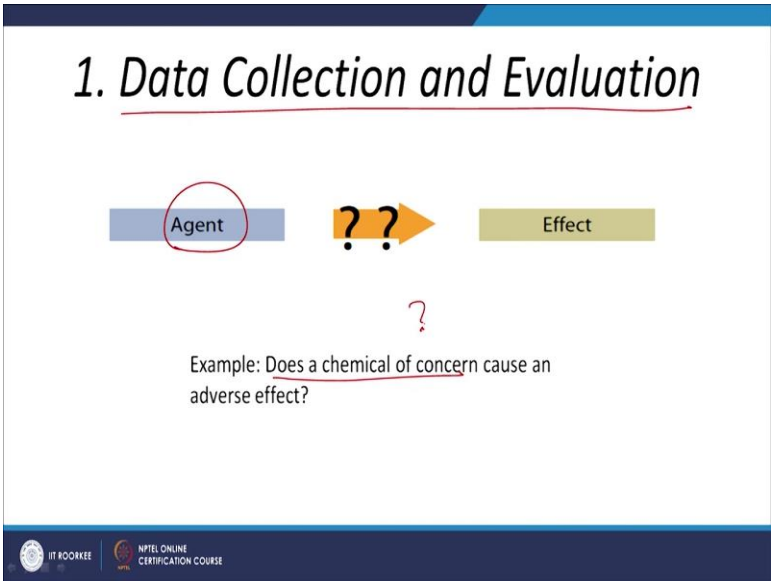

So moving on obviously as we talked about data collection or hazard identification: so what are the chemicals of concern, for example what are the chemicals of concern and does it have an adverse effect, so again generic aspects.

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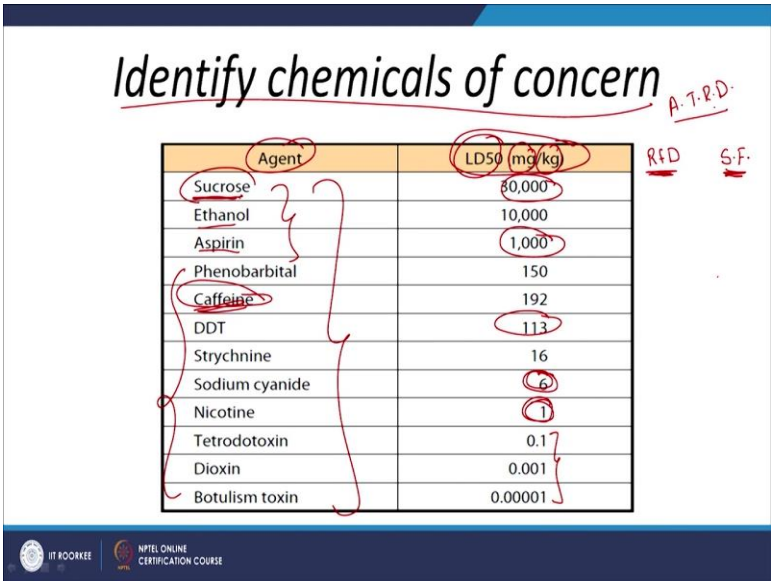

So for example, how can I identify chemicals of concern. So here I have an illustrative example because I wanted to explain couple of other points too. As in here we have different compounds listed here, from sucrose to ethanol, aspirin, some of the commonly used compounds to different toxins here, all pesticides here and so on here, obviously caffeine we have that out there in coffee and so.

And here we have a metric called LD50, which is mg of that particular compound per kg of body weight, so LD50 is the dose of the particular compound at which 50% of the relevant target population would die, but obviously that is not worthwhile way to look at our toxicity assessment, but I am having this table here to compare some aspects. So typically as I mentioned for noncarcinogens or toxic compounds it is a reference dose and for carcinogens it is the slope factor.

These are the two variables that are typically considered when we look at risk assessment in the context of toxic and carcinogenic compounds, so we are going to go through them later. So again why am I bringing this up here; as in every particular supposedly harmless compound can be a toxin, but obviously the key lies in the dosage. So obviously at remarkably high doses even sucrose and aspirin and so on are toxic too. So the poison lies in the dose, that is something that I am trying to convey here.

And obviously as I come down to various pesticides, cyanides or we know different poisons are such, nicotine again something that is present in cigarettes, you see that the concentrations are remarkably less, the lethal dose 50 doses are remarkably less. So obviously here as we can see, the poison lies in the dose. Again something that I wanted to point out, but typically we look at reference dose or slope factors and I believe you have the agency for toxicity registry database or you can play around with those particular terms. You can Google them and you will have the relevant standard values, but again we are going to go into that in greater detail later on.

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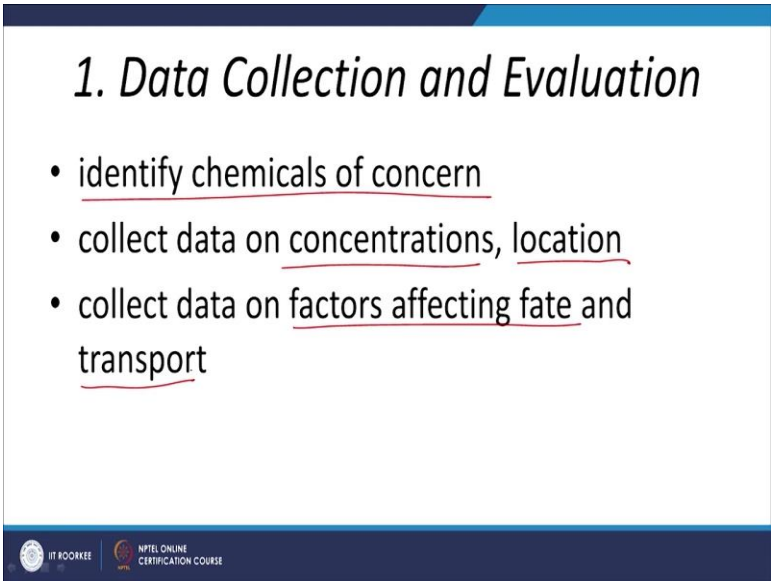

So again data collection what do I primarily look at, I need to identify the chemicals of concern and as I mentioned we need to look at concentrations and at which locations are they present, and then factors affecting the fate and transport and some of the pathways there. Again, I need to identify the chemicals that are of issue in my opinion at this initial stage and then what are the different locations they are present at and at what concentrations. And then look at what are the factors affecting their fate or the transport primarily. At least at this particular stage we need to look at the data collection and hazard identification.

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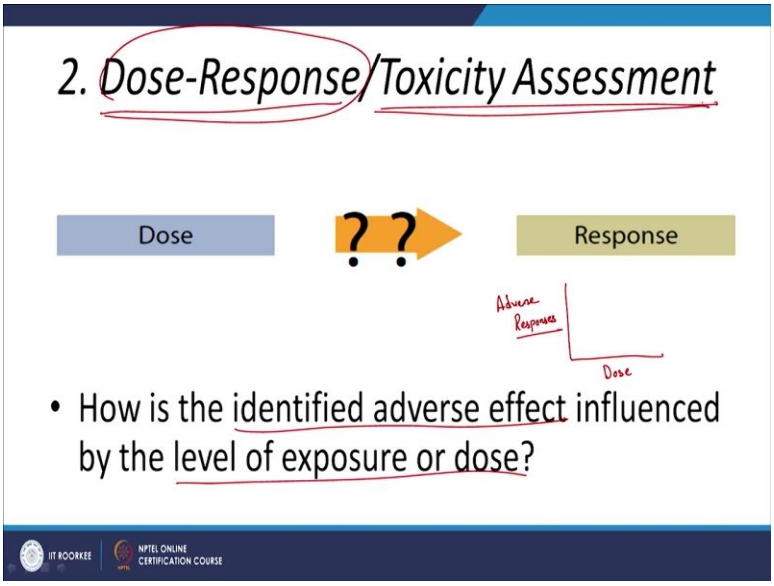

So we will move on to the next particular aspect as in we did talk about dose response and toxicity assessment. I guess, you know, dose response that is relatively self-explanatory. So here we need to look at what level of doses or sustained level of dosage there will be an adverse response in the relevant human health or such. So obviously again an example is how is the identified adverse effect influenced by the level of exposure or dose.

For example, as I mentioned earlier, so here we have different doses of the relevant compound and different adverse responses. We are going to look at this in greater detail. So obviously though you are not going to conduct this particular toxicity assessment every time or try to get the dose response behaviors every time you come up with the chemical of concern. So we do have the relevant or for almost all the known compounds that are typically out there, the regulations approve the relevant usage either for commercial or private or other uses.

Only after the relevant toxicity assessments are done, and typically they are done, how though; obviously the ideal case would be to get them done, the dose responses and behaviors' study done on humans. Obviously there are issues concern there, so you are going to look at the next best thing. You are going to look at rats or mice, whose physiological behavior is similar to the humans. Again, we are going to look at this in greater detail.

We need to look at the dose response curves or the toxicity assessment data needs to be gathered. And in that context again as I mentioned, the agency for toxicity registry database or such, that

will in general have the relevant set of data that you are looking for with respect to dose responses. But in this context we need to understand the uncertainties involved in this particular aspect, aspect as in how do we come up with the dose response behaviors and how do we extrapolate the data that we have on the animals to the humans.

And obviously here we have lot of uncertainties involved and it is worth going into it in a relatively greater detail because whenever you consider risk assessment, we need to keep in mind that there are still considerable uncertainties involved.

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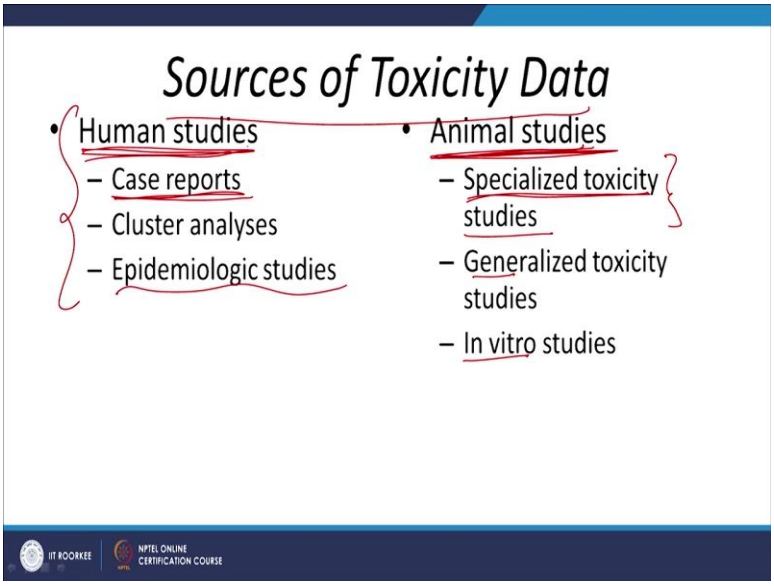

So let us move on and look at what we have here, so sources of toxicity data obviously preferably human studies. In general, if there are case reports out there that are something we can look at and typically epidemiological studies that are looked at statistically based analysis of groups of population or relatively larger population if I can use layman's terms. But here it depends upon; the efficiency of the epidemiological studies depends upon the level of controls that you have in your particular group or studies; but typically though difficult to get the studies done on humans.

So in general we conduct the toxicity studies on animals. So either we have specialized studies, generalized or in vitro as in test tube studies too, but in general we looked at specialized toxicity studies in general when possible, especially if it is a pharmaceutical drug or such, human trials to my knowledge are necessary, and in general you might have heard of reports from Bihar and

such, where obviously the poverty levels are relatively high as you are aware of.; they served as labs for relatively less stringent or relatively less regulated human trials.

As in the big pharma companies from outside the country, conducted human studies on our poor brothers out there, anyway that is how life is. Again, human studies when possible if not in general certainly animal studies. So specialized toxicity studies for pharma and such, those compounds in general though, human studies are necessary.

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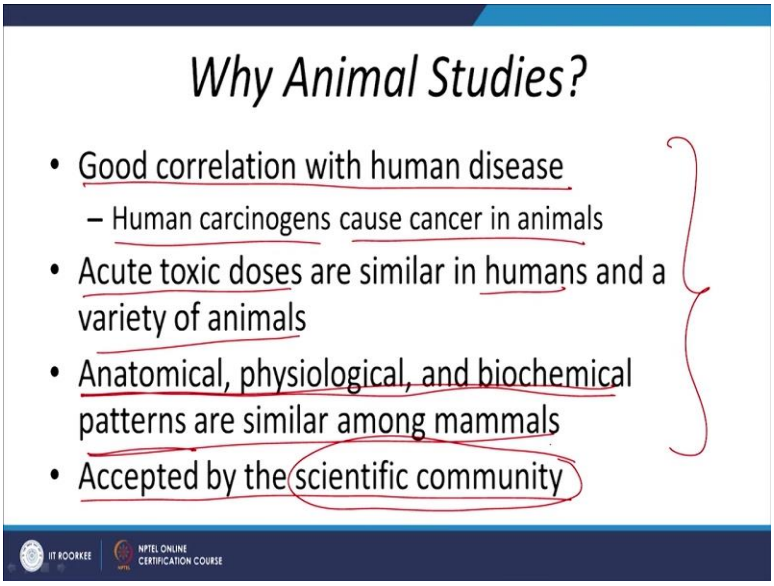

And in this context why animal studies? As we just discussed this, there is a good correlation with human disease. As in the relevant responses that you would see in the specific kinds of rats or mice in most of the kinds of disease, there is a good correlation with the diseases that you would observe if the humans take or ingest that particular compound.

And also human carcinogens seem to be causing cancer in animals too. So again acute toxicity doses are similar in humans and a variety of animals, usually rats and mice. There are two kinds of doses, acute and chronic, short-term and long-term. So looks like there are similarities, so obviously here what is the crux of the issue, you are trying to estimate the adverse effects on humans.

So for that obviously you need to choose a test specimen that would help you to come up with a worthwhile or relatively accurate estimate. Obviously there are uncertainties involved, but you need to look at the next best thing. So in that context, we have been going forth with that. So

the next aspect would be anatomical, physiological and biochemical patterns are similar among mammals. So that is a major aspect.

So primarily the physiological and biochemical patterns are similar. Again, that corresponds to more or less the bigger picture here. As in general, toxicity studies on the animals, we can have relatively greater confidence that these results can be extrapolated to estimate the effects on human health. So moving on, there has been considerable body of scientific evidence, thus these studies are accepted by the scientific community.

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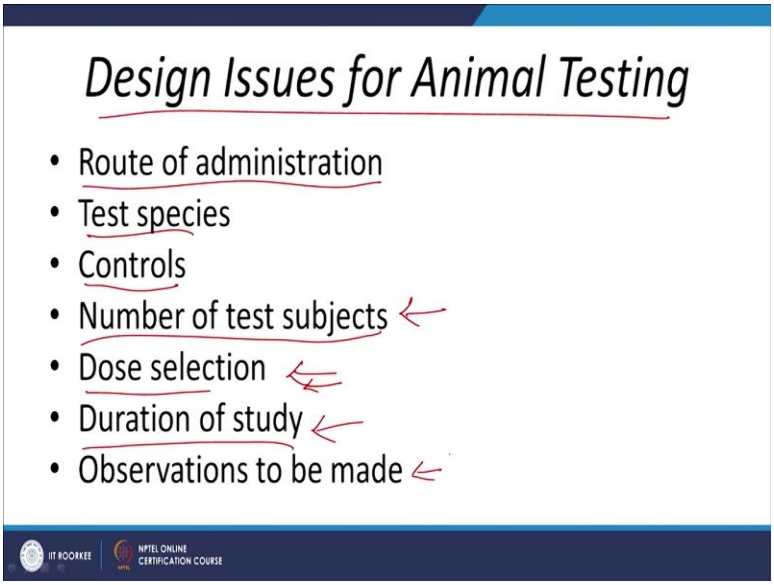

So what are some of the design issues for animal testing. So you want to obviously mimic what you would expect out there in nature. So let us look at that, obviously route of administration is an issue as in you want to look at what routes of administration that the humans would be facing and then try to keep the route of administration the same in the animals; as in if we are looking at contact through the skin, so the same case needs to be replicated on the animals.

So the kinds of test species we are going to look at that. Obviously, there are controls as in you need to have the baseline information for the relevant test species that is something that needs to be looked at. So for statistical relevance you need to look at the number of test species or subject that needs to be looked at; obviously dose selection. So this is one aspect, I mean dose selection. As in how do you come up with doses. Though there will be some preliminary trials the crux of the issue is these toxicity studies are remarkably costly.

So how do I go about trying to relatively accurately predicate the adverse effects on human health while also trying to limit the costs and resources involved. So again this is something we are going to look at in greater detail later on, and then duration of study. As in if I am looking at carcinogens, let us say, we consider, with respect to carcinogens we look at lifetime cancer risk. As in we assume that the cancer risk can be over the course of the lifetime.

So for that ideally what we need to do, we need to observe further relevant effects over the subject's lifetime or such. But obviously again due to costs and relevant time and resources that is not feasible. So what people do, they typically look at accelerated trials at higher doses, so that is again something we are going to discuss, and then relevant observations.

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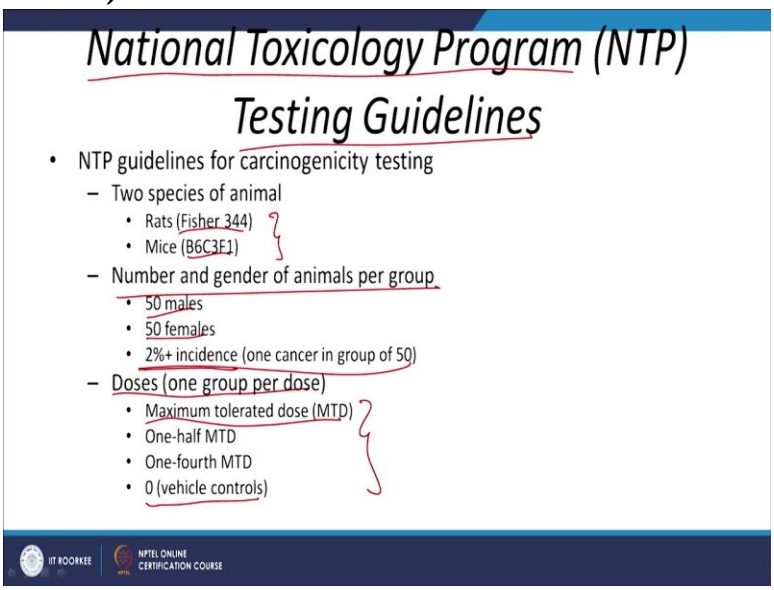

So here we are going to look at the general guidelines from the National Toxicology Program. We obviously have guidelines, obviously depending upon the case they are going to differ. We are just going to briefly summarize what it is, these generic guidelines are.

So two species, I guess, based on their physiological and biochemical behaviors and their responses seemed to be relatively similar to what would we expect in humans. Rabbits too are considered, specially when we are looking at effects on neurological system, but for most of the other aspects I believe rats and mice, these two kinds of rats and mice are looked at. So number and gender of animals per group, obviously you need to look at keeping the controls such that you would try to mimic what is out there in the nature.

So obviously we are going to look at 50% males and 50% females and 2% or higher incidence in that particular group. As in if you take a test group of humans out there, you would always have some base level of occurrence of cancer. So if I do not want to take that into account when I am conducting my study, I am going to end up overestimating the adverse effects of this particular chemical or compound when the mice or these rats are exposed to this particular compound.

So obviously I need to look at what is the base level of cancer prevalence out there. So cancer in that context or that particular adverse effect out there, I need to see to it that dose controls are relatively stringent; doses: different kinds of doses, but again depends upon the resources available, so you have maximum tolerated dose, 0 for the control. You also have to have the control as in with no dose, what would be the effects and such, so different controls here again.

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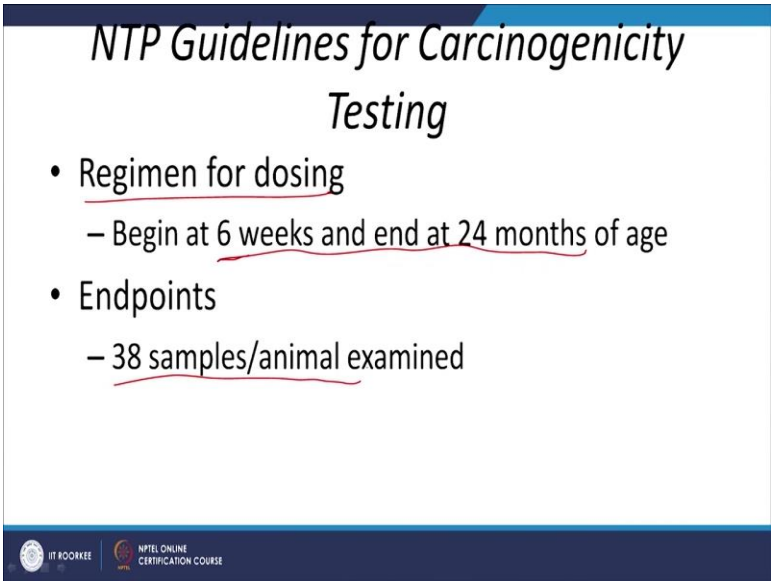

But more importantly though, the regimen for dosing again, so as we see they are typically run from 6 weeks to 24 months of age of the relevant species. So again, as we see, if we are trying to use such data for estimating lifetime cancer risks, there are considerable uncertainties involved here. Again, 38 samples or animals examined for endpoints, that is a different aspect, which we are going to look at.

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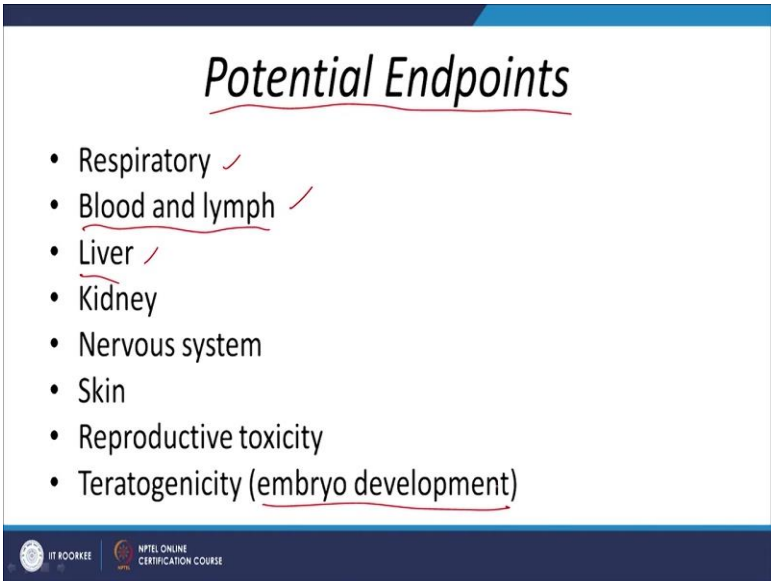

So what are the different endpoints, where you have greater probability of the adverse effects. So what are the typical endpoints, it could be the lungs, the nervous system, and different aspects, we are going to look at that. Certainly the respiratory system, blood and the lymph nodes obviously, lymph nodes typically prone to cancer, the liver, kidney, nervous system, skin, and the respiratory toxicity, and finally effects on embryo development. So these are the typical endpoints that can be affected or are usually affected by various toxic substances or carcinogens. Obviously respiratory system, blood and lymph nodes, liver and kidney, they are the cleaners of particular body. Again, I am going to skip this through.

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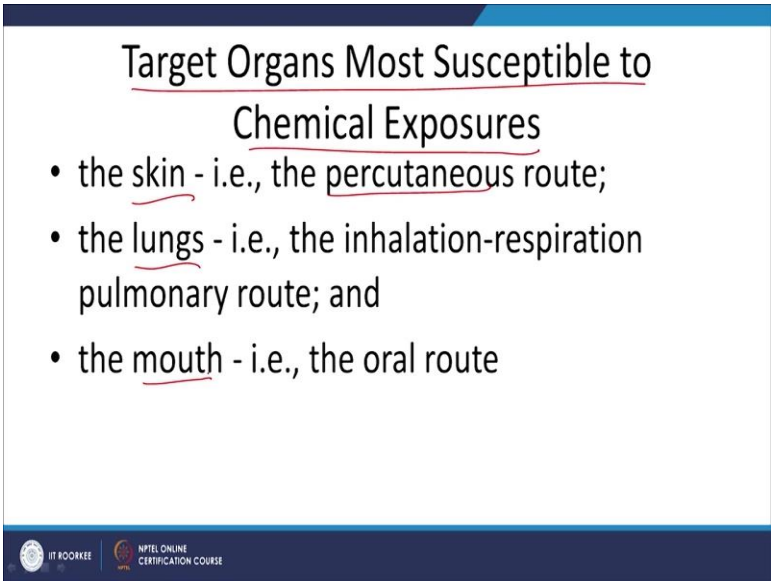

So target organs most susceptible to chemical exposure obviously depends upon the route, so percutaneous-the skin, the lungs and the mouth. These are obviously the primary route through which the chemicals are ingested. So these are the organs most susceptible obviously to chemical exposure.

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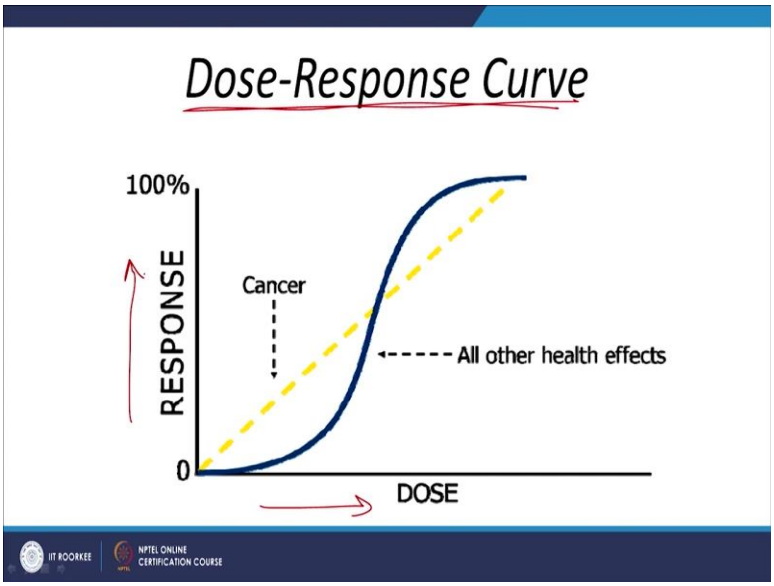

So moving on, we are now going to come into the relevant aspects or discuss the relevant aspects with respect to dose response. Again, why are we looking at this, though you will not be calculating this, whenever you come up with a number for risk assessment, people think that is the one and only number possible for risk assessment, we are going to look at those aspects too.

But obviously when we are calculating risk here, there are different variables that we use and there are uncertainties involved whenever we use these variables. So for understanding the level of uncertainties behind these variables, we need to look at the relevant aspects. So in that context obviously I need to look at dose response curves. So here I have a very generic example, here I have, with increasing dose the adverse response here, on the test subjects. So obviously here for carcinogens we usually come up with a linearized model for noncarcinogens or toxic compounds we come up a different kind of model and we are going to discuss this in greater detail.

I am again out of time, so we are going to look at the, how do I come about, let us say, the looking at or understanding the dose response behavior for carcinogens and noncarcinogens, and

then we will move on to looking at risk assessment and exposure assessment, and then come up with few examples and calculate the relevant aspects. So with that I will be ending it for this session and thank you.